

# Analysis Data Reviewer's Guide

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## 1. Introduction

### 1.1 Purpose

This document provides context for the analysis datasets and terminology that benefit from additional explanation beyond the Data Definition document (define.xml). In addition, this document provides a summary of ADaM conformance findings.

### 1.2 Acronyms

Acronym	Translation
FTND	Fagerström Test for Nicotine Dependence
HST	Human Smoking Topography
mCC	Menthol conventional cigarettes
MCEQ	Modified Cigarette Evaluation Questionnaire
MNWS	Minnesota Nicotine Withdrawal Scale
PD	Pharmacodynamic
PK	Pharmacokinetic
QSU	Questionnaire of Smoking Urges
SA	Smoking abstinence
SES	Socio-Economic Status
THSm2.2	Tobacco Heating System 2.2 Menthol

### 1.3 Study Data Standards and Dictionary Inventory

Standard or Dictionary	Versions Used
SDTM	SDTM v1.3/SDTM IG v3.1.3
ADaM	ADaM Model Document 2.1 ADaM Implementation Guide v1.0
Data Definitions	Define.xml v2.0
Fagerström Test for Nicotine Dependence	Revised version (Heatherton et al. 1991), as updated in 2012 (Fagerström et al. 2012)
Questionnaire of Smoking Urges-	Cox et al. 2001

Standard or Dictionary	Versions Used
Brief	
Modified Cigarette Evaluation Questionnaire	Cappelleri et al. 2007
Minnesota Nicotine Withdrawal Scale (revised edition) Questionnaire	Hughes and Hatsukami 2008
Medications Dictionary	WHO March 2013
Medical Events Dictionary	MedDRA v16.0

## 1.4 Source Data Used for Analysis Dataset Creation

In addition to the SDTM datasets, the source data contains CRF raw data IE\_E, IE\_E\_ADM, IE\_E\_SF, IE\_I, IE\_I\_ADM and IE\_I\_SF (these datasets were used in the creation of ADEL - see Section 5.2.11), data in the form of excel spreadsheets BANNEDMEDS.XLSX (this spreadsheet was used in the creation of ADCM to identify the half-lives for meds which impacted CYP1A2, 11-DTX-B2, and CYP2A6 - see Section 5.2.4) and DV.XLS (this spreadsheet was used to create a programmatic list of deviations after database lock that were used in the creation of ADDV - see Section 5.2.9 and note that these deviations are identified using DVSCAT='Programmatic'). The spreadsheet POTENTIAL DEVIATION.XLSX contained the types of deviations that were programmatically generated by querying the database to supplement the list manually identified in the CRF (see Section 4.3).

## 2. Protocol Description

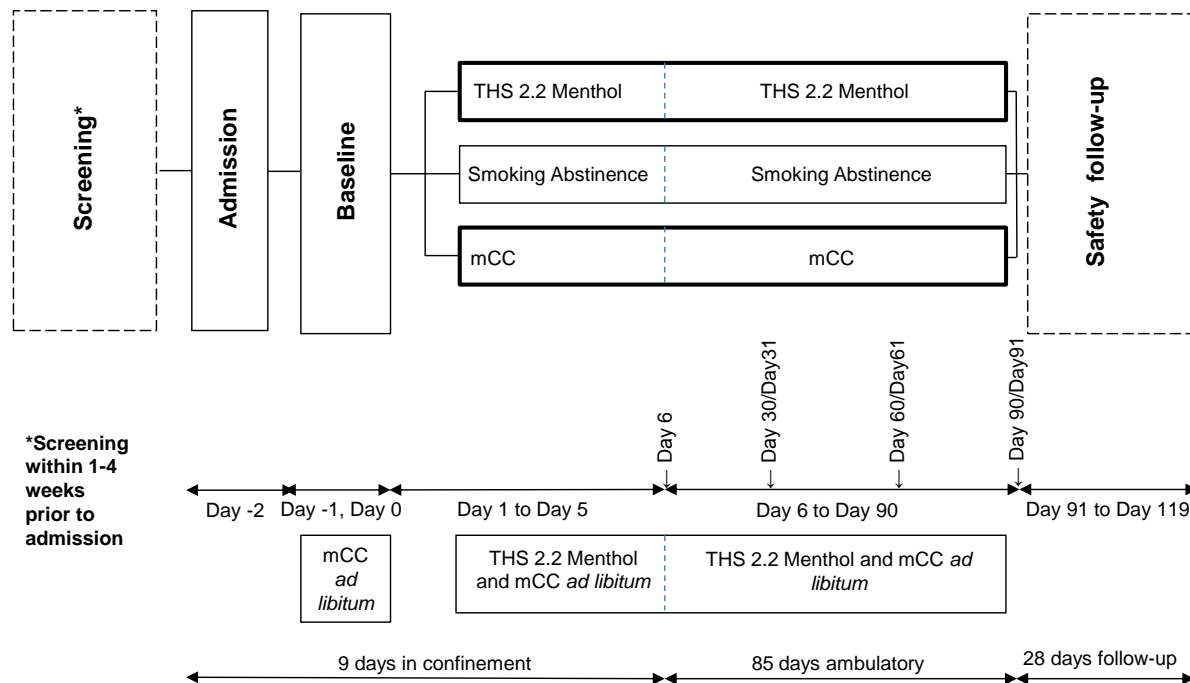
### 2.1 Protocol Number and Title

Protocol Number: ZRHM-REXA-07-JP

Protocol Title: A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 85 days in an ambulatory setting

Protocol Versions: Final 3.0, 07 April 2014

## 2.2 Protocol Design in Relation to ADaM Concepts



Abbreviations: mCC = Menthol conventional cigarette(s); THS = Tobacco Heating System; Figure not to scale.

Prior to enrolment on Day -2, as the last procedure of the eligibility assessments, subjects had a product test of the THS 2.2 Menthol. All subjects who tested the product, whether or not if they continued further into the study, were considered to be part of the Safety Population. On Day 0, subjects were randomized to one of 3 arms – THS 2.2 Menthol (THSm2.2), Smoking Abstinence (SA), or menthol conventional cigarettes (mCC). After subjects completed the Day 91 safety assessments (or if they were prematurely withdrawn from the study), they entered a 28-day safety follow-up period. This includes subjects who were not enrolled into the study but tested the product on Day -2.

Treatment group assignment was stored in the SDTM.DM domain. It was used in ADaM datasets to derive the treatment group (TRT01P/TRT01PN and TRT01A/TRT01AN) variables. There were no instances of subjects using a treatment other than what they were randomized to. The variables TRTP/TRTPN and TRTA/TRTAN are used on non-ADSL datasets for consistency with ADaM standards and contain the same values as TRT01P/TRT01PN and TRT01A/TRT01AN, respectively.

TRTSDTM and TRTEDTM refer to the start and end of randomized treatment use in the randomized treatment period from Day 1 to Day 91. Note that for subjects randomized to the SA arm who do not have exposure to randomized product, per the SAP, the treatment period starts on Day 1 at 10:00 AM and ends on the last visit date at 11:00 PM (unless they discharge earlier in the day).

Many of the BDS datasets also contain variables called APUPER/APUPERC and/or ASPER/ASPERC to designate the study period when the event or visit took place and these are used in analyses as needed. The confinement period of Days 1-6 (until discharge) is designated as Period 1. The ambulatory period

was broken into 3 smaller periods as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Each ambulatory visit is comprised of 2 study days. References to the Day 30 Visit include nominal Days 30 and 31, references to the Day 60 Visit include nominal Days 60 and 61, and references to the Day 90 Visit include nominal Days 90 and 91. Depending on the parameter, data are collected at 1 of the 2 days (see protocol Study Assessments table) during each ambulatory visit. For 24-hour urine collections taken on Days x to y (e.g., Days 5 to 6), these are referred to as collected on Day x (e.g., Day 5) in the datasets.

### 3. Analysis Considerations Related to Multiple Analysis Datasets

#### 3.1 Comparison of SDTM and ADaM Content

- Are data for screen failures, including data for run-in screening (for example, SDTM values of ARMCD='SCRNFAIL', or 'NOTASSGN') included in ADaM datasets?

Yes, all subjects in the SDTM database were used in ADaM datasets.

- Are data taken from an ongoing study?

No, this is a final locked database.

- Values of baseline are not always identical between SDTM domains (xxSTRESN/xxSTRESC where ABLFL='Y') and ADaM datasets (AVAL/AVALC where ABLFL='Y'). In the SDTMs, baseline refers to the last measurement on or before RFSTDTC (either the date/time of first randomized product used on Day 1 or Day 1 date for the SA arm). For the ADaMs, baseline is determined the same for the THSm2.2 and mCC arms but it is the last measurement on or before 10:00 AM on Day 1 for the SA arm. One exception is found in ADBX.PARAMCD=CO – this parameter is collected at 4 timepoints throughout the day on Days -1 to 5 during the confinement period and so baseline is defined separately for each timepoint as noted in BASETYPE.

#### 3.2 Core Variables

Core variables are those that are represented across all/most analysis datasets.

Variable Name	Variable Description
USUBJID	Unique subject identifier
STUDYID	Study identifier used for this protocol
SUBJID	Subject Identifier for the Study
SITEID	Study Site Identifier
AGE	Age
SEX	Sex
SEXN	Sex (N)

Variable Name	Variable Description
RACE	Race
HEIGHT	Screening Height (cm)
WEIGHTBL	Baseline Weight (kg)
BMI	Baseline Body Mass Index (kg/m <sup>2</sup> )
UCPDGR1	Usual Daily Cig Consumption Category
UCPDGR1N	Usual Daily Cig Consumption Category (N)
ENRFL	Enrolled Population Flag
SCRFFL	Screen Failure Flag
COMPLFL	Completers Population Flag
FSAFBFL	Full Safety Pop. Before Rand. Flag
FSAFAFL	Full Safety Pop. After Rand. Flag
SAFBFL	Safety Pop. Before Rand. Flag
SAFAFL	Safety Pop. After Rand. Flag
FASFL	Full Analysis Set Population Flag
PPROT1FL	Per-Protocol Population Flag - Period 1
PPROT2FL	Per-Protocol Population Flag - Period 2
PPROT3FL	Per-Protocol Population Flag - Period 3
PPROT4FL	Per-Protocol Population Flag - Period 4
RANDFL	Randomized Population Flag
EXFL	Exposed not Enrolled Flag
EXNOTRFL	Exposed not Randomized Flag
ENFL	Enrolled not Randomized Flag
TRTSDTM	Datetime of First Exposure to Treatment
TRTSDT	Date of First Exposure to Treatment
TRTEDTM	Datetime of Last Exposure to Treatment
TRTEDT	Date of Last Exposure to Treatment
TRTP	Planned Treatment
TRTPN	Planned Treatment (N)



Variable Name	Variable Description
TRTA	Actual Treatment
TRTAN	Actual Treatment (N)

### 3.3 Treatment Variables

#### ARM versus TRTxxP

- Are the values of ARM equivalent in meaning to values of TRTxxP?

For randomized subjects, ARM and TRT01P are equivalent in meaning. For non-randomized subjects, TRT01P is derived into more detail than found in ARM.

#### ACTARM versus TRTxxA

- If TRTxxA is used, then are the values of ACTARM equivalent in meaning to values of TRTxxA?

For randomized subjects, the values of ACTARM in SDTM are equivalent in meaning to the values of TRT01A, and TRT01A is the same as TRT01P. For non-randomized subjects, TRT01A and ACTARM are similar in meaning with TRT01A=Product Test used for subjects with ACTARM=Not Assigned, to help identify subjects who tested the product. Refer to the define.xml file for further details.

#### Use of ADaM Treatment Variables in Analysis

- Are both planned and actual treatment variables used in analyses?

There are no differences between the planned and actual arm for randomized subjects, therefore either can be used in analyses. For non-randomized subjects in safety summaries which contain a 'Product Test' arm (subjects who tested THSm2.2 on Day -2), then TRT01A='Product Test' is used to identify those subjects.

### 3.4 Subject Issues that Require Special Analysis Rules

There are no subjects who required any special analysis rules in this study. Due to ICH/GCP non-compliance, subjects from SITEID='SEI' were not included in any efficacy analyses. Subjects from this site were included in the 'Full Safety Population' if they had at least one exposure to THSm2.2. The data for subjects in the Full Safety Population were listed only.

### 3.5 Use of Visit Windowing, Unscheduled Visits, and Record Selection

- Was windowing used in one or more analysis datasets?

Visit windowing was applied to data in ADBX, ADEG, ADLB, ADPE, ADQSPA, ADQSSYM, ADQSSU, ADQSND, ADXT datasets. Visit windowing was used in cases where the subject terminated early from the confinement or ambulatory period and so were assigned Day

6/Discharge Confinement or Day 91/Discharge Ambulatory Visits, respectively, in SDTMs. These visits were reassigned to the closest scheduled visit.

Assessment windows noted in SAP Section 11.1.3 (Table 18) were also used to identify records in ADaMs which were out of protocol collection windows (using DEVN and DEVWC). Most of these out-of-window records were still used in analyses with the following 2 exceptions:

- ADBX: for the sensitivity analyses of biomarkers of exposure using proc mixed (see SAP section 12.6.1.3), biomarker records which were collected outside the assessment window were set to ANL01FL=missing and not used in the sensitivity analyses.
- ADPC: plasma nicotine and cotinine records which were collected outside the assessment window were set to ANL01FL=missing and not used in analyses.

In addition, in ADBX, a time-matched algorithm was created using BASETYPE for PARAMCD=CO to align the up to 4 measurements which were collected on each day during the Confinement Period with the 4 baseline measurements (see Section 4.4 for details).

- Were unscheduled visits used in any analyses?

Unscheduled visits were used as the baseline value if they were the latest value before the treatment period. Otherwise, unscheduled visits were not summarized in any analyses.

### 3.6 Imputation/Derivation Methods

- If date imputation was performed, were there rules that were used in multiple analysis datasets?

For subjects randomized to SA, the time component of TRTSDTM and TRTEDTM were imputed. The start time on Day 1 was imputed to 10:00. The end time was imputed to 23:00 (or time of discharge if discontinued early) on the last visit date. No other dates were imputed.

Additional Content of Interest

The following values were used for DTYPE across the various ADaMs:

Controlled terminology	Definition
AVERAGE	Value derived as an average of 2 or more parameter values
BLQHALF	BLQ values set to half the LLOQ during the profile refer to SAP section 12.1.5
FUNCTION	Value derived as a function of 2 or more parameter values or a unit conversion
LOCF	Value derived using last observation carried forward
RATIO	Value derived as a ratio of 2 parameter values
SUM	Value derived as a sum of 2 or more parameter values

In particular, in the efficacy analysis, PARAMTYP='DERIVED' and DTYPE='RATIO' or 'FUNCTION' if the parameter was a combination of other existing parameters. Also, in cases where the

original value was below the limit of quantification (original value contained in AVALC), a new record was created using  $1/2 \times$  the lower limit in AVAL and DTYPE='BLQHALF'. Finally, DTYPE='LOCF' was used in cases where last observation carried forward was used to impute a value. Baseline values were eligible to be carried forward to post-baseline values. For PARAMCD='CO' in which measurements on Days -1 to 5 during the confinement period were collected at 4 timepoints throughout the day, missing values were imputed using the time-matched (refer to BASETYPE) previous value (see Section 4.4).

In ADSL, there were several variables which were created using imputation. Refer to SAP Section 12.1.5 for details. In particular, if less than 75% of product use assessments over a period were available, or if product use assessments were missing over a period of more than 7 days, the Day 0 cigarette consumption data was used for the missing days to determine:

- the percentage of THS use (see SAP Section 6.3.3.1) for product use category variables PUCAT2-PUCAT4 (and GPUCAT2-GPUCAT4) for time periods 2-4, respectively. PUCAT5 (GPUCAT5) were created to determine the product use category variables over the entire ambulatory period. For subjects randomized to THSm2.2 identified as 'Primarily THS 2.2' or 'Primarily CC' (see SAP Figure 2), PUCAT2EX, PUCAT3EX, PUCAT4EX, and PUCAT5EX were used to identify whether THS 2.2. or CC were exclusively used during each respective period. PUCAT/GPUCAT variables were not available for period 1 because all subjects were compliant to the randomized product during confinement.
- compliance to randomized product (see SAP Table 16 for product compliance definition in ambulatory period) in variables CMPCP2FL-CMPCP4FL for periods 2-4, respectively

In ADSL, variables PUCAT1, GPUCAT1, and PUCAT1EX were created to capture product use categories over the entire ambulatory period without imputation. In particular, PUCAT1 was used in adverse event summaries.

## 4. Analysis Data Creation and Processing Issues

### 4.1 Split Datasets

There were no datasets that were split due to size constraints.

### 4.2 Data Dependencies

ADSL was used in the creation of all other analysis datasets. ADEX was used in the creation of ADQSSYM. ADCM was used in the creation of ADBX.

### 4.3 Intermediate Datasets

At the time of database lock, all deviations included in the database were manually identified. In order to include programmatic deviations into ADDV post database lock, an intermediate spreadsheet of potential deviations was created to query against the database (POTENTIAL DEVIATION.XLSX). Based on rules in the statistical analysis plan, these potential deviations were classified in advance as major/minor and evaluable/non-evaluable. The resulting programmatic deviations (DV.XLS) were then manually reconciled to the deviations already noted in the Case Report Form. This spreadsheet (after reconciliation, only deviations with column F 'incl' = 'Yes' were needed for inclusion) was then

combined with the manual deviations coming from SDTM.DV for the production of ADDV. The manual and programmatic deviations can be identified using ADDV.DVSCAT (= 'Manual' or 'Programmatic').

A PKMERGE intermediate dataset was used in support of the creation of ADPC as well as this file was used by the pharmacokineticist to calculate the pharmacokinetic parameters. This file was created using SDTM.DM, SDTM.SUPPDM, SDTM.DS, SDTM.DX, SDTM.EX, SDTM.PC, and SDTM.VS. This file calculated relative times from start of exposure on Study Day 5 for the nicotine and cotinine Day 5 & Day 6 concentrations in the THSm2.2 and mCC arms.

The intermediate spreadsheet, BANNEDMEDS.XLSX, was provided to the medical monitor to flag meds which could impact CYP1A2, 11-DTX-B2, and CYP2A6 assessments and to provide the corresponding half-lives for those medications. This spreadsheet was then combined with SDTM.CM in the creation of ADCM.

The raw datasets IE\_E, IE\_E\_ADM, IE\_E\_SF, IE\_I, IE\_I\_ADM and IE\_I\_SF coming from the EDC extract were used in the creation of ADEL so that all inclusion and exclusion responses (not just violations captured in SDTM.IE) could be included.

#### 4.4 Variable Conventions

In ADBX, PARAMCD='CO' is collected at 4 timepoints throughout the day on Days -1 to 5 during the confinement period and so baseline is defined as the last measurement prior to the start of treatment (for THSm2.2 and mCC arms) or 10:00 AM (for SA arm) for each timepoint as noted in BASETYPE. As such, each subject has up to 4 ABLFL='Y' values, one for each BASETYPE. For Days 6, 30, 60, and 90, in which only 1 CO measurement/day was collected, baseline was selected as the 2<sup>nd</sup> timepoint (12:00-13:30) since that generally reflected the closest timepoint. The BASE, CHG, and PCHG values were then derived using the ABLFL='Y' record on each combination of AVISIT and ATPT.

## 5. Analysis Dataset Descriptions

### 5.1 Overview

- Do the analysis datasets support all protocol- and statistical analysis plan-specified objectives?

Yes, all analyses were done using the ADaM datasets as input.

#### Additional Content of Interest

As noted in the SAP, this study has 4 Per Protocol flags created in ADSL and copied to other ADaMs. PPROT1FL-PPROT4FL represent the Per Protocol designation for each subject in each of the 4 study periods (see Section 2.2 above). As descriptive statistics and inferential analyses were summarized over time for the PP Set, the underlying analyses were repeated 4 times since the subjects included in each PP Set for the period was different. For example, when analyzing the endpoints for primary objectives at Day 5 and Day 90, the subjects with PPROT1FL='Y' were used in the Day 5 analysis while the subjects with PPROT4FL='Y' were used in the Day 90 analysis.

As noted in the SAP, the Compliant Population is a subset of the Per Protocol Set. As such, there were 4 flags created in ADSL and copied to ADBX, COMPP1FL-COMPP4FL, to represent the Compliant Population designation for each subject in each of the 4 study periods. These flags were used in a similar manner to that noted for the Per Protocol Set flags above.

As noted in the SAP, this study has a Full Safety Population and a Safety Population. Each safety population had 2 associated flags. Prior to randomization, subjects exposed to the THSm2.2 product test had FSAFBFL='Y' and the subset of those from SITEID='TOK' had SAFBFL='Y'. After randomization, randomized subjects who had at least one valid safety assessment had FSAFAFL='Y' and the subset of those from SITEID='TOK' had SAFAFL='Y'.

Many of the BDS datasets also contain variables called APUPER/APUPERC and/or ASPER/ASPERC to designate the study period when the event or visit took place and these were used in analyses as needed when summarizing data by study period.

### 5.2 Analysis Datasets

Dataset – Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	PK/PD	Primary Objective	Structure
<u>ADSL</u> : Subject Level Analysis Dataset	ADSL			X			One record per subject
<u>ADAE</u> : Adverse Event Analysis Dataset	OTHER		X				One record per subject per adverse event

Dataset – Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	PK/PD	Primary Objective	Structure
<u>ADB</u> X: Biomarker Exposure Analysis Dataset	BDS	X				X	One record per subject per visit per parameter category per parameter per timepoint per date/time per lab sequence per derivation type
<u>ADCM</u> : Concomitant Medication Analysis Dataset	OTHER		X				One record per subject per concomitant medication per date
<u>ADCO</u> : Comments Analysis Dataset	OTHER			X			One record per subject per comment.
<u>ADDE</u> : Device Events Analysis Dataset	OTHER		X				One record per subject per device event
<u>ADDS</u> : Disposition Analysis Dataset	OTHER			X			One record per subject per collection date per disposition status or protocol milestone
<u>ADDT</u> : Device Tracking and Disposition Analysis Dataset	OTHER			X			One record per subject per device event category per device ID per device event per visit

Dataset – Dataset Label	Class	Efficacy	Safety	Baseline or other subject characteristics	PK/PD	Primary Objective	Structure
<u>ADDV</u> : Protocol Deviation Analysis Dataset	OTHER			X			One record per subject per deviation category per deviation start date per visit per assessment per analysis value
<u>ADEG</u> : ECG Analysis Dataset	BDS		X				One record per subject per visit per timepoint per parameter
<u>ADEL</u> : Eligibility Analysis Dataset	BDS			X			One record per subject per visit per parameter
<u>ADEX</u> : Exposure Analysis Dataset	OTHER		X				One record per subject per visit per parameter per product use period per treatment start date/time per treatment end date/time per source domain per source domain sequence number
<u>ADFA</u> : Findings About Events or Interventions Analysis Dataset	BDS		X	X			One record per subject per visit per parameter

<b>Dataset – Dataset Label</b>	<b>Class</b>	<b>Efficacy</b>	<b>Safety</b>	<b>Baseline or other subject characteristics</b>	<b>PK/PD</b>	<b>Primary Objective</b>	<b>Structure</b>
<u>ADLB</u> : Laboratory Analysis Dataset	BDS	X	X				One record per subject per visit per timepoint per parameter per lab sequence number
<u>ADMH</u> : Medical History Analysis Dataset	OTHER		X	X			One record per subject per medical history category per medical history event
<u>ADPC</u> : Pharmacokinetic Concentration Analysis Dataset	BDS	X			X		One record per subject per visit per parameter per timepoint per sequence number per derivation type
<u>ADPE</u> : Physical Examination Analysis Dataset	BDS		X				One record per subject per visit per parameter per PE ID
<u>ADPP</u> : PK Parameters Analysis Dataset	BDS				X		One record per subject per visit per parameter category per parameter
<u>ADQSND</u> : Nicotine Dependence Analysis Dataset	BDS	X		X			One record per subject per visit per parameter category per parameter per start date
<u>ADQSPA</u> : Product Assessment Analysis Dataset	BDS	X					One record per subject per visit per parameter category per parameter



<b>Dataset – Dataset Label</b>	<b>Class</b>	<b>Efficacy</b>	<b>Safety</b>	<b>Baseline or other subject characteristics</b>	<b>PK/PD</b>	<b>Primary Objective</b>	<b>Structure</b>
<u>ADQSSU</u> : Smoking Urges Analysis Dataset	BDS	X					One record per subject per visit per parameter
<u>ADQSSYM</u> : Symptoms Questionnaire Analysis Dataset	BDS		X				One record per subject per visit per parameter
<u>ADSV</u> : Visit Incidence Analysis Dataset	OTHER			X			One record per subject per visit
<u>ADVS</u> : Vital Signs Analysis Dataset	BDS	X	X				One record per subject per visit per timepoint per parameter per sequence
<u>ADXP</u> : Pulmonary Function Analysis Dataset	BDS		X				One record per subject per visit per timepoint per parameter
<u>ADXT</u> : Smoking Profile Analysis Dataset	BDS	X					One record per subject per visit per parameter per reference ID per sequence number per filter vial number per start date/time

### 5.2.1 ADSL – Subject Level Analysis Dataset

In addition to supporting all analyses, ADSL contains variables to also support baseline characteristics and disposition analyses. The population indicator variables (Enrolled Population flag ENRLFL, Screen Failure flag SCRFFL, Completers Population flag COMPLFL, Full Safety Population Before Randomization flag FSAFBFL, Full Safety Population After Randomization flag FSAFAFL, Safety Population Before Randomization flag SAFBFL, Safety Population After Randomization flag SAFAFL,

Full Analysis Set flag FASFL, Per Protocol Population in Period 1 flag PPROT1FL, Per Protocol Population in Period 2 flag PPROT2FL, Per Protocol Population in Period 3 flag PPROT3FL, Per Protocol Population in Period 4 flag PPROT4FL, Compliant Population in Period 1 flag COMPP1FL, Compliant Population in Period 2 flag COMPP2FL, Compliant Population in Period 3 flag COMPP3FL, Compliant Population in Period 4 flag COMPP4FL, Randomized Population flag RANDFL, Exposed Not Enrolled flag EXFL, Exposed Not Randomized flag EXNOTRFL, and Enrolled Not Randomized flag ENFL) are defined in ADSL and copied into other analysis datasets as needed. All subjects in DM were included in ADSL including screen failure subjects. All covariates used in statistical analyses of primary and secondary efficacy analysis are present in ADSL and are listed below.

Treatment group – ADSL.TRT01P (ADSL.TRTP in ADBX)

Sex – ADSL.SEX

Screening cigarette consumption – ADSL.UCPDGR1

LVISIT is recorded as the last visit attended by each subject, either Screening for subjects who did not enroll, or the last post-enrollment visit for those who did enroll. The dates associated with last visit, LVISDT and LVISDTC, are the final visit dates, including any unscheduled visit dates. LVISDAY is the number of days between first randomized product use on Day 1 and the final visit date for the subject (LVISDT-TRTSDT+1).

DSREAS is the primary term for study discontinuation as recorded in the CRF.

### 5.2.2 ADAE – Adverse Event Analysis Dataset

ADAE contains all observations from AE and SUPPAE. TRTEMFL = Y is used to indicate exposure emergent AEs which were used in summary tables. This data contains observations for screen failure subjects which are listed only.

The data are coded under the System Organ Class variable AEBODSYS and Preferred Term variable AEDECOD.

The following flagging variables were provided:

ANL01FL – Indicates the AE was product emergent (TRTEMFL=Y).

ANL02FL – Indicates the AE was product emergent and subject withdrew from the study due to that AE (AEACNOTH = 'DISCONTINUED STUDY').

ANL03FL – Indicates the AE was product emergent and action was taken (AEACNP1N in 1,2,3). No observations populated for this study.

ANL04FL - Indicates the AE was product emergent and concomitant medication was taken for the AE (AECONTRT=Y).

ANL05FL – Indicates the AE was product emergent and other action was taken (AEACNOTH populated).

### 5.2.3 ADBX – Biomarker Exposure Analysis Dataset

ADBX supports the efficacy analyses of biomarkers of exposure for the primary and secondary objectives (see Protocol Table S1). ADBX contains the biomarker of exposure data captured in 24-hour urine, blood

(PARAMCD='CARBHXGB'), and exhaled breath (PARAMCD='CO') found in LB. For the 24-hour urine data, each biomarker is presented as a concentration, as well as corrected for creatinine (PARAMCD ending in 'CRE') and excreted over 24 hours (PARAMCD ending in '24U'). ADBX also contains data for CYP1A2, CYP2A6, Ames mutagenicity, and risk markers in 24-hour urine (11-DTX-B2 and 8-epi-PGF-2 $\alpha$ ) found in LB. Parameters that were derived were identified with PARAMTYP='DERIVED' and DTYPE='FUNCTION' or 'RATIO'.

Most parameters in ADBX have a single baseline value. The exception is PARAMCD='CO' which is collected at 4 timepoints throughout the day on Days -1 to 5 during the confinement period and so baseline is defined for each timepoint as noted in BASETYPE. BASETYPE takes on the format of 'TIME MATCHED DAY y (x)', where x refers to the 4 time periods within a day [1='WITHIN 15 MIN PRIOR TO SMOKING' (all arms on Day 0 or for THS/mCC arms on Day 1) or '08:00 - 09:30' (for SA arm on Day 1), 2='12:00 - 13:30', 3='16:00 - 17:30', and 4='20:00 - 21:30') and y refers to the study day (-1 or 0)]. As such, each subject has up to 4 ABLFL='Y' values, one for each BASETYPE. For Days 6, 30, 60, and 90, in which only 1 CO measurement/day was collected, baseline was selected as the 2<sup>nd</sup> timepoint (12:00-13:30) since that generally reflected the closest timepoint. The BASE, CHG, and PCHG values were then derived using the ABLFL='Y' record on each combination of AVISIT and ATPT.

Some parameters had values below the limit of quantification (AVALC contains '<' and AVAL=missing and BLOQFL='Y'). In those cases, a new record was created with AVAL set to  $\frac{1}{2}$  x the lower limit of quantification and DTYPE='BLQHALF' and AQLFL='Y'. These newly created records were flagged for analysis with ANL02FL='Y'.

Analysis visits (AVISIT) were generally derived directly from the SDTM.VISIT value. Visit windowing was only used in cases where the subject terminated early from the confinement or ambulatory period and so were assigned Day 6/Discharge Confinement or Day 91/Discharge Ambulatory Visits, respectively, in SDTMs. These visits were reassigned to the closest scheduled visit. In cases of early termination or missed scheduled visits, LOCF records were created so that scheduled visits existed for each subject for each parameter (as expected in the protocol). These records are identified with DTYPE='LOCF' and LOCF was used in the primary proc glm analysis for the biomarkers of exposure for the primary and secondary objectives. LOCF records were not use in the proc mixed sensitivity analyses.

For the efficacy analysis variables in ADBX, ANL02FL='Y' indicates the visits used in the primary proc glm analyses. For the sensitivity analyses of biomarkers of exposure using proc mixed (see SAP section 12.6.1.3), ANL01FL='Y' was also used to only select values which occurred within the visit windows noted in SAP Table 18. Additional supportive analyses for 11-DTX-B2, and CYP1A2 were conducted in which assessments performed within 5 half-lives since the use of a medication impacting their results was excluded. For these analyses, ANL03FL='Y' was also used.

Therefore, AVAL records with ANL02FL='Y' are used for the primary proc glm analysis of biomarkers of exposure. AVAL records with ANL02FL='Y' and ANL01FL='Y' and DTYPE='LOCF' were used for the proc mixed sensitivity analysis of biomarkers of exposure.

For the Per Protocol Set analyses, PPROT1FL-PPROT4FL represent the Per Protocol designation for each subject in each of the 4 study periods (see Section 2.2 above). As descriptive statistics and inferential analyses were summarized over time for the PP Set, the underlying analyses were repeated 4

times since the subjects included in each PP Set for the period was different. For example, when analyzing the endpoints for the primary objectives at Day 5 and Day 90, the subjects with PPROT1FL='Y' were used in the Day 5 analysis while the subjects with PPROT4FL='Y' were used in the Day 90 analysis. There is only 1 Full Analysis Set population flag and those analyses are designated using FASFL='Y'.

The following table shows the biomarkers of exposure analyzed.

<b>PARAMCD Value</b>	<b>PARAM Value</b>	<b>Endpoints for Primary/Secondary/Exploratory Objectives</b>
UMHBMCRE	MHBMA (pg/mg creat)	Primary
UMHBM24U	MHBMA (ng)	Secondary
U3HPMCRE	3-HPMA (ng/mg creat)	Primary
U3HPM24U	3-HPMA (ug)	Secondary
USPMACRE	S-PMA (pg/mg creat)	Primary
USPMA24U	S-PMA (ng)	Secondary
CARBHXGB	Carboxyhemoglobin (%)	Primary
UNNALCRE	Total NNAL (pg/mg creat)	Primary
UNNAL24U	Total NNAL (ng)	Secondary
CO	Exhaled CO (ppm)	Secondary
U1OHPCRE	Total 1-OHP (pg/mg creat)	Secondary
U1OHP24U	Total 1-OHP (ng)	Secondary
UNNNCRE	NNN (pg/mg creat)	Secondary
UNNN24U	NNN (ng)	Secondary

<b>PARAMCD Value</b>	<b>PARAM Value</b>	<b>Endpoints for Primary/Secondary/Exploratory Objectives</b>
U4ABPCRE	4-ABP (pg/mg creat)	Secondary
U4ABP24U	4-ABP (ng)	Secondary
U1NACRE	1-NA (pg/mg creat)	Secondary
U1NA24U	1-NA (ng)	Secondary
U2NACRE	2-NA (pg/mg creat)	Secondary
U2NA24U	2-NA (ng)	Secondary
UOTOLCRE	o-tol (pg/mg creat)	Secondary
UOTOL24U	o-tol (ng)	Secondary
UCEMACRE	CEMA (ng/mg creat)	Secondary
UCEMA24U	CEMA (ug)	Secondary
UHEMACRE	HEMA (pg/mg creat)	Secondary
UHEMA24U	HEMA (ng)	Secondary
UBAPCRE	B[a]P (fg/mg creat)	Secondary
UBAP24U	B[a]P (pg)	Secondary
UHMPMCRE	HMPMA (ng/mg creat)	Secondary
UHMPM24U	HMPMA (ug)	Secondary
USBMACRE	S-BMA (pg/mg creat)	Secondary
USBMA24U	S-BMA (ng)	Secondary
UNEQCRE	NEQ (mg/g creat)	Secondary

<b>PARAMCD Value</b>	<b>PARAM Value</b>	<b>Endpoints for Primary/Secondary/Exploratory Objectives</b>
UNEQ24U	NEQ (mg)	Secondary
UPGF2CRE	Prostaglandin F2 Alpha (pg/mg creat)	Secondary
UPGF224U	Prostaglandin F2 Alpha (ng)	Secondary
UTXB2CRE	11-Dehydro-Thromboxane B2 (pg/mg creat)	Secondary
UTXB224U	11-Dehydro-Thromboxane B2 (ng)	Secondary
CYP1A2	CYP1A2 Activity (%)	Secondary
CYP2A6	CYP2A6 Activity (%)	Exploratory

#### 5.2.4 ADCM – Concomitant Medication Analysis Dataset

ADCM contains all observations and required variables from CM and SUPPCM. Refer to an external spreadsheet BANNEDMEDS.XLSX (see Section 4.3) for the list of medications impacting CYP2A6, CYP1A2, and 11-DTX-B2, and this is used to populate CRIT1FL, CRIT2FL, CRIT3FL, and HALFLIFE. CRIT1FL=Y indicates if any medication affects CYP2A6, CRIT2FL=Y indicates if any medication affects CYP1A2, and CRIT3FL=Y indicates if any medication affects 11-DTX-B2. HALFLIFE is the corresponding half-life of the medication which impacts at least one of those 3 parameters. CMFL=Y indicates the medication is concomitant. PMFL=Y indicates the medication is prior. This dataset includes medications recorded for screen failure subjects.

#### 5.2.5 ADCO – Comments Analysis Dataset

ADCO contains all observations from CO. ADOMAIN indicates the source dataset and ASEQ indicates the sequence number from the source dataset for traceability.

#### 5.2.6 ADDE – Device Events Analysis Dataset

ADDE contains all observations and required variables from DE and SUPPDE and includes a record for any subject who took part in the device test and enrolled into the study, even if they didn't experience a device event. The variable ANYDEFL=Y indicates a device event was experienced.

### 5.2.7 ADDS - Disposition Analysis Dataset

ADDS contains all observations from DS and SUPPDS. Follow-up has not been included as a visit as it was undertaken as a telephone call so information on subjects taking part in the followup assessments are included in this dataset. This dataset includes observations for screen failure subjects.

### 5.2.8 ADDT - Device Tracking and Disposition Analysis Dataset

ADDT contains all observations from DT for the identification of devices and collection, distribution, and replacement information from the CRF.

### 5.2.9 ADDV – Protocol Deviation Analysis Dataset

ADDV contains all observations from DV as well as observations which were programmatically generated after database lock (DV.XLS – see Section 4.3). In addition, records with ADDV.DVCAT=MIS-USE OF PRODUCT IN PERIOD x deviations were created from ADSL when SITEID=TOK and CMPCPxFL=N and PPREASx ^= 'Discontinued in previous period' (for the same value of 'x') were included in ADDV. These 'mis-use of product' deviations were based on SAP Table 16 to determine major product compliance deviations in each study period according to imputation rules noted in SAP Section 12.1.5. The manual and programmatic deviations can be identified using ADDV.DVSCAT (= 'Manual' or 'Programmatic'). PARAMCD and PARAM are derived from the SAP tables 16 and 17. This dataset contains observations for screen failure subjects which are listed only.

DVSIG indicates if the protocol deviation category is (Minor/Major). For any major protocol deviations, the EVALCAT indicates if it impacts (EVALCAT=NON EVALUABLE) or does not impact (EVALCAT=EVALUABLE) the evaluability of the subject for the Per Protocol populations.

### 5.2.10 ADEG – ECG Analysis Dataset

ADEG contains all observations from EG and SUPPEG. Fridericia's Correction Formula (QTcF) is derived and included in all output for ECG data. ANL01FL=Y is used to indicate which values are used in summary statistics. Reference ranges were not used to assess this data.

### 5.2.11 ADEL – Eligibility Analysis Dataset

The CRF datasets IE\_E, IE\_E\_ADM, IE\_E\_SF, IE\_I, IE\_I\_ADM and IE\_I\_SF are used to create this dataset as only abnormal responses are stored in SDTM.IE. The description of the eligibility criteria is defined in the Parameter Value Level Metadata section contained within the define.xml. This dataset contains observations for screen failure subjects which are listed only.

### 5.2.12 ADEX – Exposure Analysis Dataset

ADEX contains all observations from EX/SUPPEX and DX/SUPPDX, as well as records from SU with SUCAT in ('NRT\_USE', 'TOB\_USE'). Exposure records from both the product administration log used during the confinement period (PARCAT2='PRODUCT USE CONFINEMENT') as well as the product diary used during the ambulatory period (PARCAT2='PRODUCT USE DIARY – ELECTRONIC' or 'PRODUCT USE DIARY – PAPER') are included.

During confinement, each THSm2.2 stick and/or each mCC used by a subject are recorded separately and derivations are then performed to calculate the number of THSm2.2 sticks and the number of mCC used by a subject each day (PARAMCD='DTHS2\_2' or 'DMCC'). During the ambulatory period, the number of THSm2.2 sticks, the number of mCC, and the number of other tobacco products are recorded per day. Derivations are then done to calculate the average number of daily products used in Periods 2, 3, and 4 (PARAMCD starting with 'PD' and period noted by APUPER) as well as the average number of daily products used over the entire ambulatory period (PARAMCD starting with 'AD').

Records with ANL01FL='Y' are used to flag the maximum daily use by subject for each product in each period for Periods 2, 3, and 4. Records with ANL02FL='Y' are used to flag the maximum daily use by subject for each product across the entire ambulatory period.

### **5.2.13 ADFA – Findings About Events or Interventions Analysis Dataset**

ADFA contains all observations from FA and SUPPFA. This dataset contains observations for screen failure subjects which are listed only.

### **5.2.14 ADLB – Laboratory Analysis Dataset**

ADLB contains all observation from LB and SUPPLB identified under LBCAT of HAEMATOLOGY, CLINICAL CHEMISTRY, SEROLOGY, COTININE SCREENING, ALCOHOL TEST, DRUG SCREEN, PREGNANCY, URINALYSIS (excluding LBTESTCD=VOLUME), and BIOMARKERS (records with LBGRPID=RISK MARKERS). ANL01FL=Y indicates the values to be used in summary statistics. This dataset contains observations for screen failure subjects which are listed only. ANRIND contains the normal range indicator while ACLSIG contains the clinical significance. Some parameters had values below the limit of quantification (BLOQFL='Y'). In those cases, AVAL was set to  $\frac{1}{2}$  x the lower limit of quantification found in AVALC.

PARCAT3='Risk Markers' identify lab parameters used in risk marker analyses. Subjects with missing risk marker data at scheduled visits have records with DTYPE=LOCF to identify records which are carried forward from an earlier visit.

PARCAT4 is used to identify whether lab tests are evaluated for toxicity grading in a single direction (high or low) or bi-directional. For those parameters with PARCAT4='Single-directional (High) CTC grade parameter', then LBTOXH indicates the toxicity name for the summary table. The grades for baseline appear in BTOXGRH, for post-baseline in ATOXGRH, and for the shift in SHIFT2. For those parameters with PARCAT4='Single-directional (Low) CTC grade parameter', then LBTOXL indicates the toxicity name for the summary table. The grades for baseline appear in BTOXGRL, for post-baseline in ATOXGRL, and for the shift in SHIFT3. For those parameters with PARCAT4='Bi-directional CTC grade parameter', then LBTOXH, BTOXGRH, ATOXGRH, and SHIFT2 indicate the high toxicities and separate summaries for LBTOXL, BTOXGRL, ATOXGRL, and SHIFT3 indicate the low toxicities.

### **5.2.15 ADMH – Medical History Analysis Dataset**

ADMH contains all observation from MH. ANYMHFL=Y indicates the observation is a medical history. ANYCDFL=Y indicates the observation is a concomitant disease. MHONGFL=Y indicates the concurrent disease is ongoing during the study.



The data are coded under the System Organ Class variable MHBODSYS and Preferred Term variable MHDECOD.

### 5.2.16 ADPC – Pharmacokinetic Concentration Analysis Dataset

ADPC supports the secondary analyses of biomarkers of exposure to nicotine (PARAMCD=NIC) and cotinine (PARAMCD=COT) in plasma. ADPC is created from the PC domain as well as from an intermediate dataset PKMERGE. PKMERGE was created to calculate relative times from start of exposure on Day 5 for the THSm2.2 and mCC arms. Nicotine and cotinine are collected in the evening (ATPT= 08:00 PM - 09:30 PM) on Days 0 to 4, collected over a 24-hour interval starting on Day 5 (every 2 hours out to 16 hours on Day 5 and 2 more times on Day 6), and then once per day at the Day 30, 60, and 90 study visits. Baseline for each parameter is the Day 0 evening measurement. Values outside of the protocol-allowed collection window were not flagged for analysis (i.e., records with DEVWC^=missing had ANL01FL=''). Records with ANL01FL='Y' were used in analysis. In addition, for the analysis of covariance statistical summary, ANL02FL='Y' was used to identify the evening (08:00 PM - 09:30 PM) records selected for analysis during the Confinement Period.

Some parameters had values below the limit of quantification (AVALC contains 'BLQ' and AVAL=missing). In those cases, a new record was created with AVAL set to  $\frac{1}{2}$  x the lower limit of quantification and DTYPE='BLQHALF'. These newly created records were flagged for analysis with ANL01FL='Y' (as long as DEVWC=missing).

### 5.2.17 ADPE – Physical Examination Analysis Dataset

ADPE contains all observations from PE. ANL01FL='Y' indicates values to be used in summary tables.

### 5.2.18 ADPP – PK Parameters Analysis Dataset

ADPP is a sponsor-defined analysis dataset following the ADaM BDS supporting the secondary analyses of biomarkers of exposure to nicotine and cotinine in plasma. ADPP contains 6 PK parameters (3 for nicotine [PARAMCD=NCAVG, NCMAX, and NTMAX] and 3 for cotinine [PARAMCD=CCAVG, CCMAX, and CTMAX]) on Day 5 for subjects randomized to the THSm2.2 and mCC arms. Records with ANL01FL='Y' were used in analysis.

### 5.2.19 ADQSND – Nicotine Dependence Analysis Dataset

ADQSND contains data from QS for the Fagerström Test for Nicotine Dependence (FTND), the Minnesota Nicotine Withdrawal Scale (MNWS) Questionnaire, and the Socio-Economic Status (SES) Questionnaire. ANL01FL=Y indicates values used in summary statistics and analysis.

For PARCAT1=Socio Economic Status Questionnaire, individual responses are captured for each question identified by PARAMCD/PARAM and the response is captured in AVALC.

For PARCAT1=Fagerstrom Test For Nicotine Dependence Questionnaire, the total score has been derived as detailed in SAP section 7.3.2 with PARAMCD=FTNDSC, numeric total score is in AVAL and the category is recorded under AVALCAT1.

For PARCAT1=Minnesota Nicotine Dependence/Withdrawal Scale, the total score has been derived as detailed in SAP section 7.3.5 with PARAMCD=MNWSRWDS and numeric total score is in AVAL.

### 5.2.20 ADQSPA – Product Assessment Analysis Dataset

ADQSPA contains data from QS for the Modified Cigarette Evaluation Questionnaire (MCEQ) and the Human Smoking Topography (HST) Questionnaire. ANL01FL=Y indicates values used in summary statistics and analysis.

For PARCAT1=Human Smoking Topography Questionnaire, individual responses are captured for each question identified by PARAMCD/PARAM and the response is captured in AVALC.

For PARCAT1=Modified Cigarette Evaluation Questionnaire, subscale scores have been derived into AVAL according to SAP section 7.3.4.

The subscale parameter information are in the following table:

Subscale	PARAMCD
Aversion Subscale	MCEQA
Craving Reduction Subscale	MCEQCR
Enjoyment of Respiratory Tract Sensation Subscale	MCEQERTS
Psychological Reward Subscale	MCEQPR
Smoking Satisfaction Subscale	MCEQSS

### 5.2.21 ADQSSU – Smoking Urges Analysis Dataset

ADQSSU contains data from QS for the Questionnaire On Smoking Urges (QSU)-Brief. Factor scores have been derived into AVAL according to SAP section 7.3.3 (Reward has PARAMCD= QSUFAC1, Relief has PARAMCD= QSUFAC2 and total score has PARAMCD= QSUTOTAL). ANL01FL=Y indicates values used in summary statistics and analysis.

### 5.2.22 ADQSSYM – Symptoms Questionnaire Analysis Dataset

ADQSSYM contains data from QS for the Cough Assessment Questionnaire. ANL01FL=Y indicates values used in summary statistics.

### 5.2.23 ADSV – Visit Incidence Analysis Dataset

ADSV contains all visit information from SV. It does not contain information on the telephone followup visit. This information is contained within ADDS. This dataset contains observations for screen failure subjects.

**5.2.24 ADVS – Vital Signs Analysis Dataset**

ADVS contains all observations from VS and SUPPVS. Reference ranges were not used to assess this data. ANL01FL=Y indicates values used in summary statistics. Subjects with missing blood pressure and waist circumference data (for risk marker analysis) at scheduled visits have DTYPE=LOCF to identify records which are carried forward from an earlier visit.

**5.2.25 ADXP – Pulmonary Function Analysis Dataset**

ADXP contains all spirometry observations from XP. The ratio between FEV<sub>1</sub> and FVC was included in the CRF for assessment of eligibility, to continue the comparison of subsequent timepoints to baseline, this parameter has also been derived for all timepoints. PARCAT2 can be used to determine if the assessment was prior to or after the bronchodilator dose. ANL01FL=Y indicates values used in summary statistics. Subjects with missing spirometry data at scheduled visits have DTYPE=LOCF to identify records which are carried forward from an earlier visit (note these records are not used in analysis).

**5.2.26 ADXT – Smoking Profile Analysis Dataset**

ADXT contains all observations from XT, including records from XTCAT=Topography, Filter Analysis, and Visual Inspection Of Tobacco Plug.

For PARCAT1=Visual Inspection Of Tobacco Plug, all records are used in the summary table. AVAL contains values of 0 (= No overheating), 1 (= White spot(s) inside the tobacco plug), and 2 (= Ashes inside the tobacco plug and burnt paper).

For PARCAT1=Topography, this includes the per-puff parameters noted in SAP Table 8, the derived per-cigarette parameters identified in SAP Table 9, and the derived average daily per-cigarette parameters used in analysis. Records with ANL02FL='Y' are used in summary statistics and analysis.

The following table shows the parameters from SAP Tables 8 and 9 as well as the parameters used in analysis.

<b>PARAMCD Value</b>	<b>PARAM Value</b>	<b>Per-Puff/Per-Cigarette/Per-Cigarette Averaged Over Visit</b>
NPC	Total number of puffs	Per-Cigarette
TVOL	Total puff volume (mL)	Per-Cigarette
AVGVI	Average puff volume (mL)	Per-Cigarette
AVGDI	Average puff duration (s)	Per-Cigarette
TDI	Total puff duration (s)	Per-Cigarette

<b>PARAMCD Value</b>	<b>PARAM Value</b>	<b>Per-Puff/Per-Cigarette/Per-Cigarette Averaged Over Visit</b>
AVGQMI	Average flow (mL/s)	Per-Cigarette
AVGQCI	Average Peak flow (mL/s)	Per-Cigarette
TII	Total inter puff interval (s)	Per-Cigarette
AVGII	Average inter puff interval (s)	Per-Cigarette
TDFI	Total smoking duration (s)	Per-Cigarette
TWI	Total Work (mJ)	Per-Cigarette
AVGWI	Average Work (mJ)	Per-Cigarette
AVGPMI	Average pressure drop (mmWg)	Per-Cigarette
AVGPCI	Average Peak pressure drop (mmWg)	Per-Cigarette
SMINT	Smoking Intensity (mL/s)	Per-Cigarette
PTI	Puffing Time Index (%)	Per-Cigarette
PFEQ	Puff Frequency (puffs/min)	Per-Cigarette
NI	Puff Number	Per-Puff
VI	Puff volume (mL)	Per-Puff
DI	Puff Duration (S)	Per-Puff
QMI	Average Flow [Vi/Di] (mL/s)	Per-Puff
QCI	Peak Flow (mL/s)	Per-Puff
II	Inter Puff Interval (S)	Per-Puff

<b>PARAMCD Value</b>	<b>PARAM Value</b>	<b>Per-Puff/Per-Cigarette/Per-Cigarette Averaged Over Visit</b>
DFI	Sum of Ii and Di (S)	Per-Puff
WI	Work [INT Pmi*FinalFlow*dt] (mJ)	Per-Puff
PMI	Average Pressure Drop (mmWG)	Per-Puff
PCI	Peak Pressure Drop (mmWG)	Per-Puff
RMI	Average Resistance [Pmi/Qmi] (mmWG/mL/s)	Per-Puff
RCI	Peak Resistance [Pci/Qci] (mmWG/mL/s)	Per-Puff
ANPC	Total number of puffs (average over visit)	Per-Cigarette Averaged Over Visit
ATVOL	Total puff volume (mL) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGVI	Average puff volume (mL) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGDI	Average puff duration (s) (average over visit)	Per-Cigarette Averaged Over Visit
ATDI	Total puff duration (s) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGQMI	Average flow (mL/s) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGQCI	Average Peak flow (mL/s) (average over visit)	Per-Cigarette Averaged Over Visit
ATII	Total inter puff interval (s) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGII	Average inter puff interval (s) (average over visit)	Per-Cigarette Averaged Over Visit
ATDFI	Total smoking duration (s) (average over visit)	Per-Cigarette Averaged Over Visit

PARAMCD Value	PARAM Value	Per-Puff/Per-Cigarette/Per-Cigarette Averaged Over Visit
ATWI	Total Work (mJ) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGWI	Average Work (mJ) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGPMI	Average pressure drop (mmWg) (average over visit)	Per-Cigarette Averaged Over Visit
AAVGPCI	Average Peak pressure drop (mmWg) (average over visit)	Per-Cigarette Averaged Over Visit
ASMINT	Smoking Intensity (mL/s) (average over visit)	Per-Cigarette Averaged Over Visit
APTI	Puffing Time Index (%) (average over visit)	Per-Cigarette Averaged Over Visit
APFEQ	Puff Frequency (puffs/min) (average over visit)	Per-Cigarette Averaged Over Visit

## 6. Data Conformance Summary

### 6.1 Conformance Inputs

- Were the analysis datasets evaluated for conformance with CDISC ADaM Validation Checks?

If yes:

- Version of CDISC ADaM Validation Checks:
- Specify software used:
  - OpenCDISC Validator Version 1.5
- Were the ADaM datasets evaluated in relation to define.xml? Yes, see below
- Was define.xml evaluated? Yes, see below

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### 6.2 Issues Summary

There were no OpenCDISC issues related to define.xml. Below are the issues for ADaM datasets.

Dataset(s)	Diagnostic Message and/or Check ID	Severity	Count and/or Issue Rate	Explanation
ADAE	Neither AVAL nor AVALC are present in dataset	Error	1	ADAE is not a BDS domain and as such AVAL and AVALC are not required as per CDISC ADaM Data Structure for Adverse Event Analysis Version 1.0. Not amended as this is an OpenCDISC issue where it has not yet had appropriate class information for the ADAE domain.
ADAE	Required variable is not present	Error	2	As above, PARAM and PARAMCD are not required under CDISC ADaM Data Structure for Adverse Event Data Analysis version 1.0.
ADBX	calculation error: $PCHG \neq (AVAL - BASE)/BASE * 100$	Error	19	the SAP says that when the baseline values is 0, 1 will be used in the denominator for calculating the percent change from baseline
ADCM	Neither AVAL nor AVALC are present in dataset	Error	1	It was determined that the BDS format was not appropriate to this data type and as such AVAL and AVALC are not appropriate. Structure was based upon ADAE and SDTM.CM structure
ADCM	Required variable is not present	Error	2	It was determined that the BDS format was not appropriate to this data type and as such PARAM and PARAMCD are not appropriate. Structure was based upon ADAE and SDTM.CM structure
ADCO	Required variable is not present	Error	2	PARAM and PARAMCD

Dataset(s)	Diagnostic Message and/or Check ID	Severity	Count and/or Issue Rate	Explanation
				were not applicable to this data type due to the collection method of the comments. Data structure reflects BDS domain as closely as possible
ADDE	Neither AVAL nor AVALC are present in dataset	Error	1	AVAL and AVALC were not applicable to this data type. Data structure reflects ADAE domain as closely as possible as these are event data type..
ADDE	Required variable is not present	Error	2	PARAM and PARAMCD were not applicable to this data. Data structure reflects ADAE domain as closely as possible as these are event data type.
ADDS	Neither AVAL nor AVALC are present in dataset	Error	1	AVAL and AVALC were not applicable to this data type. Data structure reflects ADAE domain as closely as possible as this reflected the data type.
ADDS	Required variable is not present	Error	2	PARAM and PARAMCD were not applicable to this data type. Data structure reflects ADAE domain as closely as possible as this reflected the data type.
ADDT	Neither AVAL nor AVALC are present in dataset	Error	1	AVAL and AVALC were not applicable to this data type. Data structure reflects ADAE domain as closely as possible as this reflected the data type.
ADDT	Required variable is not present	Error	2	PARAM and PARAMCD were not applicable to this data type. Data structure



Dataset(s)	Diagnostic Message and/or Check ID	Severity	Count and/or Issue Rate	Explanation
				reflects ADAE domain as closely as possible as this reflected the data type.
ADEX	Inconsistent value for PARCAT2 within a unique PARAMCD	Error	8495	we have multiple values of PARCAT2 depending on if captured during the confinement period or on the electronic diary
ADLB	calculation error: $PCHG \neq (AVAL - BASE)/BASE * 100$	Error	5	the SAP says that when the baseline values is 0, 1 will be used in the denominator for calculating the percent change from baseline
ADMH	Neither AVAL nor AVALC are present in dataset	Error	1	ADMH is not a BDS domain. It is based upon ADAE domain and as detailed under ADAE OpenCDISC does not take this into account yet.
ADMH	Required variable is not present	Error	2	ADMH is not a BDS domain. It is based upon ADAE domain and as detailed under ADAE OpenCDISC does not take this into account yet.
ADQSND	calculation error: $PCHG \neq (AVAL - BASE)/BASE * 100$	Error	2632	the SAP says that when the baseline values is 0, 1 will be used in the denominator for calculating the percent change from baseline
ADQSPA	Inconsistent value for PARCAT1 within a unique PARAMCD	Error	14	when PARAMCD=QSALL, we have PARCAT1=Modified Cigarette Evaluation Questionnaire and PARCAT1=Human Smoking Topography Questionnaire

Dataset(s)	Diagnostic Message and/or Check ID	Severity	Count and/or Issue Rate	Explanation
				depending on which form was not completed
ADSV	Neither AVAL nor AVALC are present in dataset	Error	1	Structure is not a BDS domain for this data type. Data is not used for any analysis but can be used for supporting information.
ADSV	Required variable is not present	Error	2	PARAM and PARAMCD are not appropriate for this data type. Data is not used for any analysis in its own right but can be used for information.
ADXT	calculation error: $PCHG \neq (AVAL - BASE)/BASE * 100$	Error	33165	the SAP says that when the baseline values is 0, 1 will be used in the denominator for calculating the percent change from baseline

## 7. Submission of Programs

ADaM dataset production programs have been submitted and referred to in the define.xml.

Programs for the production of primary and secondary analysis, descriptive statistics tables and figures and associated macros have also been submitted and are defined below. Submitted programs will execute on a SAS version 9.3. Library definitions will need to be modified to reflect the actual environment where run.

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.1.1.1	Forest Plot of Statistical Analysis of Biomarkers of Exposure on Day 5 and Day 90 - PP Set.	<a href="#">F15010101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADBX</a>	PPROT1FL, USUBJID, TRT01A  ANL02FL, PARAMCD, AVISIT, ATPT, PPROT1FL, PPROT4FL, AVAL, BASE, AVISITN, PARAMN, TRTP, PARAM
15.1.1.2	Biomarkers of Exposure Geometric Mean and 95% CI – PP Set	<a href="#">F15010102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, AVISIT, ATPT, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.1.3	Biomarkers of Exposure Geometric Mean and 95% CI – Compliant Population	<a href="#">F15010103_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, AVISIT, ATPT, COMPP1FL, COMPP2FL, COMPP3FL, COMPP4FL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.1.4	Biomarkers of Exposure Geometric Mean and 95% CI – FAS	<a href="#">F15010104_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, AVISIT, ATPT, FASFL, AVAL, AVISITN, PARAMN, TRTA, PARAM

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.1.2.1.1	Plasma Nicotine and Cotinine Profile (ng/mL) Geometric Mean and 95% CI – PP Set	<a href="#">F1501020101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPC</a>	ANL01FL, PARAMCD, AVISIT, ATPT, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.2.1.2	Plasma Nicotine and Cotinine Profile (ng/mL) Geometric Mean and 95% CI – FAS	<a href="#">F1501020102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPC</a>	ANL01FL, PARAMCD, AVISIT, ATPT, FASFL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.2.10	HST Parameters Averaged Over the Visit Arithmetic Mean and 95% CI – PP Set	<a href="#">F15010210_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADXT</a>	PARAMN, PARAMCD, PARAM, PPROT1FL, AVISITN, ANL02FL, PPROT2FL, PPROT3FL, PPROT4FL, AVAL, TRTA

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PARAMN, TRTA, PARAM, FASFL
15.1.2.4.1	QSU-brief Total Scores Arithmetic Mean and 95% CI – PP Set	<a href="#">F1501020401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSSU</a>	ANL01FL, PARAMCD, AVISIT, AVAL, AVISITN, PARAMN, TRTA, PARAM, FASFL
15.1.2.4.2	QSU-brief Total Scores Arithmetic Mean and 95% CI – FAS	<a href="#">F1501020402_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSSU</a>	ANL01FL, PARAMCD, AVISIT, AVAL, AVISITN, PARAMN, TRTA, PARAM, FASFL
15.1.2.5.1	QSU-brief Total Scores Least Squares Means Differences and 95% CI – PP Set	<a href="#">F1501020501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADQSSU</a>	PPROT1FL, USUBJID, TRT01A  ANL0LFL, PARAMCD, AVISIT, AVAL, BASE, AVISITN, PARAMN, TRTA



Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.1.2.5.2	QSU-brief Total Scores Least Squares Means Differences and 95% CI – FAS	<a href="#">F1501020502_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADQSSU</a>	PPROT1FL, USUBJID, TRT01A  ANL0LFL, PARAMCD, AVISIT, AVAL, BASE, AVISITN, PARAMN, TRTA
15.1.2.6.1	MCEQ Subscales Arithmetic Mean and 95% CI – PP Set	<a href="#">F1501020601_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSPA</a>	ANL01FL, PARAMCD, AVISIT, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.2.6.2	MCEQ Subscales Arithmetic Mean and 95% CI – FAS	<a href="#">F1501020602_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSPA</a>	ANL01FL, PARAMCD, AVISIT, FASFL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.2.7.1	MCEQ Subscales Least Squares Means Differences and 95% CI – PP Set	<a href="#">F1501020701_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADQSPA</a>	PPROT1FL, USUBJID, TRT01A  ANL0LFL, PARAMCD, AVISIT, AVAL, BASE, AVISITN, PARAMN, TRTA
15.1.2.7.2	MCEQ Subscales Least Squares Means Differences and 95% CI – FAS	<a href="#">F1501020702_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADQSPA</a>	FASFL, USUBJID, TRT01A  ANL0LFL, PARAMCD, AVISIT,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				AVAL, BASE, AVISITN, PARAMN, TRTA
15.1.2.8.1	MNWS Total Score Arithmetic Mean and 95% CI – PP Set	<a href="#">F1501020801_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSND</a>	ANL01FL, PARAMCD, AVISIT, ABLFL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.2.8.2	MNWS Total Score Arithmetic Mean and 95% CI – FAS	<a href="#">F1501020802_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSND</a>	ANL01FL, PARAMCD, AVISIT, ABLFL, AVAL, AVISITN, PARAMN, TRTA, PARAM
15.1.2.9.1	MNWS Total Score Least Squares Means Differences and 95% CI – PP Set	<a href="#">F1501020901_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADQSND</a>	PPROT1FL, USUBJID, TRT01A  ANL0LFL, PARAMCD, AVISIT, AVAL, BASE, AVISITN, PARAMN, TRTA
15.1.2.9.2	MNWS Total Score Least Squares Means Differences and 95% CI – FAS	<a href="#">F1501020902_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADQSND</a>	PPROT1FL, USUBJID, TRT01A  ANL0LFL, PARAMCD, AVISIT, AVAL, BASE, AVISITN, PARAMN, TRTA
15.2.1.1	Summary of Subject Disposition – All Screened Subjects	<a href="#">T15020101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>	SCRFFL, DSREAS, ENFL, RANDDT, FUPFL, TRT01AN, DISCCAT

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			SDTM.FA	FATESTCD, USUBJID, FAORRES
15.2.1.2	Summary of Reasons for Discontinuations – FAS	<a href="#">T15020102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>	FASFL, TRT01AN, DSREAS
15.2.1.3.1	Summary of Protocol Deviations – Safety Population	<a href="#">T1502010301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADDV</a>	SAFAFL, TRT01AN, CMPCP1FL, CMPCP1FL, CMPCP1FL, CMPCP1FL, DISCCAT, USUBJID  USUBJID, DVSIG, EVALCAT
15.2.1.3.2	Analysis Sets and Reasons for Exclusions from Analyses	<a href="#">T1502010302_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>	TRT01AN, RANDFL, FSAFBFL, ICFDT, FSAFBREA, RANDDT, FSAFAFL, SAFAFL, FASFL, FASREAS, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, PPRESAS1, PPRESAS2, PPRESAS3, PPRESAS4, COMPP1FL, COMPP2FL, COMPP3FL, COMPP4FL

<b>Table/Figure Number</b>	<b>Title</b>	<b>Program</b>	<b>Analysis Dataset</b>	<b>Analysis Variable(s)</b>
15.2.1.4.1	Summary of Demographics and Other Baseline Characteristics – Safety Population	<a href="#"><u>T1502010401_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADSL</u></a>  SDTM.VS  <a href="#"><u>ADQSND</u></a>	SAFBFL, TRT01AN, UCPDGR1, HEIGHT, PRODPREF, SEXC, SEXN, AGE, ETHNIC, ETHNICN, UCPDGR1N, WEIGHTBL, BMI, BMIGR1, BMIGR1N, TARGR1, TARGR1N, NICOBL, NICOGR1, NICOGR1N  VSTESTCD, VSSTRESN, VISITDY, USUBJID, VSDTC  PARAMN, USUBJID, AVISIT, AVAL, AVALC, AVALCAT1
15.2.1.4.2	Summary of Demographics and Other Baseline Characteristics – FAS	<a href="#"><u>T1502010402_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADSL</u></a>	FASFL, TRT01AN, BMI, UCPDGR1, HEIGHT, UCPDGR1N, ETHNIC, PRODPREF, SEXC, SEXN, AGE, ETHNICN, WEIGHTBL, BMIGR1, BMIGR1N, TARGR1, TARGR1N, NICOBL, NICOGR1,

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			<a href="#">ADQSND</a>	VSDTC  PARAMN, USUBJID, AVISIT, AVAL, AVALC, AVALCAT1
15.2.1.5	Summary of Current Cigarette Brands At Screening – Safety Population	<a href="#">T15020105_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADFA</a>	TRT01AN, SAFBFL, USUBJID, BRAND, PARAMCD, AVAL  USUBJID, BRAND, PARAMCD, AVAL
15.2.1.6	Summary of Medical History – Safety Population	<a href="#">T15020106_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADMH</a>  <a href="#">ADSL</a>  <a href="#">ADAE</a>	MHCAT, MHBODSYS, MHDECOD  SAFBFL, TRT01AN, TRT01A  USUBJID, TRTAN, AEBODSYS, AEDECOD
15.2.1.7	Summary of Concomitant Diseases – Safety Population	<a href="#">T15020107_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADMH</a>	SAFBFL, TRT01AN, MHCAT, TRTAN, SAFBFL  MHDECOD, STUDYID,



Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				USUBJID, MHBODSYS
15.2.2.1.1	Summary of Daily Product Use in Confinement Period – FAS	<a href="#">T1502020101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	FASFL, TRT01AN, USUBJID  USUBJID, AVISITN, AVISIT, PARCAT2, PARCAT3N, PARAMN, PARAM, AVAL
15.2.2.1.2	Summary of Daily Product Use in Confinement Period – PP Set	<a href="#">T1502020102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	PPROT1FL, TRT01AN, USUBJID  USUBJID, AVISITN, AVISIT, PARCAT2, PARCAT3N, PARAMN, PARAM, AVAL
15.2.2.2	Summary of Maximum Daily Product Use in Ambulatory Period – FAS	<a href="#">T15020202_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	FASFL, DISCCAT, TRT01AN, USUBJID  USUBJID, APUPER, APUPERC, AVAL, ANL01FL, ANL02FL, PARAMN, PARAM, AVAL
15.2.2.3.1	Summary of Average Daily Product Use in Ambulatory Period – FAS	<a href="#">T1502020301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	SAFAFL, TRT01AN, USUBJID  SAFAFL, USUBJID, APUPER, APUPERC, AVAL, DTYPE, PARCAT3,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PARAMN, PARAM
15.2.2.3.2	Summary of Average Daily Product Use in Ambulatory Period – PP Set	<a href="#">T1502020302_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	DISCCATE, TRT01AN, USUBJID  USUBJID, AVISITN, AVISIT, DTYPE, PARCAT3, PARAMN, PARAM, PPROT2FL, PPROT3FL, PPROT4FL, APUPERC, APUPER
15.2.2.4	Summary of Product Use by Product Use Category in Ambulatory Period – FAS	<a href="#">T15020204_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>	FASFL, TRT01AN, PUCAT1, PUCAT5, PUCAT2, PUCAT3, PUCAT4, DISCCAT
15.2.2.5.1	Summary of Average Daily Product Use by Product Use Category in Ambulatory Period – FAS	<a href="#">T1502020501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	FASFL, TRT01AN  FASFL, DTYPE, AVAL, PARAM, PARAMN, APUPER, APUPERC, USUBJID, PUCAT3EX, GPUCAT2N, GPUCAT3N, GPUCAT4N, PUCAT4N, PUCAT2, PUCAT3, PUCAT2EX, PUCAT4EX

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.2.5.2	Summary of Average Daily Product Use by Product Use Category During the Ambulatory Period – PP Set	<a href="#">T1502020502 ZRHM-REXA-07 JP V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	USUBJID, TRT01AN  USUBJID, DTYPE, AVAL, PARAM, PARAMN, APUPER, APUPERC, GPUCAT2N, GPUCAT3N, GPUCAT4N, PUCAT2N, PUCAT3N, PUCAT4N, PPROT2FL, PPROT3FL, PPROT4FL, PUCAT2EX, PUCAT3EX, PUCAT4EX
15.2.3.1.1	Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective – PP Set	<a href="#">T1502030101 ZRHM-REXA-07 JP V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, PARAM, ATPT, AVISIT, PPROT1FL, PPROT4FL, AVAL, BASE, TRTP, SEX, UCPDGR1
15.2.3.1.2	Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model-PP Set	<a href="#">T1502030102 ZRHM-REXA-07 JP V1</a>	<a href="#">ADBX</a>	ANL02FL, DTYPE, PARAMCD, PARAM, ATPT, AVISIT, PPROT1FL, PPROT4FL, AVAL, BASE, TRTP, SEX, UCPDGR1

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.3.1.3	Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population	<a href="#">T1502030103_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, PARAM, ATPT, AVISIT, COMPP1FL, COMPP4FL, AVAL, BASE, TRTP, SEX, UCPDGR1
15.2.3.2	Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA -PP Set	<a href="#">T15020302_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, PARAM, ATPT, AVISIT, PPROT1FL, PPROT4FL, AVAL, BASE, TRTP, SEX, UCPDGR1
15.2.3.3	Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA – FAS	<a href="#">T15020303_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, PARAM, ATPT, AVISIT, FASFL, AVAL, BASE, TRTP, SEX, UCPDGR1
15.2.3.4	Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit – PP Set	<a href="#">T15020304_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, PARAM, ATPT, AVISIT, PPROT1FL, PPROT4FL, AVAL, BASE, TRTP, SEX, UCPDGR1
15.2.3.5	Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit – FAS	<a href="#">T15020305_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	ANL02FL, PARAMCD, PARAM, ATPT, AVISIT, FASFL, AVAL, BASE, TRTP, SEX, UCPDGR1

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.1.1.1	Descriptive Statistics of Blood COHb (%) by Sex – PP Set	<a href="#">T150204010101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, PCHG, ABLFL, BLOQFL, AULQFL, ANL02FL  PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01P, SEX, USUBJID
15.2.4.1.1.2	Descriptive Statistics of Blood COHb (%) by Cigarette Consumption – PP Set	<a href="#">T150204010102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, PCHG, ABLFL, BLOQFL, AULQFL, ANL02FL  FASFL, TRT01P, USUBJID
15.2.4.1.2	Descriptive Statistics of Blood COHb (%) – FAS	<a href="#">T1502040102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID,

<b>Table/Figure Number</b>	<b>Title</b>	<b>Program</b>	<b>Analysis Dataset</b>	<b>Analysis Variable(s)</b>
				PARAM, FASFL
15.2.4.1.3	Descriptive Statistics of Blood COHb (%)– Compliant Population	<a href="#">T1502040103_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>          <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, COMPP1FL, COMPP2FL, COMPP3FL, COMPP4FL       TRT01P, USUBJID, PARAM, COMPP1FL, COMPP2FL, COMPP3FL, COMPP4FL
15.2.4.10.1	Descriptive Statistics of 1-NA in 24-hour Urine Collection – PP Set	<a href="#">T1502041001_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			<a href="#">ADSL</a>	PPROT4FL  TRT01P, PARAM, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.10.2	Descriptive Statistics of 1-NA in 24-hour Urine Collection – FAS	<a href="#">T1502041002_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, PARAM, USUBJID, FASFL
15.2.4.11.1	Descriptive Statistics of 2-NA in 24-hour Urine Collection – PP Set	<a href="#">T1502041101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, PPROT1FL,



Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.11.2	Descriptive Statistics of 2-NA in 24-hour Urine Collection – FAS	<a href="#">T1502041102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.12.1	Descriptive Statistics of o-tol in 24-hour Urine Collection – PP Set	<a href="#">T1502041201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.12.2	Descriptive Statistics of o-tol in 24-hour Urine Collection – FAS	<a href="#">T1502041202_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, PARAM, USUBJID, FASFL
15.2.4.13.1	Descriptive Statistics of CEMA in 24-hour Urine Collection – PP Set	<a href="#">T1502041301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.13.2	Descriptive Statistics of CEMA in 24-hour Urine Collection – FAS	<a href="#">T1502041302_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.14.1	Descriptive Statistics of HEMA in 24-hour Urine Collection – PP Set	<a href="#">T1502041401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.14.2	Descriptive Statistics of HEMA in 24-hour Urine Collection – FAS	<a href="#">T1502041402_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.15.1	Descriptive Statistics of B[a]P in 24-hour Urine Collection – PP Set	<a href="#">T1502041501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.15.2	Descriptive Statistics of B[a]P in 24-hour Urine Collection – FAS	<a href="#">T1502041502_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.16.1	Descriptive Statistics of HMPMA in 24-hour Urine Collection – PP Set	<a href="#">T1502041601_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.16.2	Descriptive Statistics of HMPMA in 24-hour Urine Collection – FAS	<a href="#">T1502041602_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.17.1	Descriptive Statistics of S-BMA in 24-hour Urine Collection – PP Set	<a href="#">T1502041701_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, PARAM, USUBJID, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.17.2	Descriptive Statistics of S-BMA in 24-hour Urine Collection – FAS	<a href="#">T1502041702_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.18.1	Descriptive Statistics of NEQ in 24-hour Urine Collection – PP Set	<a href="#">T1502041801_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.18.2	Descriptive Statistics of NEQ in 24-hour Urine Collection – FAS	<a href="#">T1502041802_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.19.1	Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) – PP Set	<a href="#">T1502041901_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, ANL01FL  TRT01P, USUBJID, PARAM,



Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.19.2	Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) – FAS	<a href="#">T1502041902_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL, ANL01FL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.2.1	Descriptive Statistics of MHBMA in 24-hour Urine Collection – PP Set	<a href="#">T1502040201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.2.1.1	Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (units) in 24-hour Urine Collection by Sex – PP Set	<a href="#">T150204020101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM, SEX, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.20.2	Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days – FAS	<a href="#">T1502042002_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPC</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, APUPER, ANL02FL, ANL01FL, USUBJID, FASFL  USUBJID, FASFL, TRT01A
15.2.4.21.1	Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 – PP Set	<a href="#">T1502042101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPP</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , ANL01FL, USUBJID, PPROT1FL, TRTA  USUBJID, PPROT1FL, TRT01A
15.2.4.21.2	Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 – FAS	<a href="#">T1502042102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPP</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , ANL01FL, USUBJID, FASFL, TRTA  USUBJID, FASFL, TRT01A
15.2.4.22.1	Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 – PP Set	<a href="#">T1502042201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPP</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, APUPER, ANL01FL, USUBJID,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			<a href="#">ADSL</a>	PPROT1FL, TRTA  USUBJID, PPROT1FL, TRT01A
15.2.4.22.2	Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 – FAS	<a href="#">T1502042202_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPP</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, APUPER, ANL01FL, USUBJID, FASFL, TRTA  USUBJID, FASFL, TRT01A,
15.2.4.23.1	Descriptive Statistics of CYP1A2 Activity (%) – PP Set	<a href="#">T1502042301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, USUBJID, PPROT1FL, PPROT4FL, TRTP, TRTA  USUBJID, PPROT1FL, PPROT4FL, TRT01P
15.2.4.23.1.1	Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting	<a href="#">T150204230101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, ANL03FL, USUBJID, PPROT1FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
	CYP1A2 Activity – PP Set		<a href="#">ADSL</a>	PPROT4FL, TRTP, TRTA  USUBJID, FASFL, TRT01P, PPROT1FL, PPROT4FL
15.2.4.23.2	Descriptive Statistics of CYP1A2 Activity (%) – FAS	<a href="#">T1502042302_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, USUBJID, FASFL, TRTP, TRTA  USUBJID, FASFL, TRT01P, FASFL
15.2.4.23.2.1	Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity – FAS	<a href="#">T150204230201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, ANL03FL, USUBJID, FASFL, TRTP, TRTA  USUBJID, FASFL, TRT01P, FASFL
15.2.4.24.1	Analysis of CYP1A2 Activity (%) – PP Set	<a href="#">T1502042401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, ANL02FL, USUBJID, PPROT1FL, PPROT4FL, TRTA

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT4FL, TRT01A
15.2.4.25.2	Analysis of Risk Markers – FAS	<a href="#">T1502042502_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBx</a>  <a href="#">ADLB</a>  <a href="#">ADXP</a>  <a href="#">ADVS</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, ANL02FL, USUBJID, FASFL, TRTA, DTYPE, ATPT, APUPER  PARAMN, AVISITN, ANL01FL, DTYPE, ATPT, PARAMCD, AVAL, BASE, AVISIT, ABLFL, FASFL  ABLFL, ATPT, FASFL, PARAMCD, AVISITN, AVAL, BASE, ANL01FL, DTYPE  PARAMN, AVISITN, ANL01FL, DTYPE, ATPT, PARAMCD, AVAL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			<a href="#">ADSL</a>	BASE, AVISIT  USUBJID, FASFL, TRT01A
15.2.4.25.2.1	Analysis of 11-DTX-B2 (units) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 – FAS	<a href="#">T150204250201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBx</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, ANL02FL, ANL03FL, USUBJID, FASFL, TRTA, DTYPE, ATPT  USUBJID, FASFL, TRT01A

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.26.1	Descriptive Statistics of Blood Pressure (mmHg) – PP Set	<a href="#">T1502042601_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADVS</a>	PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.26.2	Descriptive Statistics of Blood Pressure (mmHg) – FAS	<a href="#">T1502042602_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADVS</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, FASFL, AVAL
15.2.4.27.1	Descriptive Statistics of hs-CRP (units), homocysteine (units), blood glucose (units), LDL (units), HDL (units), TG (units), and TC (units) – PP Set	<a href="#">T1502042701_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, PPROT1FL, PPROT2FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				PPROT3FL, PPROT4FL
15.2.4.27.2	Descriptive Statistics of hs-CRP (units), homocysteine (units), blood glucose (units), LDL (units), HDL (units), TG (units), and TC (units) – FAS	<a href="#">T1502042702_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, FASFL, AVAL
15.2.4.28.1	Descriptive Statistics of Fibrinogen (units) – PP Set	<a href="#">T1502042801_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, , PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.28.2	Descriptive Statistics of Fibrinogen (units) – FAS	<a href="#">T1502042802_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				AVISIT, TRTA, ANL01FL, FASFL, AVAL
15.2.4.29.1	Descriptive Statistics of HbA1c (units) – PP Set	<a href="#">T1502042901_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, PPROT4FL, AVAL
15.2.4.29.2	Descriptive Statistics of HbA1c (units) – FAS	<a href="#">T1502042902_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, FASFL, AVAL
15.2.4.3.1	Descriptive Statistics of 3-HPMA in 24-hour Urine Collection – PP Set	<a href="#">T1502040301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADB</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, USUBJID, PARAM,

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<b>Table/Figure Number</b>	<b>Title</b>	<b>Program</b>	<b>Analysis Dataset</b>	<b>Analysis Variable(s)</b>
15.2.4.3.1.2	Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (units) in 24-hour Urine Collection by Cigarette Consumption – PP Set	<a href="#">T150204030102_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>          <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL       TRT01P, USUBJID, PARAM, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, UCPDGR1
15.2.4.3.2	Descriptive Statistics of 3-HPMA in 24-hour Urine Collection – FAS	<a href="#">T1502040302_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>          <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL       TRT01P, USUBJID, PARAM, FASFL

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.30.2	Descriptive Statistics of sICAM (units) – FAS	<a href="#">T1502043002 ZRHM-REXA-07 JP V4</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, FASFL, AVAL
15.2.4.31.1	Descriptive Statistics of Total WBC Count (units), Neutrophils Counts (units), Basophils Counts (Units), Eosinophils Counts (units), Lymphocytes Counts (units), Monocytes Counts (units) and Platelet Count (units) – PP Set	<a href="#">T1502043101 ZRHM-REXA-07 JP V4</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.31.2	Descriptive Statistics of Total WBC Count (units), Neutrophils Counts (units), Basophils Counts (Units), Eosinophils Counts (units), Lymphocytes Counts (units), Monocytes Counts (units) and Platelet Count (units) – FAS	<a href="#">T1502043102 ZRHM-REXA-07 JP V4</a>	<a href="#">ADSL</a>  <a href="#">ADLB</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, FASFL, AVAL

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.32.1	Descriptive Statistics of 8-epi-PGF2a (units) and 11 DTX-B2 (units) – PP Set	<a href="#">T1502043201_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADBX</a>	PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL02FL, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.32.1.1	Descriptive Statistics of 11-DTX-B2 (units) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 – PP Set	<a href="#">T150204320101_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADBX</a>	PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL02FL, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, , ANL03FL
15.2.4.32.2	Descriptive Statistics of 8-epi-PGF2a (units) and 11 DTX-B2 (units) – FAS	<a href="#">T1502043202_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADBX</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				AVISIT, TRTA, ANL01FL, FASFL, AVAL, ANL02FL, AVAL
15.2.4.32.2.1	Descriptive Statistics of 11-DTX-B2 (units) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 – FAS	<a href="#">T150204320201_ZRHM-REXA-07_JP_V4</a>	<a href="#">ADSL</a>  <a href="#">ADBX</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL02FL, FASFL, , ANL03FL, AVAL
15.2.4.33.1	Descriptive Statistics of Body weight (kg) and waist circumference (cm) – PP Set	<a href="#">T1502043301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADVS</a>	PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.33.2	Descriptive Statistics of Body weight (kg) and waist circumference (cm) – FAS	<a href="#">T1502043302_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADVS</a>	FASFL, USUBJID, TRT01A  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTA, ANL01FL, FASFL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				AVAL
15.2.4.34.1	Descriptive Statistics of Fagerström Test for Nicotine Dependence Results – PP Set	<a href="#">T1502043401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSND</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, PPROT4FL, TRTA, AVALCAT1, SHIFT1  USUBJID, PPROT4FL, TRT01A
15.2.4.34.2	Descriptive Statistics of Fagerström Test for Nicotine Dependence Results – FAS	<a href="#">T1502043402_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSND</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, FASFL, TRTA, AVALCAT1, SHIFT1  USUBJID, FASFL, TRT01A
15.2.4.34.3	Descriptive Statistics of Fagerström Test for Nicotine Dependence Results – Compliant Population	<a href="#">T1502043403_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSND</a>  <a href="#">ADSL</a>	ADQSND:, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, PARAM, ANL01FL, USUBJID, COMPP4FL, TRTA, AVALCAT1, SHIFT1  USUBJID, COMPP4FL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				TRT01A
15.2.4.35.1	Descriptive Statistics of QSU-brief Factors and Total Scores – PP Set	<a href="#">T1502043501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSSU</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, PARAM, ANL01FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRTA  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A
15.2.4.35.2	Descriptive Statistics of QSU-brief Factors and Total Scores – FAS	<a href="#">T1502043502_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSSU</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, FASFL, TRTA  USUBJID, FASFL, TRT01A

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.36.1	Analysis of QSU-brief Factors and Total Scores – PP Set	<a href="#">T1502043601_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSSU</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, DTYPE, APUPER  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A
15.2.4.36.2	Analysis of QSU-brief Factors and Total Scores – FAS	<a href="#">T1502043602_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSSU</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, USUBJID, FASFL, DTYPE  USUBJID, FASFL, TRT01A



Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.37.1	Descriptive Statistics of MCEQ Subscales – PP Set	<a href="#">T1502043701_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSPA</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRTP  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01P
15.2.4.37.2	Descriptive Statistics of MCEQ Subscales – FAS	<a href="#">T1502043702_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSPA</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, FASFL, TRTP  USUBJID, FASFL, TRT01P
15.2.4.38.1	Analysis of MCEQ Subscales – PP Set	<a href="#">T1502043801_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSPA</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, DTYPE, APUPER

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			<a href="#">ADSL</a>	USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A
15.2.4.38.2	Analysis of MCEQ Subscales – FAS	<a href="#">T1502043802_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSPA</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, USUBJID, FASFL, DTYPE  USUBJID, FASFL, TRT01A
15.2.4.39.1	Descriptive Statistics of MNWS Total Scores – PP Set	<a href="#">T1502043901_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSND</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRTA  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.39.2	Descriptive Statistics of MNWS Total Scores – FAS	<a href="#">T1502043902_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSND</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, FASFL, TRTA  USUBJID, FASFL, TRT01A
15.2.4.4.1	Descriptive Statistics of S-PMA in 24-hour Urine Collection – PP Set	<a href="#">T1502040401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, PARAM, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				UCPDGR1
15.2.4.4.2	Descriptive Statistics of S-PMA in 24-hour Urine Collection – FAS	<a href="#">T1502040402_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.4.3	Descriptive Statistics of S-PMA in 24-hour Urine Collection – Compliant Population	<a href="#">T1502040403_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, COMPP1FL, COMPP2FL, COMPP3FL, COMPP4FL  TRT01P, USUBJID, PARAM,

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<b>Table/Figure Number</b>	<b>Title</b>	<b>Program</b>	<b>Analysis Dataset</b>	<b>Analysis Variable(s)</b>
			<a href="#"><u>ADSL</u></a>	USUBJID, FASFL, TRT01A
15.2.4.41	Descriptive Statistics of HST Questionnaire Data – PP Set	<a href="#"><u>T15020441_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADQSPA</u></a>  <a href="#"><u>ADSL</u></a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL01FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRTA, PARCAT1N  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A
15.2.4.42	Descriptive Statistics of HST Parameters per Cigarette – PP Set	<a href="#"><u>T15020442_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADXT</u></a>  <a href="#"><u>ADSL</u></a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRTA  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A

<b>Table/Figure Number</b>	<b>Title</b>	<b>Program</b>	<b>Analysis Dataset</b>	<b>Analysis Variable(s)</b>
15.2.4.43	Analysis of HST Parameters per Cigarette – PP Set	<a href="#">T15020443_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADXT</a>          <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, DTYPE, APUPER       USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A
15.2.4.44.1	Descriptive Statistics of CYP2A6 Activity (%) – PP Set	<a href="#">T1502044401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBx</a>          <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, USUBJID, PPROT1FL, PPROT4FL, TRTA, TRTP       USUBJID, PPROT1FL, PPROT4FL, TRT01P



Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.44.1.1	Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity – PP Set	<a href="#">T150204440101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, USUBJID, PPROT1FL, PPROT4FL, TRTA, TRTP, ANL03FL  USUBJID, PPROT1FL, PPROT4FL, TRT01P
15.2.4.44.2	Descriptive Statistics of CYP2A6 Activity (%) – FAS	<a href="#">T1502044402_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, USUBJID, FASFL, TRTA, TRTP  USUBJID, FASFL, TRT01P
15.2.4.44.2.1	Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity – FAS	<a href="#">T150204440201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL, USUBJID, FASFL, TRTA, TRTP, ANL03FL  USUBJID, FASFL, TRT01P

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.45.1	Analysis of CYP2A6 Activity (%) – PP Set	<a href="#">T1502044501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL02FL, USUBJID, PPROT1FL, , PPROT4FL, DTYPE, ATPT  USUBJID, PPROT1FL, PPROT4FL, TRT01A
15.2.4.45.1.1	Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity – PP Set	<a href="#">T150204450101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL02FL, USUBJID, PPROT1FL, PPROT4FL, DTYPE, ATPT, ANL03FL  USUBJID, PPROT1FL, PPROT4FL, TRT01A
15.2.4.45.2	Analysis of CYP2A6 Activity (%) – FAS	<a href="#">T1502044502_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL02FL, USUBJID, FASFL, DTYPE, ATPT

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			<a href="#">ADSL</a>	USUBJID, FASFL, TRT01A
15.2.4.45.2.1	Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity – FAS	<a href="#">T150204450201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBx</a>  <a href="#">ADSL</a>	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL02FL, USUBJID, FASFL, DTYPE, ATPT, ANL03FL  USUBJID, FASFL, TRT01A
15.2.4.46.1	Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) – PP Set	<a href="#">T1502044601_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADBx</a>	PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, USUBJID, TRT01P  USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, PCHG, ABLFL, BLOQFL, AULQFL, ANL02FL

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.46.2	Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) – FAS	<a href="#">T1502044602_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADBX</a>	FASFL, USUBJID, TRT01P  USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, PCHG, ABLFL, BLOQFL, AULQFL, ANL02FL
15.2.4.47	Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data – FAS	<a href="#">T15020447_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADXT</a>	FASFL, USUBJID, TRT01P  USUBJID, PARAMCD, PARAM, AVISITN, AVAL
15.2.4.48	Descriptive Statistics of Filter Analysis from the THS 2.2 Menthol Products – FAS	<a href="#">T15020448_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADXT</a>	FASFL, USUBJID, TRT01P  USUBJID, PARAMCD, PARAM, AVISITN, AVAL, ABLFL
15.2.4.49	Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission – FAS	<a href="#">T15020449_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADEX</a>	FASFL, USUBJID, TRT01AN  USUBJID, PARAM, PARAMN, APUPER, APUPERC, FASFL, DTYPE, AVAL, PARCAT3N, PRODPREF

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.5.2	Descriptive Statistics of Total NNAL in 24-hour Urine Collection – FAS	<a href="#">T1502040502 ZRHM-REXA-07 JP V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.5.3	Descriptive Statistics of Total NNAL in 24-hour Urine Collection – Compliant Population	<a href="#">T1502040503 ZRHM-REXA-07 JP V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, COMPP1FL, COMPP2FL, COMPP3FL, COMPP4FL  TRT01P, USUBJID, PARAM, COMPP1FL, COMPP2FL, COMPP3FL, COMPP4FL
15.2.4.50	Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission – FAS	<a href="#">T15020450 ZRHM-REXA-07 JP V1</a>	<a href="#">ADSL</a>	FASFL, PRODPREF, TRT01AN, USUBJID

<b>Table/Figure Number</b>	<b>Title</b>	<b>Program</b>	<b>Analysis Dataset</b>	<b>Analysis Variable(s)</b>
15.2.4.6.1	Descriptive Statistics of Exhaled CO (ppm) – PP Set	<a href="#"><u>T1502040601_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADBX</u></a>             <a href="#"><u>ADSL</u></a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, EPOCH, TRTP, BASETYPE, BASE             TRT01P, USUBJID, PARAM, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.6.2	Descriptive Statistics of Exhaled CO (ppm) – FAS	<a href="#"><u>T1502040602_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADBX</u></a>             <a href="#"><u>ADSL</u></a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL, EPOCH, TRTP, BASETYPE, BASE             TRT01P, USUBJID, PARAM, FASFL



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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.4.9.1	Descriptive Statistics of 4-ABP in 24-hour Urine Collection – PP Set	<a href="#">T1502040901_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL  TRT01P, PARAM, USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL
15.2.4.9.2	Descriptive Statistics of 4-ABP in 24-hour Urine Collection – FAS	<a href="#">T1502040902_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADBX</a>  <a href="#">ADSL</a>	USUBJID, PARAMCD, PARAM, APUPER, AVISITN, AVISIT, ATPTN, ATPT, AVAL, ABLFL, BLOQFL, AULQFL, ANL02FL, PCHG, FASFL  TRT01P, USUBJID, PARAM, FASFL
15.2.4.25.1.2	Analysis of FEV1 without Bronchodilator at Day 90 – PP Set	<a href="#">PH-001 FEV1</a>	ADSL  ADXP	PPROT4FL, USUBJID, TRT01P  USUBJID, PARAMCD, PARAM, AVISITN, AVISIT, TRTP, AVAL,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				ANL01FL, PPROT4FL
15.2.4.42.1	Descriptive Statistics of HST Parameters per Cigarette – PP Set	<a href="#">t1502044201_ZRHM-REXA-07_JP_v1_PMI</a>	ADXT  ADSL	AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, , PARAM, ANL02FL  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, TRT01A
15.2.4.43.1	Analysis of HST Parameters per Cigarette – PP Set	<a href="#">t1502044301_ZRHM-REXA-07_JP_v1_PMI</a>	ADXT  ADSL	SEX, BASE, UCPDGR1, TRTP, AVAL, AVISITN, AVISIT, PARAMCD, PARAMN, ANL01FL  USUBJID, PPROT1FL, PPROT2FL, PPROT3FL, PPROT4FL, DTYPE, APUPER
15.2.5.1	Summary of Compliance as Measured by Exhaled CO (ppm) During Confinement Period – FAS in the SA Arm	<a href="#">T15020501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>  <a href="#">ADBX</a>	FASFL, TRT01AN, USUBJID  FASFL, TRTAN, PARAMCD, AVISITN, ATPTN, AVALCAT1
15.2.5.2	Summary of Compliance by Period and Overall – FAS	<a href="#">T15020502_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADSL</a>	USUBJID, DISCCAT, COMPP1FL, CMPCP1FL, COMPP2FL, CMPCP2FL, COMPP3FL, CMPCP3FL,

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Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.6.12.1	Summary of Serious Adverse Events by System Organ Class and Preferred Term – Safety Population	<a href="#">T1502061201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAF AFL, SAFBFL, AESER  USUBJID, TRT01AN, TRT01A, SAF AFL, SAFBFL
15.2.6.13.1	Summary of Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term – Safety Population	<a href="#">T1502061301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAF AFL, SAFBFL, AEACNOTH  USUBJID, TRT01AN, TRT01A, SAF AFL, SAFBFL
15.2.6.14.1	Summary of Adverse Events Leading to Study Discontinuation by Product Use Category, System Organ Class and Preferred Term – Safety Population	<a href="#">T1502061401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAF AFL, AEACNOTH  USUBJID, TRT01AN, TRT01A, SAF AFL
15.2.6.15.1	Summary of THS 2.2 Menthol Device Events – Safety Population	<a href="#">T1502061501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAF AFL, SAFBFL, ANYDEFL, AEREL, DESEV

[illegible]

[illegible]



Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.6.19.1	Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 – Safety Population	<a href="#">T1502061901_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADCM</a>  <a href="#">ADSL</a>	USUBJID, ASPER, CMCAT1, CMCAT2, SAF AFL, SAFBFL  USUBJID, TRT01AN, TRT01A, SAF AFL, SAFBFL
15.2.6.19.2	Summary of Concomitant Medication by Preferred Drug Name – Safety Population	<a href="#">T1502061902_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADCM</a>  <a href="#">ADSL</a>	USUBJID, ASPER, CMDECOD, SAF AFL, SAFBFL  USUBJID, TRT01AN, TRT01A, SAF AFL, SAFBFL
15.2.6.2.1	Summary of Adverse Events by Product Use Category in Ambulatory – Safety Population	<a href="#">T1502060201_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, AESER, AEREL, AERELSP, AESEV, AEACNP1, AECONTRT, AEACNOTH, SAFBFL  USUBJID, TRT01AN, TRT01A, SAF AFL
15.2.6.20	Summary of Supine Vital Signs – Safety Population	<a href="#">T15020620_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADVS</a>	SAF AFL, AVISITN, TRTAN, ABLFL, VSPOS, AVAL, ANL01FL, DTYPE, PARAMN, PARAM, AVALU, AVALC, USUBJID

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
			<a href="#">ADSL</a>	USUBJID, SAFAFL, TRT01AN
15.2.6.21	Summary of ECG Results – Safety Population	<a href="#">T15020621_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADEG</a>  <a href="#">ADSL</a>	SAFAFL, AVISITN, TRTAN, ABLFL, ANL01FL, PARAMCD, PARAMN, PARAM, AVALC, USUBJID, EGCLSIG  USUBJID, SAFAFL, TRT01AN
15.2.6.22	Summary of Spirometry Results – Safety Population	<a href="#">T15020622_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADXP</a>  <a href="#">ADSL</a>	SAFAFL, AVISITN, TRTAN, ABLFL, ANL01FL, PARAMCD, PARAMN, PARAM, AVALC, USUBJID, XPCLSIG, AVALU  USUBJID, SAFAFL, TRT01AN
15.2.6.23	Summary of Physical Examination of Body Systems – Safety Population	<a href="#">T15020623_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADPE</a>	SAFAFL, AVISITN, TRTAN, ABLFL, ANL01FL, PARAMCD, PARAMN, PARAM, AVALC,

<b>Table/Figure Number</b>	<b>Title</b>	<b>Program</b>	<b>Analysis Dataset</b>	<b>Analysis Variable(s)</b>
			<a href="#"><u>ADSL</u></a>	USUBJID, PECLSIG, AVALU, SHIFT1  USUBJID, SAFAFL, TRT01AN
15.2.6.24	Summary of Weight, Waist Circumference and BMI Results – Safety Population	<a href="#"><u>T15020624_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADVS</u></a>          <a href="#"><u>ADSL</u></a>	SAFAFL, AVISITN, TRTAN, ABLFL, VSPOS, AVAL, ANL01FL, PARAMN, PARAM, AVALU, USUBJID, AVALC       USUBJID, SAFAFL, TRT01AN
15.2.6.25	Summary of Cough Assessments Over Study – Safety Population	<a href="#"><u>T15020625_ZRHM-REXA-07_JP_V1</u></a>	<a href="#"><u>ADQSSYM</u></a>          <a href="#"><u>ADSL</u></a>	SAFBFL, USUBJID, TRTAN, PERIOD, PARAMN, PARAM, AVISITN, AVISIT, AVALC       USUBJID, SAFBFL, TRT01AN, SAFAFL

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
15.2.6.25.1	Summary of Cough Assessments by Study Day – Safety Population	<a href="#">T1502062501_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADQSSYM</a>  <a href="#">ADSL</a>	SAFBFL, USUBJID, TRTAN, PERIOD, PARAMN, PARAM, AVISITN, AVISIT, AVALC  USUBJID, SAFBFL, TRT01AN
15.2.6.3.1	Summary of Adverse Events by System Organ Class and Preferred Term – Safety Population	<a href="#">T1502060301_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAFBFL, SAFAFL  USUBJID, TRT01AN, TRT01A, SAFAFL, SAFBFL
15.2.6.3.1.1	Summary of Adverse Events (Incidence >5% in any Study Arm) by System Organ Class and Preferred Term – Safety Population	<a href="#">T150206030101_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAFBFL, SAFAFL  USUBJID, TRT01AN, TRT01A, SAFAFL, SAFBFL
15.2.6.4.1	Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term – Safety Population	<a href="#">T1502060401_ZRHM-REXA-07_JP_V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAFAFL  USUBJID,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				TRT01AN, TRT01A, SAF AFL
15.2.6.5.1	Summary of Adverse Events by System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness – Safety Population	<a href="#">T1502060501 ZRHM-REXA-07 JP V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAF AFL, AEREL, AERELN, AEEXPEC, AEEXPECN  USUBJID, TRT01AN, TRT01A, SAF AFL
15.2.6.6.1	Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness – Safety Population	<a href="#">T1502060601 ZRHM-REXA-07 JP V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAF AFL, AEREL, AERELN,  USUBJID, TRT01AN, TRT01A, SAF AFL
15.2.6.7.1	Summary of Adverse Events Leading to Study Product Discontinuation, Interruption, or Reduction by System Organ Class and Preferred Term – Safety Population	<a href="#">T1502060701 ZRHM-REXA-07 JP V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAF AFL, SAFBFL, AEACNOTH, ANL03FL  USUBJID, TRT01AN,

Table/Figure Number	Title	Program	Analysis Dataset	Analysis Variable(s)
				TRT01A, SAFAFL, SAFBFL
15.2.6.8.1	Summary of Adverse Events Leading to Study Product Discontinuation, Interruption, or Reduction by Product Use Category, System Organ Class, and Preferred Term – Safety Population	<a href="#">T1502060801 ZRHM-REXA-07 JP V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAFAFL, AEACNOTH, ANL03FL  USUBJID, TRT01AN, TRT01A, SAFAFL, ,
15.2.6.9.1	Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term – Safety Population	<a href="#">T1502060901 ZRHM-REXA-07 JP V1</a>	<a href="#">ADAE</a>  <a href="#">ADSL</a>	USUBJID, ASPER, AEBODSYS, AEDECOD, SAFAFL, SAFBFL, AERELSPN  USUBJID, TRT01AN, TRT01A, SAFAFL, SAFBFL

Macro Program Name	Macro used in
<a href="#">M_totper</a>	Analysis datasets for derivation of period assessment
<a href="#">M_perall</a>	Analysis datasets for allocation of TRTP, TRTPN, TRTA and TRTAN

## **8. Appendix**

Not applicable.