

Subject Case Report Forms

PROD 08.000 (MAIN) SP 28JUL14 - Case Book

Generated On: 30 Sep 2014 09:30:37

All time stamps listed in this document are displayed in GMT

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Subject (Site level)
Generated On: 30 Sep 2014 09:30:37

Subject (site level)

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Subject
Generated On: 30 Sep 2014 09:30:37

Screening number

Site number

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Deviation Form
Generated On: 30 Sep 2014 09:30:37

Cohort _____

Subject _____

Assessment _____

Visit

Screening ☐

Admission (Day -2) ☐

Baseline (Day -1) ☐

Baseline (Day 0) ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 6 ☐

Discharge (confinement) ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

Discharge (ambulatory) ☐

Other ☐

Other, Specify _____

Timepoint _____

Description of Deviation _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Deviation Form
Generated On: 30 Sep 2014 09:30:37

Date Deviation Occurred

DD/MMM/YYYY

Date Deviation Reported

DD/MMM/YYYY

Date Deviation Ended

DD/MMM/YYYY

Resolution of the Deviation

Source of the Deviation

CRA ☐
Site personnel ☐
Sponsor ☐
CRO ☐
Labs ☐
IXRS ☐
ePRO ☐

Deviation Category

Violation ☐
Mis-randomization ☐
Mis-use of product ☐
Concomitant medication ☐
Time deviation ☐
Time missing ☐
Assessment missing ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Deviation Form
Generated On: 30 Sep 2014 09:30:37

Deviation Type

Major ☐

Minor ☐

If Major, Evaluation Category

Evaluable ☐

Non Evaluable ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Subject Status
Generated On: 30 Sep 2014 09:30:37

Date of 'Screen Failed' Event

Fixed Unit:
DD/MMM/YYYY

Date of 'Discontinued From
Enrollment' Event

Fixed Unit:
DD/MMM/YYYY

Randomization Date

Fixed Unit:
DD/MMM/YYYY

Randomization Time

Fixed Unit:
hour:min 24-hour clock

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Site Accountability
Generated On: 30 Sep 2014 09:30:37

Date of batch dispensed _____

Batch number _____

Category _____ Received ☐

Returned ☐

Batch Expiration Date (only for received event)
DD/MMM/YYYY _____

Number of unused packs returned _____

Number of unused sticks returned (only for returned
event) _____

Number of packs received _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Screen Failure

Generated On: 30 Sep 2014 09:30:37

Reason for Screen Failure

Entry criteria not met ☐

Withdrawal by subject ☐

Adverse Event ☐

Other ☐

If Other, Specify: _____

Is there a pregnancy event?

No ☐

Yes ☐

NA ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Date of Visit<Ambulatory/>
Generated On: 30 Sep 2014 09:30:37

Visit Not Done

If Not Done, Specify Reason

Date of Visit

Fixed Unit:
DD/MMM/YYYY

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Date of Visit
Generated On: 30 Sep 2014 09:30:37

Date of Visit

Fixed Unit:
DD/MMM/YYYY

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Date of Discharge
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Date of Visit

Fixed Unit:
DD/MMM/YYYY

Discharge Time

Fixed Unit:
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

No ☐
Yes ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Additional Informed Consent
Generated On: 30 Sep 2014 09:30:37

Has the subject given written informed consent for
Bio-banking for Biomarkers of Exposure and Risk
Markers?

No ☐
Yes ☐

Consent Date

Fixed Unit:
DD/MMM/YYYY

Has the subject given written informed consent for
Bio-banking for Transcriptomics (Pharmacogenomics)?

No ☐
Yes ☐

Consent Date

Fixed Unit:
DD/MMM/YYYY

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Inclusion Criteria

Generated On: 30 Sep 2014 09:30:37

Inclusion Criterion

Subject has signed the ICF ☒
and is able
to understand the
information
provided in the Subject
Information
Sheet and ICF.
Subject is aged from 23 to ☐
65 years
(inclusive).
Subject is Japanese. ☐
Smoking, healthy subject ☐
as judged
by the Investigator based
on all
available assessments from
the
Screening period/day of
Admission
(e.g. safety laboratory,
spirometry[FEV1/FVC >0.7
at
post-bronchodilator
spirometry,
post-bronchodilator FEV1
>80%
predicted value, and
post-bronchodilator FVC
>80%
predicted value], vital
signs, physical
examination, ECG, chest
X-ray and
medical history).

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Inclusion Criteria

Generated On: 30 Sep 2014 09:30:37

Subject smokes at least 10 ☐
commercially available
menthol mCCs per day (no
brand restrictions) with a
maximum yield of 1 mg
nicotine ISO/mCC, as
labelled on the cigarette
package, for the last 4
weeks, based on
self-reporting.
Furthermore, the subject
has been smoking for at
least the last three
consecutive years. The
smoking status will be
verified based on a urinary
cotinine test (cotinine \geq
200 ng/mL).
The subject does not plan ☐
to quit
smoking in the next 3
months.
The subject is ready to ☐
accept
interruptions of smoking
for up to 90 days.
The subject is ready to ☐
accept using the THS 2.2
Menthol.

Result No ☐
Yes ☐

Inclusion Criterion Number 2

Exclusion Criterion

As per Investigator judgment, the subject cannot participate in the study for any reason (e.g. medical, psychiatric and/or social reason). ☒

A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g. emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated). ☐

The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐

The subject has a body mass index (BMI) <18.5 or ≥ 32 kg/m². ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Exclusion Criteria

Generated On: 30 Sep 2014 09:30:37

As per Investigator or ☐
designee judgment, the
subject has medical
conditions which require or
will require in the course of
the study, a medical
intervention (e.g., start of
treatment, surgery,
hospitalization) which may
interfere with the study
participation and/or study
results.

The subject has used ☐
nicotine containing
products other than
commercially available
mCC (either tobacco-based
products or NRT) as well as
electronic cigarettes and
similar devices, within 4
weeks prior to assessment.

The subject has received ☐
medication (prescription or
over-the-counter) within
14 days or within five half
lives of the drug
(whichever is longer) prior
to the Admission Day (Day
-2), which has an impact
on CYP1A2 or CYP2A6
activity.

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Exclusion Criteria

Generated On: 30 Sep 2014 09:30:37

If a subject has received ☐
any

medication (prescribed or
over-the-counter)

within 14 days prior to
Screening or prior to the
Admission

Day (Day -2), it will be
decided at the
discretion of the

Investigator if these
can potentially interfere
with the
study objectives or
subject's safety.

Concomitant use of NSAIDs ☐
or

acetylsalicylic acid.

The subject has a positive ☐
alcohol test

and/or the subject has a
history of
alcohol abuse that could
interfere

with the subject's
participation in the
study.

The subject has a positive ☐
urine drug
test.

Positive serology test for ☐
HIV1/2, hepatitis B or
hepatitis C.

Donation or receipt of ☐
whole blood or
blood products within 3
months prior
to Admission.

The subject is a current or former
employee of the tobacco
industry or
of their first-degree
relatives (parent,
sibling, child). ☐

The subject is an employee
of the
investigational site or any
other
parties involved in the
study or of
their first-degree relatives
(parent,
sibling, child). ☐

The subject has
participated in a
clinical study within 3
months prior
to the Screening Visit. ☐

The subject has previously
participated in the same
study at a
different time (i.e. each
subject can be
included in the study
population only
once). ☐

For women only: Subject is
pregnant (does not have
negative pregnancy tests
at Screening and at
Admission) or is breast
feeding. ☐

For women only: Subject
does not agree to use an
acceptable method of
effective contraception ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Randomization
Generated On: 30 Sep 2014 09:30:37

Randomization number (4 digits) _____

Allocation Arm

THS 2.2 menthol ☐

mCC ☐

SA ☐

Cigarette Consumption

10 – 19 conventional
menthol cigarettes per day ☐

Greater than 19 ☐
conventional menthol
cigarettes per day

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Demographics
Generated On: 30 Sep 2014 09:30:37

Date of Birth

Fixed Unit:
DD/MMM/YYYY

Sex

Male ☐
Female ☐

Is the subject Japanese?

No ☐
Yes ☐

Date the Subject signed the Main
Informed Consent

Fixed Unit:
DD/MMM/YYYY

Time the Subject signed the Main Informed Consent

Fixed Unit:
hour:min 24-hour clock

Age(Derived)

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Medical History/Concomitant Disease
Generated On: 30 Sep 2014 09:30:37

Date of collection

Fixed Unit:
DD/MMM/YYYY

Has the subject experienced any past and/ or
concomitant diseases?

No ☐
Yes ☐

Category for Medical History

Medical History

Number

Diagnosis Description

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

H_NOW (Derived):

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Vital Signs<Screening/>

Generated On: 30 Sep 2014 09:30:37

Were Vitals Signs assessed?

No ☐
Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☐
Yes ☐

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Pulse rate

Fixed Unit:
beats per minute

Respiratory rate

Fixed Unit:
breaths per minute

Blood Pressure (systolic)

Fixed Unit:
mmHg

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Vital Signs<Screening/>
Generated On: 30 Sep 2014 09:30:37

Blood Pressure (diastolic)

Fixed Unit:
mmHg

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Vital Signs

Generated On: 30 Sep 2014 09:30:37

Were Vitals Signs assessed?

No ☐

Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☐

Yes ☐

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Pulse rate

Fixed Unit:
beats per minute

Respiratory rate

Fixed Unit:
breaths per minute

Blood Pressure (systolic)

Fixed Unit:
mmHg

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Vital Signs
Generated On: 30 Sep 2014 09:30:37

Blood Pressure (diastolic)

Fixed Unit:
mmHg

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Physical Examination<Screening/>
Generated On: 30 Sep 2014 09:30:37

Was the physical examination performed?

No ☐
Yes ☐

If No, please specify the reason: _____

Date of assessment

Fixed Unit:
DD/MMM/YYYY

System

General Appearance ☒

HEENT ☐
(head, eyes, ears, nose,
throat)

Thyroid Gland ☐

Heart ☐

Chest ☐

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

Other, Specify _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Physical Examination<Screening/>

Generated On: 30 Sep 2014 09:30:37

Outcome Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant No ☐
Yes ☐

Not Done _____

Not Done; please specify the reason: _____

System General Appearance ☐
HEENT ☒
(head, eyes, ears, nose, throat)
Thyroid Gland ☐
Heart ☐
Chest ☐
Lungs ☐
Gastrointestinal ☐
Cardiovascular System ☐
Neurologic ☐
Skin ☐
Back ☐
Musculoskeletal ☐
Abdomen ☐
Dentition ☐
Other ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product preference
Generated On: 30 Sep 2014 09:30:37

Which product would you prefer to be randomized to:

THS 2.2 menthol ☐
mCC ☐
SA ☐
No preference ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Advice on the risk of smoking and debriefing
Generated On: 30 Sep 2014 09:30:37

Date

Fixed Unit:
DD/MMM/YYYY

Has the subject received advices on the risks of
smoking?

No ☐
Yes ☐

Has a debriefing been performed about THS 2.2?

No ☐
Yes ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Physical Examination

Generated On: 30 Sep 2014 09:30:37

Was the physical examination performed?

No ☐

Yes ☐

If No, please specify the reason:

Date of Assessment

Fixed Unit:
DD/MMM/YYYY

System

General Appearance ☒

HEENT ☐

(head, eyes, ears, nose,
throat)

Thyroid Gland ☐

Heart ☐

Chest ☐

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

Other, Specify

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Physical Examination

Generated On: 30 Sep 2014 09:30:37

Outcome Normal ☐
Abnormal ☐

Abnormal, please specify _____

Clinically significant No ☐
Yes ☐

Not Done _____

Not Done; please specify the reason: _____

System General Appearance ☐
HEENT ☒
(head, eyes, ears, nose, throat)
Thyroid Gland ☐
Heart ☐
Chest ☐
Lungs ☐
Gastrointestinal ☐
Cardiovascular System ☐
Neurologic ☐
Skin ☐
Back ☐
Musculoskeletal ☐
Abdomen ☐
Dentition ☐
Other ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Identification of Current Cigarette Brand
Generated On: 30 Sep 2014 09:30:37

Date

Fixed Unit:
DD/MMM/YYYY

Brand name

ISO Tar Yield

Fixed Unit:
MG

ISO Tar Yield unit

Milligram ☒

ISO Nicotine Yield

Fixed Unit:
MG

ISO Nicotine Yield unit

Milligram ☒

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: THS 2.2 menthol product test
Generated On: 30 Sep 2014 09:30:37

Was the THS 2.2 menthol product trial performed?

No ☐
Yes ☐

If the THS 2.2 menthol product trial was not performed,
please explain _____

How many THS 2.2 menthol tobacco sticks did the
subject use on this day? _____

Is the subject willing and able to use the product during
the study?

No ☐
Yes ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: THS 2.2 menthol product demonstration
Generated On: 30 Sep 2014 09:30:37

Has the subject seen a THS 2.2 menthol product demonstration?

No ☐
Yes ☐

If the subject did not see the demonstration please explain

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product administration-mCC

Generated On: 30 Sep 2014 09:30:37

H_NOW (Derived): _____

At Day 0, Day 1 and Day 4, complete all SODIM related questions

At Day 30, Day 60 and Day 90 complete the Time in the 'HST' form.

Date of product use
DD/MMM/YYYY _____

Visit

Day -2 ☐
Day -1 ☐
Day 0 ☐
Day 1 ☐
Day 2 ☐
Day 3 ☐
Day 4 ☐
Day 5 ☐
Day 6 ☐
Day 30 ☐
Day 60 ☐
Day 90 ☐

Type of Product Use

mCC ☒
THS 2.2 Menthol ☐

If type of Product Use different from the randomization
please explain _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product administration-mCC
Generated On: 30 Sep 2014 09:30:37

Time of distribution	<hr/>
<hr/>	
Time of butt return	<hr/>
<hr/>	
CC with SODIM?	<hr/>
<hr/>	
CC not compatible?	<hr/>
<hr/>	
SODIM device number	<hr/>
<hr/>	
SODIM sample holder number	<hr/>
<hr/>	
SODIM file number	<hr/>
<hr/>	
Comment	<hr/>
<hr/>	

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product administration-THS menthol
Generated On: 30 Sep 2014 09:30:37

H_NOW (Derived):

At Day 0, Day 1 and Day 4 complete all SODIM related questions

At Day 30, Day 60, Day 90 complete the Time in 'HST' Form.

Date of product use
DD/MMM/YYYY

Visit

Day -2 ☐
Day 0 ☐
Day 1 ☐
Day 2 ☐
Day 3 ☐
Day 4 ☐
Day 5 ☐
Day 6 ☐
Day 30 ☐
Day 60 ☐
Day 90 ☐

Type of Product Use

mCC ☐
THS 2.2 Menthol ☒

If type of Product Use different from the randomization
please explain

Time of distribution

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product administration-THS menthol
Generated On: 30 Sep 2014 09:30:37

Time of product return	
SODIM device number	
SODIM sample holder number	
Filter kit number	
Filter vial number	
Tobacco plug kit number	
Tobacco plug vial number	
SODIM file number	
Comment	
Batch Number	

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Smoking History

Generated On: 30 Sep 2014 09:30:37

Date of Assessment

Fixed Unit:
DD/MMM/YYYY

1. Does the subject plan to quit smoking during the next 3 months?

No ☐
Yes ☐

2. Did the subject smoke for at least 3 consecutive years?

No ☐
Yes ☐

3. How many menthol cigarettes per day has the subject smoked on average during the last 4 weeks?

<10 ☐
10 to 19 ☐
>19 ☐

4. Did the subject smoke menthol cigarettes in the last 4 weeks?

No ☐
Yes ☐

5. The subject has used nicotine-containing products other than commercially available mCC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment.

No ☐
Yes ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: HST 4 hours
Generated On: 30 Sep 2014 09:30:37

H_NOW (Derived): _____

Visit Day 30 ☒
Day 60 ☐
Day 90 ☐

Not Done _____

If Not Done, please specify _____

Date
DD/MMM/YYYY _____

SODIM device distribution time
hour:min 24-hour clock _____

SODIM device collection time
hour:min 24-hour clock _____

Visit Day 30 ☐
Day 60 ☒
Day 90 ☐

Not Done _____

If Not Done, please specify _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Topography files status for mCC
Generated On: 30 Sep 2014 09:30:37

SODIM file number _____

File Status Accepted ☐
Rejected ☐
Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator Valerie Poux ☐
Thierry Bachmann ☐
Anthony Bruchet ☐

Comment _____

Modified File Number _____

H_NOW (Derived): _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Topography files status for THS menthol
Generated On: 30 Sep 2014 09:30:37

SODIM file number _____

File Status

Accepted ☐

Rejected ☐

Error ☐

Rejection / Error reason _____

Date of analysis
DD/MMM/YYYY _____

Operator

Valerie Poux ☐

Thierry Bachmann ☐

Anthony Bruchet ☐

Comment _____

Modified File Number _____

H_NOW (Derived): _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: FTND Questionnaire
Generated On: 30 Sep 2014 09:30:37

Type	FTND
------	------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment	Fixed Unit:
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	Fixed Unit:
	hour:min 24-hour clock

Assessment Status	Completed <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

1. How soon after you wake up do you smoke your first cigarette?	31-60 minutes <input type="checkbox"/>
	6-30 minutes <input type="checkbox"/>
	Within 5 minutes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>
	After 60 minutes <input type="checkbox"/>

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: FTND Questionnaire

Generated On: 30 Sep 2014 09:30:37

3. Which cigarette would you hate most to give up? The first in the morning ☐
Any other ☐
Abandoned ☐

4. How many cigarettes per day do you smoke? 10 or less ☐
11-20 ☐
21-30 ☐
31 or more ☐
Abandoned ☐

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day? Yes ☐
No ☐
Abandoned ☐

6. Do you smoke even if you are so ill that you are in bed most of the day? Yes ☐
No ☐
Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Visual Inspection of the Tobacco Plugs Results for THS

Generated On: 30 Sep 2014 09:30:37

Tobacco plug kit number

Tobacco plug vial number

Level

0 ☐

1 ☐

2 ☐

NA ☐

Observation

Ashes not anymore visible
when shooting picture ☐

No tobacco in plug ☐

Not enough tobacco in the
plug to perform the
analysis ☐

Tobacco plug destroyed,
analysis impossible ☐

No tobacco plug in the vial ☐

Other error ☐

Picture File Name

Date of analysis
DD/MMM/YYYY

H_NOW (Derived):

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Weight and Height
Generated On: 30 Sep 2014 09:30:37

Measurement(s) assessed?

No ☐
Yes ☐

If No, please specify the reason: _____

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Weight

Fixed Unit:
kg

Height

Fixed Unit:
cm

BMI (Derived)

Fixed Unit:
kg/m2

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Weight

Generated On: 30 Sep 2014 09:30:37

Measurement(s) assessed?

No ☐

Yes ☐

If No, please specify the reason: _____

Date of Assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Weight

Fixed Unit:
kg

Waist circumference

Fixed Unit:
cm

BMI

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: ECG (12-Lead Standard) <Screening/>
Generated On: 30 Sep 2014 09:30:37

Method of ECG Test

12 Lead Placement Cabrera ☒

Was the ECG performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Date of assessment:

Fixed Unit:
DD/MMM/YYYY

Position

Sitting ☐

Standing ☐

Supine ☒

Heart Rate

Fixed Unit:
beats per minute

Heart Rate unit

beats per minute

QRS Interval

Fixed Unit:
msec

QRS Interval unit

msec

QT Interval

Fixed Unit:
msec

PROD 08.000 (MAIN) SP
28JUL14 (640)

191 of 466

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: ECG (12-Lead Standard) <Screening/>
Generated On: 30 Sep 2014 09:30:37

QT Interval unit msec

QTcB Interval Fixed Unit:
msec

QTcB Interval unit msec

PR Interval Fixed Unit:
msec

PR Interval unit msec

Interpretation Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance Not clinically significant ☐
Clinically significant ☐

If Not Clinically significant or clinically Significant, Please
specify the finding(s)

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: ECG (12-Lead Standard)

Generated On: 30 Sep 2014 09:30:37

Method of ECG Test

12 Lead Placement Cabrera ☒

Was the ECG performed?

No ☐

Yes ☐

If No, please specify the reason:

Date of Assessment

Fixed Unit:
DD/MMM/YYYY

Position

Sitting ☐

Standing ☐

Supine ☒

Heart Rate

Fixed Unit:
beats per minute

Heart Rate unit

beats per minute

QRS Interval

Fixed Unit:
msec

QRS Interval unit

msec

QT Interval

Fixed Unit:
msec

PROD 08.000 (MAIN) SP

28JUL14 (640)

193 of 466

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: ECG (12-Lead Standard)
Generated On: 30 Sep 2014 09:30:37

QT Interval unit msec

QTcB Interval Fixed Unit:
msec

QTcB Interval unit msec

PR Interval Fixed Unit:
msec

PR Interval unit msec

Interpretation Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance Not clinically significant ☐
Clinically significant ☐

If Not Clinically significant or clinically Significant, Please
specify the finding(s)

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Spirometry

Generated On: 30 Sep 2014 09:30:37

Was the spirometry performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Category

With short-acting
bronchodilator ☐
Without short-acting
bronchodilator ☒

Date of assessment
DD/MMM/YYYY

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

Percent of predicted FVC value

Fixed Unit:
%

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Spirometry

Generated On: 30 Sep 2014 09:30:37

Best measured FEV1 value

Fixed Unit:
L

Predicted FEV1 value

Fixed Unit:
L

Percent of predicted FEV1 value

Fixed Unit:
%

Calculated ratio between FEV1/FVC

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

Was the spirometry performed?

No ☐
Yes ☐

If No, please specify the reason:

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Spirometry

Generated On: 30 Sep 2014 09:30:37

Category

With short-acting
bronchodilator ☒
Without short-acting
bronchodilator ☐

Date of assessment
DD/MMM/YYYY

Time of assessment

Name of bronchodilator

Dose

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

Percent of predicted FVC value

Fixed Unit:
%

Best measured FEV1 value

Fixed Unit:
L

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Spirometry
Generated On: 30 Sep 2014 09:30:37

Predicted FEV1 value

Fixed Unit:
L

Percent of predicted FEV1 value

Fixed Unit:
%

Calculated ratio between FEV1/FVC

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Spirometry without a short-acting bronchodilator

Generated On: 30 Sep 2014 09:30:37

Was the spirometry performed?

No ☐

Yes ☐

If No, please specify the reason:

Category

With short-acting
bronchodilator ☐
Without short-acting
bronchodilator ☒

Date of assessment

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

Percent of predicted FVC value

Fixed Unit:
%

Best measured FEV1 value

Fixed Unit:
L

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Spirometry without a short-acting bronchodilator

Generated On: 30 Sep 2014 09:30:37

Predicted FEV1 value

Fixed Unit:
L

Percent of predicted FEV1 value

Fixed Unit:
%

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Chest X-Ray

Generated On: 30 Sep 2014 09:30:37

Category for Examination

Chest X-Ray ☒

Was a chest X-Ray with anterior-posterior and left lateral views performed?

No ☐

Yes ☐

If No, please specify the reason: _____

Date of assessment

Fixed Unit:
DD/MMM/YYYY

System

General Appearance ☐

HEENT ☐

(head, eyes, ears, nose, throat)

Thyroid Gland ☐

Heart ☐

Chest ☒

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Chest X-Ray
Generated On: 30 Sep 2014 09:30:37

Interpretation	Normal	<input type="radio"/>
	Abnormal	<input type="radio"/>

Clinically significant	No	<input type="radio"/>
	Yes	<input type="radio"/>

Abnormal, please specify:	<hr/>
---------------------------	-------

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Socio-Economic Status

Generated On: 30 Sep 2014 09:30:37

Date _____

Q1. In total, including yourself, how many people live in your household?

Total number of people living in the household _____

Prefer not to say _____

Q2. What is the highest level of education you have attained or are currently attending?

Elementary school / Junior ☐

high school

Senior high school ☐

College ☐

University / Postgraduate ☐

Prefer not to say ☐

Q3. How many income earners are in your household?

None – all are unemployed ☐

Just one income earner ☐

Two or more income earners ☐

Those who have one or more income earners

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Socio-Economic Status

Generated On: 30 Sep 2014 09:30:37

Q4. What is your occupation?

- General white collar ☐
- Professional/ technical worker ☐
- General blue collar ☐
- Working in service industry ☐
- Manager (kacho or above) ☐
- Director/president (30 employees or more) ☐
- Proprietor (29 employees or less) ☐
- Professional/technical worker (Lawyer, Accountant, Professor etc) ☐
- Farming/forestry/fishing ☐
- Shop keeper ☐
- Part-time worker (More than one day per week) ☐
- Student ☐
- Housewife (Including part-time less than one day per week) ☐
- Unemployed ☐
- Others ☐

Those who have one or more income earners

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Socio-Economic Status

Generated On: 30 Sep 2014 09:30:37

Q5a. What is your approximate MONTHLY household income from all sources before tax?

- Below 100,000 yen ☐
- 100,000 yen – 199,999 yen ☐
- 200,000 yen – 299,999 yen ☐
- 300,000 yen – 399,999 yen ☐
- 400,000 yen – 499,999 yen ☐
- 500,000 yen – 599,999 yen ☐
- 600,000 yen – 699,999 yen ☐
- 700,000 yen – 799,999 yen ☐
- 800,000 yen – 899,999 yen ☐
- 900,000 yen – 999,999 yen ☐
- 1,000,000 yen or above ☐
- Don't know ☐
- Prefer not to say ☐

Those who don't know / prefer not to say about household income

[ASK IF CODES 12 or 13 SELECTED AT Q5a]

Q5b. Would your MONTHLY household income be over or under 800,000 yen?

- Under 800,000yen ☐
- 800,000yen or more ☐
- Don't know ☐
- Prefer not to say ☐
-

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Haematology

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☒
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?

No ☐
Yes ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Clinical Chemistry

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☒
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

Was the subject fasting for at least 10 hours at time of sample collection?

No ☐
Yes ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Urine analysis

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☒
Cotinine Screening ☐
Alcohol Breath Test ☐

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Serology for HIV and Hepatitis B and C
Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☒
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Not Done

If Not Done, please specify the reason:

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Urine Drug Screen<Screening/>

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐

Drug Screen ☒

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Breath Test ☐

Not Done? _____

If Not Done, please specify the reason: _____

Date of sample collection

Fixed Unit:
DD/MMM/YYYY

Time of sample collection

Fixed Unit:
hour:min 24-hour clock

Drug type

Amphetamines ☒

Barbiturates ☐

Benzodiazepines ☐

Cannabinoids ☐

Cocaine ☐

Opiates ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Urine Drug Screen<Screening/>
Generated On: 30 Sep 2014 09:30:37

Result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>

Drug type	Amphetamines	<input type="checkbox"/>
	Barbiturates	<input checked="" type="checkbox"/>
	Benzodiazepines	<input type="checkbox"/>
	Cannabinoids	<input type="checkbox"/>
	Cocaine	<input type="checkbox"/>
	Opiates	<input type="checkbox"/>

Result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>

Drug type	Amphetamines	<input type="checkbox"/>
	Barbiturates	<input type="checkbox"/>
	Benzodiazepines	<input checked="" type="checkbox"/>
	Cannabinoids	<input type="checkbox"/>
	Cocaine	<input type="checkbox"/>
	Opiates	<input type="checkbox"/>

Result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Urine Drug Screen

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐

Drug Screen ☒

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Breath Test ☐

Not Done? _____

If Not Done, please specify the reason: _____

Time of sample collection

Fixed Unit:
hour:min 24-hour clock

Drug type

Amphetamines ☒

Barbiturates ☐

Benzodiazepines ☐

Cannabinoids ☐

Cocaine ☐

Opiates ☐

Result

Negative ☐

Positive ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Alcohol Breath Test<Screening/>

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☒

Was the alcohol breath test performed?

No ☐
Yes ☐

If No, please specify the reason: _____

Date of assessment

Fixed Unit:
DD/MMM/YYYY

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Result

Negative ☐
Positive ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Alcohol Breath Test

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☒

Was the alcohol breath test performed?

No ☐
Yes ☐

If No, please specify the reason: _____

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Result

Negative ☐
Positive ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Urine Pregnancy Test<Screening/>
Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☒
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Not Done

If Not Done, specify reason

Date of Test

Fixed Unit:
DD/MMM/YYYY

Time of Test

Fixed Unit:
hour:min 24-hour clock

Specify result

Negative ☐
Positive ☐
Unclear ☐

If unclear, please confirm with FSH test

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Urine Pregnancy Test<Screening/>
Generated On: 30 Sep 2014 09:30:37

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Urine Pregnancy Test

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☒
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Not Done

If Not Done, specify reason

Date of Test

Fixed Unit:
DD/MMM/YYYY

Time of Test

Fixed Unit:
hour:min 24-hour clock

Specify result

Negative ☐
Positive ☐
Unclear ☐

If unclear, please confirm with FSH test

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Urine Pregnancy Test
Generated On: 30 Sep 2014 09:30:37

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Urine Cotinine Test<Screening/>

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☒

Alcohol Breath Test ☐

Not Done

If Not Done, please specify the reason:

Date of Sample Collection

Fixed Unit:
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Result

Negative <200 ng/ml ☐

Positive >=200 ng/ml ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Urine Cotinine Test

Generated On: 30 Sep 2014 09:30:37

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☒
Alcohol Breath Test ☐

Not Done

If Not Done, please specify the reason:

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Result

Negative <200 ng/ml ☐
Positive >=200 ng/ml ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Plasma Nicotine Sample
Generated On: 30 Sep 2014 09:30:37

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

Record Number

1

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Plasma Cotinine Sample
Generated On: 30 Sep 2014 09:30:37

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

Record number

1

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: CoHb Blood Sample<SA_Arm/>
Generated On: 19 Jun 2014 14:49:18

Not Done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐
12:00 - 13:30 ☐
16:00 - 17:30 ☐
20:00 - 21:30 ☐
08:00 - 09:30 ☒

Not Done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐
12:00 - 13:30 ☒
16:00 - 17:30 ☐
20:00 - 21:30 ☐
08:00 - 09:30 ☐

Not Done _____

If Not Done, please specify the reason: _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: CoHb Blood Sample<CC/THS Arm/>
Generated On: 19 Jun 2014 14:49:18

Not Done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☒
12:00 - 13:30 ☐
16:00 - 17:30 ☐
20:00 - 21:30 ☐
08:00 - 09:30 ☐

Not Done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐
12:00 - 13:30 ☒
16:00 - 17:30 ☐
20:00 - 21:30 ☐
08:00 - 09:30 ☐

Not Done _____

If Not Done, please specify the reason: _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: CoHb Blood Sample
Generated On: 30 Sep 2014 09:30:37

Not Done

If Not Done, please specify the reason:

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: CO Breath Test
Generated On: 19 Jun 2014 14:49:18

Assessment not done

If Not Done, please specify the reason:

Actual Date of Assessment

Fixed Unit:
DD/MMM/YYYY

Actual Time of Assessment

Fixed Unit:
hour:min 24-hour clock

Result

Fixed Unit:
ppm

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: CO Breath Test <Repeat/>
Generated On: 19 Jun 2014 14:49:18

Assessment not done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☒

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Actual Time of Assessment
hour:min 24-hour clock _____

Result(ppm) _____

Assessment not done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐

12:00 - 13:30 ☒

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: CO Breath Test <SA arm/>
Generated On: 19 Jun 2014 14:49:18

Assessment not done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐
12:00 - 13:30 ☐
16:00 - 17:30 ☐
20:00 - 21:30 ☐
08:00 - 09:30 ☒

Actual Time of Assessment
hour:min 24-hour clock _____

Result(ppm) _____

Assessment not done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐
12:00 - 13:30 ☒
16:00 - 17:30 ☐
20:00 - 21:30 ☐
08:00 - 09:30 ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: CYP2A6 activity Sample
Generated On: 19 Jun 2014 14:49:18

Not Done

If Not Done, please specify the reason:

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

trans-3'-hydroxycotinine ☒
cotinine ☐

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

trans-3'-hydroxycotinine ☐
cotinine ☒

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: CYP1A2 activity Sample

Generated On: 19 Jun 2014 14:49:18

Time of caffeine tablet intake

Fixed Unit:
hour:min 24-hour clock

Sample collection Not Done

If Not Done, please specify the reason:

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

Caffeine ☒
Paraxanthine ☐

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Parameter

Caffeine ☐
Paraxanthine ☒

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL

Generated On: 19 Jun 2014 14:49:18

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Risk Marker: s-ICAM-1
Generated On: 19 Jun 2014 14:49:18

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Risk Marker: HbA1c
Generated On: 19 Jun 2014 14:49:18

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary
Generated On: 19 Jun 2014 14:49:18

Type	Product Use
Date of Birth	<hr/>
Date of completion DD/MMM/YYYY	<hr/>
Time of completion hh:mm	<hr/>
Date the questionnaire was completed for DD/MMM/YYYY	<hr/>
Assessment Status	Completed <input type="checkbox"/> Abandoned <input type="checkbox"/>

What tobacco/nicotine product did you use today?

- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- Abandoned ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary

Generated On: 19 Jun 2014 14:49:18

THS 2.2, Other tobacco product and Electronic cigarette ☐

CC, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, Other tobacco product and Electronic cigarette ☐

NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐

CC, NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today?

How many CC/ roll-your-own did you smoke today?

What NRT product did you used today?

- Nicotine Inhaler ☐
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary

Generated On: 19 Jun 2014 14:49:18

Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch ☐

Nicotine Gum and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Gum and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐

Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler and Other NRT Product ☐

Nicotine Nasal Spray and Other NRT Product ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary

Generated On: 19 Jun 2014 14:49:18

Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product ☐

Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary

Generated On: 19 Jun 2014 14:49:18

Nicotine Patch and Other ☐
NRT Product

Nicotine Inhaler, Nicotine ☐
Patch and Other NRT
Product

Nicotine Nasal Spray, ☐
Nicotine Patch and Other
NRT Product

Nicotine Inhaler, Nicotine ☐
Nasal Spray, Nicotine Patch
and Other NRT Product

Nicotine Gum, Nicotine ☐
Patch and Other NRT
Product

Nicotine Inhaler, Nicotine ☐
Gum, Nicotine Patch and
Other NRT Product

How many times did you use an inhaler today? _____

How many times did you use a nasal spray today? _____

How many gums did you use today? _____

How many lozenges did you use today? _____

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☐
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary
Generated On: 19 Jun 2014 14:49:18

How many times did you use chewable/smokeless tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today not listed previously? _____

How many times did you use an electronic cigarette today? _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Adverse Events Y/N
Generated On: 19 Jun 2014 14:49:18

Was there any Adverse Event for this subject?

No ☐
Yes ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Adverse Events
Generated On: 19 Jun 2014 14:49:18

AE Identifier

Adverse Event

Start Date

DD/MMM/YYYY

End Date

DD/MMM/YYYY

Ongoing at final contact No ☐

Yes ☐

Severity Mild Adverse Event ☐

Moderate Adverse Event ☐

Severe Adverse Event ☐

Serious AE No ☐

Yes ☐

Seriousness Criteria Fatal ☐

Is life-threatening ☐

Requires hospitalization ☐

Results in ☐

disability/incapacity

Congenital anomaly/birth defect ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Adverse Events
Generated On: 19 Jun 2014 14:49:18

Treatment given No ☐
Yes ☐

AE related to Study Procedure Related ☐
Not Related ☐

Relationship to CC/THS Related ☐
Not Related ☐

AE expectedness No ☐
Yes ☐

Action taken with study product Product use Interrupted ☐
Product use Stopped ☐
Product use Reduced ☐
Not Applicable ☐
None ☐

Other action taken _____

Outcome Death Related to Adverse ☐
Event ☐
Not Recovered or Not ☐
Resolved ☐
Recovered or Resolved ☐
Recovered or Resolved ☐
with Sequelae ☐
Recovering or Resolving ☐
Unknown ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Adverse Events
Generated On: 19 Jun 2014 14:49:18

H_NOW (Derived):

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Previous and Concomitant Medication Y/N
Generated On: 19 Jun 2014 14:49:18

Has the subject taken previous or concomitant
medication?

No ☐
Yes ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Previous and Concomitant Medication
Generated On: 19 Jun 2014 14:49:18

Brand Name

Start Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing at final contact

Total Daily dose - Dose

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Previous and Concomitant Medication
Generated On: 19 Jun 2014 14:49:18

Total Daily dose - Unit

- Ampule Dosing Unit ☐
 - Bolus Dosing Unit ☐
 - Capsule Dosing Unit ☐
 - Gram ☐
 - Inhalation Dosing Unit ☐
 - International Unit ☐
 - Milligram ☐
 - Milliliter ☐
 - Nebule Dosing Unit ☐
 - Patch Dosing Unit ☐
 - Puff Dosing Unit ☐
 - Suppository Dosing Unit ☐
 - Tablet Dosing Unit ☐
 - Tablespoon Dosing Unit ☐
 - Teaspoon Dosing Unit ☐
 - Microgram per Day ☐
 - Not Applicable ☐
 - Other Dosing Unit ☐
 - Application ☐
-

Route

- Auricular Route of Administration ☐
- Buccal Route of Administration ☐
- Conjunctival Route of Administration ☐
- Cutaneous Route of Administration ☐
- Dental Route of Administration ☐
- Electro-osmosis Route of Administration ☐
- Endocervical Route of Administration ☐
- Endosinusial Route of Administration ☐
- Endotracheal Route of Administration ☐
- Enteral Route of Administration ☐
- Epidural Route of Administration ☐
- Extraamniotic Route of Administration ☐
- Extracorporeal Circulation Route of Administration ☐
- Administration Via Hemodialysis ☐
- Infiltration Route of Administration ☐
- Interstitial Route of Administration ☐
- Intraabdominal Route of Administration ☐
- Intraamniotic Route of Administration ☐
- Intraarterial Route of Administration ☐
- Intraarticular Route of Administration ☐

- Intrabiliary Route of Administration ☐
- Intrabronchial Route of Administration ☐
- Intrabursal Route of Administration ☐
- Intracardiac Route of Administration ☐
- Intracartilaginous Route of Administration ☐
- Intracaudal Route of Administration ☐
- Intracavernous Route of Administration ☐
- Intracavitary Route of Administration ☐
- Intracerebral Route of Administration ☐
- Intracisternal Route of Administration ☐
- Intracorneal Route of Administration ☐
- Intracoronar Dental Route of Administration ☐
- Intracoronary Route of Administration ☐
- Intracorporus Cavernosum Route of Administration ☐
- Intradermal Route of Administration ☐
- Intradiscal Route of Administration ☐
- Intraductal Route of Administration ☐
- Intraduodenal Route of Administration ☐
- Intradural Route of Administration ☐
- Intraepidermal Route of Administration ☐

- Intraesophageal Route of Administration ☐
- Intragastric Route of Administration ☐
- Intragingival Route of Administration ☐
- Intraileal Route of Administration ☐
- Intralesional Route of Administration ☐
- Intraluminal Route of Administration ☐
- Intralymphatic Route of Administration ☐
- Intramedullary Route of Administration ☐
- Intrameningeal Route of Administration ☐
- Intramuscular Route of Administration ☐
- Intraocular Route of Administration ☐
- Intraovarian Route of Administration ☐
- Intrapericardial Route of Administration ☐
- Intraperitoneal Route of Administration ☐
- Intrapleural Route of Administration ☐
- Intraprostatic Route of Administration ☐
- Intrapulmonary Route of Administration ☐
- Intrasinal Route of Administration ☐
- Intraspinal Route of Administration ☐
- Intrasynovial Route of Administration ☐

- Intratendinous Route of Administration ☐
- Intratesticular Route of Administration ☐
- Intrathecal Route of Administration ☐
- Endothoracic Route of Administration ☐
- Intratubular Route of Administration ☐
- Intratumoral Route of Administration ☐
- Intratympanic Route of Administration ☐
- Intrauterine Route of Administration ☐
- Intravascular Route of Administration ☐
- Intravenous Route of Administration ☐
- Intravenous Bolus ☐
- Intravenous Drip ☐
- Intraventricular Route of Administration ☐
- Intravesical Route of Administration ☐
- Intravitreal Route of Administration ☐
- Iontophoresis Route of Administration ☐
- Irrigation-Route of Administration ☐
- Laryngeal Route of Administration ☐
- Nasal Route of Administration ☐
- Nasogastric Route of Administration ☐
- Route of Administration Not Applicable ☐

- Occlusive Dressing ☐
- Technique ☐
- Ophthalmic Route of ☐
- Administration ☐
- Oral Route of ☐
- Administration ☐
- Oropharyngeal Route of ☐
- Administration ☐
- Other Route of ☐
- Administration ☐
- Parenteral Route of ☐
- Administration ☐
- Percutaneous Route of ☐
- Administration ☐
- Periarticular Route of ☐
- Administration ☐
- Peridural Route of ☐
- Administration ☐
- Perineural Route of ☐
- Administration ☐
- Periodontal Route of ☐
- Administration ☐
- Rectal Route of ☐
- Administration ☐
- Inhalation Route of ☐
- Administration ☐
- Retrobulbar Route of ☐
- Administration ☐
- Soft Tissue Route Of ☐
- Administration ☐
- Subarachnoid Route of ☐
- Administration ☐
- Subconjunctival Route of ☐
- Administration ☐
- Subcutaneous Route of ☐
- Administration ☐
- Sublingual Route of ☐
- Administration ☐
- Submucosal Route of ☐
- Administration ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Previous and Concomitant Medication
Generated On: 19 Jun 2014 14:49:18

Topical Route of Administration ☐
Transdermal Route of Administration ☐
Mucosal Route of Administration ☐
Transplacental Route of Administration ☐
Transtracheal Route of Administration ☐
Transtympanic Route of Administration ☐
Unassigned Route of Administration ☐
Unknown Route of Administration ☐
Ureteral Route of Administration ☐
Intraurethral Route of Administration ☐
Vaginal Route of Administration ☐

Indication _____

Concomitant Disease Number _____

AE Number _____

Other _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: End of study
Generated On: 19 Jun 2014 14:49:18

End of study date

Fixed Unit:
DD/MMM/YYYY

Has the subject completed the study ?

No ☐
Yes ☐

If No, please specify the reason:

Adverse Events ☐
Protocol Violation ☐
Withdrawal by Subject ☐
Lost To Follow-up ☐
Other ☐

Details:

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: 24 hour urine collections
Generated On: 19 Jun 2014 14:49:18

Start Date	Fixed Unit: DD/MMM/YYYY
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Start Time	Fixed Unit: hour:min 24-hour clock
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End Date	Fixed Unit: DD/MMM/YYYY
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End Time	Fixed Unit: hour:min 24-hour clock
----------	---------------------------------------

Volume	
--------	--

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Sample Urine Collection
Generated On: 19 Jun 2014 14:49:18

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

How many primary tubes were collected? _____

How many back up tubes were collected? _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Questionnaire on smoking urges (QSU)
Generated On: 19 Jun 2014 14:49:18

Type	QSU
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Date of Birth	<hr/>
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Date of assessment

DD/MMM/YYYY	<hr/>
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Time of assessment

hour:min 24-hour clock	<hr/>
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Assessment Status	Completed <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

1. I have a desire for a cigarette right now	Strongly disagree <input type="checkbox"/>
	Disagree <input type="checkbox"/>
	Somewhat disagree <input type="checkbox"/>
	Do not agree or disagree <input type="checkbox"/>
	Somewhat agree <input type="checkbox"/>
	Agree <input type="checkbox"/>
	Strongly agree <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

2. Nothing would be better than smoking a cigarette right now

- Strongly disagree ☐
- Disagree ☐
- Somewhat disagree ☐
- Do not agree or disagree ☐
- Somewhat agree ☐
- Agree ☐
- Strongly agree ☐
- Abandoned ☐

3. If it were possible I would probably smoke now

- Strongly disagree ☐
- Disagree ☐
- Somewhat disagree ☐
- Do not agree or disagree ☐
- Somewhat agree ☐
- Agree ☐
- Strongly agree ☐
- Abandoned ☐

4. I could control things better right now if I could smoke

- Strongly disagree ☐
- Disagree ☐
- Somewhat disagree ☐
- Do not agree or disagree ☐
- Somewhat agree ☐
- Agree ☐
- Strongly agree ☐
- Abandoned ☐
-

5. All I want right now is a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

6. I have an urge for a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

8. I would do almost anything for a cigarette now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 19 Jun 2014 14:49:18

Type	Behaviour Rating Scale Self-Report
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Date of Birth	<hr/>
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Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
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Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Assessment Status	Completed <input type="checkbox"/> Abandoned <input type="checkbox"/>
-------------------	--

Please indicate for each of the items below, how you have been feeling over the past 24 hours

How have you been feeling over the past 24 hours?	None <input type="checkbox"/>
	Slight <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 19 Jun 2014 14:49:18

How have you been feeling over the past 24 hours?

2. Anxious, nervous

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

3. Depressed Mood, sad

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

4. Desire or craving to smoke

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

5. Difficulty concentrating

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 19 Jun 2014 14:49:18

How have you been feeling over the past 24 hours?

6. Increased appetite, hungry, weight gain

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

7. Insomnia, sleep problems, awakening at night

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

8. Restless

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

9. Impatient

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 19 Jun 2014 14:49:18

How have you been feeling over the past 24 hours?

10. Constipation

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

11. Dizziness

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

12. Coughing

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

13. Dreaming or nightmares

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 19 Jun 2014 14:49:18

How have you been feeling over the past 24 hours?

14. Nausea

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

How have you been feeling over the past 24 hours?

15. Sore Throat

None ☐
Slight ☐
Mild ☐
Moderate ☐
Severe ☐
Abandoned ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 19 Jun 2014 14:49:18

Type	MCEQ
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Date of Birth	<hr/>
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Date of assessment= DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
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Time of assessment	Fixed Unit: hour:min 24-hour clock
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Assessment Status	Completed <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

1. Was smoking satisfying?	Not at all <input type="checkbox"/>
	Very little <input type="checkbox"/>
	Little <input type="checkbox"/>
	Moderately <input type="checkbox"/>
	A lot <input type="checkbox"/>
	Quite a lot <input type="checkbox"/>
	Extremely <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

2. Did cigarettes taste good?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

3. Did you enjoy the sensation in your throat and chest?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

4. Did smoking calm you down?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

5. Did smoking make you feel more awake?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

6. Did smoking make you feel less irritable?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

7. Did smoking help you concentrate?

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

8. Did smoking reduce your hunger for food? Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

9. Did smoking make you dizzy? Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

10. Did smoking make you nauseous? Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 19 Jun 2014 14:49:18

11. Did smoking immediately relieve your craving for a cigarette?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

12. Did you enjoy smoking?

Not at all ☐
Very little ☐
Little ☐
Moderately ☐
A lot ☐
Quite a lot ☐
Extremely ☐
Abandoned ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Cough Assessment
Generated On: 19 Jun 2014 14:49:18

Type	VAS for Cough
------	---------------

Date of Birth	<hr/>
---------------	-------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Assessment Status	Completed <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

If YES, please answer the following questions:

First Question: Cough Impact Scale How much is your cough bothering you?	<hr/>
---	-------

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Cough Assessment
Generated On: 19 Jun 2014 14:49:18

Second Question: Cough Intensity Scale:
How intense is your cough?

- Very mild ☐
 - Mild ☐
 - Moderate ☐
 - Severe ☐
 - Very severe ☐
 - Abandoned ☐
 - Not Applicable ☐
-

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

- Rarely ☐
 - Sometimes ☐
 - Fairly often ☐
 - Often ☐
 - Almost always ☐
 - Abandoned ☐
 - Not Applicable ☐
-

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

- No sputum ☐
 - A moderate amount of sputum ☐
 - A large amount of sputum ☐
 - A very large amount of sputum ☐
 - Abandoned ☐
 - Not Applicable ☐
-

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Human Smoking Topography Questionnaire
Generated On: 19 Jun 2014 14:49:18

Type	Human Smoking Topography Questionnaire
------	---

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
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Date of assessment	Fixed Unit: DD/MMM/YYYY
--------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.	Strongly agree <input type="checkbox"/>
	Agree <input type="checkbox"/>
	Neither agree nor disagree <input type="checkbox"/>
	Disagree <input type="checkbox"/>
	Strongly disagree <input type="checkbox"/>

If you agree or strongly agree, please describe :	<hr/>
---	-------

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Human Smoking Topography Questionnaire
Generated On: 19 Jun 2014 14:49:18

2. You enjoy smoking with the device as much as without it.

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

If you disagree or strongly disagree, please describe : _____

3. The taste of the conventional cigarettes/products is different with the device.

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

If you agree or strongly agree, please describe : _____

4. The device is easy to use.

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

If you disagree or strongly disagree, please describe : _____

5. Your smoking is disturbed by the device.

Strongly agree ☐

Agree ☐

Neither agree nor disagree ☐

Disagree ☐

Strongly disagree ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Human Smoking Topography Questionnaire
Generated On: 19 Jun 2014 14:49:18

If you agree or strongly agree, please describe : _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 19 Jun 2014 14:49:18

Were there any events with the device? No ☐
Yes ☐

Event Log Number _____

Date of Device Event
DD/MMM/YYYY _____

Time of
Device Event
hour:min 24-hour clock _____

Event Relates to Device Type: THS 2.2 Cigarette Holder

Unique Device Identifier Serial Number _____

Event Description CH stops heating before ☐
end of smoking experience
CH does not charge when ☐
inserted into the Mobil unit
CH heater broken (LED ☐
blinking red)
Smoking experience does ☐
not start when pressing the
button
Electronic malfunction ☐
during
the smoking experience
Other ☐

Other Describe _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Device report - THS 2.2 menthol Cigarette Holder
Generated On: 19 Jun 2014 14:49:18

Severity of Event	Minor (can be resolved easily) <input type="checkbox"/>
	Major (cannot be resolved. Device needs to be exchanged) <input type="checkbox"/>

Adverse Event Relationship	Is related to AE <input type="checkbox"/>
	Is not related to AE <input type="checkbox"/>

If Related to AE, AE Number

Solution Proposed:	Device Replaced <input type="checkbox"/>
	Device Recharged <input type="checkbox"/>
	Device Withdrawn <input type="checkbox"/>

If the device was replaced, New Device Serial Number:

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Device report - THS 2.2 menthol Charging Unit

Generated On: 19 Jun 2014 14:49:18

Were there any events with the device?

No ☐

Yes ☐

Event Log Number

Date of Device Event
DD/MMM/YYYY

Time of
Device Event
hour:min 24-hour clock

Event Relates to
Device Type:

THS 2.2 Charging Unit

Unique Device Identifier Serial Number

Event Description

Battery Malfunction ☐

Device Discharged ☐

Other ☐

Other Describe

Severity of Event

Minor (can be resolved
easily) ☐

Major (cannot be resolved.
Device needs to be
exchanged) ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Device report - THS 2.2 menthol Charging Unit

Generated On: 19 Jun 2014 14:49:18

Adverse Event
Relationship

Is related to AE ☐
Is not related to AE ☐

Solution Proposed:

Device Replaced ☐
Device Recharged ☐
Device Withdrawn ☐

If the device was replaced, New Device Serial Number: _____

Date of Device Event Closure
DD/MMM/YYYY

Time of Device Event Closure
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Device Inventory - THS 2.2 menthol Cigarette Holder

Generated On: 19 Jun 2014 14:49:18

Device Inventory
Log Number

Date of Device Distribution
DD/MMM/YYYY

Time of
Device Distribution
hour:min 24-hour clock

Device Type

THS 2.2 Cigarette Holder

Device Serial Number

Date of Device Collection
DD/MMM/YYYY

Time of
Device Collection
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Device Inventory - THS 2.2 menthol Charging Unit
Generated On: 19 Jun 2014 14:49:18

Device Inventory
Log Number

Date of Device Distribution
DD/MMM/YYYY

Time of
Device Distribution
hour:min 24-hour clock

Device Type

THS 2.2 Charging Unit

Device Serial Number

Date of Device Collection
DD/MMM/YYYY

Time of
Device Collection
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Bio-banking (Transcriptomics)
Generated On: 19 Jun 2014 14:49:18

Was a Bio-banking sample for transcriptomics taken?

No ☐
Yes ☐

Date of Sample Collection

Fixed Unit:
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐
Yes ☐

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Bio-banking (Biomarkers of exposure and risk markers)

Generated On: 19 Jun 2014 14:49:18

Was a Bio-banking sample for biomarkers of exposure
and risk markers taken?

No ☐
Yes ☐

Date of Sample Collection

Fixed Unit:
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐
Yes ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Vital Signs<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Date of assessment
DD/MMM/YYYY

Time of assessment
hour:min 24-hour clock

Has the subject smoked within 15 minutes prior to
assessment

No ☐
Yes ☐

Pulse rate
beats per minute

Respiratory rate
breaths per minute

Blood Pressure (systolic)
mmHg

Blood Pressure (diastolic)
mmHg

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Date of assessment
DD/MMM/YYYY

Position

Sitting ☐
Standing ☐
Supine ☒

Heart Rate
(beats per minute)

QRS Interval
(msec)

QT Interval
(msec)

QTcB Interval
(msec)

PR Interval
(msec)

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

If Not Clinically significant or clinically Significant, Please
specify the finding(s) _____

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Spirometry<Unscheduled />

Generated On: 19 Jun 2014 14:49:18

Category

With short-acting
bronchodilator ☐
Without short-acting
bronchodilator ☐

Date of assessment:
DD/MMM/YYYY

Time of assessment:
hour:min 24-hour clock

Name of bronchodilator

Dose

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

Percent of predicted FVC value

Fixed Unit:
%

Best measured FEV1 value

Fixed Unit:
L

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Spirometry<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Predicted FEV1 value

Fixed Unit:
L

Percent of predicted FEV1 value

Fixed Unit:
%

Interpretation

Normal ☐
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐
Clinically significant ☐

If Not Clinically Significant or Clinically Significant, Please
specify the finding(s)

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Physical Examination<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Date of assessment

Fixed Unit:
DD/MMM/YYYY

System

General Appearance ☒

HEENT ☐
(head, eyes, ears, nose,
throat)

Thyroid Gland ☐

Heart ☐

Chest ☐

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

Other, Specify

Outcome

Normal ☐

Abnormal ☐

Abnormal, please specify:

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Physical Examination<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Clinically significant

No ☐
Yes ☐

Not Done

Not Done; please specify the reason:

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Weight<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Date of assessment
DD/MMM/YYYY

Time of assessment
hour:min 24-hour clock

Weight

Fixed Unit:
kg

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: X-Ray<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Category for Examination

Chest X-Ray ☒

Date of assessment
DD/MMM/YYYY

System

General Appearance ☐
HEENT ☐
(head, eyes, ears, nose,
throat)
Thyroid Gland ☐
Heart ☐
Chest ☒
Lungs ☐
Gastrointestinal ☐
Cardiovascular System ☐
Neurologic ☐
Skin ☐
Back ☐
Musculoskeletal ☐
Abdomen ☐
Dentition ☐
Other ☐

Interpretation

Normal ☐
Abnormal ☐

Clinically significant

No ☐
Yes ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: X-Ray<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Abnormal, please specify: _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Clinical Chemistry<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Category

Clinical Chemistry ☒
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐
Yes ☐

Date of Sample Collection
DD/MMM/YYYY

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Haematology<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☒
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Was the subject fasting for at least 10 hours at time of
sample collection?

No ☐
Yes ☐

Date of Sample Collection
DD/MMM/YYYY

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Urine analysis<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☒
Cotinine Screening ☐
Alcohol Breath Test ☐

Date of sample collection
DD/MMM/YYYY

Time of sample collection
hour:min 24-hour clock

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Serology for HIV and Hepatitis B and C<Unscheduled />

Generated On: 19 Jun 2014 14:49:18

Category

Clinical Chemistry ☐

Drug Screen ☐

Haematology ☐

Serology ☒

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Breath Test ☐

Date of Sample Collection

DD/MMM/YYYY

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Urine Drug Screen<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Category

Clinical Chemistry ☐
Drug Screen ☒
Haematology ☐
Serology ☐
Pregnancy Testing ☐
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Date of sample collection

Fixed Unit:
DD/MMM/YYYY

Time of sample collection

Fixed Unit:
hour:min 24-hour clock

Drug type

Amphetamines ☒
Barbiturates ☐
Benzodiazepines ☐
Cannabinoids ☐
Cocaine ☐
Opiates ☐

Result

Negative ☐
Positive ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Alcohol Breath Test<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Category	Clinical Chemistry	<input type="checkbox"/>
	Drug Screen	<input type="checkbox"/>
	Haematology	<input type="checkbox"/>
	Serology	<input type="checkbox"/>
	Pregnancy Testing	<input type="checkbox"/>
	Urinalysis	<input type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input checked="" type="checkbox"/>

Date of assessment	
DD/MMM/YYYY	<hr/>

Time of assessment	
hour:min 24-hour clock	<hr/>

Result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Urine Pregnancy Test<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Category

Clinical Chemistry ☐
Drug Screen ☐
Haematology ☐
Serology ☐
Pregnancy Testing ☒
Urinalysis ☐
Cotinine Screening ☐
Alcohol Breath Test ☐

Date of Test
DD/MMM/YYYY

Time of Test
hour:min 24-hour clock

Specify result

Negative ☐
Positive ☐
Unclear ☐

Specify result of FSH test

< 20 IU/L ☐
>= 20 IU/L ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Blood Samples<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Scheduled Time

Sample Type

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: CO Breath Test<Unscheduled />
Generated On: 19 Jun 2014 14:49:18

Date of Assessment
DD/MMM/YYYY

Actual Time of Assessment
hour:min 24-hour clock

Result
ppm

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Plasma Nicotine Sample(D5)
Generated On: 19 Jun 2014 14:49:18

H_NOW (Derived): _____

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

Timepoint

T0 -15 min ☒

T1 ☐

T2 ☐

T3 ☐

T4 ☐

T5 ☐

T6 ☐

T7 ☐

T8 ☐

T0 + 20H ☐

T0 + 24H ☐

Not Done _____

If Not Done, please specify the reason: _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Plasma Nicotine Sample(D6)
Generated On: 30 Sep 2014 09:30:37

H_NOW (Derived): _____

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

Timepoint	T0 -15 min	<input type="checkbox"/>
	T1	<input type="checkbox"/>
	T2	<input type="checkbox"/>
	T3	<input type="checkbox"/>
	T4	<input type="checkbox"/>
	T5	<input type="checkbox"/>
	T6	<input type="checkbox"/>
	T7	<input type="checkbox"/>
	T8	<input type="checkbox"/>
	T0 + 20H	<input checked="" type="checkbox"/>
	T0 + 24H	<input type="checkbox"/>

Not Done _____

If Not Done, please specify the reason: _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Plasma Cotinine Sample(D5)
Generated On: 19 Jun 2014 14:49:18

H_NOW (Derived): _____

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

Timepoint	T0 -15 min <input checked="" type="radio"/>
	T1 <input type="radio"/>
	T2 <input type="radio"/>
	T3 <input type="radio"/>
	T4 <input type="radio"/>
	T5 <input type="radio"/>
	T6 <input type="radio"/>
	T7 <input type="radio"/>
	T8 <input type="radio"/>
	T0 + 20H <input type="radio"/>
	T0 + 24H <input type="radio"/>

Not Done _____

If Not Done, please specify the reason: _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Plasma Cotinine Sample(D6)
Generated On: 30 Sep 2014 09:30:37

H_NOW (Derived): _____

Not Done _____

If Not Done, please specify the reason: _____

Date
DD/MMM/YYYY _____

Time
hour:min 24-hour clock _____

Timepoint

T0 -15 min	<input type="checkbox"/>
T1	<input type="checkbox"/>
T2	<input type="checkbox"/>
T3	<input type="checkbox"/>
T4	<input type="checkbox"/>
T5	<input type="checkbox"/>
T6	<input type="checkbox"/>
T7	<input type="checkbox"/>
T8	<input type="checkbox"/>
T0 + 20H	<input checked="" type="checkbox"/>
T0 + 24H	<input type="checkbox"/>

Not Done _____

If Not Done, please specify the reason: _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Questionnaire on smoking urges (QSU) (Paper)
Generated On: 30 Sep 2014 09:30:37

Type	Questionnaire on smoking urges
------	-----------------------------------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment	
DD/MMM/YYYY	<hr/>

Time of assessment	
hour:min 24-hour clock	<hr/>

1. I have a desire for a cigarette right now	Strongly disagree <input type="checkbox"/>
	Disagree <input type="checkbox"/>
	Somewhat disagree <input type="checkbox"/>
	Do not agree or disagree <input type="checkbox"/>
	Somewhat agree <input type="checkbox"/>
	Agree <input type="checkbox"/>
	Strongly agree <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Questionnaire on smoking urges (QSU) (Paper)

Generated On: 30 Sep 2014 09:30:37

2. Nothing would be better than smoking a cigarette
right now

Strongly disagree ☐
Disagree ☐
Somewhat disagree ☐
Do not agree or disagree ☐
Somewhat agree ☐
Agree ☐
Strongly agree ☐
Abandoned ☐

3. If it were possible I would probably smoke now

Strongly disagree ☐
Disagree ☐
Somewhat disagree ☐
Do not agree or disagree ☐
Somewhat agree ☐
Agree ☐
Strongly agree ☐
Abandoned ☐

4. I could control things better right now if I could smoke

Strongly disagree ☐
Disagree ☐
Somewhat disagree ☐
Do not agree or disagree ☐
Somewhat agree ☐
Agree ☐
Strongly agree ☐
Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Questionnaire on smoking urges (QSU) (Paper)

Generated On: 30 Sep 2014 09:30:37

5. All I want right now is a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

6. I have an urge for a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Questionnaire on smoking urges (QSU) (Paper)

Generated On: 30 Sep 2014 09:30:37

8. I would do almost anything for a cigarette now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Generated On: 30 Sep 2014 09:30:37

Type	Modifier Cigarette Evaluation Questionnaire
------	--

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment	Fixed Unit:
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	Fixed Unit:
	hour:min 24-hour clock

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)

Generated On: 30 Sep 2014 09:30:37

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Did cigarettes taste good? ☐

Did you enjoy the sensation in your throat and chest? ☐

Did smoking calm you down? ☐

Did smoking make you feel more awake? ☐

Did smoking make you feel less irritable? ☐

Did smoking help you concentrate? ☐

Did smoking reduce your hunger for food? ☐

Did smoking make you dizzy? ☐

Did smoking make you nauseous? ☐

Did smoking immediately relieve your craving for a cigarette? ☐

Did you enjoy smoking? ☐

Response

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Cough Assessment (Paper)
Generated On: 30 Sep 2014 09:30:37

Type	Cough Assessment
------	------------------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

If YES, please answer the following questions:

First Question: Cough Impact Scale How much is your cough bothering you?	<hr/>
---	-------

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Cough Assessment (Paper)

Generated On: 30 Sep 2014 09:30:37

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☐
Mild ☐
Moderate ☐
Severe ☐
Very severe ☐
Abandoned ☐
Not Applicable ☐

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each
day?

Rarely ☐
Sometimes ☐
Fairly often ☐
Often ☐
Almost always ☐
Abandoned ☐
Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☐
A moderate amount of sputum ☐
A large amount of sputum ☐
A very large amount of sputum ☐
Abandoned ☐
Not Applicable ☐

Are there any other important observations that you
would like to share with us about you coughing? (open
question)

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Generated On: 30 Sep 2014 09:30:37

Type	MNWS
------	------

Was paper questionnaire used?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Reason not done	<hr/>
-----------------	-------

Type	Behaviour Rating Scale Self-Report
------	---------------------------------------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Please indicate for each of the items below, how you have been feeling over the past 24 hours

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)

Generated On: 30 Sep 2014 09:30:37

-
1. Angry, irritable, frustrated ☒
 2. Anxious, tense ☐
 3. Depressed Mood, sad ☐
 4. Desire or craving to smoke ☐
 5. Difficulty concentrating ☐
 6. Increased appetite, hungry, weight gain ☐
 7. Insomnia, sleep problems, awakening at night ☐
 8. Restless ☐
 9. Impatient ☐
 10. Constipation ☐
 11. Dizziness ☐
 12. Coughing ☐
 13. Dreaming or nightmares ☐
 14. Nausea ☐
 15. Sore throat ☐

Result

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: LABSTAT results
Generated On: 19 Jun 2014 14:49:18

Cohort Number

Kit Number

Vial Number

Day Number

Sample Collection Date

Group No.

Run No.

Port No.

Sample ID

Number of Filters

Extraction Volume (ml)

Date of Extraction

Sample Volume (ml)

Dilution Volume (ml)

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: LABSTAT results

Generated On: 19 Jun 2014 14:49:18

Total Volume (ml) _____

Date of analysis (UV) _____

Absolute UV Absorbance Mouthpiece part of the Filter _____

Absolute UV Absorbance 'PLA + HAT' part of the Filter _____

Absolute UV Absorbance Full Filter _____

Normalized UV Absorbance Mouthpiece part of the Filter _____

Normalized UV Absorbance 'PLA + HAT' part of the Filter _____

Normalized UV Absorbance Full Filter _____

Date of analysis (Nicotine) _____

Nicotine Amount Mouthpiece part of the Filter (mg/ml) _____

Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml) _____

Nicotine Amount Full Filter (mg/ml) _____

Nicotine Amount Mouthpiece part of the Filter (mg/filter) _____

Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)_____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: LABSTAT results
Generated On: 19 Jun 2014 14:49:18

Nicotine Amount Full Filter (mg/filter) _____

Comments _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Biomarker(Blood)
Generated On: 19 Jun 2014 14:49:18

Sample type

Sample Barcode

Analyte

Result

Result Unit

Lab Status

Sample comment

Detection method

Planned time point (Hour)

Day of Visit

Celerion Study Number

Date of Collection

Timepoint-minutes

Urine Start Day

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Biomarker(Blood)
Generated On: 19 Jun 2014 14:49:18

Urine End Day

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Biomarker(Urine)
Generated On: 19 Jun 2014 14:49:18

Sample type	
Sample Barcode	
Analyte	
Result	
Result Unit	
Lab Status	
Sample comment	
Detection method	
Planned time point (Hour)	
Day of Visit	
Celerion Study Number	
Date of Collection	
Timepoint-minutes	
Urine Start Day	

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Biomarker(Urine)
Generated On: 19 Jun 2014 14:49:18

Urine End Day

Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Lab-BU

Generated On: 19 Jun 2014 14:49:18

Test Category

Date of Sample Collection

Date (BU)

Blood Sample time(BU)

Urine Sample time(BU)

Time of Blood Sample Collection

Time of Urine Sample Collection

Test Name

Result

Text Result

Unit

Lower limit

Upper limit

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Lab-BU
Generated On: 19 Jun 2014 14:49:18

Flag	Out of Reference Range <input type="checkbox"/>
	Low <input type="checkbox"/>
	High <input type="checkbox"/>

Clinically Significant?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>

Comment	<hr/>
---------	-------

Result Category	<hr/>
-----------------	-------

Text Result Code	<hr/>
------------------	-------

Reference Value Category	<hr/>
--------------------------	-------

Timepoint(COHB)	<hr/>
-----------------	-------

Material Code	<hr/>
---------------	-------

Chyle Comment Code	<hr/>
--------------------	-------

Chyle Comment English	<hr/>
-----------------------	-------

Hemolysis Comment Code	<hr/>
------------------------	-------

Hemolysis Comment English	<hr/>
---------------------------	-------

Specimen Comment Code 1	<hr/>
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Final Version 7.0(Main CRF): Case Book

Project Name: ZRHM-REXA-07-JP

Form: Lab-BU

Generated On: 19 Jun 2014 14:49:18

Specimen English Comment 1

Specimen Comment Code 2

Specimen English Comment 2

Result Supplementary Comment Code 1

Result Supplementary English Comment Code 1

Result Supplementary Comment Code 2

Result Supplementary English Comment Code 2

Accession No.

Please document clinically relevant abnormalities in the AE form

H_NOW (Derived):

Derived Form name

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)
Generated On: 30 Sep 2014 09:30:37

Type	Product Use
------	-------------

Date of completion DD/MMM/YYYY	<hr/>
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Time of completion hh:mm	<hr/>
-----------------------------	-------

Date the questionnaire was completed for DD/MMM/YYYY	<hr/>
---	-------

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary(Paper)

Generated On: 30 Sep 2014 09:30:37

What tobacco/nicotine product did you use today?

- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- Abandoned ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary(Paper)

Generated On: 30 Sep 2014 09:30:37

THS 2.2, Other tobacco product and Electronic cigarette ☐

CC, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, Other tobacco product and Electronic cigarette ☐

NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐

CC, NRT, Other tobacco product and Electronic cigarette ☐

THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today? _____

How many CC/ roll-your-own did you smoke today? _____

What NRT product did you used today?

- Nicotine Inhaler ☐
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary(Paper)

Generated On: 30 Sep 2014 09:30:37

- Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch ☐
- Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐
- Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐
- Nicotine Inhaler and Other NRT Product ☐
- Nicotine Nasal Spray and Other NRT Product ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary(Paper)

Generated On: 30 Sep 2014 09:30:37

Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product ☐

Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary(Paper)

Generated On: 30 Sep 2014 09:30:37

Nicotine Patch and Other
NRT Product ☐

Nicotine Inhaler, Nicotine
Patch and Other NRT
Product ☐

Nicotine Nasal Spray,
Nicotine Patch and Other
NRT Product ☐

Nicotine Inhaler, Nicotine
Nasal Spray, Nicotine Patch
and Other NRT Product ☐

Nicotine Gum, Nicotine
Patch and Other NRT
Product ☐

Nicotine Inhaler, Nicotine
Gum, Nicotine Patch and
Other NRT Product ☐

How many times did you use an inhaler today? _____

How many times did you use a nasal spray today? _____

How many gums did you use today? _____

How many lozenges did you use today? _____

How many patches did you use today? _____

How many times did you use other NRT products today
not listed previously? _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Product use diary(Paper)

Generated On: 30 Sep 2014 09:30:37

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☐
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)
Generated On: 30 Sep 2014 09:30:37

How many times did you use chewable/smokeless tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today not listed previously? _____

How many times did you use an electronic cigarette today? _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Lab_BU_CCLS
Generated On: 19 Jun 2014 14:49:18

Actual Collection Date _____

Transmission Type _____ Cumulative ☐
Incremental ☐

Subject ID or Number _____

Subject Sex _____

Subject Date of Birth _____

Visit Name _____

Visit Type _____ Scheduled ☐
Unscheduled ☐

Accession ID _____

Actual Collection Time _____

Specimen Condition _____

Battery ID _____

Battery Name _____

Lab Test ID _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Lab_BU_CCLS
Generated On: 19 Jun 2014 14:49:18

Lab Test Name _____

Test ID _____

Test Status Done ☐
Not Performed (Pending) ☐
Cancelled ☐

Reported Text Result _____

Reported Numeric Result _____

Reference Range low _____

Reference Range high _____

Range Units _____

Conventional Text Result _____

Conventional Numeric Result _____

Conventional Reference Range Low _____

Conventional Reference Range High _____

Conventional Units _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Lab_BU_CCLS
Generated On: 19 Jun 2014 14:49:18

SI Text Result

SI Numeric Result

SI Reference Range Low

SI Reference Range High

SI Units

Reported Result Type

Coded ☐

Numeric ☐

Text ☐

Greater Than (quantifiable limit) ☐

Less Than (quantifiable limit) ☐

Range ☐

Alert Flag

Low Panic ☐

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐

Clinically Significant?

No ☐

Yes ☐

Comment

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Lab_BU Risk markers
Generated On: 19 Jun 2014 14:49:18

Actual Collection Date

Transmission Type

Cumulative ☐

Incremental ☐

Subject ID or Number

Subject Sex

Subject Date of Birth

Visit ID or Number

Visit Type

Scheduled ☐

Unscheduled ☐

Accession ID

Actual Collection Time

Specimen Condition

Battery ID

Battery Name

Lab Test ID

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Lab_BU Risk markers
Generated On: 19 Jun 2014 14:49:18

Test ID _____

Lab Test Name _____

Test Status Done ☐
Not Performed (Pending) ☐
Cancelled ☐

Reported Text Result _____

Reported Numeric Result _____

Reference Range low _____

Reference Range high _____

Range Units _____

Conventional Text Result _____

Conventional Numeric Result _____

Conventional Reference Range Low _____

Conventional Reference Range High _____

Conventional Units _____

Final Version 7.0(Main CRF): Case Book
Project Name: ZRHM-REXA-07-JP
Form: Lab_BU Risk markers
Generated On: 19 Jun 2014 14:49:18

SI Text Result _____

SI Reference Range Low _____

SI Reference Range High _____

SI Units _____

Reported Result Type

Coded ☐

Numeric ☐

Text ☐

Greater Than (quantifiable limit) ☐

Less Than (quantifiable limit) ☐

Range ☐

Alert Flag

Low Panic ☐

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐

SI Numeric Result _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

Type	Cough Assessment
------	------------------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Timepoint	Baseline (Day 0) <input type="checkbox"/>
	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>
	Day 3 <input type="checkbox"/>
	Day 4 <input type="checkbox"/>
	Day 5 <input type="checkbox"/>
	Day 6 <input type="checkbox"/>
	Day 30 <input type="checkbox"/>
	Day 60 <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

If YES, please answer the following questions:

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

First Question: Cough Impact Scale
How much is your cough bothering you? _____

Second Question: Cough Intensity Scale:
How intense is your cough?

Very mild ☐

Mild ☐

Moderate ☐

Severe ☐

Very severe ☐

Abandoned ☐

Not Applicable ☐

Third Question: Cough Frequency Scale:
How frequently do you normally have to cough each day?

Rarely ☐

Sometimes ☐

Fairly often ☐

Often ☐

Almost always ☐

Abandoned ☐

Not Applicable ☐

Fourth Question: Sputum Production
To what extent do you produce sputum when coughing?

No sputum ☐

A moderate amount of sputum ☐

A large amount of sputum ☐

A very large amount of sputum ☐

Abandoned ☐

Not Applicable ☐

Are there any other important observations that you would like to share with us about you coughing? (open question) _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Cough Assessment (Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

Type	MNWS
------	------

Type	Behaviour Rating Scale Self-Report
------	---------------------------------------

Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
-----------------------------------	----------------------------

Timepoint	Baseline (Day 0) <input type="checkbox"/>
	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>
	Day 3 <input type="checkbox"/>
	Day 4 <input type="checkbox"/>
	Day 5 <input type="checkbox"/>
	Day 6 <input type="checkbox"/>
	Day 30 <input type="checkbox"/>
	Day 60 <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit: hour:min 24-hour clock
--------------------	---------------------------------------

Please indicate for each of the items below, how you have been feeling over the past 24 hours

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
(Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

-
1. Angry, irritable, frustrated ☒
 2. Anxious, tense ☐
 3. Depressed Mood, sad ☐
 4. Desire or craving to smoke ☐
 5. Difficulty concentrating ☐
 6. Increased appetite, hungry, weight gain ☐
 7. Insomnia, sleep problems, awakening at night ☐
 8. Restless ☐
 9. Impatient ☐
 10. Constipation ☐
 11. Dizziness ☐
 12. Coughing ☐
 13. Dreaming or nightmares ☐
 14. Nausea ☐
 15. Sore throat ☐

Result

None ☐

Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

Type	Product Use
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Date of completion DD/MMM/YYYY	<hr/>
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Timepoint	Discharge <input type="checkbox"/>
	Day 30 <input type="checkbox"/>
	Day 60 <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of completion hh:mm	<hr/>
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Date the questionnaire was completed for DD/MMM/YYYY	<hr/>
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PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
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What tobacco/nicotine product did you use today?

- THS 2.2 ☐
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- Abandoned ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

- THS 2.2, Other tobacco product and Electronic cigarette ☐
- CC, Other tobacco product and Electronic cigarette ☐
- THS 2.2, CC, Other tobacco product and Electronic cigarette ☐
- NRT, Other tobacco product and Electronic cigarette ☐
- THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐
- CC, NRT, Other tobacco product and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today? _____

How many CC/ roll-your-own did you smoke today? _____

What NRT product did you used today?

- Nicotine Inhaler ☐
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
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Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch ☐

Nicotine Gum and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Gum and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch ☐

Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch ☐

Nicotine Inhaler and Other NRT Product ☐

Nicotine Nasal Spray and Other NRT Product ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product ☐

Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product ☐

Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product ☐

Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

- Nicotine Patch and Other NRT Product ☐
- Nicotine Inhaler, Nicotine Patch and Other NRT Product ☐
- Nicotine Nasal Spray, Nicotine Patch and Other NRT Product ☐
- Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Patch and Other NRT Product ☐
- Nicotine Gum, Nicotine Patch and Other NRT Product ☐
- Nicotine Inhaler, Nicotine Gum, Nicotine Patch and Other NRT Product ☐

How many times did you use an inhaler today? _____

How many times did you use a nasal spray today? _____

How many gums did you use today? _____

How many lozenges did you use today? _____

How many patches did you use today? _____

How many times did you use other NRT products today not listed previously? _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☐
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book
Project Name: ZRHM-REXA-07-JP
Form: Product use diary(Paper)<Unscheduled>
Generated On: 30 Sep 2014 09:30:37

How many times did you use chewable/smokeless tobacco today? _____

How many cigars/cigarillos did you smoke today? _____

How many times did you smoke a pipe today? _____

How many times did you use a tobacco product today not listed previously? _____

How many times did you use an electronic cigarette today? _____

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

Type	Questionnaire on smoking urges
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Date of assessment

DD/MMM/YYYY

Timepoint

Baseline (Day -1) ☐

Baseline (Day 0) ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

Time of assessment

hour:min 24-hour clock

1. I have a desire for a cigarette right now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

2. Nothing would be better than smoking a cigarette
right now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

3. If it were possible I would probably smoke now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

4. I could control things better right now if I could smoke

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

5. All I want right now is a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

6. I have an urge for a cigarette

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

8. I would do almost anything for a cigarette now

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 30-Sep-2014 09:30:37

Type	Modifier Cigarette Evaluation Questionnaire
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Date of assessment	Fixed Unit:
DD/MMM/YYYY	DD/MMM/YYYY

Timepoint	Baseline (Day -1) <input type="checkbox"/>
	Baseline (Day 0) <input type="checkbox"/>
	Day 1 <input type="checkbox"/>
	Day 2 <input type="checkbox"/>
	Day 3 <input type="checkbox"/>
	Day 4 <input type="checkbox"/>
	Day 5 <input type="checkbox"/>
	Day 30 <input type="checkbox"/>
	Day 60 <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit:
	hour:min 24-hour clock

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated On: 30-Sep-2014 09:30:37

If you have smoked since you last completed this questionnaire, please mark what best represents how smoking made you feel

Was smoking satisfying? ☒

Did cigarettes taste good? ☐

Did you enjoy the sensation in your throat and chest? ☐

Did smoking calm you down? ☐

Did smoking make you feel more awake? ☐

Did smoking make you feel less irritable? ☐

Did smoking help you concentrate? ☐

Did smoking reduce your hunger for food? ☐

Did smoking make you dizzy? ☐

Did smoking make you nauseous? ☐

Did smoking immediately relieve your craving for a cigarette? ☐

Did you enjoy smoking? ☐

Response

Not at all ☐

Very little ☐

Little ☐

Moderately ☐

A lot ☐

Quite a lot ☐

Extremely ☐

Abandoned ☐

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

Type	FTND
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Date of assessment DD/MMM/YYYY	Fixed Unit: DD/MMM/YYYY
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Timepoint	Screening <input type="checkbox"/>
	Day 90 <input type="checkbox"/>

Time of assessment	Fixed Unit: hour:min 24-hour clock
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1. How soon after you wake up do you smoke your first cigarette?	31-60 minutes <input type="checkbox"/>
	6-30 minutes <input type="checkbox"/>
	Within 5 minutes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>
	After 60 minutes <input type="checkbox"/>

2. Do you find it difficult to refrain from smoking in places where it is forbidden?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

3. Which cigarette would you hate most to give up?	The first in the morning <input type="checkbox"/>
	Any other <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

PROD 08.000 (MAIN) SP 28JUL14: Case Book

Project Name: ZRHM-REXA-07-JP

Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>

Generated On: 30 Sep 2014 09:30:37

4. How many cigarettes per day do you smoke? 10 or less ☐

11-20 ☐

21-30 ☐

31 or more ☐

Abandoned ☐

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day? Yes ☐

No ☐

Abandoned ☐

6. Do you smoke even if you are so ill that you are in bed most of the day? Yes ☐

No ☐

Abandoned ☐
