

Subject Case Report Forms

Final version 6.0 (Main CRF) - Case Book

Generated On: 25 Apr 2014 13:34:34

All time stamps listed in this document are displayed in GMT

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Subject
Generated On: 25 Apr 2014 13:34:34

Screening number

Site number

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Subject Status
Generated On: 25 Apr 2014 13:34:34

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Screen Failure
Generated On: 25 Apr 2014 13:34:34

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 ☐

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Date of Visit

Generated On: 25 Apr 2014 13:34:34

Date of Visit

Fixed Unit:
DD/MMM/YYYY

Final version 1.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Date of Visit

Generated On: 03 Jul 2013 16:43:15

Date of Visit

Fixed Unit:
DD/MMM/YYYY

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Date of Discharge
Generated On: 25 Apr 2014 13:34:34

Date of Visit

Fixed Unit:
DD/MMM/YYYY

Discharge Time

Fixed Unit:
hour:min 24-hour clock

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Additional Informed Consent
Generated On: 25 Apr 2014 13:34:34

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

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 21 to ☐ 65 years (inclusive).
Subject is of Caucasian ☐ origin.
Smoking, healthy subject ☐ as judged by the Investigator based on all available assessments in the Screening period/day of Admission
Subject is a current smoker ☐ (based on self-reporting), who for the last 4 weeks has smoked at least 10 commercially available non-menthol CCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO per cigarette, as labeled on the cigarette package. Furthermore, the subject has smoked for at least the last 3 consecutive years. The smoking status will be verified with a urinary cotinine test (cotinine 200 ng/ml).

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Inclusion Criteria
Generated On: 25 Apr 2014 13:34:34

The subject is a current smoker who does not plan to quit smoking in the next 3 months. ☐

The subject is ready to accept 5 days of SA. ☐

The subject is ready to accept using the THS 2.2 product. ☐

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. ☐

The subject has medical condition requiring smoking cessation, or clinically relevant diseases in the judgment of the Investigator. ☐

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

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 CC 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 5 half
lives of the drug
(whichever is longer) prior
to the Admission Day (Day
-2), which has an impact
on CYP1A2 or CYP2A6
activity.

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

Concomitant use of ☐
nonsteroidal
anti-inflammatory drugs
(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 subject's
participation in the study.

The subject has a positive ☐
urine drug test.

Positive serology test for ☐
human immunodeficiency
virus (HIV) 1/2, Hepatitis B
or Hepatitis C.

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Exclusion Criteria

Generated On: 25 Apr 2014 13:34:34

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, or 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). ☐

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

Subject does not agree to use an acceptable method of effective contraception ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Exclusion Criteria
Generated On: 25 Apr 2014 13:34:34

Result	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
	NA <input type="checkbox"/>

Exclusion Criterion Number	2
----------------------------	---

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Randomization
Generated On: 25 Apr 2014 13:34:34

Randomization number (4 digits) _____

Allocation Arm

THS 2.2 ☐

CC ☐

SA ☐

Cigarette Consumption

10 – 19 conventional ☐
cigarettes

per day

Greater than 19 ☐
conventional
cigarettes per day

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Demographics
Generated On: 25 Apr 2014 13:34:34

Date of Birth

Fixed Unit:
DD/MMM/YYYY

Sex

Male ☐
Female ☐

Race

White ☒
Black or African American ☐
American Indian or Alaska
Native ☐
Asian ☐
Native Hawaiian or Other
Pacific Islander ☐
Other ☐

Other, specify

Ethnicity

Caucasian ☐
Not Caucasian ☐

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Demographics
Generated On: 25 Apr 2014 13:34:34

Age(Derived)

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Medical History/Concomitant Disease
Generated On: 25 Apr 2014 13:34:34

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):

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Vital Signs Screening
Generated On: 25 Apr 2014 13:34:34

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Vital Signs Screening
Generated On: 25 Apr 2014 13:34:34

Blood Pressure (diastolic)

Fixed Unit:
mmHg

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Vital Signs
Generated On: 25 Apr 2014 13:34:34

Were Vitals Signs assessed?

No ☐
Yes ☐

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment

No ☐
Yes ☐

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

Blood Pressure (diastolic)

Fixed Unit:
mmHg

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Vital Signs
Generated On: 25 Apr 2014 13:34:34

Vital Signs Position of Subject

Sitting ☐
Standing ☐
Supine ☒

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Physical Examination screening
Generated On: 25 Apr 2014 13:34:34

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 _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Physical Examination screening
Generated On: 25 Apr 2014 13:34:34

Outcome	Normal	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>

Abnormal, please specify _____

Clinically significant

No	<input type="checkbox"/>
Yes	<input type="checkbox"/>

Not Done _____

Not Done; please specify the reason: _____

System	General Appearance	<input type="checkbox"/>
	HEENT	<input checked="" type="checkbox"/>
	(head, eyes, ears, nose, throat)	
	Thyroid Gland	<input type="checkbox"/>
	Heart	<input type="checkbox"/>
	Chest	<input type="checkbox"/>
	Lungs	<input type="checkbox"/>
	Gastrointestinal	<input type="checkbox"/>
	Cardiovascular System	<input type="checkbox"/>
	Neurologic	<input type="checkbox"/>
	Skin	<input type="checkbox"/>
	Back	<input type="checkbox"/>
	Musculoskeletal	<input type="checkbox"/>
	Abdomen	<input type="checkbox"/>
	Dentition	<input type="checkbox"/>
	Other	<input type="checkbox"/>

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Advice on the risk of smoking and debriefing
Generated On: 25 Apr 2014 13:34:34

Has the subject received advices on the risks of smoking?

No ☐
Yes ☐

Has a debriefing been performed about THS 2.2?

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Physical Examination
Generated On: 25 Apr 2014 13:34:34

Was the physical examination performed? No ☐
Yes ☐

If No, 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 ☐

Other, Specify _____

Outcome Normal ☐
Abnormal ☐

Abnormal, please specify _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Physical Examination
Generated On: 25 Apr 2014 13:34:34

Clinically significant No ☐
Yes ☐

Not Done _____

Not Done; please specify the reason: _____

System	General Appearance <input type="checkbox"/>
	HEENT <input checked="" type="checkbox"/>
	(head, eyes, ears, nose, throat)
	Thyroid Gland <input type="checkbox"/>
	Heart <input type="checkbox"/>
	Chest <input type="checkbox"/>
	Lungs <input type="checkbox"/>
	Gastrointestinal <input type="checkbox"/>
	Cardiovascular System <input type="checkbox"/>
	Neurologic <input type="checkbox"/>
	Skin <input type="checkbox"/>
	Back <input type="checkbox"/>
	Musculoskeletal <input type="checkbox"/>
	Abdomen <input type="checkbox"/>
	Dentition <input type="checkbox"/>
	Other <input type="checkbox"/>

Other, Specify _____

Outcome Normal ☐
Abnormal ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Product administration-CC
Generated On: 25 Apr 2014 13:34:34

H_NOW (Derived):

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 ☐

Type of Product Use

Conventional Cigarettes ☒
Tobacco Heating System ☐

If type of Product Use different from the randomization
please explain

Time of distribution

Time of butt return

CC with SODIM?

CC not compatible?

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Product administration-CC
Generated On: 25 Apr 2014 13:34:34

SODIM device number

SODIM sample holder number

SODIM file number

Comment

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Identification of Current Cigarette Brand
Generated On: 25 Apr 2014 13:34:34

Date	Fixed Unit: DD/MMM/YYYY
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Brand name	
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ISO Tar Yield	Fixed Unit: MG
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ISO Tar Yield unit	Milligram <input checked="" type="radio"/>
--------------------	--

ISO Nicotine Yield	Fixed Unit: MG
--------------------	-------------------

ISO Nicotine Yield unit	Milligram <input checked="" type="radio"/>
-------------------------	--

ISO CO Yield	Fixed Unit: MG
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ISO CO Yield unit	Milligram <input checked="" type="radio"/>
-------------------	--

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: THS 2.2 product test
Generated On: 25 Apr 2014 13:34:34

Was the THS 2.2 product trial performed?

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: THS 2.2 product demonstration
Generated On: 25 Apr 2014 13:34:34

Has the subject seen a THS 2.2 product demonstration?

No ☐
Yes ☐

If the subject did not see the demonstration please
explain

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Product administration-THS
Generated On: 25 Apr 2014 13:34:34

H_NOW (Derived): _____

Date of product use
DD/MMM/YYYY _____

Visit	Screen Failure <input type="checkbox"/>
	Day -2 <input type="checkbox"/>
	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"/>

Type of Product Use	Conventional Cigarettes <input type="checkbox"/>
	Tobacco Heating System <input checked="" type="checkbox"/>

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

Time of distribution _____

Time of product return _____

SODIM device number _____

SODIM sample holder number _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Product administration-THS
Generated On: 25 Apr 2014 13:34:34

Filter kit number	<hr/>
Filter vial number	<hr/>
Tobacco plug kit number	<hr/>
Tobacco plug vial number	<hr/>
SODIM file number	<hr/>
Comment	<hr/>
Batch Number	<hr/>

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Smoking History
Generated On: 25 Apr 2014 13:34:34

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 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 CC (either tobacco-based products or nicotine-replacement therapy [NRT]), electronic cigarettes and similar devices, within 4 weeks prior to assessment.

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Topography files status for CC
Generated On: 25 Apr 2014 13:34:34

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):

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: FTND Questionnaire
Generated On: 25 Apr 2014 13:34:34

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

Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
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Date of assessment= YYYY MMM DD	Fixed Unit: YYYY MMM DD
------------------------------------	----------------------------

Time of assessment= hour:min 24-hour clock	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?	After 60 minutes <input type="checkbox"/>
	31-60 minutes <input type="checkbox"/>
	6-30 minutes <input type="checkbox"/>
	Within 5 minutes <input type="checkbox"/>
	Abandoned <input type="checkbox"/>

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

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? No ☐
Yes ☐
Abandoned ☐

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Topography files status for THS
Generated On: 25 Apr 2014 13:34:34

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 Name _____

H_NOW (Derived): _____

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Visual Inspection of the Tobacco Plugs Results for THS

Generated On: 25 Apr 2014 13:34:34

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):

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Weight and Height
Generated On: 25 Apr 2014 13:34:34

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Weight
Generated On: 25 Apr 2014 13:34:34

Measurement(s) assessed?

No ☐
Yes ☐

If No, please specify the reason: _____

Time of assessment

Fixed Unit:
hour:min 24-hour clock

Weight

Fixed Unit:
kg

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: ECG (12-Lead Standard) screening
Generated On: 25 Apr 2014 13:34:34

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

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(421)

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: ECG (12-Lead Standard) screening
Generated On: 25 Apr 2014 13:34:34

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)

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: ECG (12-Lead Standard)
Generated On: 25 Apr 2014 13:34:34

Method of ECG Test 12 Lead Placement Cabrera ☐

Was the ECG performed? No ☐
Yes ☐

If No, please specify the reason: _____

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

QT Interval unit

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: ECG (12-Lead Standard)
Generated On: 25 Apr 2014 13:34:34

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)

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Spirometry
Generated On: 25 Apr 2014 13:34:34

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

Fixed Unit:
MG

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Spirometry
Generated On: 25 Apr 2014 13:34:34

Percent of predicted FVC value

Fixed Unit:
%

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)

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Spirometry without a short-acting bronchodilator
Generated On: 25 Apr 2014 13:34:34

Was the spirometry performed? No ☐
Yes ☐

If No, please specify the reason: _____

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

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Spirometry without a short-acting bronchodilator
Generated On: 25 Apr 2014 13:34:34

Predicted FEV1 value	Fixed Unit: L
----------------------	------------------

Percent of predicted FEV1 value	Fixed Unit: %
---------------------------------	------------------

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

If Abnormal, Clinical Significance	Not clinically significant <input type="radio"/>
	Clinically significant <input type="radio"/>

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Chest X-Ray
Generated On: 25 Apr 2014 13:34:34

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 ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Chest X-Ray
Generated On: 25 Apr 2014 13:34:34

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

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

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Haematology
Generated On: 25 Apr 2014 13:34:34

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine analysis
Generated On: 25 Apr 2014 13:34:34

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Clinical Chemistry
Generated On: 25 Apr 2014 13:34:34

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Serology for HIV and Hepatitis B and C
Generated On: 25 Apr 2014 13:34:34

Experiment Type	SEROLOGY
-----------------	----------

Not Done	<hr/>
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If Not Done, please specify the reason:	<hr/>
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Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Drug Screen screening
Generated On: 25 Apr 2014 13:34:34

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 checked="" type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Drug Screen screening
Generated On: 25 Apr 2014 13:34:34

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"/>

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Drug Screen
Generated On: 25 Apr 2014 13:34:34

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 checked="" type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

Not Done? ☐

If Not Done, please specify the reason:

Time of sample collection Fixed Unit:
hour:min 24-hour clock

Drug type	Amphetamines	<input checked="" type="checkbox"/>
	Barbiturates	<input 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"/>

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Alcohol Breath Test screening
Generated On: 25 Apr 2014 13:34:34

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 ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Alcohol Breath Test
Generated On: 25 Apr 2014 13:34:34

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 ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Pregnancy Test screening
Generated On: 25 Apr 2014 13:34:34

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 checked="" type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

Not Done	<hr/>
----------	-------

If Not Done, specify reason	<hr/>
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Date of Test	Fixed Unit: DD/MMM/YYYY
<hr/>	<hr/>

Time of Test	Fixed Unit: hour:min 24-hour clock
<hr/>	<hr/>

Specify result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>
	Unclear	<input type="checkbox"/>

If unclear, please confirm with FSH test	<hr/>
--	-------

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Pregnancy Test screening
Generated On: 25 Apr 2014 13:34:34

Specify result of FSH test

< 20 IU/L ☐

>= 20 IU/L ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Pregnancy Test
Generated On: 25 Apr 2014 13:34:34

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 checked="" type="checkbox"/>
	Cotinine Screening	<input type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

Not Done	<hr/>
----------	-------

If Not Done, specify reason	<hr/>
-----------------------------	-------

Time of Test	Fixed Unit: hour:min 24-hour clock
	<hr/>

Specify result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>
	Unclear	<input type="checkbox"/>

If unclear, please confirm with FSH test	<hr/>
--	-------

Specify result of FSH test	< 20 IU/L	<input type="checkbox"/>
	>= 20 IU/L	<input type="checkbox"/>

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Cotinine Test screening
Generated On: 25 Apr 2014 13:34:34

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 checked="" type="checkbox"/>
	Alcohol Breath Test	<input type="checkbox"/>

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 <input type="checkbox"/>
	Positive >=200 ng/ml <input type="checkbox"/>

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Cotinine Test
Generated On: 25 Apr 2014 13:34:34

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 ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Plasma Nicotine Sample
Generated On: 25 Apr 2014 13:34:34

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Plasma Nicotine Sample(D5)
Generated On: 25 Apr 2014 13:34:34

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: _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Plasma Cotinine Sample
Generated On: 25 Apr 2014 13:34:34

Not Done

If Not Done, please specify the reason:

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Plasma Cotinine Sample(D5)
Generated On: 25 Apr 2014 13:34:34

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:

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: COHb Blood Sample<SA_Arm/>
Generated On: 25 Apr 2014 13:34:34

Not Done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐
12:00 - 14:00 ☐
16:00 - 18:00 ☐
20:00 - 22:00 ☐
08:00 - 10:00 ☒

Not Done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐
12:00 - 14:00 ☒
16:00 - 18:00 ☐
20:00 - 22:00 ☐
08:00 - 10:00 ☐

Not Done _____

If Not Done, please specify the reason: _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: COHb Blood Sample<CC/THS Arm/>
Generated On: 25 Apr 2014 13:34:34

Not Done

If Not Done, please specify the reason:

Scheduled Time

Within 15 min prior to smoking ☒

12:00 - 14:00 ☐

16:00 - 18:00 ☐

20:00 - 22:00 ☐

08:00 - 10:00 ☐

Not Done

If Not Done, please specify the reason:

Scheduled Time

Within 15 min prior to smoking ☐

12:00 - 14:00 ☒

16:00 - 18:00 ☐

20:00 - 22:00 ☐

08:00 - 10:00 ☐

Not Done

If Not Done, please specify the reason:

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: COHb Blood Sample

Generated On: 25 Apr 2014 13:34:34

Not Done

If Not Done, please specify the reason:

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: CO Breath Test
Generated On: 25 Apr 2014 13:34:34

Assessment not done

If Not Done, please specify the reason:

Actual Time of Assessment

Fixed Unit:
hour:min 24-hour clock

Result

Fixed Unit:
ppm

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: CO Breath Test <SA arm/>
Generated On: 25 Apr 2014 13:34:34

Assessment not done _____

If Not Done, please specify the reason: _____

Scheduled Time

Within 15 min prior to smoking ☐

12:00 - 14:00 ☐

16:00 - 18:00 ☐

20:00 - 22:00 ☐

08:00 - 10:00 ☒

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 - 14:00 ☒

16:00 - 18:00 ☐

20:00 - 22:00 ☐

08:00 - 10:00 ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: CYP2A6 activity Sample
Generated On: 25 Apr 2014 13:34:34

Not Done _____

If Not Done, please specify the reason: _____

H_NOW (Derived): _____

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: CYP1A2 activity Sample
Generated On: 25 Apr 2014 13:34:34

Time of coffee 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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Adverse Events Y/N
Generated On: 25 Apr 2014 13:34:34

Was there any Adverse Event for this subject?

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Adverse Events
Generated On: 25 Apr 2014 13:34:34

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

Treatment given No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Adverse Events
Generated On: 25 Apr 2014 13:34:34

Relationship to study procedures 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 ☐

H_NOW (Derived): _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Previous and Concomitant Medication Y/N
Generated On: 25 Apr 2014 13:34:34

Has the subject taken previous or concomitant
medication?

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Previous and Concomitant Medication
Generated On: 25 Apr 2014 13:34:34

Brand Name

Start Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing at final contact

Total Daily dose - Dose

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Previous and Concomitant Medication
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Previous and Concomitant Medication
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: End of study
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: 24 hour urine collections
Generated On: 25 Apr 2014 13:34:34

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	
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Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Sample Urine Collection
Generated On: 25 Apr 2014 13:34:34

Were samples collected?

No ☐
Yes ☐

If No, please specify the reason: _____

How many primary tubes were collected? _____

How many back up tubes were collected? _____

Date of Sample Collection
DD/MMM/YYYY

Time of Sample Collection _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Questionnaire on smoking urges (QSU)
Generated On: 25 Apr 2014 13:34:34

Type	QSU
------	-----

Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
------------------------------	----------------------------

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

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

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

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 ☐

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 ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Questionnaire on smoking urges (QSU)
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)
Generated On: 25 Apr 2014 13:34:34

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

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

Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
------------------------------	----------------------------

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

Time of assessment hour:min 24-hour clock	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

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 25 Apr 2014 13:34:34

How have you been feeling over the past 24 hours?

1. Angry, irritable, frustrated

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

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 ☐

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 25 Apr 2014 13:34:34

How have you been feeling over the past 24 hours?

5. Difficulty concentrating

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

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 ☐

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 25 Apr 2014 13:34:34

How have you been feeling over the past 24 hours?

9. Impatient

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

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 ☐

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)

Generated On: 25 Apr 2014 13:34:34

How have you been feeling over the past 24 hours?

13. Dreaming or nightmares

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

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)
Generated On: 25 Apr 2014 13:34:34

Type	MCEQ
------	------

Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
------------------------------	----------------------------

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

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

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 ☐

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Cough Assessment
Generated On: 25 Apr 2014 13:34:34

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

Date of Birth YYYY MMM DD	Fixed Unit: YYYY MMM DD
------------------------------	----------------------------

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

Time of assessment hour:min 24-hour clock	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?

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Cough Assessment
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Human Smoking Topography Questionnaire
Generated On: 25 Apr 2014 13:34:34

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

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 :

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

If you agree or strongly agree, please describe : _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Device report - THS 2.2 Cigarette Holder
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Device report - THS 2.2 Cigarette Holder
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Device report - THS 2.2 Charging Unit
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Device report - THS 2.2 Charging Unit
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Device Inventory - THS 2.2 Cigarette Holder
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Device Inventory - THS 2.2 Charging Unit
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Bio-banking (Transcriptomics)
Generated On: 25 Apr 2014 13:34:34

Was a Bio-banking sample for transcriptomics taken?

No ☐
Yes ☐

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Deviation
Generated On: 25 Apr 2014 13:34:34

Cohort _____

Subject _____

Assessment _____

Visit Screen Failure ☐
Screening ☐
Admission (Day -2) ☐
Baseline (Day -1) ☐
Baseline (Day 0) ☐
Day 1 ☐
Day 2 ☐
Day 3 ☐
Day 4 ☐
Day 5 ☐
Day 6 ☐
Discharge ☐
Other ☐

Other, Specify _____

Timepoint _____

Description of Deviation _____

Date Deviation Occurred

DD/MMM/YYYY _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Deviation
Generated On: 25 Apr 2014 13:34:34

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 ☐

Deviation Type

Major ☐
Minor ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Deviation
Generated On: 25 Apr 2014 13:34:34

If Major, Evaluation Category

Evaluable ☐
Non Evaluable ☐

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

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

Generated On: 25 Apr 2014 13:34:34

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

No ☐
Yes ☐

Time of Sample Collection

Fixed Unit:
hour:min 24-hour clock

Was the subject fasting for at least 8 hours at time of
sample collection?

No ☐
Yes ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Vital Signs<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: ECG (12-Lead Standard)<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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

Final version 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: Spirometry<Unscheduled />

Generated On: 25 Apr 2014 13:34:34

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

Fixed Unit:
MG

Predicted FVC value

Fixed Unit:
L

Best measured FVC value

Fixed Unit:
L

Percent of predicted FVC value

Fixed Unit:
%

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Spirometry<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

Best measured FEV1 value

Fixed Unit:
L

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Physical Examination<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Physical Examination<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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 ☐

Other, Specify _____

Outcome Normal ☐
Abnormal ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Weight<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

Date of assessment
DD/MMM/YYYY

Time of assessment
hour:min 24-hour clock

Weight

Fixed Unit:
kg

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: X-Ray<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: X-Ray<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

Abnormal, please specify: _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Drug Screen<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Alcohol Breath Test<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

Category

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

Date of assessment
DD/MMM/YYYY

Time of assessment
hour:min 24-hour clock

Result

Negative ☐
Positive ☐

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Urine Pregnancy Test<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

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

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

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

Specify result	Negative	<input type="checkbox"/>
	Positive	<input type="checkbox"/>
	Unclear	<input type="checkbox"/>

Specify result of FSH test	< 20 IU/L	<input type="checkbox"/>
	>= 20 IU/L	<input type="checkbox"/>

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Blood Samples<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

Date
DD/MMM/YYYY

Time
hour:min 24-hour clock

Scheduled Time

Sample Type

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: CO Breath Test<Unscheduled />
Generated On: 25 Apr 2014 13:34:34

Date of Assessment
DD/MMM/YYYY

Actual Time of Assessment
hour:min 24-hour clock

Result
ppm

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Subject (Site level)
Generated On: 25 Apr 2014 13:34:34

Subject (site level)

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Site Accountability
Generated On: 25 Apr 2014 13:34:34

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) _____

Batch number _____

Number of packs received _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: LABSTAT results
Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book

Project Name: ZRHR-REXC-03-EU

Form: LABSTAT results

Generated On: 25 Apr 2014 13:34:34

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 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: LABSTAT results
Generated On: 25 Apr 2014 13:34:34

Nicotine Amount Full Filter (mg/filter) _____

Comments _____

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Lab-BU
Generated On: 25 Apr 2014 13:34:34

Experiment Type	
Date of Sample Collection	
Time of Sample Collection	
Analyte Name	
Result	
Unit	
Lower limit	
Upper limit	

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Lab-BU
Generated On: 25 Apr 2014 13:34:34

Flag	Normal	<input type="checkbox"/>
	Low	<input type="checkbox"/>
	High	<input type="checkbox"/>
	Abnormal	<input type="checkbox"/>
	Grade 1 high	<input type="checkbox"/>
	Grade 2 high	<input type="checkbox"/>
	Grade 3 high	<input type="checkbox"/>
	Panic high	<input type="checkbox"/>
	Panic Low	<input type="checkbox"/>
	Exclusion	<input type="checkbox"/>
	Test not performed	<input type="checkbox"/>
	Grade 1 low	<input type="checkbox"/>
	Grade 2 low	<input type="checkbox"/>
	Grade 3 low	<input type="checkbox"/>
	Grade 1	<input type="checkbox"/>
	Grade 1 abnormal	<input type="checkbox"/>
	Grade 2	<input type="checkbox"/>
	Grade 3	<input type="checkbox"/>
	Grade 2 abnormal	<input type="checkbox"/>
	Grade 3 abnormal	<input type="checkbox"/>

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

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

Data Type unique identifier	<hr/>
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Random number	<hr/>
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Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Lab-BU
Generated On: 25 Apr 2014 13:34:34

Sex

Date of Birth-BU

Visit ID

Lab Comments

Site Number

Please document clinically relevant abnormalities in the AE form

Derived Form name(Lab Type-Date)

H_NOW (Derived):

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Biomarker(Blood)
Generated On: 25 Apr 2014 13:34:34

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Biomarker(Blood)
Generated On: 25 Apr 2014 13:34:34

Urine Start Day

Urine End Day

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Biomarker(Urine)
Generated On: 25 Apr 2014 13:34:34

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

Final version 6.0 (Main CRF): Case Book
Project Name: ZRHR-REXC-03-EU
Form: Biomarker(Urine)
Generated On: 25 Apr 2014 13:34:34

Urine Start Day

Urine End Day
