

Subject Case Report Forms

1119 (Prod: Covance Clinical Development Services, Daytona Beach, Florida)

Generated On: 20 Jul 2016 14:58:24

All time stamps listed in this document are displayed in GMT

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Form: Subject

Data signed: (hfarmer1) 26 Mar 2015 19:02:10

Generated On: 20 Jul 2016 14:58:24

Screening number	1119
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Site number	DAY
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Subject Status

Form: Subject Status

Data signed: (hfarmer1) 26 Mar 2015 19:02:10

Generated On: 20 Jul 2016 14:58:24

Date of 'Screen Failed' Event

Date of 'Discontinued From
Enrollment' Event

12 FEB 2014
DD/MMM/YYYY

Randomization Date

Randomization Time

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Date of Visit

27 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Additional Informed Consent

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

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

Yes ☒

Consent Date

27 JAN 2014
DD/MMM/YYYY

Has the subject given written informed consent for
Bio-banking for Transcriptomics (Pharmacogenomics),
Nasal Epithelial collection and Buccal Collection?

No ☐

Consent Date

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	1
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Inclusion Criterion	Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.
---------------------	---

Result	Yes
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*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	2
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Inclusion Criterion	Subject is at a minimum 22 years of age(inclusive).	<input checked="" type="radio"/>
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Result	Yes	<input checked="" type="radio"/>
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*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

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Inclusion Criterion Number	3
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Inclusion Criterion	Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).
---------------------	--

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	4
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Inclusion Criterion	Subject smokes at least 10 commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).
---------------------	---

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Inclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	5
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Inclusion Criterion	The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.
---------------------	--

Result	Yes
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*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Inclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	6
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Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).
---------------------	---

Result	Yes
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*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
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Folder: Screening

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

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Exclusion Criterion Number	1
----------------------------	---

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

Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

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Exclusion Criterion Number	2
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Exclusion Criterion	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).
---------------------	--

Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number

3

Exclusion Criterion

The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.

Result

No

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

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Exclusion Criterion Number	4
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Exclusion Criterion	Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) <0.7 and FEV1 <80% predicted value at postbronchodilator spirometry (GOLD, 2013).
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	5
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Exclusion Criterion	Subject with asthma condition (FEV1/FVC < 0.75 and reversibility in FEV1 > 12% (or > 200 mL) from pre to post-bronchodilator values).
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	6
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Exclusion Criterion	Subjects with renal insufficiency as defined by serum creatinine levels of >1.3 mg/dL for females and >1.5 mg/dL for males.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

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Exclusion Criterion Number	7
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Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥ 35 kg/m ² . <input checked="" type="radio"/>
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	8
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Exclusion Criterion	As per Investigator 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.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	9
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Exclusion Criterion	Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.
---------------------	--

Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	10
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Exclusion Criterion	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.
---------------------	---

Result	No
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*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	12
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Exclusion Criterion	<p>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.</p>
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	13
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Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	14
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Exclusion Criterion	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.
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Result	No <input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	15
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Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
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Result	No <input type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	16
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Exclusion Criterion	Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B or hepatitis C.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	17
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Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.	<input checked="" type="radio"/>
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Result	No	<input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	18
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Exclusion Criterion	The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (18)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	19
----------------------------	----

Exclusion Criterion	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, and child).
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (19)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	20
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Exclusion Criterion	The subject has participated in a clinical study within 3 months prior to the Screening Visit.
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Result	No
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (20)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	21
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Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.	<input checked="" type="radio"/>
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Result	No	<input checked="" type="radio"/>
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*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Exclusion Criteria (21)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	22
----------------------------	----

Exclusion Criterion	For women only : Subject does not agree to use an acceptable method of effective contraception
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Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Demographics

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Date of Birth	(b) (6)
Sex	Female
Race	White
Other, specify	
Ethnicity	Not Hispanic
Date the Subject signed the Informed Consent	27 JAN 2014 DD/MMM/YYYY
Time the Subject signed the Informed Consent	08:57 hour:min 24-hour clock
Age(Derived)	36

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (1)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection	27 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	1
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Diagnosis Description	TONSILLECTOMY
-----------------------	---------------

Onset Date DD/MMM/YYYY	UN UNK 1986
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN UNK 1986
--------------------------	-------------

Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (2)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection	27 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	2
--------	---

Diagnosis Description	EDENTULOUS, FULL UPPER AND LOWER
-----------------------	-------------------------------------

Onset Date DD/MMM/YYYY	UN UNK 2008
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (3)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection	27 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	3
--------	---

Diagnosis Description	HYSTERECTOMY
-----------------------	--------------

Onset Date DD/MMM/YYYY	UN MAY 2002
---------------------------	-------------

Stop Date DD/MMM/YYYY	UN MAY 2002
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (4)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

4

Diagnosis Description

NORMAL PREGNANCY

Onset Date
DD/MMM/YYYY

(b) (6)

Stop Date
DD/MMM/YYYY

(b) (6)

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (5)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection	27 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	5
--------	---

Diagnosis Description	DIABETES, TYPE II
-----------------------	-------------------

Onset Date DD/MMM/YYYY	UN UNK 2008
---------------------------	-------------

Stop Date DD/MMM/YYYY	
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Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (6)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection	27 JAN 2014 DD/MMM/YYYY
--------------------	----------------------------

Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	6
--------	---

Diagnosis Description	SULFA ALLERGY
-----------------------	---------------

Onset Date DD/MMM/YYYY	UN UNK 2006
---------------------------	-------------

Stop Date DD/MMM/YYYY	
--------------------------	--

Ongoing?	True
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (7)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

7

Diagnosis Description

ATTENTION DEFICIT
DISORDER

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (8)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

8

Diagnosis Description

ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (9)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

9

Diagnosis Description

THALASSEMIA

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (10)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

10

Diagnosis Description

REYE'S SYNDROME

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (11)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection	27 JAN 2014 DD/MMM/YYYY
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Has the subject experienced any past and/ or concomitant diseases?	Yes <input checked="" type="radio"/>
---	--------------------------------------

Number	11
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Diagnosis Description	LEUKOCYTOSIS
-----------------------	--------------

Onset Date DD/MMM/YYYY	<hr/>
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Stop Date DD/MMM/YYYY	<hr/>
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Ongoing?	False
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (12)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

12

Diagnosis Description

BILATERAL
SALPINO-OOPHORECTOMY

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Medical History/Concomitant Disease (13)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of collection

27 JAN 2014
DD/MMM/YYYY

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

Yes ☒

Number

13

Diagnosis Description

OVARIAN CANCER

Onset Date
DD/MMM/YYYY

Stop Date
DD/MMM/YYYY

Ongoing?

False

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Vital Signs<Screening/<

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Were Vitals Signs assessed?

Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to
assessment

No ☒

Date of assessment

27 JAN 2014
DD/MMM/YYYY

Time of assessment

10:27
hour:min 24-hour clock

Pulse rate

94
beats per minute

Respiratory rate

16
breaths per minute

Blood Pressure (systolic)

114
mmHg

Blood Pressure (diastolic)

73
mmHg

Vital Signs Position of Subject

Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

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

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Neurologic ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Skin ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Back ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Abdomen ☒

Outcome

Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done

False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

Date of assessment 27 JAN 2014
DD/MMM/YYYY

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify UPPER AND LOWER
DENTURES

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 19:02:16

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 19:02:19

Generated On: 20 Jul 2016 14:58:24

Date

27 JAN 2014
DD/MMM/YYYY

Brand name

MARLBORO MENTHOL

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: THS 2.2 menthol product demonstration

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Has the subject seen a THS 2.2 menthol product
demonstration?

Yes ☒

If the subject did not see the demonstration please
explain

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 19:02:19

Generated On: 20 Jul 2016 14:58:24

Date of Assessment

27 JAN 2014
DD/MMM/YYYY

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

No ☐

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

Yes ☐

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

10 to 19 ☐

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

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 ☐

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Weight and Height

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Date of assessment

27 JAN 2014
DD/MMM/YYYY

Weight

105.0
kg

Height

175
cm

BMI (Derived)

34.3
kg/m2

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

Was the ECG performed?

Yes ☒

If No, please specify the reason: _____

Date of assessment:

27 JAN 2014
DD/MMM/YYYY

Position

Supine ☒

Heart Rate

87
beats per minute

QRS Interval

104
msec

QT Interval

362
msec

QTcB Interval

436
msec

QTcF Interval

409
msec

PR Interval

147
msec

Interpretation

Normal ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: ECG (12-Lead Standard)

Data signed: (hfarmer1) 26 Mar 2015 19:02:11

Generated On: 20 Jul 2016 14:58:24

If Abnormal, Clinical Significance _____

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Spirometry (1)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category Without short-acting ☒
bronchodilator

Position SITTING

Has the subject smoked within 1 hour prior to assessment? No ☒

Date of assessment 27 JAN 2014
DD/MMM/YYYY

Time of assessment 11:15

Predicted FVC value 4.36
L

Best measured FVC value 4.53
L

Percent of predicted FVC value 104
%

Best measured FEV1 value 3.43
L

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Spirometry (1)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Predicted FEV1 value	3.57 L
----------------------	-----------

Percent of predicted FEV1 value	96 %
---------------------------------	---------

Calculated ratio between FEV1/FVC	0.76
-----------------------------------	------

MEF 25/75 value	3.02 L/s
-----------------	-------------

Interpretation	Normal <input checked="" type="radio"/>
----------------	---

If Abnormal, Clinical Significance	<hr/>
------------------------------------	-------

If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	<hr/>
---	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Spirometry (2)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Was the spirometry performed? Yes ☒

If No, please specify the reason: _____

Category With short-acting ☒
bronchodilator

Position SITTING

Has the subject smoked within 1 hour prior to assessment? No ☒

Date of assessment 27 JAN 2014
DD/MMM/YYYY

Time of assessment 11:45

Name of bronchodilator ALBUTEROL SULFATE

Dose 180 MCG

Predicted FVC value 4.36
L

Best measured FVC value 3.76
L

Percent of predicted FVC value 86
%

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Spirometry (2)

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Best measured FEV1 value	3.30 L
Predicted FEV1 value	3.57 L
Percent of predicted FEV1 value	92 %
Calculated ratio between FEV1/FVC	0.88
MEF 25/75 value	4.00 L/s
Interpretation	Normal <input checked="" type="radio"/>
If Abnormal, Clinical Significance	
If Not Clinically Significant or Clinically Significant, Please specify the finding(s)	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Chest X-Ray

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

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

Yes ☒

If No, please specify the reason: _____

Date of assessment

06 FEB 2014
DD/MMM/YYYY

System

Chest ☒

Interpretation

Normal ☒

Clinically significant _____

Abnormal, please specify: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Haematology

Data signed: (hfarmer1) 26 Mar 2015 19:02:15

Generated On: 20 Jul 2016 14:58:24

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Clinical Chemistry

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Were samples collected?

Yes ☒

If No, please specify the reason: _____

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

Yes ☒

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Urine analysis

Data signed: (hfarmer1) 26 Mar 2015 19:02:15

Generated On: 20 Jul 2016 14:58:24

Were samples collected?

Yes ☒

If No, please specify the reason: _____

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Serology for HIV and Hepatitis B and C

Data signed: (hfarmer1) 26 Mar 2015 19:02:15

Generated On: 20 Jul 2016 14:58:24

Category

Serology ☒

Not Done

False

If Not Done, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 19:02:14

Generated On: 20 Jul 2016 14:58:24

Not Done?	False
-----------	-------

If Not Done, please specify the reason: _____

Date of sample collection	27 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of sample collection	09:48 hour:min 24-hour clock
---------------------------	---------------------------------

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Urine Drug Screen (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:14

Generated On: 20 Jul 2016 14:58:24

Drug type	Result
Cannabinoids	Negative
Cocaine	Negative
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Date of assessment 27 JAN 2014
DD/MMM/YYYY

Time of assessment 09:59
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 14:58:24

Category	Pregnancy Testing <input checked="" type="radio"/>
----------	--

Not Done	False
----------	-------

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

Date of Test	27 JAN 2014 DD/MMM/YYYY
--------------	----------------------------

Time of Test	09:57 hour:min 24-hour clock
--------------	---------------------------------

Specify result	Negative <input checked="" type="radio"/>
----------------	---

If unclear, please confirm with FSH test

Specify result of FSH test	<hr/>
----------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Urine Cotinine Test

Data signed: (hfarmer1) 26 Mar 2015 19:02:13

Generated On: 20 Jul 2016 14:58:24

Category	Cotinine Screening <input checked="" type="radio"/>
----------	---

Not Done	False
----------	-------

If Not Done, please specify the reason: _____

Date of Sample Collection	27 JAN 2014 DD/MMM/YYYY
---------------------------	----------------------------

Time of Sample Collection	09:48 hour:min 24-hour clock
---------------------------	---------------------------------

Result	Positive >=200 ng/ml <input checked="" type="radio"/>
--------	---

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type	CHEMISTRY
-----------------	-----------

Date of Sample Collection YYYY/MM/DD	27 JAN 2014
---	-------------

Subject Number	
----------------	--

Date of Birth	(b) (6)
---------------	---------

Gender	Female <input checked="" type="radio"/>
--------	---

Time of Sample Collection	11:03
---------------------------	-------

Analyte Name	GLUCOSE, SERUM
--------------	----------------

Code	001032
------	--------

Result	110
--------	-----

Unit	MG/DL
------	-------

Lower limit	65
-------------	----

Upper limit	99
-------------	----

Flag	High <input checked="" type="radio"/>
------	---------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp CHEMISTRY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

BUN

Code

001040

Result

12

Unit

MG/DL

Lower limit

6

Upper limit

20

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

CHOLESTEROL, TOTAL

Code

001065

Result

175

Unit

MG/DL

Lower limit

100

Upper limit

199

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

PROTEIN, TOTAL, SERUM

Code

001073

Result

7.1

Unit

G/DL

Lower limit

6.0

Upper limit

8.5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	ALBUMIN, SERUM
Code	001081
Result	4.6
Unit	G/DL
Lower limit	3.5
Upper limit	5.5
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type	CHEMISTRY
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Date of Sample Collection YYYY/MM/DD	27 JAN 2014
---	-------------

Subject Number	
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Date of Birth	(b) (6)
---------------	---------

Gender	Female <input checked="" type="radio"/>
--------	---

Time of Sample Collection	11:03
---------------------------	-------

Analyte Name	BILIRUBIN, TOTAL
--------------	------------------

Code	001099
------	--------

Result	0.3
--------	-----

Unit	MG/DL
------	-------

Lower limit	0.0
-------------	-----

Upper limit	1.2
-------------	-----

Flag	
------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

ALKALINE PHOSPHATASE, S

Code

001107

Result

76

Unit

IU/L

Lower limit

39

Upper limit

117

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	LDH
Code	001115
Result	157
Unit	IU/L
Lower limit	0
Upper limit	214
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

AST (SGOT)

Code

001123

Result

17

Unit

IU/L

Lower limit

0

Upper limit

40

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	TRIGLYCERIDES
Code	001172
Result	215
Unit	MG/DL
Lower limit	0
Upper limit	149
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

POTASSIUM, SERUM

Code

001180

Result

4.0

Unit

MMOL/L

Lower limit

3.5

Upper limit

5.2

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

SODIUM, SERUM

Code

001198

Result

138

Unit

MMOL/L

Lower limit

134

Upper limit

144

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type	CHEMISTRY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	BILIRUBIN, DIRECT
Code	001222
Result	0.10
Unit	MG/DL
Lower limit	0.00
Upper limit	0.40
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

CREATININE, SERUM

Code

001370

Result

0.66

Unit

MG/DL

Lower limit

0.57

Upper limit

1.00

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

ALT (SGPT)

Code

001545

Result

22

Unit

IU/L

Lower limit

0

Upper limit

32

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

GGT

Code

001958

Result

15

Unit

IU/L

Lower limit

0

Upper limit

60

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Experiment Type

CHEMISTRY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

HEP C VIRUS AB

Code

140683

Result

0.4

Unit

S/CO RATIO

Lower limit

0.0

Upper limit

0.9

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:20

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

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

Date of Sample Collection YYYY/MM/DD	27 JAN 2014
---	-------------

Subject Number	_____
----------------	-------

Date of Birth	(b) (6)
---------------	---------

Gender	Female <input checked="" type="radio"/>
--------	---

Time of Sample Collection	11:03
---------------------------	-------

Analyte Name	HIV 1/O/2 ABS, QUAL
--------------	---------------------

Code	001725
------	--------

Result	NON REACTIVE
--------	--------------

Unit	_____
------	-------

Lower limit	NON REACTIVE
-------------	--------------

Upper limit	_____
-------------	-------

Flag	_____
------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp SEROLOGY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

HBSAG SCREEN

Code

006510

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

SEROLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

HIV 1/O/2 ABS-INDEX VALUE

Code

150010

Result

<1.00

Unit

Lower limit

<1.00

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	WBC
Code	005025
Result	10.0
Unit	X10E3/UL
Lower limit	3.4
Upper limit	10.8
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp HEMATOLOGY(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	RBC
Code	005033
Result	5.56
Unit	X10E6/UL
Lower limit	3.77
Upper limit	5.28
Flag	High <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	HEMOGLOBIN
Code	005041
Result	14.0
Unit	G/DL
Lower limit	11.1
Upper limit	15.9
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

HEMATOCRIT

Code

005058

Result

42.3

Unit

%

Lower limit

34.0

Upper limit

46.6

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	MCV
Code	015065
Result	76
Unit	FL
Lower limit	79
Upper limit	97
Flag	Low <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	MCH
Code	015073
Result	25.2
Unit	PG
Lower limit	26.6
Upper limit	33.0
Flag	Low <input checked="" type="radio"/>

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant?

No ☒

Comment

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

MCHC

Code

015081

Result

33.1

Unit

G/DL

Lower limit

31.5

Upper limit

35.7

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

NEUTROPHILS

Code

015107

Result

68

Unit

%

Lower limit

40

Upper limit

74

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

LYMPHS

Code

015123

Result

26

Unit

%

Lower limit

14

Upper limit

46

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

MONOCYTES

Code

015131

Result

5

Unit

%

Lower limit

4

Upper limit

12

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

EOS

Code

015149

Result

1

Unit

%

Lower limit

0

Upper limit

5

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

BASOS

Code

015156

Result

0

Unit

%

Lower limit

0

Upper limit

3

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

PLATELETS

Code

015172

Result

198

Unit

X10E3/UL

Lower limit

155

Upper limit

379

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	NEUTROPHILS (ABSOLUTE)
Code	015909
Result	6.6
Unit	X10E3/UL
Lower limit	1.4
Upper limit	7.0
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type

HEMATOLOGY

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

11:03

Analyte Name

LYMPHS (ABSOLUTE)

Code

015917

Result

2.6

Unit

X10E3/UL

Lower limit

0.7

Upper limit

3.1

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	MONOCYTES(ABSOLUTE)
Code	015925
Result	0.5
Unit	X10E3/UL
Lower limit	0.1
Upper limit	0.9
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	EOS (ABSOLUTE)
Code	015933
Result	0.1
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.4
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Experiment Type	HEMATOLOGY
Date of Sample Collection YYYY/MM/DD	27 JAN 2014
Subject Number	
Date of Birth	(b) (6)
Gender	Female <input checked="" type="radio"/>
Time of Sample Collection	11:03
Analyte Name	BASO (ABSOLUTE)
Code	015941
Result	0.0
Unit	X10E3/UL
Lower limit	0.0
Upper limit	0.2
Flag	

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (18)

Data signed: (hfarmer1) 26 Mar 2015 19:02:22

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number

02757100110

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Please document clinically relevant abnormalities in the AE form

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

09:54

Analyte Name

SPECIFIC GRAVITY

Code

13060

Result

1.005

Unit

Lower limit

1.001

Upper limit

1.035

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp URINALYSIS(27 JAN 2014)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

09:54

Analyte Name

PH

Code

13078

Result

6

Unit

Lower limit

5

Upper limit

8

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

09:54

Analyte Name

GLUCOSE

Code

13086

Result

NORMAL

Unit

Lower limit

NORMAL

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

09:54

Analyte Name

PROTEIN

Code

13094

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

09:54

Analyte Name

OCCULT BLOOD

Code

13102

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

09:54

Analyte Name

BILIRUBIN

Code

13104

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Experiment Type

URINALYSIS

Date of Sample Collection
YYYY/MM/DD

27 JAN 2014

Subject Number

Date of Birth

(b) (6)

Gender

Female ☒

Time of Sample Collection

09:54

Analyte Name

NITRITE, URINE

Code

13106

Result

NEGATIVE

Unit

Lower limit

NEGATIVE

Upper limit

Flag

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: Lab-BU-LabCorp (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Clinically Significant? _____

Comment _____

Please document clinically relevant abnormalities in the AE form

Requisition or Accession number _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

Form: FTND Questionnaire

Generated On: 20 Jul 2016 14:58:24

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

Date of Birth	(b) (6)
---------------	---------

Date of assessment	2014 JAN 27
DD/MMM/YYYY	DD/MMM/YYYY

Time of assessment	12:07
	hour:min 24-hour clock

Assessment Status	Completed <input checked="" type="radio"/>
-------------------	--

1. How soon after you wake up do you smoke your first cigarette?	6-30 minutes <input checked="" type="radio"/>
--	---

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

3. Which cigarette would you hate most to give up?	The first in the morning <input checked="" type="radio"/>
--	---

4. How many cigarettes per day do you smoke?	11-20 <input checked="" type="radio"/>
--	--

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?	No <input checked="" type="radio"/>
---	-------------------------------------

6. Do you smoke even if you are so ill that you are in bed most of the day?	Yes <input checked="" type="radio"/>
---	--------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Screening

**Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit
Smoking**

Data signed: (hfarmer1) 26 Mar 2015 19:02:19

Generated On: 20 Jul 2016 14:58:24

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 27 JAN 2014
DD/MMM/YYYY

Time of assessment 09:10
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit
smoking for at least 24 hours? 3

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Date of Visit

11 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Inclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Inclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number

3

Inclusion Criterion

Smoking, apparently healthy subject as judged by the Investigator based on all available assessments from the Screening period/Day of Admission (e.g., safety laboratory, spirometry, vital signs, physical examination, ECG, chest X-ray, and medical history).

Result

Yes

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Inclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	4
----------------------------	---

Inclusion Criterion	Subject smokes at least 10 commercially available mCCs per day (no brand restrictions), for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last 3 consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine \geq 200 ng/mL).
---------------------	---

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Inclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	5
----------------------------	---

Inclusion Criterion	The subject does not plan to quit smoking within the next 6 months as assessed by the Prochaska 'Stage of Change' questionnaire.
---------------------	--

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Inclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Inclusion Criterion Number	6
----------------------------	---

Inclusion Criterion	The subject is ready to comply with study protocol (e.g readiness to accept interruptions of smoking for up to 91 days and to use THS 2.2 Menthol).
---------------------	--

Result	Yes
--------	-----

*If any has been answered No, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Exclusion Criteria

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	1
----------------------------	---

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

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number

3

Exclusion Criterion

The subject has clinically relevant diseases which required medications (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary, and cardiovascular disease or any other medical condition (including safety laboratory as per CTCAE), which in the opinion of the Investigator would jeopardize the safety of the subject.

Result

No

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	7
----------------------------	---

Exclusion Criterion	The subject has a body mass index (BMI) <18.5 or ≥35 kg/m2.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	8
----------------------------	---

Exclusion Criterion	As per Investigator 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.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	9
----------------------------	---

Exclusion Criterion	Any subject with an history of adverse events linked to caffeine or caffeine containing drugs (e.g., Vivarin), such as but not limited to hypersensitivity or allergy.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	10
----------------------------	----

Exclusion Criterion	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.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	11
----------------------------	----

Exclusion Criterion	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.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	12
----------------------------	----

Exclusion Criterion	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.
---------------------	--

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Exclusion Criteria (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	13
----------------------------	----

Exclusion Criterion	Concomitant use of nonsteroidal anti-inflammatory drugs (NSAIDs) or acetylsalicylic acid.	<input checked="" type="radio"/>
---------------------	---	----------------------------------

Result	No	<input checked="" type="radio"/>
--------	----	----------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	14
----------------------------	----

Exclusion Criterion	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.
---------------------	---

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Exclusion Criteria (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	15
----------------------------	----

Exclusion Criterion	The subject has a positive urine drug test. <input checked="" type="radio"/>
---------------------	--

Result	No <input type="radio"/>
--------	--------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Exclusion Criteria (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	17
----------------------------	----

Exclusion Criterion	Donation or receipt of whole blood or blood products within 3 months prior to Admission.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	No	<input checked="" type="radio"/>
--------	----	----------------------------------

*If any has been answered Yes, subject must not be included in the study.

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Exclusion Criteria (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	21
----------------------------	----

Exclusion Criterion	For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.	<input checked="" type="radio"/>
---------------------	--	----------------------------------

Result	No	<input checked="" type="radio"/>
--------	----	----------------------------------

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Exclusion Criteria (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Exclusion Criterion Number	22
----------------------------	----

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

Result	No
--------	----

*If any has been answered Yes, subject must not be included in the study.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Vital Signs

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Were Vitals Signs assessed? Yes ☒

If No, please specify the reason: _____

Has the subject smoked within 15 minutes prior to assessment No ☒

Time of assessment 12:54
hour:min 24-hour clock

Pulse rate 79
beats per minute

Respiratory rate 12
breaths per minute

Blood Pressure (systolic) 111
mmHg

Blood Pressure (diastolic) 66
mmHg

Vital Signs Position of Subject Supine ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Product preference

Data signed: (hfarmer1) 26 Mar 2015 19:02:26

Generated On: 20 Jul 2016 14:58:24

Which Product Arm would you prefer to be randomized
to:

No preference ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Advice on the risk of smoking and debriefing

Data signed: (hfarmer1) 26 Mar 2015 19:02:26

Generated On: 20 Jul 2016 14:58:24

Has the subject received advices on the risks of
smoking?

Yes ☒

Has a debriefing been performed about THS 2.2?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason:

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Physical Examination (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System General Appearance ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Physical Examination (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System ☒ HEENT
(head, eyes, ears, nose, throat)

Outcome ☒ Normal

Abnormal, please specify _____

Clinically significant _____

Not Done ☐ False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Physical Examination (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Thyroid Gland ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Physical Examination (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Heart ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Chest ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Lungs ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Physical Examination (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Gastrointestinal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Cardiovascular System ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Physical Examination (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Neurologic ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Skin ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Back ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Physical Examination (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Musculoskeletal ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Abdomen ☒

Outcome Normal ☒

Abnormal, please specify _____

Clinically significant _____

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed? Yes ☒

If No, please specify the reason: _____

System Dentition ☒

Outcome Abnormal ☒

Abnormal, please specify UPPER AND LOWER
DENTURES

Clinically significant No ☒

Not Done False

Not Done; please specify the reason: _____

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (18)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Physical Examination (19)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the physical examination performed?

Yes ☒

If No, please specify the reason: _____

System

Other ☒

Other, Specify _____

Outcome _____

Abnormal, please specify _____

Clinically significant _____

Not Done

True

Not Done; please specify the reason: _____

NOT EXAMINED

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Identification of Current Cigarette Brand

Data signed: (hfarmer1) 26 Mar 2015 19:02:26

Generated On: 20 Jul 2016 14:58:24

Brand name

MARLBORO MENTHOL

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: THS 2.2 menthol product test

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Was the THS 2.2 menthol product trial performed?

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?

1

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

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Smoking History

Data signed: (hfarmer1) 26 Mar 2015 19:02:26

Generated On: 20 Jul 2016 14:58:24

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

3. How many menthol cigarettes per day has the subject smoked on average during the last 4 weeks? 10 to 19 ☐

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

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Weight

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Measurement(s) assessed?

Yes ☒

If No, please specify the reason: _____

Time of assessment

12:41
hour:min 24-hour clock

Weight

104.8
kg

Waist circumference

122
cm

BMI

34.2

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Urine Drug Screen

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Not Done?	False
-----------	-------

If Not Done, please specify the reason: _____

Time of sample collection	13:06
	hour:min 24-hour clock

Drug type	Result
Amphetamines	Negative
Barbiturates	Negative
Benzodiazepines	Negative
Cannabinoids	Negative
Cocaine	Negative

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Urine Drug Screen (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Drug type	Result
Opiates	Negative

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Alcohol Test

Data signed: (hfarmer1) 26 Mar 2015 19:02:25

Generated On: 20 Jul 2016 14:58:24

Was the alcohol test performed? Yes ☒

If No, please specify the reason: _____

Method used Breath test ☒

Time of assessment 12:07
hour:min 24-hour clock

Result Negative ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: Urine Pregnancy Test

Generated On: 20 Jul 2016 14:58:24

Not Done	False
----------	-------

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

Time of Test	12:56
	hour:min 24-hour clock

Specify result	Negative <input checked="" type="radio"/>
----------------	---

If unclear, please confirm with FSH test

Specify result of FSH test	<hr/>
----------------------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Admission (Day -2)

Form: CO Breath Test

Data signed: (hfarmer1) 26 Mar 2015 19:02:24

Generated On: 20 Jul 2016 14:58:24

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Actual Time of Assessment	12:06
	hour:min 24-hour clock

Result	12
	ppm

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Admission (Day -2)

Form: Prochaska "Stage of Change" Questionnaire: Intention to Quit Smoking

Data signed: (hfarmer1) 26 Mar 2015 19:02:26

Generated On: 20 Jul 2016 14:58:24

Was paper questionnaire used? Yes ☒

Reason not done _____

Type PROCHASKA STAGE OF
CHANGE QUESTIONNAIRE:
INTENTION TO QUIT
SMOKING

Date of assessment 11 FEB 2014
DD/MMM/YYYY

Time of assessment 13:14
hour:min 24-hour clock

1. Are you currently a smoker? Yes, I currently smoke ☒

2. In the last year, how many times have you quit smoking for at least 24 hours? 3

3. Are you seriously thinking of quitting smoking? No, not thinking of quitting ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Baseline (Day -1)

Form: Date of Visit

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Date of Visit

12 FEB 2014
DD/MMM/YYYY

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Baseline (Day -1)

Form: CO Breath Test (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Assessment not done	False
---------------------	-------

If Not Done, please specify the reason: _____

Scheduled Time	Within 15 min prior to smoking <input checked="" type="radio"/>
----------------	---

Actual Time of Assessment hour:min 24-hour clock	06:44
---	-------

Result(ppm)	10
-------------	----

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Baseline (Day -1)

Form: CO Breath Test (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT DISCHARGE FROM UNIT
---	--------------------------------

Scheduled Time	12:00 - 13:30 <input checked="" type="radio"/>
----------------	--

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

Result(ppm)	<hr/>
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Baseline (Day -1)

Form: CO Breath Test (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT DISCHARGE FROM UNIT
---	--------------------------------

Scheduled Time	16:00 - 17:30 <input checked="" type="radio"/>
----------------	--

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

Result(ppm)	<hr/>
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Baseline (Day -1)

Form: CO Breath Test (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Assessment not done	True
---------------------	------

If Not Done, please specify the reason:	SUBJECT DISCHARGE FROM UNIT
---	--------------------------------

Scheduled Time	20:00 - 21:30 <input checked="" type="radio"/>
----------------	--

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

Result(ppm)	<hr/>
-------------	-------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Discharge (Confinement)

Form: Date of Discharge

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

Date of Visit	12 FEB 2014 DD/MMM/YYYY
---------------	----------------------------

Discharge Time	09:11 hour:min 24-hour clock
----------------	---------------------------------

Is the subject continuing in the ambulatory period?	No <input checked="" type="radio"/>
---	-------------------------------------

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Product Use

Form: Product administration-mCC

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Product Use

Form: Product administration-mCC (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:27

Generated On: 20 Jul 2016 14:58:24

Date of product use DD/MMM/YYYY	12 FEB 2014
------------------------------------	-------------

Visit	Day -1 <input checked="" type="radio"/>
-------	---

Type of Product Use	mCC <input checked="" type="radio"/>
---------------------	--------------------------------------

Time of distribution	06:49
----------------------	-------

Time of butt return	06:56
---------------------	-------

CC with SODIM?	False
----------------	-------

CC not compatible?	False
--------------------	-------

SODIM device number	<hr/>
---------------------	-------

SODIM sample holder number	<hr/>
----------------------------	-------

SODIM file number	<hr/>
-------------------	-------

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

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Product Use

Form: Product administration-THS menthol

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

Date of product use DD/MMM/YYYY	11 FEB 2014
------------------------------------	-------------

Visit	Day -2 <input type="radio"/>
-------	------------------------------

Type of Product Use	THS 2.2 Menthol <input type="radio"/>
---------------------	---------------------------------------

Time of distribution	16:24
----------------------	-------

Time of product return	<input type="text"/>
------------------------	----------------------

SODIM device number	<input type="text"/>
---------------------	----------------------

SODIM sample holder number	<input type="text"/>
----------------------------	----------------------

Tobacco plug kit number	<input type="text"/>
-------------------------	----------------------

Tobacco plug vial number	<input type="text"/>
--------------------------	----------------------

SODIM file number	<input type="text"/>
-------------------	----------------------

Comment	<input type="text"/>
---------	----------------------

Batch Number	B08545
--------------	--------

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Product Use

Form: Product administration-THS menthol (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

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.

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Adverse Events

Form: Adverse Events Y/N

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

Was there any Adverse Event for this subject?

Yes ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

AE Identifier	1
---------------	---

Adverse Event	EMESIS
---------------	--------

Start Date	12 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date	12 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

AE Identifier	2
---------------	---

Adverse Event	NAUSEA
---------------	--------

Start Date	12 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date	12 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

AE Identifier	3
---------------	---

Adverse Event	SINUSITIS
---------------	-----------

Start Date	12 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date	22 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Severe Adverse Event <input type="radio"/>
----------	--

Serious AE	Yes <input type="radio"/>
------------	---------------------------

Seriousness Criteria	Requires hospitalization <input type="radio"/>
----------------------	--

Treatment given	Yes <input type="radio"/>
-----------------	---------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

AE Identifier	4
---------------	---

Adverse Event	HEADACHE
---------------	----------

Start Date	12 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date	22 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Mild Adverse Event <input type="radio"/>
----------	--

Serious AE	No <input type="radio"/>
------------	--------------------------

Seriousness Criteria

Treatment given	No <input type="radio"/>
-----------------	--------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

AE Identifier	5
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Adverse Event	DIABETIC KETOACIDOSIS
---------------	-----------------------

Start Date	12 FEB 2014
------------	-------------

DD/MMM/YYYY

End Date	14 FEB 2014
----------	-------------

DD/MMM/YYYY

Ongoing at final contact	No <input type="radio"/>
--------------------------	--------------------------

Severity	Severe Adverse Event <input type="radio"/>
----------	--

Serious AE	Yes <input type="radio"/>
------------	---------------------------

Seriousness Criteria	Requires hospitalization <input type="radio"/>
----------------------	--

Treatment given	Yes <input type="radio"/>
-----------------	---------------------------

AE related to Study Procedure	Not Related <input type="radio"/>
-------------------------------	-----------------------------------

Relationship to mCC/THS	Not Related <input type="radio"/>
-------------------------	-----------------------------------

AE expectedness	
-----------------	--

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:28

Generated On: 20 Jul 2016 14:58:24

Action taken with study product

None ☒

Other action taken

Outcome

Recovered or Resolved ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication Y/N

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Has the subject taken previous or concomitant
medication?

Yes ☒

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (1)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name

METFORMIN

Start Date
DD/MMM/YYYY

UN UNK 2008

Stop Date
DD/MMM/YYYY

Ongoing at final contact

True

Total Daily dose - Dose

2000

Total Daily dose - Unit

Milligram ☒

Route

Oral Route of
Administration ☒

Indication

DIABETES TYPE II

Concomitant Disease Number

5

AE Number

Other

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (2)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	GLUCOSE TAB
Start Date DD/MMM/YYYY	UN UNK 2013
Stop Date DD/MMM/YYYY	27 JAN 2014
Ongoing at final contact	False
Total Daily dose - Dose	4
Total Daily dose - Unit	Gram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	LOW BLOOD SUGAR
Concomitant Disease Number	5
AE Number	
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (3)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	ONDANSETRON HCI
------------	-----------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	24
-------------------------	----

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Intravenous Route of Administration <input checked="" type="radio"/>
-------	--

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (4)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	ACETAMINOPHEN
Start Date DD/MMM/YYYY	12 FEB 2014
Stop Date DD/MMM/YYYY	13 FEB 2014
Ongoing at final contact	False
Total Daily dose - Dose	650
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
Concomitant Disease Number	
AE Number	3 AND 5
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (5)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	ZOLPIDEM TARTATE
------------	------------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	5
-------------------------	---

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (6)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	DOCUSATE SODIUM
------------	-----------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	100
-------------------------	-----

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (7)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	PROCHLROPREZANINE
------------	-------------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	25
-------------------------	----

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Rectal Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (8)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	ACETAMINOPHEN/ HYDROCODONE 325 MG/5
------------	--

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	14 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	1
-------------------------	---

Total Daily dose - Unit	Tablet Dosing Unit <input checked="" type="radio"/>
-------------------------	---

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (9)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	ENOXAPARIN SODIUM
------------	-------------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	14 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	40
-------------------------	----

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Subcutaneous Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (10)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	ALUMINUM/ MAGNESIUM / SIMETH
------------	---------------------------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	30
-------------------------	----

Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	--

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (11)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	MAGNESIUM OXIDE
------------	-----------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	30
-------------------------	----

Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (12)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	CALCIUM CARBONATE
Start Date DD/MMM/YYYY	12 FEB 2014
Stop Date DD/MMM/YYYY	12 FEB 2014
Ongoing at final contact	False
Total Daily dose - Dose	1000
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
Concomitant Disease Number	
AE Number	3 AND 5
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (13)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	MORPHINE SULFATE
------------	------------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	2
-------------------------	---

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Intravenous Route of Administration <input checked="" type="radio"/>
-------	--

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (14)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	METOCLOPRAMIDE HCI
------------	--------------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	10
-------------------------	----

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Intravenous Route of Administration <input checked="" type="radio"/>
-------	--

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (15)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	TAMAZEPAM
Start Date DD/MMM/YYYY	12 FEB 2014
Stop Date DD/MMM/YYYY	12 FEB 2014
Ongoing at final contact	False
Total Daily dose - Dose	15
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
Concomitant Disease Number	
AE Number	3 AND 5
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (16)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	PANTOPRAZOLE
Start Date DD/MMM/YYYY	12 FEB 2014
Stop Date DD/MMM/YYYY	12 FEB 2014
Ongoing at final contact	False
Total Daily dose - Dose	40
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Intravenous Route of Administration <input checked="" type="radio"/>
Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
Concomitant Disease Number	
AE Number	3 AND 5
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (17)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	INSULIN NOVOLIN
------------	-----------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	13 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	<hr/>
-------------------------	-------

Total Daily dose - Unit	<hr/>
-------------------------	-------

Route	Subcutaneous Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (18)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	AZITHROMYCIN
------------	--------------

Start Date DD/MMM/YYYY	13 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	14 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
--------------------------	-------

Total Daily dose - Dose	500
-------------------------	-----

Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
-------------------------	--

Route	Oral Route of Administration <input checked="" type="radio"/>
-------	---

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
------------	--

Concomitant Disease Number	<hr/>
----------------------------	-------

AE Number	3 AND 5
-----------	---------

Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (19)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	LORATADINE
Start Date DD/MMM/YYYY	13 FEB 2014
Stop Date DD/MMM/YYYY	14 FEB 2014
Ongoing at final contact	False
Total Daily dose - Dose	10
Total Daily dose - Unit	Milligram <input checked="" type="radio"/>
Route	Oral Route of Administration <input checked="" type="radio"/>
Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
Concomitant Disease Number	
AE Number	3 AND 5
Other	

ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (20)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	NOVOLOG INSULIN
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Start Date DD/MMM/YYYY	13 FEB 2014
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Stop Date DD/MMM/YYYY	14 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	10
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Total Daily dose - Unit	Other Dosing Unit <input checked="" type="radio"/>
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Route	Subcutaneous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (21)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	FLUTICASONE PROPIONATE
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Start Date DD/MMM/YYYY	13 FEB 2014
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Stop Date DD/MMM/YYYY	14 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	1
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Total Daily dose - Unit	Other Dosing Unit <input checked="" type="radio"/>
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Route	Nasal Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (22)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	SODIUM CHLORIDE 0.9% SOLUTION
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Start Date DD/MMM/YYYY	12 FEB 2014
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Stop Date DD/MMM/YYYY	13 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
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Total Daily dose - Dose	1000
-------------------------	------

Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Intravenous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (23)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	DEXTROSE IN 0.45 SODIUM CHLORIDE KCL 20 MEQ
------------	--

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
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Total Daily dose - Dose	1000
-------------------------	------

Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Intravesical Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (24)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	DEXT 5%/ SODIUM CHLORIDE 0.45%
------------	-----------------------------------

Start Date DD/MMM/YYYY	12 FEB 2014
---------------------------	-------------

Stop Date DD/MMM/YYYY	12 FEB 2014
--------------------------	-------------

Ongoing at final contact	False
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Total Daily dose - Dose	1000
-------------------------	------

Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Intraventricular Route of Administration <input checked="" type="radio"/>
-------	--

Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (25)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name

SODIUM CHLORIDE /
POTASSIUM 20 MEQ

Start Date
DD/MMM/YYYY

13 FEB 2014

Stop Date
DD/MMM/YYYY

14 FEB 2014

Ongoing at final contact

False

Total Daily dose - Dose

1000

Total Daily dose - Unit

Milliliter ☒

Route

Intravascular Route of
Administration ☒

Indication

DIABETIC KETOACIDOSIS
PRECIPITATED BY SINUSITIS

Concomitant Disease Number

AE Number

3 AND 5

Other

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (26)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	POTASSIUM CHLORIDE/ AQUEOUS SOLUTION 40 MEQ
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Start Date DD/MMM/YYYY	12 FEB 2014
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Stop Date DD/MMM/YYYY	12 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	100
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Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Intravenous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (27)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	MAGNESIUM SULFATE 1 GM/ DEXTROSE
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Start Date DD/MMM/YYYY	13 FEB 2014
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Stop Date DD/MMM/YYYY	13 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	200
-------------------------	-----

Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Intravenous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (28)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	INSULIN REGULAR
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Start Date DD/MMM/YYYY	12 FEB 2014
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Stop Date DD/MMM/YYYY	12 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	1
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Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Intravenous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (29)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	MAGNESIUM SULFATE 1 GM/ SODIUM CHLORIDE 0.9%
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Start Date DD/MMM/YYYY	12 FEB 2014
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Stop Date DD/MMM/YYYY	13 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	100
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Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
-------------------------	---

Route	Intravenous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (30)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	SODIUM PHOSPHATE 15 MMOL/5 ML/ SODIUM CHLORIDE 0.9% SOL
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Start Date DD/MMM/YYYY	12 FEB 2014
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Stop Date DD/MMM/YYYY	12 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	250
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Total Daily dose - Unit	Milliliter <input checked="" type="radio"/>
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Route	Intravenous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (31)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	PROCHLORPERAZINE 25 MG
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Start Date DD/MMM/YYYY	12 FEB 2014
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Stop Date DD/MMM/YYYY	12 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	1
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Total Daily dose - Unit	Suppository Dosing Unit <input checked="" type="radio"/>
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Route	Rectal Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (32)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	OXYCODONE/ACETAMINOPHE N 5MG/325 MG
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Start Date DD/MMM/YYYY	12 FEB 2014
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Stop Date DD/MMM/YYYY	12 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	1
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Total Daily dose - Unit	Tablespoon Dosing Unit <input checked="" type="radio"/>
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Route	Oral Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (33)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	INSULIN ASPART PROTAMINE/ASPART 70/30
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Start Date DD/MMM/YYYY	13 FEB 2014
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Stop Date DD/MMM/YYYY	13 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	15
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Total Daily dose - Unit	Other Dosing Unit <input checked="" type="radio"/>
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Route	Subcutaneous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (34)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	INSULIN HUMAN
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Start Date DD/MMM/YYYY	13 FEB 2014
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Stop Date DD/MMM/YYYY	13 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	1
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Total Daily dose - Unit	Other Dosing Unit <input checked="" type="radio"/>
-------------------------	--

Route	Intravenous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach, Florida: 1119

Folder: Previous and Concomitant Medication

Form: Previous and Concomitant Medication (35)

Data signed: (hfarmer1) 26 Mar 2015 19:02:29

Generated On: 20 Jul 2016 14:58:24

Brand Name	LEVEMIR
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Start Date DD/MMM/YYYY	13 FEB 2014
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Stop Date DD/MMM/YYYY	13 FEB 2014
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Ongoing at final contact	False
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Total Daily dose - Dose	1
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Total Daily dose - Unit	Other Dosing Unit <input checked="" type="radio"/>
-------------------------	--

Route	Subcutaneous Route of Administration <input checked="" type="radio"/>
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Indication	DIABETIC KETOACIDOSIS PRECIPITATED BY SINUSITIS
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Concomitant Disease Number	<hr/>
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AE Number	3 AND 5
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Other	<hr/>
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**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Form: End of study

Data signed: (hcoleman1) 18 Jun 2015 20:52:35

Generated On: 20 Jul 2016 14:58:24

End of study date

12 MAR 2014
DD/MMM/YYYY

Has the subject completed the study ?

No ☒

If No, please specify the reason:

Other ☐

Details:

PRIVATE INVESTIGATORS
DISCRETION DUE TO
NONCOMPLIANCE OF
DIABETIC MEDICATION

**ZRHM-REXA-08-US: Covance Clinical Development Services, Daytona Beach,
Florida: 1119**

Form: Consent Withdrawal

Data signed: (hfarmer1) 26 Mar 2015 19:02:10

Generated On: 20 Jul 2016 14:58:24

Did the subject withdraw it's consent to the biobanking
for BoExp and risk markers?

No ☒

Date of withdrawal of consent for biobanking for BoEXP
and risk markers

Did the subject withdraw it's consent to the
transcriptomics analysis?

Date of withdrawal of consent for transcriptomics
analysis
