



## PMI RESEARCH & DEVELOPMENT

### **Study ZRHM-REXA-07-JP**

### **Clinical Study Report Appendix 16.1.2**

### **Sample Case Report Form, Subject Questionnaire, and**

### **Subject Smoking Diary**

<b>Study Title:</b>	A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 85 days in an ambulatory setting
<b>Study Number:</b>	ZRHM-REXA-07-JP
<b>Product Name:</b>	Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)
<b>Study Initiated (first subject screened):</b>	01 August 2013
<b>Study Completed (last subject last visit):</b>	03 July 2014
<b>Principal Investigator and Affiliation:</b>	Mamoru Oki, MD, PhD, Seishukai Clinic 3-18-5, Matsugaya, Taitou-ku Tokyo 111-0036, Japan Professor Masahiro Endo, MD, Tokyo Heart Center Oaski Hospital, 5-4-12, Kita-Shinagawa, Shinagawa-ku, Tokyo 141-0001, Japan
<b>Sponsor:</b>	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
<b>Sponsor Signatories:</b>	Christelle Haziza, PhD, Manager P1 Clinical Program, Clinical Scientist Nicola Lama, PhD, Biostatistician Andrea Donelli, Clinical Scientist Patrick Picavet, MD, Medical Safety Officer
<b>Version:</b>	1.0
<b>Date:</b>	24 February 2016

This study was conducted in accordance with Good Clinical Practice.

#### **Confidentiality Statement**

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This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.

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## 16.1.2 Sample Case Report Form, Subject Questionnaire and Subject Smoking Diary

### 16.1.2.1 Sample Case Report Form



Subject Case Report Forms

PROD 08.000 (MAIN) SP 28JUL14 - Case Book

Signature Prompt: I hereby confirm that all data is accurate to the best of my knowledge.



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Subject (Site level)**


**Generated On: 18 Sep 2014 07:49:14**

Subject (site level)





**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Subject (Site level)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 SUBJ_DUM MY	\$4				SUBJ_DUM MY



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Subject**

**Generated On: 18 Sep 2014 07:49:14**

Screening number

①

Site number

②

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Subject****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SUBJNUM	\$4				SUBJNUM
②	SITEID	\$3				SITEID



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:49:14**

Cohort	<input type="text"/>	①
Subject	<input type="text"/>	②
Assessment	<input type="text"/>	③
Visit	<div>Screening <input type="checkbox"/></div> <div>Admission (Day -2) <input type="checkbox"/></div> <div>Baseline (Day -1) <input type="checkbox"/></div> <div>Baseline (Day 0) <input type="checkbox"/></div> <div>Day 1 <input type="checkbox"/></div> <div>Day 2 <input type="checkbox"/></div> <div>Day 3 <input type="checkbox"/></div> <div>Day 4 <input type="checkbox"/></div> <div>Day 5 <input type="checkbox"/></div> <div>Day 6 <input type="checkbox"/></div> <div>Discharge (confinement) <input type="checkbox"/></div> <div>Day 30 <input type="checkbox"/></div> <div>Day 60 <input type="checkbox"/></div> <div>Day 90 <input type="checkbox"/></div> <div>Discharge (ambulatory) <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>	④
Other, Specify	<input type="text"/>	⑤
Timepoint	<input type="text"/>	⑥
Description of Deviation	<input type="text"/>	⑦

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:49:14**Date Deviation Occurred 8

DD/MMM/YYYY

Date Deviation Reported 9

DD/MMM/YYYY

Date Deviation Ended 10

DD/MMM/YYYY

Resolution of the Deviation 11Source of the Deviation 12

CRA ☐

Site personnel ☐

Sponsor ☐

CRO ☐

Labs ☐

IXRS ☐

ePRO ☐

Deviation Category 13

Violation ☐

Mis-randomization ☐

Mis-use of product ☐

Concomitant medication ☐

Time deviation ☐

Time missing ☐

Assessment missing ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Deviation Form**  
**Generated On: 18 Sep 2014 07:49:14**

Deviation Type

Major ☒ 14  
Minor ☐

If Major, Evaluation Category

Evaluable ☒ 15  
Non Evaluable ☐





**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COHORT	\$200				COHORT
②	SUBJ	\$4				SUBJ
③	ASSESS	\$200				ASSESS
④	PDVIS	2		1 = Screening 2 = Admission (Day -2) 3 = Baseline (Day -1) 4 = Baseline (Day 0) 5 = Day 1 6 = Day 2 7 = Day 3 8 = Day 4 9 = Day 5 10 = Day 6 11 = Discharge (confinement) 12 = Day 30 13 = Day 60 14 = Day 90		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:49:14**


Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Discharge (ambulatory ) 16 = Other		PDVIS
5 PDVISSPEC	\$200				PDVISSPEC
6 PDTPT	\$200				PDTPT
7 PDDESC	\$200				PDDESC
8 PDSTDT	dd MMM YYYY				PDSTDT
9 PDRPDT	dd MMM YYYY				PDRPDT
10 PDENDT	dd MMM YYYY				PDENDT
11 PDRES	\$200				PDRES
12 PDSOR	\$200		1 = CRA 2 = Site personnel		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Sponsor 4 = CRO 5 = Labs 6 = IXRS 7 = ePRO		PDSOR
 PDCAT	2		1 = Violation 2 = Mis-random ization 3 = Mis-use of product 4 = Concomitan t medication 5 = Time deviation 6 = Time missing 7 = Assessment missing		PDCAT
 PDTYP	2		1 = Major 2 = Minor		PDTYP



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PDEVAL	2		1 = Evaluable 2 = Non Evaluable		PDEVAL

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Subject Status****Generated On: 18 Sep 2014 07:49:14**

Date of 'Screen Failed' Event

Fixed Unit: ①  
DD/MMM/YYYYDate of 'Discontinued From  
Enrollment' EventFixed Unit: ②  
DD/MMM/YYYY

Randomization Date

Fixed Unit: ③  
DD/MMM/YYYY

Randomization Time

Fixed Unit: ④  
hour:min 24-hour clock

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Subject Status****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SRNFDT	dd MMM YYYY				SRNFDT
②	DFEDT	dd MMM YYYY				DFEDT
③	RANDDAT	dd MMM YYYY				RANDDAT
④	RANDTIM	HH:nn				RANDTIM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Site Accountability****Generated On: 18 Sep 2014 07:49:14**

Date of batch dispensed	_____	①
Batch number	_____	②
Category	Received <input type="checkbox"/> ③ Returned <input type="checkbox"/>	
Batch Expiration Date (only for received event) DD/MMM/YYYY	_____	④
Number of unused packs returned	_____	⑤
Number of unused sticks returned (only for returned event)	_____	⑥
Number of packs received	_____	⑦

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Site Accountability****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	ACCDAT	dd MMM YYYY				ACCDAT
②	BATCHNO	\$10				BATCHNO
③	ACC_CAT	1		1 = Received 2 = Returned		ACC_CAT
④	BATCHDAT	dd MMM YYYY				BATCHDAT
⑤	ACCPACK	4				ACCPACK
⑥	ACCSTICK	6				ACCSTICK
⑦	PACREC	4				PACREC





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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Screen Failure****Generated On: 18 Sep 2014 07:49:14**

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Reason for Screen FailureEntry criteria not met ☐ ①Withdrawal by subject ☐Adverse Event ☐Other ☐

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If Other, Specify: 

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Is there a pregnancy event?No ☐ ③Yes ☐NA ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Screen Failure****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① SRNFRSN	1		1 = Entry criteria not met 2 = Withdrawal by subject 3 = Adverse Event 4 = Other		SRNFRSN
② RSNSPEC	\$200				RSNSPEC
③ PGNYN	\$2		N = No Y = Yes NA = NA		PGNYN



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Date of Visit<Ambulatory/>**

**Generated On: 18 Sep 2014 07:49:14**

Visit Not Done

①

If Not Done, Specify Reason

②

Date of Visit

Fixed Unit:  
DD/MMM/YYYY

③

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Date of Visit<Ambulatory/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VISND	1				VISND
②	VISNDRSN	\$200				VISNDRSN
③	VISDAT	dd MMM YYYY				VISDAT



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Date of Visit**

**Generated On: 18 Sep 2014 07:49:14**

Date of Visit

Fixed Unit: ①  
DD/MMM/YYYY

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Date of Visit****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VISDAT	dd MMM YYYY				VISDAT



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Date of Discharge**

**Generated On: 18 Sep 2014 07:49:14**

Date of Visit

Fixed Unit: ①  
DD/MMM/YYYY

Discharge Time

Fixed Unit: ②  
hour:min 24-hour clock

Is the subject continuing in the ambulatory period?

No ☐ ③  
Yes ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Date of Discharge****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VISDAT	dd MMM YYYY				VISDAT
②	DISTIM	HH:nn				DISTIM
③	CONTYN	\$1		N = No Y = Yes		CONTYN





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Additional Informed Consent**  
**Generated On: 18 Sep 2014 07:49:14**

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

No ☐ ①  
Yes ☐

Consent Date

Fixed Unit: ②  
DD/MMM/YYYY

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

No ☐ ③  
Yes ☐

Consent Date

Fixed Unit: ④  
DD/MMM/YYYY

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Additional Informed Consent****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	ICUPB	1		0 = No 1 = Yes		ICUPB
②	ICUPBDAT	dd MMM YYYY				ICUPBDAT
③	ICTRS	1		0 = No 1 = Yes		ICTRS
④	ICTRSDAT	dd MMM YYYY				ICTRSDAT



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Inclusion Criteria**

**Generated On: 18 Sep 2014 07:49:14**

Inclusion Criterion Number

①

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

## Inclusion Criterion

Subject has signed the ICF ☒ 2  
and is able  
to understand the  
information  
provided in the Subject  
Information  
Sheet and ICF.  
Subject is aged from 23 to ☐  
65 years  
(inclusive).  
Subject is Japanese. ☐  
Smoking, healthy subject ☐  
as judged  
by the Investigator based  
on all  
available assessments from  
the  
Screening period/day of  
Admission  
(e.g. safety laboratory,  
spirometry[FEV1/FVC >0.7  
at  
post-bronchodilator  
spirometry,  
post-bronchodilator FEV1  
>80%  
predicted value, and  
post-bronchodilator FVC  
>80%  
predicted value], vital  
signs, physical  
examination, ECG, chest  
X-ray and  
medical history).



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Inclusion Criteria

Generated On: 18 Sep 2014 07:49:14

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

Result


No ☒ 3  
Yes ☐

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

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		1 2 3 4 5 6 7	1: 1 2: 2 3: 3 4: 4 5: 5 6: 6 7: 7	IETESTCD

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 IETEST_I	\$200		1 = Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Subject is aged from 23 to 65 years (inclusive).		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Subject is Japanese.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Smoking, healthy subject as judged by the Investigator based on all available assessment s from the Screening period/day of Admission (e.g. safety laboratory, spirometry[ FEV1/FVC >0.7 at post-bronch odilator spirometry, post-bronch odilator FEV1 >80% predicted value, and post-bronch odilator FVC >80% predicted value], vital signs, physical examination , ECG, chest X-ray and medical history).		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Subject smokes at least 10 commercially available menthol mCCs per day (no brand restrictions) with a maximum yield of 1 mg nicotine ISO/mCC, as labelled on the cigarette package, for the last 4 weeks, based on self-reporting. Furthermore, the subject has been smoking for at least the last three consecutive years. The smoking status will be verified based on a urinary cotinine test (cotinine > 200 ng/mL).		
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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = The subject does not plan to quit smoking in the next 3 months.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = The subject is ready to accept interruptions of smoking for up to 90 days.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = The subject is ready to accept using the THS 2.2 Menthol.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF. 2: Subject is aged from 23 to 65 years (inclusive). 3: Subject is Japanese. 4: Smoking, healthy subject as judged by the Investigator based on all available assessments from the Screening period/day of Admission (e.g. safety laboratory, spirometry[FEV1/FVC >0.7 at post-bronchodilator spirometry, post-bronchodilator FEV1 >80% predicted value, and post-bronchodilator FVC	IETEST_I
PROD 08.000 (MAIN) SP 28JUL14 (640)					38 of 656

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Inclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ IE_I_ORRE S	\$1		N = No Y = Yes		IE_I_ORRE S





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Exclusion Criteria**

**Generated On: 18 Sep 2014 07:49:14**

Exclusion Criterion Number

①

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

## Exclusion Criterion

- As per Investigator judgment, the subject cannot participate in the study for any reason (e.g. medical, psychiatric and/or social reason). ☒ 2
- A subject who is legally incompetent, physically or mentally incapable of giving consent (e.g. emergency situation, under guardianship, subject in a social or sanitary establishment, prisoners or subjects who are involuntarily incarcerated). ☐
- The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematological, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters]) in the judgment of the Investigator. ☐
- The subject has a body mass index (BMI) <18.5 or  $\geq 32$  kg/m<sup>2</sup>. ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Exclusion Criteria**

**Generated On: 18 Sep 2014 07:49:14**

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

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

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



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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Exclusion Criteria**

**Generated On: 18 Sep 2014 07:49:14**

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- If a subject has received any medication (prescribed or over-the-counter) within 14 days prior to Screening or prior to the Admission Day (Day -2), it will be decided at the discretion of the Investigator if these can potentially interfere with the study objectives or subject's safety. ☐
- Concomitant use of NSAIDs or acetylsalicylic acid. ☐
- The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with the subject's participation in the study. ☐
- The subject has a positive urine drug test. ☐
- Positive serology test for HIV1/2, hepatitis B or hepatitis C. ☐
- Donation or receipt of whole blood or blood products within 3 months prior to Admission. ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Exclusion Criteria

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- 
- The subject is a current or former ☐  
employee of the tobacco  
industry or  
of their first-degree  
relatives (parent,  
sibling, child).
- The subject is an employee ☐  
of the  
investigational site or any  
other  
parties involved in the  
study or of  
their first-degree relatives  
(parent,  
sibling, child).
- The subject has ☐  
participated in a  
clinical study within 3  
months prior  
to the Screening Visit.
- The subject has previously ☐  
participated in the same  
study at a  
different time (i.e. each  
subject can be  
included in the study  
population only  
once).
- For women only: Subject is ☐  
pregnant (does not have  
negative pregnancy tests  
at Screening and at  
Admission) or is breast  
feeding.
- For women only: Subject ☐  
does not agree to use an  
acceptable method of  
effective contraception
-



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Exclusion Criteria**

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Result


No ☒ 3  
Yes ☐  
NA ☐

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

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① IETESTCD	\$2		1 2 3 4 5 6 1: 1  8 9 10 11 12: 2 12 13 14 15: 3 5 16 17 18: 4  19  5: 5 6: 6 7: 8 8: 9 9: 10 10: 11 11: 12 12: 13 13: 14 14: 15 15: 16 16: 17 17: 18 18: 19		IETESTCD

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 IETEST	\$200		1 = As per Investigator judgment, the subject cannot participate in the study for any reason (e.g. medical, psychiatric and/or social reason).		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = A subject who is legally incompeten t, physically or mentally incapable of giving consent (e.g. emergency situation, under guardianshi p, subject in a social or sanitary establishe nt, prisoners or subjects who are involuntarily incarcerate d).		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = The subject has medical condition requiring smoking cessation, or clinically relevant diseases (including but not limited to gastrointestinal, renal, hepatic, neurological, hematologic, al, endocrine, oncological, urological, immunological, pulmonary and cardiovascular disease or any other medical condition [including but not limited to clinically relevant abnormal laboratory parameters PROD 08.000 (MAIN) SP 28JUL14 (640)		49 of 656
			)) in the judgment of the Investigator		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = The subject has a body mass index (BMI) <18.5 or ≥ 32 kg/m <sup>2</sup> .		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = As per Investigator or designee judgment, the subject has medical conditions which require or will require in the course of the study, a medical intervention (e.g., start of treatment, surgery, hospitalization) which may interfere with the study participation and/or study results.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = 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.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = The subject has received medication (prescription or over-the-counter) within 14 days or within five half lives of the drug (whichever is longer) prior to the Admission Day (Day -2), which has an impact on CYP1A2 or CYP2A6 activity.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 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.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
------------	-----------	-------	--------	-------------------	-------------------

9 =  
Concomitant use of  
NSAIDs or  
acetylsalicylic acid.



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = 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.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = The subject has a positive urine drug test.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = Positive serology test for HIV1/2, hepatitis B or hepatitis C.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			13 = Donation or receipt of whole blood or blood products within 3 months prior to Admission.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, child).		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = The subject is an employee of the investigational site or any other parties involved in the study or of their first-degree relatives (parent, sibling, child).		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = The subject has participated in a clinical study within 3 months prior to the Screening Visit.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			17 = The subject has previously participated in the same study at a different time (i.e. each subject can be included in the study population only once).		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			18 = For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			19 = For women only: Subject does not agree to use an acceptable method of effective contraception		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: As per Investigator judgment, the subject cannot participate in the study for any reason (e.g. medical, psychiatric and/or social reason). 2: 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).	IETEST
PROD 08.000 (MAIN) SP 28JUL14 (640)				3: The subject has medical condition requiring smoking cessation, or clinically relevant	66 of 656

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Exclusion Criteria****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ IE_E_ORRE \$8 S			N = No Y = Yes NA = NA		IE_E_ORRE S

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Randomization****Generated On: 18 Sep 2014 07:49:14**

Randomization number (4 digits) \_\_\_\_\_

①

Allocation Arm

THS 2.2 menthol ☐

②

mCC ☐SA ☐

Cigarette Consumption

10 – 19 conventional  
menthol cigarettes per day ☐

③

Greater than 19  
conventional menthol  
cigarettes per day ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Randomization****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	RANDNO	\$4				RANDNO
②	TRTGP	1		1 = THS 2.2 menthol 2 = mCC 3 = SA		TRTGP
③	CIGCON	1		1 = 10 - 19 conventiona l menthol cigarettespe r day 2 = Greater than 19 conventiona l menthol cigarettes per day		CIGCON

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Demographics****Generated On: 18 Sep 2014 07:49:14**

Date of Birth

Fixed Unit: ①  
DD/MMM/YYYY

Sex

Male ②  
Female

Is the subject Japanese?

No ③  
YesDate the Subject signed the Main  
Informed ConsentFixed Unit: ④  
DD/MMM/YYYY

Time the Subject signed the Main Informed Consent

Fixed Unit: ⑤  
hour:min 24-hour clock

Age(Derived)

⑥

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Demographics****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DOB	dd MMM YYYY				DOB
②	SEX	\$8		M = Male F = Female		SEX
③	ETHNIC	1		0 = No 1 = Yes		ETHNIC
④	INFORMDT	dd MMM YYYY				INFORMDT
⑤	INFORMTM	HH:nn				INFORMTM
⑥	AGE	2				AGE





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Medical History/Concomitant Disease**  
**Generated On: 18 Sep 2014 07:49:14**

Date of collection	Fixed Unit: DD/MMM/YYYY	①
<hr/>		
Has the subject experienced any past and/ or concomitant diseases?	No <input type="checkbox"/> Yes <input type="checkbox"/>	②
<hr/>		
Category for Medical History	Medical History	③
<hr/>		
Number		④
<hr/>		
Diagnosis Description		⑤
<hr/>		
Onset Date DD/MMM/YYYY		⑥
<hr/>		
Stop Date DD/MMM/YYYY		⑦
<hr/>		
Ongoing?		⑧
<hr/>		
H_NOW (Derived):		⑨
<hr/>		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Medical History/Concomitant Disease**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	MHDAT	dd MMM YYYY				MHDAT
②	MHYN	\$1		N = No Y = Yes		MHYN
③	MHCAT	\$20		Medical History		MHCAT
④	MHSPID	\$10				MHSPID
⑤	MHTERM	\$200				MHTERM
⑥	MHSTDAT	dd- MMM- YYYY				MHSTDAT
⑦	MHENDAT	dd- MMM- YYYY				MHENDAT
⑧	MHONGO	1				MHONGO
⑨	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Were Vitals Signs assessed?

No ☐ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

Has the subject smoked within 15 minutes prior to assessment

No ☐ ③  
Yes ☐

Date of assessment

Fixed Unit: ④  
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑤  
hour:min 24-hour clock

Pulse rate

Fixed Unit: ⑥  
beats per minute

Respiratory rate

Fixed Unit: ⑦  
breaths per minute

Blood Pressure (systolic)

Fixed Unit: ⑧  
mmHg

Blood Pressure (diastolic)

Fixed Unit: ⑨  
mmHgPROD 08.000 (MAIN) SP  
28JUL14 (640)

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Vital Signs<Screening/>**  
**Generated On: 18 Sep 2014 07:49:14**

Vital Signs Position of Subject

Sitting ☒ 10  
Standing ☐  
Supine ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs<Screening/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT	\$1		N = No Y = Yes		VSSTAT
②	VSREASND	\$200				VSREASND
③	VSSMKYN	\$1		N = No Y = Yes		VSSMKYN
④	VSDAT	dd MMM YYYY				VSDAT
⑤	VSTIM	HH:nn				VSTIM
⑥	VSORRES_P3 ULSE					VSORRES_P ULSE
⑦	VSORRES_R3 ESP					VSORRES_R ESP
⑧	VSORRES_S3 YSBP					VSORRES_S YSBP
⑨	VSORRES_3 DIABP					VSORRES_ DIABP
⑩	VSPOS	\$10		SITTING = Sitting		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			STANDING = Standing SUPINE = Supine		VSPOS

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs****Generated On: 18 Sep 2014 07:49:14**

Were Vitals Signs assessed?

No ☐ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

Has the subject smoked within 15 minutes prior to assessment

No ☐ ③  
Yes ☐

Date of assessment

Fixed Unit: ④  
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑤  
hour:min 24-hour clock

Pulse rate

Fixed Unit: ⑥  
beats per minute

Respiratory rate

Fixed Unit: ⑦  
breaths per minute

Blood Pressure (systolic)

Fixed Unit: ⑧  
mmHg

Blood Pressure (diastolic)

Fixed Unit: ⑨  
mmHgPROD 08.000 (MAIN) SP  
28JUL14 (640)

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Vital Signs**

**Generated On: 18 Sep 2014 07:49:14**

Vital Signs Position of Subject

Sitting ☒ **10**  
Standing ☐  
Supine ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT	\$1		N = No Y = Yes		VSSTAT
②	VSREASND	\$200				VSREASND
③	VSSMKYN	\$1		N = No Y = Yes		VSSMKYN
④	VSDAT	dd MMM YYYY				VSDAT
⑤	VSTIM	HH:nn				VSTIM
⑥	VSORRES_P3 ULSE					VSORRES_P ULSE
⑦	VSORRES_R3 ESP					VSORRES_R ESP
⑧	VSORRES_S3 YSBP					VSORRES_S YSBP
⑨	VSORRES_3 DIABP					VSORRES_ DIABP
⑩	VSPOS	\$10		SITTING = Sitting		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			STANDING = Standing SUPINE = Supine		VSPOS



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Screening/>**  
**Generated On: 18 Sep 2014 07:49:14**

Was the physical examination performed?

No ☐ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

Date of assessment

Fixed Unit: ③  
DD/MMM/YYYY

System

General Appearance ☐ ④  
HEENT ☐  
(head, eyes, ears, nose,  
throat)  
Thyroid Gland ☐  
Heart ☐  
Chest ☐  
Lungs ☐  
Gastrointestinal ☐  
Cardiovascular System ☐  
Neurologic ☐  
Skin ☐  
Back ☐  
Musculoskeletal ☐  
Abdomen ☐  
Dentition ☐  
Other ☐

Other, Specify \_\_\_\_\_ ⑤

Outcome

Normal ☐ ⑥  
Abnormal ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Screening/>**  
**Generated On: 18 Sep 2014 07:49:14**

Abnormal, please specify \_\_\_\_\_ **7**

Clinically significant No ☒ **8**  
Yes ☐

Not Done \_\_\_\_\_ **9**

Not Done; please specify the reason: \_\_\_\_\_ **10**

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination<Screening/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PESTAT	\$1		N = No Y = Yes		PESTAT
②	PEREASND1	\$200				PEREASND1
③	PEDAT	dd MMM YYYY				PEDAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ PETESTCD	\$200		GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat)		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Physical Examination<Screening/>

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			THYROID = Thyroid Gland		
			HEART = Heart		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Physical Examination<Screening/>

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CHEST = Chest		
			LUNGS = Lungs		
			GASTRO = Gastrointest inal		





PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Physical Examination<Screening/>

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
CVS = Cardiovascu lar System					
NEURO = Neurologic					



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Physical Examination<Screening/>

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			SKIN = Skin		
			BACK =		
			Back		
			MUSCULO		
			=		
			Musculoskel		
			etal		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Physical Examination<Screening/>

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
ABDOMEN = Abdomen DENTN = Dentition OTHER = Other					

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: General Appearance 2: HEENT (head, eyes, ears, nose, throat) 3: Thyroid Gland 4: Heart 5: Chest 6: Lungs 7: Gastrointestinal 8: Cardiovascular System 9: Neurologic 10: Skin 11: Back 12: Musculoskeletal 13: Abdomen 14: Dentition 15: Other 16: Other 17: Other 18: Other 19: Other	PETESTCD
5 PESPEC	\$200				PESPEC

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination<Screening/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	PEORRES	\$8		NORMAL = Normal ABNORMAL = Abnormal		PEORRES
7	PETERM	\$200				PETERM
8	PECLSIG	\$1		N = No Y = Yes		PECLSIG
9	PESTAT2	1				PESTAT2
10	PEREASND2	\$200				PEREASND2



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Product preference**

**Generated On: 18 Sep 2014 07:49:14**

Which product would you prefer to be randomized to:

THS 2.2 menthol ☒ 1  
mCC ☐  
SA ☐  
No preference ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product preference****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PRODPREF	1		1 = THS 2.2 menthol 2 = mCC 3 = SA 4 = No preference		PRODPREF



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Advice on the risk of smoking and debriefing**  
**Generated On: 18 Sep 2014 07:49:14**

Date

Fixed Unit: ①  
DD/MMM/YYYY

Has the subject received advices on the risks of smoking?

No ☒ ②  
Yes ☐

Has a debriefing been performed about THS 2.2?

No ☒ ③  
Yes ☐





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Advice on the risk of smoking and debriefing**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SRDAT	dd MMM YYYY				SRDAT
②	SRAYN	\$1		N = No Y = Yes		SRAYN
③	SRDYN	\$1		N = No Y = Yes		SRDYN

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

Was the physical examination performed?

No ☐ 1  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ 2

Date of Assessment

Fixed Unit: ☐ 3  
DD/MMM/YYYY

System

General Appearance ☐ 4HEENT ☐  
(head, eyes, ears, nose,  
throat)Thyroid Gland ☐Heart ☐Chest ☐Lungs ☐Gastrointestinal ☐Cardiovascular System ☐Neurologic ☐Skin ☐Back ☐Musculoskeletal ☐Abdomen ☐Dentition ☐Other ☐

Other, Specify \_\_\_\_\_ 5

Outcome

Normal ☐ 6  
Abnormal ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Physical Examination**

**Generated On: 18 Sep 2014 07:49:14**

Abnormal, please specify \_\_\_\_\_ 7

Clinically significant No ☒ 8  
Yes ☐

Not Done \_\_\_\_\_ 9

Not Done; please specify the reason: \_\_\_\_\_ 10

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PESTAT	\$1		N = No Y = Yes		PESTAT
②	PEREASND1	\$200				PEREASND1
③	PEDAT	dd MMM YYYY				PEDAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
④ PETESTCD	\$200		GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat)		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Physical Examination

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			THYROID = Thyroid Gland		
			HEART = Heart		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CHEST = Chest		
			LUNGS = Lungs		
			GASTRO = Gastrointest inal		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Physical Examination**

**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
CVS = Cardiovascu lar System					
NEURO = Neurologic					



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			SKIN = Skin		
			BACK =		
			Back		
			MUSCULO		
			=		
			Musculoskel		
			etal		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
ABDOMEN = Abdomen DENTN = Dentition OTHER = Other					

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: General Appearance 2: HEENT (head, eyes, ears, nose, throat) 3: Thyroid Gland 4: Heart 5: Chest 6: Lungs 7: Gastrointestinal 8: Cardiovascular System 9: Neurologic 10: Skin 11: Back 12: Musculoskeletal 13: Abdomen 14: Dentition 15: Other 16: Other 17: Other 18: Other 19: Other	PETESTCD
5 PESPEC	\$200				PESPEC

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	PEORRES	\$8		NORMAL = Normal ABNORMAL = Abnormal		PEORRES
7	PETERM	\$200				PETERM
8	PECLSIG	\$1		N = No Y = Yes		PECLSIG
9	PESTAT2	1				PESTAT2
10	PEREASND2	\$200				PEREASND2



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Identification of Current Cigarette Brand**  
**Generated On: 18 Sep 2014 07:49:14**

Date \_\_\_\_\_ Fixed Unit: ①  
DD/MMM/YYYY

Brand name \_\_\_\_\_ ②

ISO Tar Yield \_\_\_\_\_ Fixed Unit: ③  
MG

ISO Tar Yield unit \_\_\_\_\_ Milligram ④

ISO Nicotine Yield \_\_\_\_\_ Fixed Unit: ⑤  
MG

ISO Nicotine Yield unit \_\_\_\_\_ Milligram ⑥



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Identification of Current Cigarette Brand**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SCDAT	dd MMM YYYY				SCDAT
②	SCORRES_C\$200 BNAM					SCORRES_C BNAM
③	SCORRES_C3.1 YTAR					SCORRES_C YTAR
④	SCORRESU \$40 _CYTAR			MG = Milligram		SCORRESU _CYTAR
⑤	SCORRES_C2.1 YNIC					SCORRES_C YNIC
⑥	SCORRESU \$40 _CYNIC			MG = Milligram		SCORRESU _CYNIC



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: THS 2.2 menthol product test**

**Generated On: 18 Sep 2014 07:49:14**

Was the THS 2.2 menthol product trial performed?

No ☐ ①  
Yes ☐

If the THS 2.2 menthol product trial was not performed,  
please explain \_\_\_\_\_ ②

How many THS 2.2 menthol tobacco sticks did the  
subject use on this day? \_\_\_\_\_ ③

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

No ☐ ④  
Yes ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: THS 2.2 menthol product test****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	TSHPRFYN	1		0 = No 1 = Yes		TSHPRFYN
②	TSHNDRSN	\$200				TSHNDRSN
③	TSHNO	2				TSHNO
④	TSHWILYN	1		0 = No 1 = Yes		TSHWILYN





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: THS 2.2 menthol product demonstration**  
**Generated On: 18 Sep 2014 07:49:14**

Has the subject seen a THS 2.2 menthol product demonstration?

No ☐ ①  
Yes ☐

If the subject did not see the demonstration please explain

②



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: THS 2.2 menthol product demonstration**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① THSDEMOY \$1 N			N = No Y = Yes		THSDEMOY N
② THSNDRSN \$200					THSNDRSN

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product administration-mCC****Generated On: 18 Sep 2014 07:49:14**Date of product use  
DD/MMM/YYYY

①

Visit

Day -2 ②

Day -1

Day 0

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 30

Day 60

Day 90

Type of Product Use

mCC ③

THS 2.2 Menthol

If type of Product Use different from the randomization  
please explain

④

Time of distribution

⑤

Time of butt return

⑥

CC with SODIM?

⑦

CC not compatible?

⑧



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Product administration-mCC**

**Generated On: 18 Sep 2014 07:49:14**

SODIM device number	_____	9
SODIM sample holder number	_____	10
SODIM file number	_____	11
Comment	_____	12
H_NOW (Derived):	_____	13

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.

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product administration-mCC****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXSTDTC	dd MMM YYYY				EXSTDAT
②	EXTPT_CC	2		1 = Day -2 2 = Day -1 3 = Day 0 4 = Day 1 5 = Day 2 6 = Day 3 7 = Day 4 8 = Day 5 9 = Day 6 10 = Day 30 11 = Day 60 12 = Day 90		EXTPT_CC
③	EXCAT	\$80		CONVENTI ONAL CIGARETTE S = mCC THS = THS 2.2 Menthol	1: mCC	EXCAT
④	EXSPEC	\$200				EXSPEC
⑤	EXDISTTIM	HH:nn				EXDISTTIM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product administration-mCC****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	EXRETTIM	HH:nn				EXRETTIM
7	EXSODIM	1				EXSODIM
8	EXCOMPAT	1				EXCOMPAT
9	EXSODIMN	\$4				EXSODIMN O
10	EXSAMPNO	\$4				EXSAMPNO
11	EXSODIMFN	\$20				EXSODIMFN O
12	EXCOM	\$200				EXCOM
13	H_NOW	dd MMM yyyy hh:nn:ss				H_NOW



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product administration-THS menthol**  
**Generated On: 18 Sep 2014 07:49:14**

Date of product use  
DD/MMM/YYYY

①

Visit

Day -2 ②

Day 0

Day 1

Day 2

Day 3

Day 4

Day 5

Day 6

Day 30

Day 60

Day 90

Type of Product Use

mCC ③

THS 2.2 Menthol

If type of Product Use different from the randomization  
please explain

④

Time of distribution

⑤

Time of product return

⑥

SODIM device number

⑦

SODIM sample holder number

⑧

Filter kit number

⑨

PROD 08.000 (MAIN) SP  
28JUL14 (640)

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product administration-THS menthol**  
**Generated On: 18 Sep 2014 07:49:14**

Filter vial number	_____	10
Tobacco plug kit number	_____	11
Tobacco plug vial number	_____	12
SODIM file number	_____	13
Comment	_____	14
Batch Number	_____	15
H_NOW (Derived):	_____	16

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.



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product administration-THS menthol****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① EXSTDTC	dd MMM YYYY				EXSTDAT
② EXTPT_THS 2			1 = Day -2 2 = Day 0 3 = Day 1 4 = Day 2 5 = Day 3 6 = Day 4 7 = Day 5 8 = Day 6 9 = Day 30 10 = Day 60 11 = Day 90		EXTPT_THS
③ EXCAT	\$80		CONVENTI ONAL CIGARETTE S = mCC THS = THS 2.2 Menthol	1: THS 2.2 EXCAT Menthol	
④ EXSPEC	\$200				EXSPEC
⑤ EXDISTTIM	HH:nn				EXDISTTIM



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product administration-THS menthol  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	EXRETTIM	HH:nn				EXRETTIM
7	EXSODIMN O	\$4				EXSODIMN O
8	EXSAMPNO	\$4				EXSAMPNO
9	EXFKITNO	\$5				EXFKITNO
10	EXFVIALNO	2				EXFVIALNO
11	EXPKITNO	\$5				EXPKITNO
12	EXPVIALNO	2				EXPVIALNO
13	EXSODIMFN O	\$20				EXSODIMFN O
14	EXCOM	\$200				EXCOM
15	BATCHNO	\$10				BATCHNO
16	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Smoking History****Generated On: 18 Sep 2014 07:49:14**

Date of Assessment

Fixed Unit: **1**  
DD/MMM/YYYY

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

No **2**  
Yes

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

No **3**  
Yes

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

<10 **4**  
10 to 19  
>19

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

No **5**  
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 **6**  
Yes

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Smoking History****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SHDAT	dd MMM YYYY				SHDAT
②	SHORRES1	\$1		N = No Y = Yes		SHORRES1
③	SHORRES2	\$1		N = No Y = Yes		SHORRES2
④	SHORRES3	\$8		1 = <10 2 = 10 to 19 3 = >19		SHORRES3
⑤	SHORRES4	\$1		N = No Y = Yes		SHORRES4
⑥	SHORRES5	\$1		N = No Y = Yes		SHORRES5

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: HST 4 hours****Generated On: 18 Sep 2014 07:49:14**

Visit \_\_\_\_\_ Day 30 ☐ ①  
Day 60 ☐  
Day 90 ☐

Not Done \_\_\_\_\_ ②

If Not Done, please specify \_\_\_\_\_ ③

Date \_\_\_\_\_ ④  
DD/MMM/YYYY

SODIM device distribution time \_\_\_\_\_ ⑤  
hour:min 24-hour clock

SODIM device collection time \_\_\_\_\_ ⑥  
hour:min 24-hour clock

H\_NOW (Derived): \_\_\_\_\_ ⑦

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: HST 4 hours****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	HSTVIS	1		1 = Day 30 2 = Day 60 3 = Day 90	1: Day 30 2: Day 60 3: Day 90	HSTVIS
②	HSTND	1				HSTND
③	HSTNDRSN	\$200				HSTNDRSN
④	HSTDAT	dd MMM yyyy				HSTDAT
⑤	HSTDISTIM	HH:nn				HSTDISTIM
⑥	HSTCOLTIM	HH:nn				HSTCOLTIM
⑦	H_NOW	dd MMM yyyy hh:nn:ss				H_NOW

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Topography files status for mCC****Generated On: 18 Sep 2014 07:49:14**SODIM file number  ①File Status  ②  
Accepted ☐  
Rejected ☐  
Error ☐Rejection / Error reason  ③Date of analysis  ④  
DD/MMM/YYYYOperator  ⑤  
Valerie Poux ☐  
Thierry Bachmann ☐  
Anthony Bruchet ☐Comment  ⑥Modified File Number  ⑦H\_NOW (Derived):  ⑧

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Topography files status for mCC****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXSODIMFN	\$20				EXSODIMFN
		O				O
②	HSTSTATUS	1		1 = Accepted 2 = Rejected 3 = Error		HSTSTATUS
③	HSTREAS	\$50				HSTREAS
④	HSTDAT	dd MMM YYYY				HSTDAT
⑤	HSTOPERAT	\$80		1 = Valerie Poux 2 = Thierry Bachmann 3 = Anthony Bruchet		HSTOPERAT
		ER				ER
⑥	EXCOM	\$200				EXCOM
⑦	MOD_FINE	\$22				MOD_FINE
	NUM					NUM





PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Topography files status for mCC

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
®	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Topography files status for THS menthol**  
**Generated On: 18 Sep 2014 07:49:14**

SODIM file number \_\_\_\_\_ ①

File Status \_\_\_\_\_ ②  
Accepted ☐  
Rejected ☐  
Error ☐

Rejection / Error reason \_\_\_\_\_ ③

Date of analysis \_\_\_\_\_ ④  
DD/MMM/YYYY

Operator \_\_\_\_\_ ⑤  
Valerie Poux ☐  
Thierry Bachmann ☐  
Anthony Bruchet ☐

Comment \_\_\_\_\_ ⑥

Modified File Number \_\_\_\_\_ ⑦

H\_NOW (Derived): \_\_\_\_\_ ⑧



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Topography files status for THS menthol  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXSODIMFN	\$20				EXSODIMFN
	O					O
②	HSTSTATUS	1		1 = Accepted 2 = Rejected 3 = Error		HSTSTATUS
③	HSTREAS	\$50				HSTREAS
④	HSTDAT	dd MMM YYYY				HSTDAT
⑤	HSTOPERAT	\$80		1 = Valerie Poux 2 = Thierry Bachmann 3 = Anthony Bruchet		HSTOPERAT
	ER					ER
⑥	EXCOM	\$200				EXCOM
⑦	MOD_FINE	\$22				MOD_FINE
	NUM					NUM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Topography files status for THS menthol**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
®	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: FTND Questionnaire

Generated On: 18 Sep 2014 07:49:14

Type  FTND **1**Was paper questionnaire used? No ☐ **2**  
Yes ☐Reason not done  **3**Date of assessment  Fixed Unit: **4**  
DD/MMM/YYYY DD/MMM/YYYYTime of assessment  Fixed Unit: **5**  
hour:min 24-hour clockAssessment Status Completed ☐ **6**  
Abandoned ☐1. How soon after you wake up do you smoke your first cigarette? 31-60 minutes ☐ **7**  
6-30 minutes ☐  
Within 5 minutes ☐  
Abandoned ☐  
After 60 minutes ☐2. Do you find it difficult to refrain from smoking in places where it is forbidden? Yes ☐ **8**  
No ☐  
Abandoned ☐



---

**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: FTND Questionnaire**

**Generated On: 18 Sep 2014 07:49:14**

---

3. Which cigarette would you hate most to give up?      The first in the morning ☒ 9  
Any other ☐  
Abandoned ☐

---

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

---

5. Do you smoke more frequently during the first hours  
after awakening than during the  
rest of the day?      Yes ☒ 11  
No ☐  
Abandoned ☐

---

6. Do you smoke even if you are so ill that you are in  
bed most of the day?      Yes ☒ 17  
No ☐  
Abandoned ☐

---

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: FTND Questionnaire****Generated On: 18 Sep 2014 07:49:14**


	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		FTND		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	ASSESSME NTSTATUS	8		1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑦	QS_FTND_ ORRES_1	8		1 = 31-60 minutes 2 = 6-30 minutes 3 = Within 5 minutes -1 = Abandoned 0 = After 60 minutes		QS_FTND_ ORRES_1

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: FTND Questionnaire****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 QS_FTND_ 8 ORRES_2			1 = Yes 2 = No -1 = Abandoned		QS_FTND_ ORRES_2
9 QS_FTND_ 8 ORRES_3			1 = The first in the morning 0 = Any other -1 = Abandoned		QS_FTND_ ORRES_3
10 QS_FTND_ 8 ORRES_4			0 = 10 or less 1 = 11-20 2 = 21-30 3 = 31 or more -1 = Abandoned		QS_FTND_ ORRES_4
11 QS_FTND_ 8 ORRES_5			1 = Yes 2 = No -1 = Abandoned		QS_FTND_ ORRES_5



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: FTND Questionnaire****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QS_FTND_8 ORRES_6			1 = Yes 2 = No -1 = Abandoned		QS_FTND_ ORRES_6

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Visual Inspection of the Tobacco Plugs Results for THS****Generated On: 18 Sep 2014 07:49:14**Tobacco plug kit number  ①Tobacco plug vial number  ②Level ☐ 0 ③  
☐ 1  
☐ 2  
☐ NAObservation ☐ Ashes not anymore visible when shooting picture ④  
☐ No tobacco in plug  
☐ Not enough tobacco in the plug to perform the analysis  
☐ Tobacco plug destroyed, analysis impossible  
☐ No tobacco plug in the vial  
☐ Other errorPicture File Name  ⑤Date of analysis DD/MM/YYYY  ⑥H\_NOW (Derived):  ⑦



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Visual Inspection of the Tobacco Plugs Results for THS**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EXPKITNO	\$5				EXPKITNO
②	EXPVIALNO	2				EXPVIALNO
③	HSTLEVEL	\$2		0 = 0 1 = 1 2 = 2 NA = NA		HSTLEVEL
④	HSTOBS	1		1 = Ashes not anymore visible when shooting picture 2 = No tobacco in plug 3 = Not enough tobacco in the plug to perform the analysis 4 = Tobacco plug destroyed, analysis impossible		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Visual Inspection of the Tobacco Plugs Results for THS**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = No tobacco plug in the vial 6 = Other error		HSTOBS
5 HSTFILE	\$200				HSTFILE
6 HSTADAT	dd MMM YYYY				HSTADAT
7 H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Weight and Height****Generated On: 18 Sep 2014 07:49:14**

Measurement(s) assessed?

No ☐ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

Date of assessment

Fixed Unit: ③  
DD/MMM/YYYY

Weight

Fixed Unit: ④  
kg

Height

Fixed Unit: ⑤  
cm

BMI (Derived)

Fixed Unit: ⑥  
kg/m<sup>2</sup>

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Weight and Height****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT_W H	\$1		N = No Y = Yes		VSSTAT_W H
②	VSREASND _WH	\$200				VSREASND _WH
③	VSDAT	dd MMM YYYY				VSDAT
④	VSORRES_ WEIGHT	4.1				VSORRES_ WEIGHT
⑤	VSORRES_ HEIGHT	4.1				VSORRES_ HEIGHT
⑥	VSORRES_B3.1 MI					VSORRES_B MI

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Weight****Generated On: 18 Sep 2014 07:49:14**

Measurement(s) assessed?

No ☐ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

Date of Assessment

Fixed Unit: ③  
DD/MMM/YYYY

Time of assessment

Fixed Unit: ④  
hour:min 24-hour clock

Weight

Fixed Unit: ⑤  
kg

Waist circumference

Fixed Unit: ⑥  
cm

BMI

⑦

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Weight****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSSTAT_W H	\$1		N = No Y = Yes		VSSTAT_W H
②	VSREASND _WH	\$200				VSREASND _WH
③	VSDAT	dd MMM YYYY				VSDAT
④	VSTIM	HH:nn				VSTIM
⑤	VSORRES_ WEIGHT	4.1				VSORRES_ WEIGHT
⑥	VSORRES_ WC	3				VSORRES_ WC
⑦	VSORRES_B3.1 MI					VSORRES_B MI





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: ECG (12-Lead Standard) <Screening/>**  
**Generated On: 18 Sep 2014 07:49:14**

Method of ECG Test 12 Lead Placement Cabrera ☒ ①

Was the ECG performed? No ☐ ②  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ③

Date of assessment: \_\_\_\_\_ Fixed Unit: ④  
DD/MMM/YYYY

Position Sitting ☐ ⑤  
Standing ☐  
Supine ☒

Heart Rate \_\_\_\_\_ Fixed Unit: ⑥  
beats per minute

Heart Rate unit \_\_\_\_\_ beats per minute ⑦

QRS Interval \_\_\_\_\_ Fixed Unit: ⑧  
msec

QRS Interval unit \_\_\_\_\_ msec ⑨

QT Interval \_\_\_\_\_ Fixed Unit: ⑩  
msec

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: ECG (12-Lead Standard) <Screening/>**  
**Generated On: 18 Sep 2014 07:49:14**

QT Interval unit msec **11**

QTcB Interval Fixed Unit: **12**  
msec

QTcB Interval unit msec **13**

PR Interval Fixed Unit: **14**  
msec

PR Interval unit msec **15**

Interpretation Normal ☐ **16**  
Abnormal ☐

If Abnormal, Clinical Significance Not clinically significant ☐ **17**  
Clinically significant ☐

If Not Clinically significant or clinically Significant, Please specify the finding(s) **18**



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: ECG (12-Lead Standard) <Screening/>  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EGMETHOD	\$20		12 LEAD STANDARD = 12 Lead Placement Cabrera		EGMETHOD
②	EGSTAT	\$1		N = No Y = Yes		EGSTAT
③	EGREASND	\$200				EGREASND
④	EGDAT	dd MMM YYYY				EGDAT
⑤	EGPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine		EGPOS
⑥	EGORRES_ HR	3				EGORRES_ HR
⑦	EGORRESU _HR	\$10		beats per minute		EGORRESU _HR
⑧	EGORRES_ QRS	3				EGORRES_ QRS



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: ECG (12-Lead Standard) <Screening/>  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	EGORRESU_QRS	\$10		msec		EGORRESU_QRS
10	EGORRES_3QT					EGORRES_3QT
11	EGORRESU_QT	\$10		msec		EGORRESU_QT
12	EGORRES_3QTC					EGORRES_3QTC
13	EGORRESU_QTC	\$10		msec		EGORRESU_QTC
14	EGORRES_P3R					EGORRES_P3R
15	EGORRESU_PR	\$10		msec		EGORRESU_PR
16	EGINTP	\$40		NORMAL = Normal ABNORMAL = Abnormal		EGINTP
17	EGCLSIG	\$40		NCS = Not clinically significant		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: ECG (12-Lead Standard) <Screening/>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CS = Clinically significant		EGCLSIG
EGTERM	\$200				EGTERM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: ECG (12-Lead Standard)**  
**Generated On: 18 Sep 2014 07:49:14**

Method of ECG Test 12 Lead Placement Cabrera ☒ ①

Was the ECG performed? No ☐ ②  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ③

Date of Assessment Fixed Unit:  ④  
DD/MMM/YYYY

Position Sitting ☐ ⑤  
Standing ☐  
Supine ☒

Heart Rate Fixed Unit:  ⑥  
beats per minute

Heart Rate unit beats per minute ⑦

QRS Interval Fixed Unit:  ⑧  
msec

QRS Interval unit msec ⑨

QT Interval Fixed Unit:  ⑩  
msec

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: ECG (12-Lead Standard)****Generated On: 18 Sep 2014 07:49:14**QT Interval unit msec **11**QTcB Interval Fixed Unit: **12**  
msecQTcB Interval unit msec **13**PR Interval Fixed Unit: **14**  
msecPR Interval unit msec **15**Interpretation Normal ☐ **16**  
Abnormal ☐If Abnormal, Clinical Significance Not clinically significant ☐ **17**  
Clinically significant ☐If Not Clinically significant or clinically Significant, Please specify the finding(s) **18**



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: ECG (12-Lead Standard)

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EGMETHOD	\$20		12 LEAD STANDARD = 12 Lead Placement Cabrera		EGMETHOD
②	EGSTAT	\$1		N = No Y = Yes		EGSTAT
③	EGREASND	\$200				EGREASND
④	EGDAT	dd MMM YYYY				EGDAT
⑤	EGPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine		EGPOS
⑥	EGORRES_ HR	3				EGORRES_ HR
⑦	EGORRESU _HR	\$10		beats per minute		EGORRESU _HR
⑧	EGORRES_ QRS	3				EGORRES_ QRS





## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: ECG (12-Lead Standard)

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	EGORRESU_QRS	\$10		msec		EGORRESU_QRS
10	EGORRES_3QT					EGORRES_QT
11	EGORRESU_QT	\$10		msec		EGORRESU_QT
12	EGORRES_3QTC					EGORRES_QTC
13	EGORRESU_QTC	\$10		msec		EGORRESU_QTC
14	EGORRES_P3R					EGORRES_P_R
15	EGORRESU_PR	\$10		msec		EGORRESU_PR
16	EGINTP	\$40		NORMAL = Normal ABNORMAL = Abnormal		EGINTP
17	EGCLSIG	\$40		NCS = Not clinically significant		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: ECG (12-Lead Standard)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CS = Clinically significant		EGCLSIG
EGTERM	\$200				EGTERM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Spirometry****Generated On: 18 Sep 2014 07:49:14**

Was the spirometry performed?

No ☐ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

Category

With short-acting  
bronchodilator ☐ ③  
Without short-acting  
bronchodilator ☐Date of assessment  
DD/MMM/YYYY \_\_\_\_\_ ④

Time of assessment \_\_\_\_\_ ⑤

Name of bronchodilator \_\_\_\_\_ ⑥

Dose \_\_\_\_\_ ⑦

Predicted FVC value

Fixed Unit: ⑧  
L

Best measured FVC value

Fixed Unit: ⑨  
L

Percent of predicted FVC value

Fixed Unit: ⑩  
%PROD 08.000 (MAIN) SP  
28JUL14 (640)

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Spirometry****Generated On: 18 Sep 2014 07:49:14**

Best measured FEV1 value

Fixed Unit: **11**  
L

Predicted FEV1 value

Fixed Unit: **12**  
L

Percent of predicted FEV1 value

Fixed Unit: **13**  
%

Calculated ratio between FEV1/FVC

**14**

Interpretation

Normal ☐ **15**  
Abnormal ☐

If Abnormal, Clinical Significance

Not clinically significant ☐ **16**  
Clinically significant ☐If Not Clinically Significant or Clinically Significant, Please  
specify the finding(s)**17**

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Spirometry****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTSTAT	\$1		N = No Y = Yes		PTSTAT
②	PTREASND	\$200				PTREASND
③	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor 1: Without PTCAT short-acting bronchodila tor 2: With short-acting bronchodila tor		
④	PTDAT	dd MMM YYYY				PTDAT
⑤	PTTIM	HH:nn				PTTIM
⑥	PTBD	\$200				PTBD
⑦	PTDOSE	\$10				PTDOSE




## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Spirometry

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 PTORRES_F 4.2 VCPRED					PTORRES_F VCPRED
9 PTORRES_F 4.2 VCMEAS					PTORRES_F VCMEAS
10 PTORRES_F 4.1 VCMPR					PTORRES_F VCMPR
11 PTORRES_F 4.2 EV1MEAS					PTORRES_F EV1MEAS
12 PTORRES_F 4.2 EV1PRED					PTORRES_F EV1PRED
13 PTORRES_F 4.1 EV1MPR					PTORRES_F EV1MPR
14 PTRATIO	4.2				PTRATIO
15 PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
16 PTCL SIG	\$40		NCS = Not clinically significant		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Spirometry****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CS = Clinically significant		PTCLSIG
 PTTERM	\$200				PTTERM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Spirometry without a short-acting bronchodilator**  
**Generated On: 18 Sep 2014 07:49:14**

Was the spirometry performed?

No ☐ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

Category

With short-acting  
bronchodilator ☐ ③  
Without short-acting  
bronchodilator ☒

Date of assessment \_\_\_\_\_ ④

Time of assessment

Fixed Unit: ⑤  
hour:min 24-hour clock

Predicted FVC value

Fixed Unit: ⑥  
L

Best measured FVC value

Fixed Unit: ⑦  
L

Percent of predicted FVC value

Fixed Unit: ⑧  
%

Best measured FEV1 value

Fixed Unit: ⑨  
L





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Spirometry without a short-acting bronchodilator**  
**Generated On: 18 Sep 2014 07:49:14**

Predicted FEV1 value Fixed Unit: ☒ L

Percent of predicted FEV1 value Fixed Unit: ☒ %

Interpretation Normal ☒  
Abnormal ☐

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

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



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Spirometry without a short-acting bronchodilator**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTSTAT	\$1		N = No Y = Yes		PTSTAT
②	PTREASND	\$200				PTREASND
③	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor		PTCAT
④	PTDAT	dd MMM YYYY				PTDAT
⑤	PTTIM	HH:nn				PTTIM
⑥	PTORRES_F4.2 VCPRED					PTORRES_F VCPRED
⑦	PTORRES_F4.2 VCMEAS					PTORRES_F VCMEAS



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Spirometry without a short-acting bronchodilator**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 PTORRES_F 4.1 VCMR					PTORRES_F VCMR
9 PTORRES_F 4.2 EV1MEAS					PTORRES_F EV1MEAS
10 PTORRES_F 4.2 EV1PRED					PTORRES_F EV1PRED
11 PTORRES_F 4.1 EV1MPR					PTORRES_F EV1MPR
12 PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
13 PTCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		PTCLSIG
14 PTTERM	\$200				PTTERM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Chest X-Ray****Generated On: 18 Sep 2014 07:49:14**

Category for Examination

Chest X-Ray ☒ ①

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

No ☒ ②Yes ☐

If No, please specify the reason: \_\_\_\_\_ ③

Date of assessment

Fixed Unit: ☒ ④  
DD/MMM/YYYY

System

General Appearance ☒ ⑤HEENT ☐

(head, eyes, ears, nose, throat)

Thyroid Gland ☐Heart ☐Chest ☒Lungs ☐Gastrointestinal ☐Cardiovascular System ☐Neurologic ☐Skin ☐Back ☐Musculoskeletal ☐Abdomen ☐Dentition ☐Other ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Chest X-Ray**  
**Generated On: 18 Sep 2014 07:49:14**

Interpretation

Normal ☒ 6  
Abnormal ☐

Clinically significant

No ☒ 7  
Yes ☐

Abnormal, please specify:

☒ 8

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Chest X-Ray****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PECAT	\$80		CHEST XRAY = Chest X-Ray		XRPECAT
②	XRPESTAT	\$1		N = No Y = Yes		XRPESTAT
③	XRPEREASN	\$200 D				XRPEREASN D
④	XRPEDAT	dd- MMM- YYYY				XRPEDAT
⑤	XRPESTC	\$200 D		GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat) THYROID = Thyroid Gland HEART = Heart CHEST = Chest		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Chest X-Ray****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			LUNGS = Lungs GASTRO = Gastrointest inal CVS = Cardiovascu lar System NEURO = Neurologic SKIN = Skin BACK = Back MUSCULO = Musculoskel etal ABDOMEN = Abdomen DENTN = Dentition OTHER = Other		XRPETESTC D
6 XRPEORRES\$8			NORMAL = Normal ABNORMAL = Abnormal		XRPEORRES

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Chest X-Ray****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ XRPECSIG	\$1		N = No Y = Yes		XRPECSIG
⑧ XRPETERM1	\$200				XRPETERM1



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

Date \_\_\_\_\_ ①

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

Total number of people living in the household \_\_\_\_\_ ③

Prefer not to say \_\_\_\_\_ ④

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

Elementary school / Junior high school ☐ ⑤  
Senior high school ☐  
College ☐  
University / Postgraduate ☐  
Prefer not to say ☐

Q3. How many income earners are in your household? None – all are unemployed ☐ ⑥

Just one income earner ☐

Two or more income earners ☐

Those who have one or more income earners



---

**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Socio-Economic Status**

**Generated On: 18 Sep 2014 07:49:14**

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Q4. What is your occupation?

- General white collar ☒ 8
- Professional/ technical worker ☐
- General blue collar ☐
- Working in service industry ☐
- Manager (kacho or above) ☐
- Director/president (30 employees or more) ☐
- Proprietor (29 employees or less) ☐
- Professional/technical worker (Lawyer, Accountant, Professor etc) ☐
- Farming/forestry/fishing ☐
- Shop keeper ☐
- Part-time worker (More than one day per week) ☐
- Student ☐
- Housewife (Including part-time less than one day per week) ☐
- Unemployed ☐
- Others ☐

---

Those who have one or more income earners

---

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

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

- Below 100,000 yen ☒ 10
- 100,000 yen – 199,999 yen ☐
- 200,000 yen – 299,999 yen ☐
- 300,000 yen – 399,999 yen ☐
- 400,000 yen – 499,999 yen ☐
- 500,000 yen – 599,999 yen ☐
- 600,000 yen – 699,999 yen ☐
- 700,000 yen – 799,999 yen ☐
- 800,000 yen – 899,999 yen ☐
- 900,000 yen – 999,999 yen ☐
- 1,000,000 yen or above ☐
- Don't know ☐
- Prefer not to say ☐

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

[ASK IF CODES 12 or 13 SELECTED AT Q5a]

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


- Under 800,000yen ☒ 11
- 800,000yen or more ☐
- Don't know ☐
- Prefer not to say ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	SESDAT	dd MMM YYYY				SESDAT
③	SES_P1	2				SES_P1
④	SES_P2	1				SES_P2
⑤	SES_E	1		1 = Elementary school / Junior high school 2 = Senior high school 3 = College 4 = University / Postgraduate 5 = Prefer not to say		SES_E
⑥	SES_I	1		1 = None - all are unemployed 2 = Just one income earner		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Two or more income earners		SES_I

 SES_O	2	1 = General white collar 2 = Professional / technical worker 3 = General blue collar 4 = Working in service industry 5 = Manager (kacho or above) 6 = Director/pre sident (30 employees or more)
---	---	---

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Proprietor (29 employees or less) 8 = Professional /technical worker (Lawyer, Accountant, Professor etc) 9 = Farming/for estry/fishin g 10 = Shop keeper 11 = Part-time worker (More than one day per week) 12 = Student 13 = Housewife (Including part-time less than one day per week)		


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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = Unemployed 15 = Others		SES_O
SES_I2	2		1 = Below 100,000 yen 2 = 100,000 yen – 199,9 99 yen 3 = 200,000 yen – 299,9 99 yen 4 = 300,000 yen – 399,9 99 yen 5 = 400,000 yen – 499,9 99 yen 6 = 500,000 yen – 599,9 99 yen		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = 600,000 yen - 699,9 99 yen 8 = 700,000 yen - 799,9 99 yen 9 = 800,000 yen - 899,9 99 yen 10 = 900,000 yen - 999,9 99 yen 11 = 1,000,000 yen or above 12 = Don't know 13 = Prefer not to say		SES_I2
 SES_I3	\$8		1 = Under 800,000yen 2 = 800,000yen or more 3 = Don't know		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Socio-Economic Status****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Prefer not to say		SES_I3



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Haematology

Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☐ ①  
Drug Screen ☐  
Haematology ☒  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☐

Were samples collected?

No ☐ ②  
Yes ☐

If No, please specify the reason: \_\_\_\_\_

③

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

No ☐ ④  
Yes ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Haematology****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② LBSTAT	\$1		N = No		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Haematology****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		LBSTAT
③ LBREASND	\$200				LBREASND
④ LBFSTYN	\$1		N = No Y = Yes		LBFSTYN



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Clinical Chemistry

Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☒ ①

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☐

Urinalysis ☐

Cotinine Screening ☐

Alcohol Breath Test ☐

Were samples collected?

No ☒ ②

Yes ☐

If No, please specify the reason: \_\_\_\_\_

③

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

No ☒ ④

Yes ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Clinical Chemistry****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② LBSTAT	\$1		N = No		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Clinical Chemistry****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		LBSTAT
③ LBREASND	\$200				LBREASND
④ LBFSTYN	\$1		N = No Y = Yes		LBFSTYN



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Urine analysis

Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☒ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☒  
Cotinine Screening ☐  
Alcohol Breath Test ☐

Were samples collected?

No ☒ ②  
Yes ☐

If No, please specify the reason:

③



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine analysis****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② LBSTAT	\$1		N = No		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine analysis****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		LBSTAT
③ LBREASND	\$200				LBREASND



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Serology for HIV and Hepatitis B and C**  
**Generated On: 18 Sep 2014 07:49:14**

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input type="radio"/>
	Haematology <input type="radio"/>
	Serology <input checked="" type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input type="radio"/>
	Alcohol Breath Test <input type="radio"/>

Not Done	_____ ②
----------	---------

If Not Done, please specify the reason:	_____ ③
---	---------



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Serology for HIV and Hepatitis B and C  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② LBBSTAT	1				LBBSTAT



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Serology for HIV and Hepatitis B and C**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ LBREASND	\$200				LBREASND



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Urine Drug Screen<Screening/>**  
**Generated On: 18 Sep 2014 07:49:14**

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input checked="" type="radio"/>
	Haematology <input type="radio"/>
	Serology <input type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input type="radio"/>
	Alcohol Breath Test <input type="radio"/>
Not Done?	_____ ②
If Not Done, please specify the reason:	_____ ③
Date of sample collection	Fixed Unit: _____ ④ DD/MMM/YYYY
Time of sample collection	Fixed Unit: _____ ⑤ hour:min 24-hour clock
Drug type	Amphetamines <input type="radio"/> ⑥
	Barbiturates <input type="radio"/>
	Benzodiazepines <input type="radio"/>
	Cannabinoids <input type="radio"/>
	Cocaine <input type="radio"/>
	Opiates <input type="radio"/>



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Urine Drug Screen<Screening/>**  
**Generated On: 18 Sep 2014 07:49:14**

Result

Negative ☒ 7  
Positive ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② DRUGSTAT 1					DRUGSTAT



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen<Screening/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	ALCREASN D	\$200				DRUGREASN D
4	DRUGDAT	dd MMM YYYY				DRUGDAT
5	DRUGTIM	HH:nn				DRUGTIM
6	DRUGTEST	\$20		AMPHETAM INES = Amphetami nes BARBITURA TES = Barbiturates BENZODIAZ EPINES = Benzodiaze pines CANNABIN OIDS = Cannabinoi ds COCAINE = Cocaine		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
<hr/>					
			OPIATES = Opiates	1: Amphetamines 2: Barbiturates 3: Benzodiazepines 4: Cannabinoids 5: Cocaine 6: Opiates	DRUGTEST
<hr/>					
⑦ DRUGORRES	\$8		NEGATIVE = Negative POSITIVE = Positive		DRUGORRES
<hr/>					

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen****Generated On: 18 Sep 2014 07:49:14**

Category

Clinical Chemistry ☐ ①Drug Screen ☒Haematology ☐Serology ☐Pregnancy Testing ☐Urinalysis ☐Cotinine Screening ☐Alcohol Breath Test ☐

Not Done? \_\_\_\_\_ ②

If Not Done, please specify the reason: \_\_\_\_\_ ③

Time of sample collection

Fixed Unit: ④  
hour:min 24-hour clock

Drug type

Amphetamines ☐ ⑤Barbiturates ☐Benzodiazepines ☐Cannabinoids ☐Cocaine ☐Opiates ☐

Result

Negative ☐ ⑥Positive ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT

② DRUGSTAT 1	DRUGSTAT
--------------	----------

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③ ALCREASN D	\$200				DRUGREAS ND
④ DRUGTIM	HH:nn				DRUGTIM
⑤ DRUGTEST	\$20		AMPHETAM INES = Amphetami nes BARBITURA TES = Barbiturates BENZODIAZ EPINES = Benzodiaze pines CANNABIN OIDS = Cannabinoi ds COCAINE = Cocaine OPIATES = Opiates	1: Amphetami nes 2: Barbiturates 3: Benzodiaze pines 4: Cannabinoi ds 5: Cocaine 6: Opiates	DRUGTEST

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6 DRUGORRE \$8 S			NEGATIVE = Negative POSITIVE = Positive		DRUGORRE S

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Category

Clinical Chemistry ☒ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☒

Was the alcohol breath test performed?

No ☒ ②  
Yes ☐

If No, please specify the reason: \_\_\_\_\_

③

Date of assessment

Fixed Unit: ④  
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑤  
hour:min 24-hour clock

Result

Negative ☒ ⑥  
Positive ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② ALCSTAT	\$1		N = No		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		ALCSTAT
③ ALCREASN D	\$200				ALCREASN D
④ ALCDAT	dd MMM YYYY				ALCDAT
⑤ ALCTIM	HH:nn				ALCTIM
⑥ ALCORRES	\$30		NEGATIVE = Negative POSITIVE = Positive		ALCORRES

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test****Generated On: 18 Sep 2014 07:49:14**

Category

Clinical Chemistry ☒ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☒

Was the alcohol breath test performed?

No ☒ ②  
Yes ☐

If No, please specify the reason: \_\_\_\_\_

③

Time of assessment

Fixed Unit: ☒ ④  
hour:min 24-hour clock

Result

Negative ☒ ⑤  
Positive ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② ALCSTAT	\$1		N = No		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		ALCSTAT
③ ALCREASN D	\$200				ALCREASN D
④ ALCTIM	HH:nn				ALCTIM
⑤ ALCORRES	\$30		NEGATIVE = Negative POSITIVE = Positive		ALCORRES



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Urine Pregnancy Test<Screening/>  
Generated On: 18 Sep 2014 07:49:14

Category \_\_\_\_\_ Clinical Chemistry ☒ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☒  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☐

Not Done \_\_\_\_\_ ②

If Not Done, specify reason \_\_\_\_\_ ③

Date of Test \_\_\_\_\_ Fixed Unit: ☒ ④  
DD/MMM/YYYY

Time of Test \_\_\_\_\_ Fixed Unit: ☒ ⑤  
hour:min 24-hour clock

Specify result \_\_\_\_\_ Negative ☒ ⑥  
Positive ☐  
Unclear ☐

If unclear, please confirm with FSH test \_\_\_\_\_

Specify result of FSH test \_\_\_\_\_ < 20 IU/L ☒ ⑧  
>= 20 IU/L ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Pregnancy Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② PGNSTAT	1				PGNSTAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Pregnancy Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	PGNREASN	\$200				PGNREASN D
4	PGNDAT	dd MMM YYYY				PGNDAT
5	PGNTIM	HH:nn				PGNTIM
6	PGNORRES	\$8		NEGATIVE = Negative POSITIVE = Positive UNCLEAR = Unclear		PGNORRES
8	PGNORRES	\$8		1 = < 20 IU/L 2 = >= 20 IU/L		PGNORRES N



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Urine Pregnancy Test

Generated On: 18 Sep 2014 07:49:14

Category \_\_\_\_\_

Clinical Chemistry ☐ ①

Drug Screen ☐

Haematology ☐

Serology ☐

Pregnancy Testing ☒

Urinalysis ☐

Cotinine Screening ☐

Alcohol Breath Test ☐

Not Done \_\_\_\_\_ ②

If Not Done, specify reason \_\_\_\_\_ ③

Date of Test \_\_\_\_\_

Fixed Unit: DD/MMM/YYYY ④

Time of Test \_\_\_\_\_

Fixed Unit: hour:min 24-hour clock ⑤

Specify result \_\_\_\_\_

Negative ☐ ⑥

Positive ☐

Unclear ☐

If unclear, please confirm with FSH test \_\_\_\_\_

Specify result of FSH test \_\_\_\_\_

< 20 IU/L ☐ ⑧

>= 20 IU/L ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Pregnancy Test****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② PGNSTAT	1			PGNSTAT	

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Pregnancy Test****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	PGNREASN	\$200				PGNREASN D
4	PGNDAT	dd MMM YYYY				PGNDAT
5	PGNTIM	HH:nn				PGNTIM
6	PGNORRES	\$8		NEGATIVE = Negative POSITIVE = Positive UNCLEAR = Unclear		PGNORRES
8	PGNORRES	\$8		1 = < 20 IU/L 2 = >= 20 IU/L		PGNORRES N

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Cotinine Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input type="radio"/>
	Haematology <input type="radio"/>
	Serology <input type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input checked="" type="radio"/>
	Alcohol Breath Test <input type="radio"/>
Not Done	_____ ②
If Not Done, please specify the reason:	_____ ③
Date of Sample Collection	Fixed Unit: _____ ④ DD/MMM/YYYY
Time of Sample Collection	Fixed Unit: _____ ⑤ hour:min 24-hour clock
Result	Negative <200 ng/ml <input type="radio"/> ⑥ Positive >=200 ng/ml <input type="radio"/>

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Cotinine Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② LBBSTAT	1				LBBSTAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Cotinine Test<Screening/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
③	LBREASND	\$200				LBREASND
④	COTDAT	dd MMM YYYY				COTDAT
⑤	COTTIM	HH:nn				COTTIM
⑥	COTORRES	\$8		1 = Negative <200 ng/ml 2 = Positive ≥200 ng/ml		COTORRES

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Cotinine Test****Generated On: 18 Sep 2014 07:49:14**

Category

Clinical Chemistry ☒ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☒  
Alcohol Breath Test ☐

Not Done

②

If Not Done, please specify the reason:

③

Time of Sample Collection

Fixed Unit: ④  
hour:min 24-hour clock

Result

Negative <200 ng/ml ☒ ⑤  
Positive ≥200 ng/ml ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Cotinine Test****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② LBBSTAT	1				LBBSTAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Cotinine Test****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
3	LBREASND	\$200				LBREASND
4	COTTIM	HH:nn				COTTIM
5	COTORRES	\$8		1 = Negative <200 ng/ml 2 = Positive ≥200 ng/ml		COTORRES



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Nicotine Sample****Generated On: 18 Sep 2014 07:49:14**

Not Done	_____	①
If Not Done, please specify the reason:	_____	②
Date DD/MM/YYYY	_____	③
Time hour:min 24-hour clock	_____	④
Record Number	_____	⑤

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Nicotine Sample****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	REC_NUM	1		1	1: 1	REC_NUM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Cotinine Sample****Generated On: 18 Sep 2014 07:49:14**

Not Done	_____	①
If Not Done, please specify the reason:	_____	②
Date DD/MM/YYYY	_____	③
Time hour:min 24-hour clock	_____	④
Record number	_____	⑤

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Cotinine Sample****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	REC_NUM	1		1	1: 1	REC_NUM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: CoHb Blood Sample<SA\_Arm/>**

**Generated On: 18 Sep 2014 07:49:14**

Not Done

①

If Not Done, please specify the reason:

②

Scheduled Time

Within 15 min prior to smoking

③

12:00 - 13:30

16:00 - 17:30

20:00 - 21:30

08:00 - 09:30

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CoHb Blood Sample<SA\_Arm/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PCBSTAT	1				PCBSTAT
② PCBREASN	\$200				PCBREASN
	D				D
③ PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30	1: 08:00 - 09:30 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	PCBCTPT



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: CoHb Blood Sample<CC/THS Arm/>**  
**Generated On: 18 Sep 2014 07:49:14**

Not Done \_\_\_\_\_ ①

If Not Done, please specify the reason: \_\_\_\_\_ ②

Scheduled Time \_\_\_\_\_

Within 15 min prior to smoking ③

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CoHb Blood Sample<CC/THS Arm/>****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① PCBSTAT	1				PCBSTAT
② PCBREASN	\$200				PCBREASN
	D				D
③ PCBCTPT	\$40		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30	1: Within 15 min prior to smoking 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	PCBCTPT





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: CoHb Blood Sample**

**Generated On: 18 Sep 2014 07:49:14**

Not Done

①

If Not Done, please specify the reason:

②

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CoHb Blood Sample****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CO Breath Test****Generated On: 18 Sep 2014 07:49:14**

Assessment not done

①

If Not Done, please specify the reason:

②

Actual Date of Assessment

Fixed Unit:  
DD/MMM/YYYY

③

Actual Time of Assessment

Fixed Unit:  
hour:min 24-hour clock

④

Result

Fixed Unit:  
ppm

⑤

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CO Breath Test****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COSTAT	1				COSTAT
②	COREASND	\$200				COREASND
③	CPDAT	dd MMM YYYY				CPDAT
④	CPTIM	HH:nn				CPTIM
⑤	COORRES	3				COORRES

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CO Breath Test <Repeat/>****Generated On: 18 Sep 2014 07:49:14**

---

Assessment not done ①

---

If Not Done, please specify the reason: ②

---

Scheduled Time ③

Within 15 min prior to smoking

12:00 - 13:30 ☐

16:00 - 17:30 ☐

20:00 - 21:30 ☐

08:00 - 09:30 ☐

---

Actual Time of Assessment ④  
hour:min 24-hour clock

---

Result(ppm) ⑤

---



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: CO Breath Test &lt;Repeat/&gt;

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COSTAT	1				COSTAT
②	COREASND	\$200				COREASND
③	COTPT	\$200		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30	1: Within 15 min prior to smoking 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	COTPT
④	CPTIM	HH:nn				CPTIM
⑤	COORRES	3				COORRES

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CO Breath Test <SA arm/>****Generated On: 18 Sep 2014 07:49:14**

Assessment not done

①

If Not Done, please specify the reason:

②

Scheduled Time

Within 15 min prior to  
smoking

③

12:00 - 13:30

☐

16:00 - 17:30

☐

20:00 - 21:30

☐

08:00 - 09:30

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

④

Result(ppm)

⑤

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CO Breath Test <SA arm/>****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COSTAT	1				COSTAT
②	COREASND	\$200				COREASND
③	COTPT	\$200		1 = Within 15 min prior to smoking 2 = 12:00 - 13:30 3 = 16:00 - 17:30 4 = 20:00 - 21:30 5 = 08:00 - 09:30	1: 08:00 - 09:30 2: 12:00 - 13:30 3: 16:00 - 17:30 4: 20:00 - 21:30	COTPT
④	CPTIM	HH:nn				CPTIM
⑤	COORRES	3				COORRES



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CYP2A6 activity Sample****Generated On: 18 Sep 2014 07:49:14**

---

Not Done ☐ ①

---

If Not Done, please specify the reason: ☐ ②

---

Date of sample collection ☐ ③  
DD/MMM/YYYY

---

Time of sample collection ☐ ④  
hour:min 24-hour clock

---

Parameter ☐ trans-3'-hydroxycotinine ☐ ⑤  
cotinine ☐

---



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: CYP2A6 activity Sample

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	PCBCAT	1		1 = trans-3'-hy droxycotin ine 2 = cotinine	1: trans-3'-hy droxycotin ine 2: cotinine	PCBCAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CYP1A2 activity Sample****Generated On: 18 Sep 2014 07:49:14**

Time of caffeine tablet intake

Fixed Unit: ①  
hour:min 24-hour clock

Sample collection Not Done ②

If Not Done, please specify the reason: ③

Date of sample collection  
DD/MMM/YYYY ④Time of sample collection  
hour:min 24-hour clock ⑤

Parameter

Caffeine ⑥  
Paraxanthine ⑦

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CYP1A2 activity Sample****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCB_MEATI M	HH:nn				PCB_MEATI M
②	PCBSTAT	1				PCBSTAT
③	PCBREASN D	\$200				PCBREASN D
④	PCBDAT	dd MMM YYYY				PCBDAT
⑤	PCBTIM	HH:nn				PCBTIM
⑥	PCBCAT1	1		1 = Caffeine 2 = Paraxanthin e	1: Caffeine 2: Paraxanthin e	PCBCAT1



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

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

**Generated On: 18 Sep 2014 07:49:14**

Not Done

①

If Not Done, please specify the reason:

②

Date

DD/MM/YYYY

③

Time

hour:min 24-hour clock

④

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Risk markers: hs-CRP, fibrinogen, homocysteine, LDL, HDL****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Risk Marker: s-ICAM-1**

**Generated On: 18 Sep 2014 07:49:14**

Not Done \_\_\_\_\_ ①

If Not Done, please specify the reason: \_\_\_\_\_ ②

Date  
DD/MM/YYYY \_\_\_\_\_ ③

Time  
hour:min 24-hour clock \_\_\_\_\_ ④

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Risk Marker: s-ICAM-1****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Risk Marker: HbA1c**

**Generated On: 18 Sep 2014 07:49:14**

Not Done	_____	①
If Not Done, please specify the reason:	_____	②
Date DD/MM/YYYY	_____	③
Time hour:min 24-hour clock	_____	④

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Risk Marker: HbA1c****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Type	Product Use	①
Date of Birth		②
Date of completion DD/MM/YYYY		③
Time of completion hh:mm		④
Date the questionnaire was completed for DD/MM/YYYY		⑤
Assessment Status	Completed <input type="checkbox"/> Abandoned <input type="checkbox"/>	⑥



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Product use diary

Generated On: 18 Sep 2014 07:49:14

What tobacco/nicotine product did you use today?

- THS 2.2 ☒ 7
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- Abandoned ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Product use diary

Generated On: 18 Sep 2014 07:49:14

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

How many THS 2.2 tobacco sticks did you use today?  8

How many CC/ roll-your-own did you smoke today?  9

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

What NRT product did you used today?

- Nicotine Inhaler ☒ 10
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Product use diary

Generated On: 18 Sep 2014 07:49:14

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



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Product use diary

Generated On: 18 Sep 2014 07:49:14

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



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

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

How many times did you use an inhaler today? \_\_\_\_\_ 11

How many times did you use a nasal spray today? \_\_\_\_\_ 12

How many gums did you use today? \_\_\_\_\_ 13

How many lozenges did you use today? \_\_\_\_\_ 14

How many patches did you use today? \_\_\_\_\_ 15

How many times did you use other NRT products today  
not listed previously? \_\_\_\_\_ 16

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☒ 17
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

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

16

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

How many cigars/cigarillos did you smoke today? \_\_\_\_\_ 19

How many times did you smoke a pipe today? \_\_\_\_\_ 20

How many times did you use a tobacco product today  
not listed previously? \_\_\_\_\_ 21

How many times did you use an electronic cigarette  
today? \_\_\_\_\_ 22

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Product Use		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	EXDATE_E	yyyy MMM dd				EXDATE_E
④	EXTIME	HH:nn				EXTIME
⑤	EXDATE_1_E	yyyy MMM dd				EXDATE_1_E
⑥	ASSESSME NTSTATUS	8		1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑦	EXPROD	8		1 = THS 2.2 2 = CC 4 = NRT 8 = Other tobacco product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Electronic cigarette		
			32 = None of the above		
			-1 = Abandoned		
			3 = THS		
			2.2 and CC		
			5 = THS		
			2.2 and NRT		
			6 = CC and NRT		
			7 = THS		
			2.2, CC and NRT		
			9 = THS		
			2.2 and Other tobacco product		
			10 = CC and Other tobacco product		
			12 = NRT and Other tobacco product		
			13 = THS		
			2.2, NRT and Other tobacco product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = CC, NRT and Other tobacco product 15 = THS 2.2, CC, NRT and Other tobacco product 17 = THS 2.2 and Electronic cigarette 18 = CC and Electronic cigarette 20 = NRT and Electronic cigarette 21 = THS 2.2, NRT and Electronic cigarette 22 = CC, NRT and Electronic cigarette		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			23 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		
			24 = Other tobacco product and Electronic cigarette		
			25 = THS 2.2, Other tobacco product and Electronic cigarette		
			26 = CC, Other tobacco product and Electronic cigarette		
			27 = THS 2.2, CC, Other tobacco product and Electronic cigarette		
			28 = NRT, Other tobacco product and Electronic cigarette		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			29 = THS 2.2, NRT, Other tobacco product and Electronic cigarette 30 = CC, NRT, Other tobacco product and Electronic cigarette 31 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		EXPROD
THSNUM	8				THSNUM
CCNUM	8				CCNUM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10 NRTPROD	8		1 = Nicotine Inhaler 2 = Nicotine Nasal Spray 4 = Nicotine Gum 8 = Nicotine Lozenge 16 = Nicotine Patch 32 = Other NRT Product -1 = Abandoned -9 = Not Applicable 3 = Nicotine Inhaler and Nicotine Nasal Spray		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Nicotine Inhaler and Nicotine Gum		
			6 = Nicotine Nasal Spray and Nicotine Gum		
			7 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Gum		
			9 = Nicotine Inhaler and Nicotine Lozenge		
			10 = Nicotine Nasal Spray and Nicotine Lozenge		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Lozenge		
			12 = Nicotine Gum and Nicotine Lozenge		
			13 = Nicotine Inhaler, Nicotine Gum and Nicotine Lozenge		
			14 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		
			17 = Nicotine Inhaler and Nicotine Patch		
			18 = Nicotine Nasal Spray and Nicotine Patch		
			19 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = Nicotine Gum and Nicotine Patch		
			21 = Nicotine Inhaler, Nicotine Gum and Nicotine Patch		
			22 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		
			23 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			24 = Nicotine Lozenge and Nicotine Patch		
			25 = Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch		
			26 = Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		
			27 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			28 = Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			29 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			30 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			31 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			33 = Nicotine Inhaler and Other NRT Product		
			34 = Nicotine Nasal Spray and Other NRT Product		
			35 = Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			36 = Nicotine Gum and Other NRT Product		
			37 = Nicotine Inhaler, Nicotine Gum and Other NRT Product		
			38 = Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		
			39 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			40 = Nicotine Lozenge and Other NRT Product		
			41 = Nicotine Inhaler, Nicotine Lozenge and Other NRT Product		
			42 = Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		
			43 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			44 = Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			45 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			46 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			47 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			48 = Nicotine Patch and Other NRT Product		
			49 = Nicotine Inhaler, Nicotine Patch and Other NRT Product		
			50 = Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			51 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Patch and Other NRT Product: 52 = Nicotine Gum,Nicotin e Patch and Other NRT Product: 53 = Nicotine Inhaler, Nicotine Gum,Nicotin e Patch and Other NRT Product:		NRTPROD

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
11	INHFREQ	8				INHFREQ
12	NASPFREQ	8				NASPFREQ
13	GUMFREQ	8				GUMFREQ
14	LOZFREQ	8				LOZFREQ
15	PATFREQ	8				PATFREQ
16	OTHNRTRF EQ	8				OTHNRTRF EQ
17	OTHPROD	8		1 = Chewable/S mokeless Tobacco 2 = Cigars/Cigar illos 4 = Pipe 8 = Other Tobacco Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		
			-9 = Not Applicable		
			3 = Chewable/S mokeless Tobacco and Cigars/Cigar illos		
			5 = Chewable/S mokeless Tobacco and Pipe		
			6 = Cigars/Cigar illos and Pipe		
			7 = Chewable/S mokeless Tobacco, Cigars/Cigar illos and Pipe		
			9 = Chewable/S mokeless Tobacco and Other Tobacco Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Cigars/Cigar illos and Other Tobacco Product: 11 = Chewable/S mokeless Tobacco and Cigars/Cigar illos and Other Tobacco Product: 12 = Pipe and Other Tobacco Product: 13 = Chewable/S mokeless Tobacco, Pipe and Other Tobacco Product: 14 = Cigars/Cigar illos, Pipe and Other Tobacco Product:		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Chewable/S mokeless Tobacco, Cigars/Cigar illos, Pipe and Other Tobacco Product		OTHPROD
18 TOBFREQ	8				TOBFREQ
19 CIGFREQ	8				CIGFREQ
20 PIPFREQ	8				PIPFREQ
21 TOBNFREQ	8				TOBNFREQ
22 ECNUM	8				ECNUM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**


**Form: Adverse Events Y/N**

**Generated On: 18 Sep 2014 07:49:14**

Was there any Adverse Event for this subject?

No ☒ 1  
Yes ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Adverse Events Y/N****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 AEYN	\$1		N = No Y = Yes		AEYN

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Adverse Events****Generated On: 18 Sep 2014 07:49:14**AE Identifier  ①Adverse Event  ②Start Date  ③DD/MMM/YYYY End Date  ④DD/MMM/YYYY Ongoing at final contact No ☐ ⑤  
Yes ☐Severity Mild Adverse Event ☐ ⑥  
Moderate Adverse Event ☐  
Severe Adverse Event ☐Serious AE No ☐ ⑦  
Yes ☐Seriousness Criteria Fatal ☐ ⑧  
Is life-threatening ☐  
Requires hospitalization ☐  
Results in ☐  
disability/incapacity ☐  
Congenital anomaly/birth ☐  
defect ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Adverse Events****Generated On: 18 Sep 2014 07:49:14**

Treatment given No ☒ 9  
Yes ☐

AE related to Study Procedure Related ☒ 10  
Not Related ☐

Relationship to CC/THS Related ☒ 11  
Not Related ☐

AE expectedness No ☒ 17  
Yes ☐

Action taken with study product Product use Interrupted ☒ 18  
Product use Stopped ☐  
Product use Reduced ☐  
Not Applicable ☐  
None ☐

Other action taken ☒ 14

Outcome Death Related to Adverse Event ☒ 15  
Not Recovered or Not Resolved ☐  
Recovered or Resolved ☐  
Recovered or Resolved with Sequelae ☐  
Recovering or Resolving ☐  
Unknown ☐

H\_NOW (Derived): ☒ 16

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Adverse Events****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	AESPID	\$10				AESPID
②	AETERM	\$200				AETERM
③	AESTDAT	dd MMM YYYY				AESTDAT
④	AEENDAT	dd MMM YYYY				AEENDAT
⑤	AEENRF	\$1		N = No Y = Yes		AEENRF
⑥	AESEV	\$8		MILD = Mild Adverse Event MODERATE = Moderate Adverse Event SEVERE = Severe Adverse Event		AESEV
⑦	AESER	\$1		N = No Y = Yes		AESER



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Adverse Events

Generated On: 18 Sep 2014 07:49:14


Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 AESERCRIT	1		1 = Fatal 2 = Is life-threatening 3 = Requires hospitalization 4 = Results in disability/in capacity 5 = Congenital anomaly/birth defect		AESERCRIT
9 AECONTRT	\$1		N = No Y = Yes		AECONTRT
10 AEREL_S	1		1 = Related 2 = Not Related		AEREL_S
11 AEREL_1	\$20		1 = Related 2 = Not Related		AEREL_1

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Adverse Events****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17	AEEXPD	\$1		N = No Y = Yes		AEEXPD
18	AEACN	\$40		PRODUCT USE INTERRUPT ED = Product use Interrupted PRODUCT USE STOPPED = Product use Stopped PRODUCT USE REDUCED = Product use Reduced NOT APPLICABL E = Not Applicable NONE = None		AEACN
19	AEACNOTH	\$200				AEACNOTH



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Adverse Events****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 AEOUT	\$40		FATAL = Death Related to Adverse Event NOT RECOVERE D/NOT RESOLVED = Not Recovered or Not Resolved RECOVERE D/RESOLVE D = Recovered or Resolved RECOVERE D/RESOLVE D WITH SEQUELAE = Recovered or Resolved with Sequelae RECOVERIN G/RESOLVI NG = Recovering or Resolving		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Adverse Events****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			UNKNOWN = Unknown		AEOU
16 H_NOW	dd MMM yyyy hh:nn:ss				H_NOW




**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication Y/N**  
**Generated On: 18 Sep 2014 07:49:14**

Has the subject taken previous or concomitant  
medication?

No ☒ 1  
Yes ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication Y/N**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 CMYN	\$1		N = No Y = Yes		CMYN



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
**Generated On: 18 Sep 2014 07:49:14**

Brand Name \_\_\_\_\_ ①

Start Date \_\_\_\_\_ ②  
DD/MMM/YYYY

Stop Date \_\_\_\_\_ ③  
DD/MMM/YYYY

Ongoing at final contact \_\_\_\_\_ ④

Total Daily dose - Dose \_\_\_\_\_ ⑤

Total Daily dose - Unit \_\_\_\_\_ ⑥

Ampule Dosing Unit ☐

Bolus Dosing Unit ☐

Capsule Dosing Unit ☐

Gram ☐

Inhalation Dosing Unit ☐

International Unit ☐

Milligram ☐

Milliliter ☐

Nebule Dosing Unit ☐

Patch Dosing Unit ☐

Puff Dosing Unit ☐

Suppository Dosing Unit ☐

Tablet Dosing Unit ☐

Tablespoon Dosing Unit ☐

Teaspoon Dosing Unit ☐

Microgram per Day ☐

Not Applicable ☐

Other Dosing Unit ☐

Application ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
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Route	
	Auricular Route of Administration <input checked="" type="radio"/> 7
	Buccal Route of Administration <input type="radio"/>
	Conjunctival Route of Administration <input type="radio"/>
	Cutaneous Route of Administration <input type="radio"/>
	Dental Route of Administration <input type="radio"/>
	Electro-osmosis Route of Administration <input type="radio"/>
	Endocervical Route of Administration <input type="radio"/>
	Endosinusial Route of Administration <input type="radio"/>
	Endotracheal Route of Administration <input type="radio"/>
	Enteral Route of Administration <input type="radio"/>
	Epidural Route of Administration <input type="radio"/>
	Extraamniotic Route of Administration <input type="radio"/>
	Extracorporeal Circulation <input type="radio"/>
	Route of Administration Via Hemodialysis <input type="radio"/>
	Infiltration Route of Administration <input type="radio"/>
	Interstitial Route of Administration <input type="radio"/>
	Intraabdominal Route of Administration <input type="radio"/>
	Intraamniotic Route of Administration <input type="radio"/>
	Intraarterial Route of Administration <input type="radio"/>
	Intraarticular Route of Administration <input type="radio"/>
	Intrabiliary Route of Administration <input type="radio"/>



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
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- Intrabronchial Route of Administration ☐
- Intrabursal Route of Administration ☐
- Intracardiac Route of Administration ☐
- Intracartilaginous Route of Administration ☐
- Intracaudal Route of Administration ☐
- Intracavernous Route of Administration ☐
- Intracavitary Route of Administration ☐
- Intracerebral Route of Administration ☐
- Intracisternal Route of Administration ☐
- Intracorneal Route of Administration ☐
- Intracoronar Dental Route of Administration ☐
- Intracoronary Route of Administration ☐
- Intracorporus Cavemosum Route of Administration ☐
- Intradermal Route of Administration ☐
- Intradiscal Route of Administration ☐
- Intraductal Route of Administration ☐
- Intraduodenal Route of Administration ☐
- Intradural Route of Administration ☐
- Intraepidermal Route of Administration ☐
- Intraesophageal Route of Administration ☐
- Intragastric Route of Administration ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
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- Intragingival Route of Administration ☐
- Intraileal Route of Administration ☐
- Intralesional Route of Administration ☐
- Intraluminal Route of Administration ☐
- Intralymphatic Route of Administration ☐
- Intramedullary Route of Administration ☐
- Intrameningeal Route of Administration ☐
- Intramuscular Route of Administration ☐
- Intraocular Route of Administration ☐
- Intraovarian Route of Administration ☐
- Intrapericardial Route of Administration ☐
- Intraperitoneal Route of Administration ☐
- Intrapleural Route of Administration ☐
- Intraprostatic Route of Administration ☐
- Intrapulmonary Route of Administration ☐
- Intrasinal Route of Administration ☐
- Intraspinal Route of Administration ☐
- Intrasynovial Route of Administration ☐
- Intratendinous Route of Administration ☐
- Intratesticular Route of Administration ☐
- Intrathecal Route of Administration ☐





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
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- 
- Endothoracic Route of Administration ☐
  - Intratubular Route of Administration ☐
  - Intratumoral Route of Administration ☐
  - Intratympanic Route of Administration ☐
  - Intrauterine Route of Administration ☐
  - Intravascular Route of Administration ☐
  - Intravenous Route of Administration ☐
  - Intravenous Bolus ☐
  - Intravenous Drip ☐
  - Intraventricular Route of Administration ☐
  - Intravesical Route of Administration ☐
  - Intravitreal Route of Administration ☐
  - Iontophoresis Route of Administration ☐
  - Irrigation-Route of Administration ☐
  - Laryngeal Route of Administration ☐
  - Nasal Route of Administration ☐
  - Nasogastric Route of Administration ☐
  - Route of Administration ☐
  - Not Applicable ☐
  - Occlusive Dressing Technique ☐
  - Ophthalmic Route of Administration ☐
  - Oral Route of Administration ☐
  - Oropharyngeal Route of Administration ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
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- Other Route of Administration ☐
- Parenteral Route of Administration ☐
- Percutaneous Route of Administration ☐
- Periarticular Route of Administration ☐
- Peridural Route of Administration ☐
- Perineural Route of Administration ☐
- Periodontal Route of Administration ☐
- Rectal Route of Administration ☐
- Inhalation Route of Administration ☐
- Retrobulbar Route of Administration ☐
- Soft Tissue Route Of Administration ☐
- Subarachnoid Route of Administration ☐
- Subconjunctival Route of Administration ☐
- Subcutaneous Route of Administration ☐
- Sublingual Route of Administration ☐
- Submucosal Route of Administration ☐
- Topical Route of Administration ☐
- Transdermal Route of Administration ☐
- Mucosal Route of Administration ☐
- Transplacental Route of Administration ☐
- Transtracheal Route of Administration ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
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Transtympanic Route of Administration ☐  
Unassigned Route of Administration ☐  
Unknown Route of Administration ☐  
Ureteral Route of Administration ☐  
Intraurethral Route of Administration ☐  
Vaginal Route of Administration ☐

Indication \_\_\_\_\_ 8

Concomitant Disease Number \_\_\_\_\_ 9

AE Number \_\_\_\_\_ 10

Other \_\_\_\_\_ 11



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	CMTRT	\$200				CMTRT
②	CMSTDAT	dd- MMM- YYYY				CMSTDAT
③	CMENDAT	dd- MMM- YYYY				CMENDAT
④	CMENRF	1				CMENRF
⑤	CMDOSTOT	8				CMDOSTOT
⑥	CMDOSU	\$40		AMPULE = Ampule Dosing Unit BOLUS = Bolus Dosing Unit CAPSULE = Capsule Dosing Unit G = Gram INHALATIO N = Inhalation Dosing Unit IU = Internation al Unit MG = Milligram		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ML = Milliliter		
			NEBULE = Nebule		
			Dosing Unit		
			PATCH = Patch		
			Dosing Unit		
			PUFF = Puff		
			Dosing Unit		
			SUPPOSITO RY = Suppository		
			Dosing Unit		
			TABLET = Tablet		
			Dosing Unit		
			TBSP = Tablespoon		
			Dosing Unit		
			TSP = Teaspoon		
			Dosing Unit		
			UG = Microgram		
			per Day		
			NOT APPLICABL		
			E = Not Applicable		
			OTHER = Other		
			Dosing Unit		
			APPLICATIO N = Application		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
CMDOSU					

⑦ CMROUTE	\$30	AURICULAR (OTIC) = Auricular Route of Administrati on BUCCAL = Buccal Route of Administrati on CONJUNCTI VAL = Conjunctival Route of Administrati on CUTANEOU S = Cutaneous Route of Administrati on
-----------	------	--



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			DENTAL = Dental Route of Administrati on ELECTROOS MOSIS = Electro-osm osis Route of Administrati on ENDOCERVI CAL = Endocervica l Route of Administrati on ENDOSINU SIAL = Endosinusia l Route of Administrati on ENDOTRAC HEAL = Endotrache al Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			ENTERAL = Enteral Route of Administrati on EPIDURAL = Epidural Route of Administrati on EXTRA-AMN IOTIC = Extraamniot ic Route of Administrati on EXTRACORP OREAL = Extracorpor eal Circulation Route of Administrati on HEMODIALY SIS = Administrati on Via Hemodialysi s		





PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Previous and Concomitant Medication  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INFILTRATI ON = Infiltration Route of Administrati on INTERSTITI AL = Interstitial Route of Administrati on INTRAABDO MINAL = Intraabdomi nal Route of Administrati on INTRA-AMN IOTIC = Intraamniot ic Route of Administrati on INTRA-ART ERIAL = Intraarterial Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRA-ARTICULAR = Intraarticular Route of Administration		
			INTRABILIARY = Intrabiliary Route of Administration		
			INTRABRONCHIAL = Intrabronchial Route of Administration		
			INTRABURSAL = Intrabursal Route of Administration		
			INTRACARDIAC = Intracardiac Route of Administration		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRACART ILAGINOUS = Intracartilag inous Route of Administrati on INTRACAUD AL = Intracaudal Route of Administrati on INTRACAVE RNOUS = Intracavern ous Route of Administrati on INTRACAVI TARY = Intracavitar y Route of Administrati on INTRACERE BRAL = Intracerebr al Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRACIST ERNAL = Intracistern al Route of Administrati on INTRACORN EAL = Intracorneal Route of Administrati on INTRACOR ONAL DENTAL = Intracoronar Dental Route of Administrati on INTRACOR ONARY = Intracorona ry Route of Administrati on INTRACORP ORUS CAVERNOS UM = Intracorpor us Cavernosu m Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRADER MAL = Intradermal Route of Administrati on		
			INTRADISC AL = Intradiscal Route of Administrati on		
			INTRADUCT AL = Intraductal Route of Administrati on		
			INTRADUO DENAL = Intraduode nal Route of Administrati on		
			INTRADURA L = Intradural Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAEPID ERMAL = Intraepidermal Route of Administration		
			INTRAESOP HAGEAL = Intraesophageal Route of Administration		
			INTRAGAST RIC = Intragastric Route of Administration		
			INTRAGINGIVAL IVAL = Intragingival Route of Administration		
			INTRAILEAL = Intraileal Route of Administration		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRALESIONAL = Intralesional Route of Administration		
			INTRALUMINAL = Intraluminal Route of Administration		
			INTRALYMPHATIC = Intralymphatic Route of Administration		
			INTRAMEDULLARY = Intramedullary Route of Administration		
			INTRAMENINGEAL = Intrameningeal Route of Administration		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAMUSCULAR = Intramuscular Route of Administration		
			INTRAOCULAR = Intraocular Route of Administration		
			INTRAOVARIAN = Intraovarian Route of Administration		
			INTRAPERICARDIAL = Intrapericardial Route of Administration		
			INTRAPERITONEAL = Intraperitoneal Route of Administration		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAPLEU RAL = Intrapleural Route of Administrati on		
			INTRAPROS TATIC = Intraprostat ic Route of Administrati on		
			INTRAPULM ONARY = Intrapulmo nary Route of Administrati on		
			INTRASINA L = Intrasinal Route of Administrati on		
			INTRASPIN AL = Intraspinal Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRASYNO VIAL = Intrasynovi al Route of Administrati on INTRATEND INOUS = Intratendin ous Route of Administrati on INTRATEST ICULAR = Intratesticul ar Route of Administrati on INTRATHEC AL = Intrathecal Route of Administrati on INTRATHOR ACIC = Endothoraci c Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRATUBU LAR = Intratubular Route of Administrati on		
			INTRATUM OR = Intratuma l Route of Administrati on		
			INTRATYMP ANIC = Intratym nic Route of Administrati on		
			INTRAUTER INE = Intrauterine Route of Administrati on		
			INTRAVASC ULAR = Intravascu lar Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			INTRAVENO US = Intravenous Route of Administrati on INTRAVENO US BOLUS = Intravenous Bolus INTRAVENO US DRIP = Intravenous Drip INTRAVENT RICULAR = Intraventric ular Route of Administrati on INTRAVESI CAL = Intravesical Route of Administrati on INTRAVITR EAL = Intravitreal Route of Administrati on		

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28JUL14 (640)

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Previous and Concomitant Medication****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			IONTOPHO RESIS = Iontophoresis is Route of Administration IRRIGATION N = Irrigation-Route of Administration LARYNGEAL = Laryngeal Route of Administration NASAL = Nasal Route of Administration NASOGASTRIC RIC = Nasogastric Route of Administration NOT APPLICABLE E = Route of Administration Not Applicable		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Previous and Concomitant Medication****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			OCCLUSIVE DRESSING TECHNIQUE = Occlusive Dressing Technique OPHTHALMI C = Ophthalmic Route of Administrati on ORAL = Oral Route of Administrati on OROPHARY NGEAL = Oropharyng eal Route of Administrati on OTHER = Other Route of Administrati on PARENTERA L = Parenteral Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			PERCUTANEOUS = Percutaneous Route of Administration		
			PERIARTICULAR = Periarticular Route of Administration		
			PERIDURAL = Peridural Route of Administration		
			PERINEURAL = Perineural Route of Administration		
			PERIODONTAL = Periodontal Route of Administration		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			RECTAL = Rectal Route of Administrati on RESPIRATO RY (INHALATI ON) = Inhalation Route of Administrati on RETROBUL BAR = Retrobulbar Route of Administrati on SOFT TISSUE = Soft Tissue Route Of Administrati on SUBARACH NOID = Subarachno id Route of Administrati on		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			SUBCONJUNCTIVAL = Subconjunctival Route of Administration		
			SUBCUTANEOUS = Subcutaneous Route of Administration		
			SUBLINGUAL = Sublingual Route of Administration		
			SUBMUCOSAL = Submucosal Route of Administration		
			TOPICAL = Topical Route of Administration		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			TRANSDER MAL = Transderma l Route of Administrati on TRANSMUC OSAL = Mucosal Route of Administrati on TRANSPLOC ENTAL = Transplacen tal Route of Administrati on TRANSTRAC HEAL = Transtrache al Route of Administrati on TRANSTYM PANIC = Transtympan ic Route of Administrati on		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			UNASSIGNE D = Unassigned Route of Administrati on UNKNOWN = Unknown Route of Administrati on URETERAL = Ureteral Route of Administrati on URETHRAL = Intraurethra l Route of Administrati on VAGINAL = Vaginal Route of Administrati on		CMROUTE



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Previous and Concomitant Medication**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8	CMINDC	\$200				CMINDC
9	MHREFID	\$10				MHREFID
10	AEREFID	\$10				AEREFID
11	CMINDCAT	\$200				CMINDCAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: End of study****Generated On: 18 Sep 2014 07:49:14**

End of study date

Fixed Unit: **1**  
DD/MMM/YYYY

Has the subject completed the study ?

No **2**  
Yes

If No, please specify the reason:

Adverse Events **3**  
Protocol Violation  
Withdrawal by Subject  
Lost To Follow-up  
Other

Details:

**4**

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: End of study****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DSDAT	dd MMM YYYY				DSDAT
②	DSTERM	\$1		N = No Y = Yes		DSTERM
③	EOSDSDEC OD	\$200		ADVERSE EVENT = Adverse Events PROTOCOL VIOLATION = Protocol Violation WITHDRAW AL BY SUBJECT = Withdrawal by Subject LOST TO FOLLOWUP = Lost To Follow-up OTHER = Other		EOSDSDEC OD
④	DSSPEC	\$200				DSSPEC

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: 24 hour urine collections****Generated On: 18 Sep 2014 07:49:14**

Start Date

Fixed Unit: ①  
DD/MMM/YYYY

Start Time

Fixed Unit: ②  
hour:min 24-hour clock

End Date

Fixed Unit: ③  
DD/MMM/YYYY

End Time

Fixed Unit: ④  
hour:min 24-hour clock

Volume

⑤

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: 24 hour urine collections****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	URIN_STDA	Add MMM T	YYYY			URIN_STDA T
②	URIN_STTI	HH:nn M				URIN_STTI M
③	URIN_ENDA	Add MMM T	YYYY			URIN_ENDA T
④	URIN_ENTI	HH:nn M				URIN_ENTI M
⑤	URIN_VOLU	4 ME				URIN_VOLU ME





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Sample Urine Collection**  
**Generated On: 18 Sep 2014 07:49:14**

Were samples collected?

No ☒ ①  
Yes ☐

If No, please specify the reason: \_\_\_\_\_ ②

How many primary tubes were collected? \_\_\_\_\_ ③

How many back up tubes were collected? \_\_\_\_\_ ④

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Sample Urine Collection****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBSTAT	\$1		N = No Y = Yes		LBSTAT
②	LBREASND	\$200				LBREASND
③	LBTUBNO	2				LBTUBNO
④	LBBTUBNO	2				LBBTUBNO



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 18 Sep 2014 07:49:14**

Type  QSU **1**

Date of Birth  **2**

Date of assessment  **3**

DD/MM/YYYY

Time of assessment  **4**

hour:min 24-hour clock

Assessment Status ☐ Completed **5**  
☐ Abandoned

1. I have a desire for a cigarette right now ☐ Strongly disagree **6**  
☐ Disagree  
☐ Somewhat disagree  
☐ Do not agree or disagree  
☐ Somewhat agree  
☐ Agree  
☐ Strongly agree  
☐ Abandoned



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 18 Sep 2014 07:49:14**

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

Strongly disagree ☒ 7  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐

3. If it were possible I would probably smoke now

Strongly disagree ☒ 8  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐

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

Strongly disagree ☒ 9  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 18 Sep 2014 07:49:14**

5. All I want right now is a cigarette

Strongly disagree ☐ 10  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐

6. I have an urge for a cigarette

Strongly disagree ☐ 11  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐

7. A cigarette would taste good now

Strongly disagree ☐ 12  
Disagree ☐  
Somewhat disagree ☐  
Do not agree or disagree ☐  
Somewhat agree ☐  
Agree ☐  
Strongly agree ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU)**  
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8. I would do almost anything for a cigarette now

Strongly disagree ☒ 13

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☒ 14

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☒ 15

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU)  
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		QSU		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	QSDAT_E	yyyy MMM dd				QSDAT_E
④	QSTIM	HH:nn				QSTIM
⑤	ASSESSME 8 NTSTATUS			1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑥	QSORRES_ 8 1			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Strongly agree -1 = Abandoned		QSORRES_ 1
7 QSORRES_ 8 2			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 2
8 QSORRES_ 8 3			1 = Strongly disagree		





PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 3
9 QSORRES_ 4	8		1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree		

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PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU)  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_4
11 QSORRES_8 5			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_5
11 QSORRES_8 6			1 = Strongly disagree		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_6
 QSORRES_7			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree		




PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_7
QSORRES_8			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_8
QSORRES_9			1 = Strongly disagree		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 9
 QSORRES_ 8 10			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree		
PROD 08.000 (MAIN) SP 28JUL14 (640)			332 of 656		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 10

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)****Generated On: 18 Sep 2014 07:49:14**

Type Behaviour Rating Scale **1**  
Self-Report

Date of Birth **2**

Date of assessment Fixed Unit: **3**  
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment Fixed Unit: **4**  
hour:min 24-hour clock

Assessment Status Completed **5**  
Abandoned

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

How have you been feeling over the past 24 hours? **7**

1. Angry, irritable, frustrated

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



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

How have you been feeling over the past 24 hours? None ☒ 8  
Slight ☐  
2. Anxious, nervous Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 9  
Slight ☐  
3. Depressed Mood, sad Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 10  
Slight ☐  
4. Desire or craving to smoke Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 11  
Slight ☐  
5. Difficulty concentrating Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

How have you been feeling over the past 24 hours? None ☒ 17  
Slight ☐  
6. Increased appetite, hungry, weight gain Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 15  
Slight ☐  
7. Insomnia, sleep problems, awakening at night Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 14  
Slight ☐  
8. Restless Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 15  
Slight ☐  
9. Impatient Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

How have you been feeling over the past 24 hours? None ☒ 16  
Slight ☐  
10. Constipation Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 17  
Slight ☐  
11. Dizziness Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 18  
Slight ☐  
12. Coughing Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐

How have you been feeling over the past 24 hours? None ☒ 19  
Slight ☐  
13. Dreaming or nightmares Mild ☐  
Moderate ☐  
Severe ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

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How have you been feeling over the past 24 hours? None ☒ 20

14. Nausea Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

---

How have you been feeling over the past 24 hours? None ☒ 21

15. Sore Throat Slight ☐

Mild ☐

Moderate ☐

Severe ☐

Abandoned ☐

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① QSSCAT	\$40		Behaviour Rating Scale Self-Report		QSSCAT
② QSDOB	yyyy MMM dd				QSDOB
③ QSDAT_E	yyyy MMM dd				QSDAT_E
④ QSTIM	HH:nn				QSTIM
⑤ ASSESSME 8 NTSTATUS			1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑦ QSORRES_ 8 MSWS1			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS1
⑧ QSORRES_ 8 MSWS2			1 = None		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS2
9 QSORRES_ 8 MSWS3			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS3
10 QSORRES_ 8 MSWS4			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS4
11 QSORRES_ 8 MSWS5			1 = None 2 = Slight 3 = Mild		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS5
① QSORRES_ 8 MSWS6			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS6
① QSORRES_ 8 MSWS7			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS7
① QSORRES_ 8 MSWS8			1 = None 2 = Slight 3 = Mild 4 = Moderate		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Severe -1 = Abandoned		QSORRES_ MSWS8
15 QSORRES_ 8 MSWS9			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS9
16 QSORRES_ 8 MSWS10			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS10
17 QSORRES_ 8 MSWS11			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		




**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					QSORRES_ MSWS11
18 QSORRES_ 8 MSWS12			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS12
19 QSORRES_ 8 MSWS13			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS13
20 QSORRES_ 8 MSWS14			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS14





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSORRES_ 8 MSWS15			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS15



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated On: 18 Sep 2014 07:49:14**

Type \_\_\_\_\_ MCEQ **1**

Date of Birth \_\_\_\_\_ **2**

Date of assessment= \_\_\_\_\_ Fixed Unit: **3**  
DD/MMM/YYYY DD/MMM/YYYY

Time of assessment \_\_\_\_\_ Fixed Unit: **4**  
hour:min 24-hour clock

Assessment Status Completed **5**  
Abandoned ☐

1. Was smoking satisfying? Not at all **6**  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated On: 18 Sep 2014 07:49:14**

2. Did cigarettes taste good? Not at all ☒ 7  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐

3. Did you enjoy the sensation in your throat and chest? Not at all ☒ 8  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐

4. Did smoking calm you down? Not at all ☒ 9  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated On: 18 Sep 2014 07:49:14**

5. Did smoking make you feel more awake? Not at all ☒ 10  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐

6. Did smoking make you feel less irritable? Not at all ☒ 11  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐

7. Did smoking help you concentrate? Not at all ☒ 12  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
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8. Did smoking reduce your hunger for food? Not at all ☒ 13  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐

9. Did smoking make you dizzy? Not at all ☒ 14  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐

10. Did smoking make you nauseous? Not at all ☒ 15  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated On: 18 Sep 2014 07:49:14**

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

Not at all ☒ 16  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐

12. Did you enjoy smoking?

Not at all ☒ 17  
Very little ☐  
Little ☐  
Moderately ☐  
A lot ☐  
Quite a lot ☐  
Extremely ☐  
Abandoned ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		MCEQ		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	QSDAT_E	yyyy MMM dd				QSDAT_E
④	QSTIM	HH:nn				QSTIM
⑤	ASSESSME NTSTATUS	8		1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑥	MCEQ1	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ1



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7 MCEQ2	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ2
8 MCEQ3	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ3
9 MCEQ4	8		1 = Not at all		







PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ4
10 MCEQ5	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ5
11 MCEQ6	8		1 = Not at all 2 = Very little		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ6
 MCEQ7	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ7
 MCEQ8	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ8
 MCEQ9	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ9
 MCEQ10	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Extremely -1 = Abandoned		MCEQ10
16 MCEQ11	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		MCEQ11
17 MCEQ12	8		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		MCEQ12

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Cough Assessment****Generated On: 18 Sep 2014 07:49:14**Type \_\_\_\_\_ VAS for Cough **1**Date of Birth \_\_\_\_\_ **2**Date of assessment \_\_\_\_\_ Fixed Unit: **3**  
DD/MMM/YYYY DD/MMM/YYYYTime of assessment \_\_\_\_\_ Fixed Unit: **4**  
hour:min 24-hour clockAssessment Status Completed ☐ **5**  
Abandoned ☐Have you experienced a regular need to cough e.g.  
coughing several times in the last 24 hrs? Yes ☐ **6**  
No ☐  
Abandoned ☐

If YES, please answer the following questions:

First Question: Cough Impact Scale **8**  
How much is your cough bothering you? \_\_\_\_\_

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Cough Assessment****Generated On: 18 Sep 2014 07:49:14**

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

Very mild ☒ 9  
Mild ☐  
Moderate ☐  
Severe ☐  
Very severe ☐  
Abandoned ☐  
Not Applicable ☐

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

Rarely ☒ 10  
Sometimes ☐  
Fairly often ☐  
Often ☐  
Almost always ☐  
Abandoned ☐  
Not Applicable ☐

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

No sputum ☒ 11  
A moderate amount of sputum ☐  
A large amount of sputum ☐  
A very large amount of sputum ☐  
Abandoned ☐  
Not Applicable ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Cough Assessment****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		VAS for Cough		QSCAT
②	QSDOB	yyyy MMM dd				QSDOB
③	QSDAT_E	yyyy MMM dd				QSDAT_E
④	QSTIM	HH:nn				QSTIM
⑤	ASSESSME 8 NTSTATUS			1 = Completed 2 = Abandoned		ASSESSME NTSTATUS
⑥	QS_COUGH 8 _ORRES			1 = Yes 2 = No -1 = Abandoned		QS_COUGH _ORRES
⑧	QS_COUGH 8 _ORRES1					QS_COUGH _ORRES1
⑨	QS_COUGH 8 _ORRES2			1 = Very mild 2 = Mild		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Cough Assessment****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Moderate 4 = Severe 5 = Very severe -1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES2
10 QS_COUGH 8 _ORRES3			1 = Rarely 2 = Sometimes 3 = Fairly often 4 = Often 5 = Almost always -1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES3
11 QS_COUGH 8 _ORRES4			0 = No sputum 1 = A moderate amount of sputum 2 = A large amount of sputum		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Cough Assessment****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = A very large amount of sputum -1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES4



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Human Smoking Topography Questionnaire**  
**Generated On: 18 Sep 2014 07:49:14**

Type Human Smoking Topography Questionnaire **1**

Was paper questionnaire used? No ☐ **2**  
Yes ☐

Reason not done  **3**

Date of assessment Fixed Unit:  **4**  
DD/MMM/YYYY

Time of assessment Fixed Unit:  **5**  
hour:min 24-hour clock

How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device. Strongly agree ☐ **7**  
Agree ☐  
Neither agree nor disagree ☐  
Disagree ☐  
Strongly disagree ☐

If you agree or strongly agree, please describe :  **8**



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Human Smoking Topography Questionnaire**  
**Generated On: 18 Sep 2014 07:49:14**

2. You enjoy smoking with the device as much as without it. Strongly agree ☐ 9  
Agree ☐  
Neither agree nor disagree ☐  
Disagree ☐  
Strongly disagree ☐

If you disagree or strongly disagree, please describe : \_\_\_\_\_ 10

3. The taste of the conventional cigarettes/products is different with the device. Strongly agree ☐ 11  
Agree ☐  
Neither agree nor disagree ☐  
Disagree ☐  
Strongly disagree ☐

If you agree or strongly agree, please describe : \_\_\_\_\_ 12

4. The device is easy to use. Strongly agree ☐ 13  
Agree ☐  
Neither agree nor disagree ☐  
Disagree ☐  
Strongly disagree ☐

If you disagree or strongly disagree, please describe : \_\_\_\_\_ 14

5. Your smoking is disturbed by the device. Strongly agree ☐ 15  
Agree ☐  
Neither agree nor disagree ☐  
Disagree ☐  
Strongly disagree ☐



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If you agree or strongly agree, please describe : \_\_\_\_\_





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Form: Human Smoking Topography Questionnaire  
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	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Human Smoking Topography Questionnaire		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑦	QSORRES_1			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_1



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Human Smoking Topography Questionnaire  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 QSSPEC_1	\$200				QSSPEC_1
9 QSORRES_ 1 2			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 2
10 QSSPEC_2	\$200				QSSPEC_2
11 QSORRES_ 1 3			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 3




PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Human Smoking Topography Questionnaire  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
QSSPEC_3	\$200				QSSPEC_3
QSORRES_ 1 4			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 4
QSSPEC_4	\$200				QSSPEC_4
QSORRES_ 1 5			1 = Strongly agree 2 = Agree 3 = Neither agree nor disagree 4 = Disagree 5 = Strongly disagree		QSORRES_ 5





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Human Smoking Topography Questionnaire**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSSPEC_5	\$200				QSSPEC_5



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Cigarette Holder**  
**Generated On: 18 Sep 2014 07:49:14**

Were there any events with the device?

No ☐ ①  
Yes ☐

Event Log Number

②

Date of Device Event  
DD/MMM/YYYY

③

Time of  
Device Event  
hour:min 24-hour clock

④

Event Relates to Device Type:

⑤

Unique Device Identifier Serial Number

⑥

Event Description

CH stops heating before ☐ ⑦  
end of smoking experience  
CH does not charge when ☐  
inserted into the Mobil unit  
CH heater broken (LED ☐  
blinking red)  
Smoking experience does ☐  
not start when pressing the  
button  
Electronic malfunction ☐  
during  
the smoking experience  
Other ☐

Other Describe

⑧

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Device report - THS 2.2 menthol Cigarette Holder****Generated On: 18 Sep 2014 07:49:14**

Severity of Event

Minor (can be resolved easily) ☒ 9Major (cannot be resolved. Device needs to be exchanged) ☐

Adverse Event Relationship

Is related to AE ☒ 1rIs not related to AE ☐

If Related to AE, AE Number

☒ 1r

Solution Proposed:

Device Replaced ☒ 1rDevice Recharged ☐Device Withdrawn ☐

If the device was replaced, New Device Serial Number:

☒ 1rDate of Device Event Closure  
DD/MMM/YYYY☒ 1rTime of Device Event Closure  
hour:min 24-hour clock☒ 1r




**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Cigarette Holder**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DE_YN	\$1		N = No Y = Yes		DE_YN
②	DESPID	3				DESPID
③	DEDAT	dd MMM YYYY				DEDAT
④	DETIM	HH:nn				DETIM
⑤	DETYP	\$25		THS 2.2 Cigarette Holder	1: THS 2.2 Cigarette Holder	DETYP
⑥	DEID	\$8				DEID
⑦	DEDESC	\$8		1 = CH stops heating before end of smoking experience 2 = CH does not charge when inserted into the Mobil unit		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Cigarette Holder**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = CH heater broken (LED blinking red) 4 = Smoking experience does not start when pressing the button 5 = Electronic malfunction during the smoking experience 6 = Other		DEDESC
<hr/>					
 DEDESC_SP\$200 EC				DEDESC_SP EC	



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Cigarette Holder**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 DESEV	\$8		1 = Minor (can be resolved easily) 2 = Major (cannot be resolved. Device needs to be exchanged)		DESEV
10 DEREL	\$8		1 = Is related to AE 2 = Is not related to AE		DEREL
11 DEANUM	2				DEANUM
12 DESOLUTIO N	\$8		1 = Device Replaced 2 = Device Recharged 3 = Device Withdrawn		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Cigarette Holder**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					DESOLUTION
13 DEID_2	\$8				DEID_2
12 DECLOSDA T	dd MMM yyyy				DECLOSDA T
15 DECLOSTIM	HH:nn				DECLOSTIM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Charging Unit**  
**Generated On: 18 Sep 2014 07:49:14**

Were there any events with the device?

No ☒ 1  
Yes ☐

Event Log Number

2

Date of Device Event  
DD/MMM/YYYY

3

Time of  
Device Event  
hour:min 24-hour clock

4

Event Relates to  
Device Type:

5

Unique Device Identifier Serial Number

6

Event Description

Battery Malfunction ☒ 7  
Device Discharged ☐  
Other ☐

Other Describe

8

Severity of Event

Minor (can be resolved easily) ☒ 9  
Major (cannot be resolved.  
Device needs to be  
exchanged) ☐

Adverse Event  
Relationship

Is related to AE ☒ 10  
Is not related to AE ☐





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Charging Unit**  
**Generated On: 18 Sep 2014 07:49:14**

Solution Proposed:

Device Replaced ☒ 11  
Device Recharged ☐  
Device Withdrawn ☐

If the device was replaced, New Device Serial Number: \_\_\_\_\_ 17

Date of Device Event Closure DD/MM/YYYY \_\_\_\_\_ 18

Time of Device Event Closure hour:min 24-hour clock \_\_\_\_\_ 16



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Charging Unit**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DE_YN	\$1		N = No Y = Yes		DE_YN
②	DESPID	3				DESPID
③	DEDAT	dd MMM YYYY				DEDAT
④	DETIM	HH:nn				DETIM
⑤	DETYP	\$25		THS 2.2 Charging Unit	1: THS 2.2 Charging Unit	DETYP
⑥	DEID	\$8				DEID
⑦	DECUDESC	\$8		1 = Battery Malfunction 2 = Device Discharged 3 = Other		DECUDESC
⑧	DEDESC_SP\$200 EC					DEDESC_SP EC



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Device report - THS 2.2 menthol Charging Unit  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 DESEV	\$8		1 = Minor (can be resolved easily) 2 = Major (cannot be resolved. Device needs to be exchanged)		DESEV
10 DEREL	\$8		1 = Is related to AE 2 = Is not related to AE		DEREL
11 DESOLUTIO N	\$8		1 = Device Replaced 2 = Device Recharged 3 = Device Withdrawn		DESOLUTIO N



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device report - THS 2.2 menthol Charging Unit**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
17	DEID_2	\$8				DEID_2
18	DECLOSDA T	dd MMM YYYY				DECLOSDA T
19	DECLOSTIM	HH:nn				DECLOSTIM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device Inventory - THS 2.2 menthol Cigarette Holder**  
**Generated On: 18 Sep 2014 07:49:14**

Device Inventory Log Number	_____	①
Date of Device Distribution DD/MMM/YYYY	_____	②
Time of Device Distribution hour:min 24-hour clock	_____	③
Device Type	_____	④
Device Serial Number	_____	⑤
Date of Device Collection DD/MMM/YYYY	_____	⑥
Time of Device Collection hour:min 24-hour clock	_____	⑦



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device Inventory - THS 2.2 menthol Cigarette Holder**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DISPID	2				DISPID
②	DIDAT	dd MMM YYYY				DIDAT
③	DITIM	HH:nn				DITIM
④	DITYP	\$200		THS 2.2 Cigarette Holder	1: THS 2.2 Cigarette Holder	DITYP
⑤	DIID	\$8				DIID
⑥	DICOLDAT	dd MMM YYYY				DICOLDAT
⑦	DICOLTIM	HH:nn				DICOLTIM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device Inventory - THS 2.2 menthol Charging Unit**  
**Generated On: 18 Sep 2014 07:49:14**

Device Inventory Log Number	_____	①
Date of Device Distribution DD/MMM/YYYY	_____	②
Time of Device Distribution hour:min 24-hour clock	_____	③
Device Type	_____	④
Device Serial Number	_____	⑤
Date of Device Collection DD/MMM/YYYY	_____	⑥
Time of Device Collection hour:min 24-hour clock	_____	⑦



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Device Inventory - THS 2.2 menthol Charging Unit**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	DISPID	2				DISPID
②	DIDAT	dd MMM YYYY				DIDAT
③	DITIM	HH:nn				DITIM
④	DITYP	\$200		THS 2.2 Charging Unit	1: THS 2.2 Charging Unit	DITYP
⑤	DIID	\$8				DIID
⑥	DICOLDAT	dd MMM YYYY				DICOLDAT
⑦	DICOLTIM	HH:nn				DICOLTIM





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Bio-banking (Transcriptomics)**  
**Generated On: 18 Sep 2014 07:49:14**

Was a Bio-banking sample for transcriptomics taken?

No ☐ ①  
Yes ☐

Date of Sample Collection

Fixed Unit: ②  
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit: ③  
hour:min 24-hour clock

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

No ☐ ④  
Yes ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Bio-banking (Transcriptomics)**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	BIOBANKYN\$1			N = No Y = Yes		BIOBANKYN
②	BIODAT	dd MMM YYYY				BIODAT
③	BIOBTIM	HH:nn				BIOBTIM
④	BIOBFSTYN \$1			N = No Y = Yes		BIOBFSTYN



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Bio-banking (Biomarkers of exposure and risk markers)**  
**Generated On: 18 Sep 2014 07:49:14**

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

No ☐ ①  
Yes ☐

Date of Sample Collection

Fixed Unit: ②  
DD/MMM/YYYY

Time of Sample Collection

Fixed Unit: ③  
hour:min 24-hour clock

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

No ☐ ④  
Yes ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Bio-banking (Biomarkers of exposure and risk markers)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① BIOBANKYN\$1 _1			N = No Y = Yes		BIOBANKYN _1
② BIODAT	dd MMM YYYY				BIODAT
③ BIOBTIM	HH:nn				BIOBTIM
④ BIOBFSTYN \$1			N = No Y = Yes		BIOBFSTYN

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Date of assessment ①  
DD/MMM/YYYY \_\_\_\_\_

Time of assessment ②  
hour:min 24-hour clock \_\_\_\_\_

Has the subject smoked within 15 minutes prior to assessment ③  
No ☐   
Yes ☐

Pulse rate ④  
beats per minute \_\_\_\_\_

Respiratory rate ⑤  
breaths per minute \_\_\_\_\_

Blood Pressure (systolic) ⑥  
mmHg \_\_\_\_\_

Blood Pressure (diastolic) ⑦  
mmHg \_\_\_\_\_

Vital Signs Position of Subject ⑧  
Sitting ☐   
Standing ☐   
Supine ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Vital Signs<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSDAT	dd MMM YYYY				VSDAT
②	VSTIM	HH:nn				VSTIM
③	VSSMKYN	\$1		N = No Y = Yes		VSSMKYN
④	VSORRES_P3 ULSE					VSORRES_P ULSE
⑤	VSORRES_R3 ESP					VSORRES_R ESP
⑥	VSORRES_S3 YSBP					VSORRES_S YSBP
⑦	VSORRES_ 3 DIABP					VSORRES_ DIABP
⑧	VSPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine 1: Supine		VSPOS



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: ECG (12-Lead Standard)<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Date of assessment  **1**  
DD/MMM/YYYY

Position ☐ Sitting **2**  
☐ Standing  
☐ Supine

Heart Rate  **3**  
(beats per minute)

QRS Interval  **4**  
(msec)

QT Interval  **5**  
(msec)

QTcB Interval  **6**  
(msec)

PR Interval  **7**  
(msec)

Interpretation ☐ Normal **8**  
☐ Abnormal

If Abnormal, Clinical Significance ☐ Not clinically significant **9**  
☐ Clinically significant

If Not Clinically significant or clinically Significant, Please **10**  
specify the finding(s)



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: ECG (12-Lead Standard)<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	EGDAT	dd MMM YYYY				EGDAT
②	EGPOS	\$10		SITTING = Sitting STANDING = Standing SUPINE = Supine	1: Supine	EGPOS
③	EGORRES_ 3 HR					EGORRES_ HR
④	EGORRES_ 3 QRS					EGORRES_ QRS
⑤	EGORRES_ 3 QT					EGORRES_ QT
⑥	EGORRES_ 3 QTC					EGORRES_ QTC
⑦	EGORRES_P3 R					EGORRES_P R
⑧	EGINTP	\$40		NORMAL = Normal ABNORMAL = Abnormal		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: ECG (12-Lead Standard)<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
EGINTP					
9 EGCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		EGCLSIG
10 EGTERM	\$200				EGTERM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Spirometry<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Category With short-acting  
bronchodilator ☐ ①  
Without short-acting  
bronchodilator ☐

Date of assessment: ②  
DD/MMM/YYYY

Time of assessment: ③  
hour:min 24-hour clock

Name of bronchodilator ④

Dose ⑤

Predicted FVC value Fixed Unit: ⑥  
L

Best measured FVC value Fixed Unit: ⑦  
L

Percent of predicted FVC value Fixed Unit: ⑧  
%

Best measured FEV1 value Fixed Unit: ⑨  
L

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Spirometry<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Predicted FEV1 value

Fixed Unit: ☒ L

Percent of predicted FEV1 value

Fixed Unit: ☒ %

Interpretation

Normal ☒  
Abnormal ☐

If Abnormal, Clinical Significance

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



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Spirometry&lt;Unscheduled /&gt;

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PTCAT	\$80		WITH = With short-acting bronchodila tor WITHOUT = Without short-acting bronchodila tor		PTCAT
②	PTDAT	dd MMM YYYY				PTDAT
③	PTTIM	HH:nn				PTTIM
④	PTBD	\$200				PTBD
⑤	PTDOSE	\$10				PTDOSE
⑥	PTORRES_F4.2 VCPRED					PTORRES_F VCPRED
⑦	PTORRES_F4.2 VCMEAS					PTORRES_F VCMEAS



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Spirometry&lt;Unscheduled /&gt;

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 PTORRES_F 4.1 VCMR					PTORRES_F VCMR
9 PTORRES_F 4.2 EV1MEAS					PTORRES_F EV1MEAS
10 PTORRES_F 4.2 EV1PRED					PTORRES_F EV1PRED
11 PTORRES_F 4.1 EV1MPR					PTORRES_F EV1MPR
12 PTORRES_I \$40 NTP			NORMAL = Normal ABNORMAL = Abnormal		PTORRES_I NTP
13 PTCLSIG	\$40		NCS = Not clinically significant CS = Clinically significant		PTCLSIG
14 PTTERM	\$200				PTTERM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Date of assessment

Fixed Unit: ①  
DD/MMM/YYYY

System

General Appearance ②

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

Thyroid Gland ☐

Heart ☐

Chest ☐

Lungs ☐

Gastrointestinal ☐

Cardiovascular System ☐

Neurologic ☐

Skin ☐

Back ☐

Musculoskeletal ☐

Abdomen ☐

Dentition ☐

Other ☐

Other, Specify

③

Outcome

Normal ④

Abnormal ☐

Abnormal, please specify:

⑤

Clinically significant

No ⑥

Yes ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Not Done

7

Not Done; please specify the reason:

8

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Physical Examination<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PEDAT	dd MMM YYYY				PEDAT
②	PETESTCD	\$200		GAPPEAR = General Appearance		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			HEENT = HEENT (head, eyes, ears, nose, throat)		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			THYROID = Thyroid Gland		
			HEART = Heart		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			CHEST = Chest		
			LUNGS = Lungs		
			GASTRO = Gastrointest inal		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
CVS = Cardiovascular System NEURO = Neurologic					



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Physical Examination<Unscheduled />

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			SKIN = Skin BACK = Back MUSCULO = Musculoskel etal		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Physical Examination<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
ABDOMEN = Abdomen DENTN = Dentition OTHER = Other					



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Physical Examination<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: General Appearance 2: HEENT (head, eyes, ears, nose, throat) 3: Thyroid Gland 4: Heart 5: Chest 6: Lungs 7: Gastrointestinal 8: Cardiovascular System 9: Neurologic 10: Skin 11: Back 12: Musculoskeletal 13: Abdomen 14: Dentition 15: Other 16: Other 17: Other 18: Other 19: Other	PETESTCD
3 PESPEC	\$200				PEREASND1



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Physical Examination<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
4 PEORRES	\$8		NORMAL = Normal ABNORMAL = Abnormal		PEORRES
5 PETERM1	\$200				PETERM1
6 PECLSIG1	\$1		N = No Y = Yes		PECLSIG1
7 PESTAT2	1				PESTAT2
8 PEREASND2	\$200				PEREASND2



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Weight<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**Date of assessment  
DD/MMM/YYYY

①

Time of assessment  
hour:min 24-hour clock

②

Weight

Fixed Unit:  
kg

③

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Weight<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	VSDAT	dd MMM YYYY				VSDAT
②	VSTIM	HH:nn				VSTIM
③	VSORRES_ WEIGHT	4.1				VSORRES_ WEIGHT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: X-Ray<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Category for Examination

Chest X-Ray ☐ ①Date of assessment  
DD/MM/YYYY

②

System

General Appearance ☐ ③HEENT  
(head, eyes, ears, nose,  
throat)Thyroid Gland ☐Heart ☐Chest ☐Lungs ☐Gastrointestinal ☐Cardiovascular System ☐Neurologic ☐Skin ☐Back ☐Musculoskeletal ☐Abdomen ☐Dentition ☐Other ☐

Interpretation

Normal ☐ ④Abnormal ☐

Clinically significant

No ☐ ⑤Yes ☐

Abnormal, please specify:

⑥

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: X-Ray<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PECAT	\$80		CHEST XRAY = Chest X-Ray	1: Chest X-Ray	XRPECAT
②	XRPE DAT1	dd MMM YYYY				XRPE DAT1
③	XRPE TESTC \$200 D			GAPPEAR = General Appearance HEENT = HEENT (head, eyes, ears, nose, throat) THYROID = Thyroid Gland HEART = Heart CHEST = Chest LUNGS = Lungs GASTRO = Gastrointest inal CVS = Cardiovascu lar System		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: X-Ray<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			NEURO = Neurologic SKIN = Skin BACK = Back MUSCULO = Musculoskel etal ABDOMEN = Abdomen DENTN = Dentition OTHER = Other	1: Chest	XPETESTC D
④ XRPEORRES\$8			NORMAL = Normal ABNORMAL = Abnormal		XRPEORRES
⑤ XRPECLSIG \$1			N = No Y = Yes		XRPECLSIG
⑥ XRPETERM1\$200					XRPETERM1



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Clinical Chemistry<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☒ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☐

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

No ☐ ②  
Yes ☐

Date of Sample Collection  
DD/MMM/YYYY

③

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Clinical Chemistry<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT
② LBFSTYN	\$1		N = No		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Clinical Chemistry<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		LBSTYN
③ LBDAT	dd MMM yyyy				LBDAT





PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Haematology<Unscheduled />

Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☐ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☐

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

No ☐ ②  
Yes ☐

Date of Sample Collection  
DD/MMM/YYYY

③



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Haematology&lt;Unscheduled /&gt;

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test	1: Haematolog y	LBCAT
② LBFSTYN	\$1		N = No		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Haematology<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			Y = Yes		LBSTYN
③ LBDAT	dd MMM yyyy				LBDAT



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Urine analysis<Unscheduled />

Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☒ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☒  
Cotinine Screening ☐  
Alcohol Breath Test ☐

Date of sample collection  
DD/MMM/YYYY

②

Time of sample collection  
hour:min 24-hour clock

③

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine analysis<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine analysis<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
②	LBDAT	dd MMM YYYY				LBDAT
③	LBTIM	HH:nn				LBTIM



PROD 08.000 (MAIN) SP 28JUL14: Case Book

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

Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☐ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☒  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☐

Date of Sample Collection  
DD/MM/YYYY

②




PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Serology for HIV and Hepatitis B and C<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Serology for HIV and Hepatitis B and C<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 LBDAT	dd MMM YYYY				LBDAT



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Urine Drug Screen<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

Category

Clinical Chemistry ☐ ①  
Drug Screen ☒  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☐

Date of sample collection

Fixed Unit: ②  
DD/MMM/YYYY

Time of sample collection

Fixed Unit: ③  
hour:min 24-hour clock

Drug type

Amphetamines ☐ ④  
Barbiturates ☐  
Benzodiazepines ☐  
Cannabinoids ☐  
Cocaine ☐  
Opiates ☐

Result

Negative ☐ ⑤  
Positive ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		LBCAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
② DRUGDAT	dd MMM YYYY				DRUGDAT
③ DRUGTIM	HH:nn				DRUGTIM
④ DRUGTEST	\$20		AMPHETAM INES = Amphetami nes BARBITURA TES = Barbiturates BENZODIAZ EPINES = Benzodiaze pines CANNABIN OIDS = Cannabinoi ds COCAINE = Cocaine OPIATES = Opiates	1: Amphetami nes 2: Barbiturates 3: Benzodiaze pines 4: Cannabinoi ds 5: Cocaine 6: Opiates	DRUGTEST

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Urine Drug Screen<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 DRUGORRE \$8 S			NEGATIVE = Negative POSITIVE = Positive		DRUGORRE S



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Alcohol Breath Test<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Category

Clinical Chemistry ☐ ①  
Drug Screen ☐  
Haematology ☐  
Serology ☐  
Pregnancy Testing ☐  
Urinalysis ☐  
Cotinine Screening ☐  
Alcohol Breath Test ☐

Date of assessment  
DD/MMM/YYYY

②

Time of assessment  
hour:min 24-hour clock

③

Result

Negative ☐ ④  
Positive ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test		
				1: Alcohol Breath Test	LBCAT

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Alcohol Breath Test<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
②	ALCDAT	dd MMM YYYY				ALCDAT
③	ALCTIM	HH:nn				ALCTIM
④	ALCORRES	\$30		NEGATIVE = Negative POSITIVE = Positive		ALCORRES





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Urine Pregnancy Test<Unscheduled />**  
**Generated On: 18 Sep 2014 07:49:14**

Category	Clinical Chemistry <input type="radio"/> ①
	Drug Screen <input type="radio"/>
	Haematology <input type="radio"/>
	Serology <input type="radio"/>
	Pregnancy Testing <input type="radio"/>
	Urinalysis <input type="radio"/>
	Cotinine Screening <input type="radio"/>
	Alcohol Breath Test <input type="radio"/>
Date of Test DD/MM/YYYY	<input type="text"/> ②
Time of Test hour:min 24-hour clock	<input type="text"/> ③
Specify result	Negative <input type="radio"/> ④
	Positive <input type="radio"/>
	Unclear <input type="radio"/>
Specify result of FSH test	< 20 IU/L <input type="radio"/> ⑤
	>= 20 IU/L <input type="radio"/>



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Urine Pregnancy Test<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
① LBCAT	\$80		CLINICAL CHEMISTRY = Clinical Chemistry DRUG SCREEN = Drug Screen HAEMATOL OGY = Haematolog y SEROLOGY = Serology PREGNANC Y = Pregnancy Testing URINALYSI S = Urinalysis COTININE SCREENING = Cotinine Screening ALCOHOL BREATH TEST = Alcohol Breath Test	1: Pregnancy Testing	LBCAT



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Urine Pregnancy Test<Unscheduled />  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
2	PGNDAT	dd MMM YYYY				PGNDAT
3	PGNTIM	HH:nn				PGNTIM
4	PGNORRES	\$8		NEGATIVE = Negative POSITIVE = Positive UNCLEAR = Unclear		PGNORRES
5	PGNORRES	\$8 N		1 = < 20 IU/L 2 = >= 20 IU/L		PGNORRES N

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Blood Samples <Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

Date		①
DD/MMM/YYYY		
Time		②
hour:min 24-hour clock		
Scheduled Time		③
Sample Type		④

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Blood Samples<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBDAT	dd MMM YYYY				PCBDAT
②	PCBTIM	HH:nn				PCBTIM
③	PCBTPT	\$40				PCBTPT
④	SAMPTYP	\$40				SAMPTYP

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CO Breath Test<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**Date of Assessment  
DD/MMM/YYYY

①

Actual Time of Assessment  
hour:min 24-hour clock

②

Result  
ppm

③

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: CO Breath Test<Unscheduled />****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	CODAT	dd MMM YYYY				CODAT
②	CPTIM	HH:nn				CPTIM
③	COORRES	3				COORRES

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Nicotine Sample(D5)****Generated On: 18 Sep 2014 07:49:14**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date  
DD/MM/YYYY ☐ ③Time  
hour:min 24-hour clock ☐ ④

Timepoint	T0 -15 min	<input type="checkbox"/> ⑤
	T1	<input type="checkbox"/>
	T2	<input type="checkbox"/>
	T3	<input type="checkbox"/>
	T4	<input type="checkbox"/>
	T5	<input type="checkbox"/>
	T6	<input type="checkbox"/>
	T7	<input type="checkbox"/>
	T8	<input type="checkbox"/>
	T0 + 20H	<input type="checkbox"/>
	T0 + 24H	<input type="checkbox"/>

H\_NOW (Derived): ☐ ⑥



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Nicotine Sample(D5)****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	PCBTMP	2		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 -15 min 2: T1 3: T2 4: T3 5: T4 6: T5 7: T6 8: T7 9: T8	PCBTMP

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Nicotine Sample(D5)****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Nicotine Sample(D6)****Generated On: 18 Sep 2014 07:49:14**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date  
DD/MM/YYYY ☐ ③Time  
hour:min 24-hour clock ☐ ④

Timepoint	T0 -15 min	<input type="checkbox"/> ⑤
	T1	<input type="checkbox"/>
	T2	<input type="checkbox"/>
	T3	<input type="checkbox"/>
	T4	<input type="checkbox"/>
	T5	<input type="checkbox"/>
	T6	<input type="checkbox"/>
	T7	<input type="checkbox"/>
	T8	<input type="checkbox"/>
	T0 + 20H	<input type="checkbox"/>
	T0 + 24H	<input type="checkbox"/>

H\_NOW (Derived): ☐ ⑥



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Plasma Nicotine Sample(D6)

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	PCBTMP	2		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 + 20H 2: T0 + 24H	PCBTMP
⑥	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Cotinine Sample(D5)****Generated On: 18 Sep 2014 07:49:14**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date  
DD/MM/YYYY ☐ ③Time  
hour:min 24-hour clock ☐ ④

Timepoint	T0 -15 min	<input type="checkbox"/> ⑤
	T1	<input type="checkbox"/>
	T2	<input type="checkbox"/>
	T3	<input type="checkbox"/>
	T4	<input type="checkbox"/>
	T5	<input type="checkbox"/>
	T6	<input type="checkbox"/>
	T7	<input type="checkbox"/>
	T8	<input type="checkbox"/>
	T0 + 20H	<input type="checkbox"/>
	T0 + 24H	<input type="checkbox"/>

H\_NOW (Derived): ☐ ⑥



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Plasma Cotinine Sample(D5)

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	PCBTMP	2		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 -15 min 2: T1 3: T2 4: T3 5: T4 6: T5 7: T6 8: T7 9: T8	PCBTMP



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Plasma Cotinine Sample(D5)

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Plasma Cotinine Sample(D6)****Generated On: 18 Sep 2014 07:49:14**Not Done ☐ ①If Not Done, please specify the reason: ☐ ②Date  
DD/MM/YYYY ☐ ③Time  
hour:min 24-hour clock ☐ ④

Timepoint	T0 -15 min	<input type="checkbox"/> ⑤
	T1	<input type="checkbox"/>
	T2	<input type="checkbox"/>
	T3	<input type="checkbox"/>
	T4	<input type="checkbox"/>
	T5	<input type="checkbox"/>
	T6	<input type="checkbox"/>
	T7	<input type="checkbox"/>
	T8	<input type="checkbox"/>
	T0 + 20H	<input type="checkbox"/>
	T0 + 24H	<input type="checkbox"/>

H\_NOW (Derived): ☐ ⑥





## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Plasma Cotinine Sample(D6)

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCBSTAT	1				PCBSTAT
②	PCBREASN D	\$200				PCBREASN D
③	PCBDAT	dd MMM YYYY				PCBDAT
④	PCBTIM	HH:nn				PCBTIM
⑤	PCBTMP	2		1 = T0 -15 min 2 = T1 3 = T2 4 = T3 5 = T4 6 = T5 7 = T6 8 = T7 9 = T8 10 = T0 + 20H 11 = T0 + 24H	1: T0 + 20H 2: T0 + 24H	PCBTMP
⑥	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Type \_\_\_\_\_ Questionnaire on smoking urges **1**

Was paper questionnaire used? No ☐ **2**  
Yes ☐

Reason not done \_\_\_\_\_ **3**

Date of assessment \_\_\_\_\_ **4**

DD/MMM/YYYY \_\_\_\_\_

Time of assessment \_\_\_\_\_ **5**

hour:min 24-hour clock \_\_\_\_\_

1. I have a desire for a cigarette right now

Strongly disagree	<input type="checkbox"/> <b>6</b>
Disagree	<input type="checkbox"/>
Somewhat disagree	<input type="checkbox"/>
Do not agree or disagree	<input type="checkbox"/>
Somewhat agree	<input type="checkbox"/>
Agree	<input type="checkbox"/>
Strongly agree	<input type="checkbox"/>
Abandoned	<input type="checkbox"/>



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

---

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

Strongly disagree ☒ 7

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

3. If it were possible I would probably smoke now

Strongly disagree ☒ 8

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

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

Strongly disagree ☒ 9

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

---

5. All I want right now is a cigarette

Strongly disagree ☐ 10

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

6. I have an urge for a cigarette

Strongly disagree ☐ 11

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

7. A cigarette would taste good now

Strongly disagree ☐ 12

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

8. I would do almost anything for a cigarette now

Strongly disagree ☐ 13

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐ 14

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐ 15

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Questionnaire on smoking urges		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM yyyy				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QSORES_ 8 1			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 1
7 QSORRES_ 8 2			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 2
8 QSORRES_ 8 3			1 = Strongly disagree 2 = Disagree		

PROD 08.000 (MAIN) SP  
28JUL14 (640)

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PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 3
9 QSORRES_ 8 4			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree / = Strongly agree		






PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 4
10 QSORRES_ 8 5			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 5
11 QSORRES_ 8 6			1 = Strongly disagree 2 = Disagree		
PROD 08.000 (MAIN) SP 28JUL14 (640)					
				456 of 656	



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 6
 QSORRES_ 8 7			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree / = Strongly agree		

PROD 08.000 (MAIN) SP 28JUL14 (640)

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PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 7
13 QSORRES_ 8 8			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 8
14 QSORRES_ 8 9			1 = Strongly disagree 2 = Disagree		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 9
15 QSORRES_ 8 10			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree / = Strongly agree		

PROD 08.000 (MAIN) SP 28JUL14 (640)

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Questionnaire on smoking urges (QSU) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		QSORRES_ 10



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Type Modifier Cigarette Evaluation Questionnaire ①

Was paper questionnaire used? No ☐ ②  
Yes ☐

Reason not done \_\_\_\_\_ ③

Date of assessment Fixed Unit: ④  
DD/MMM/YYYY

Time of assessment Fixed Unit: ⑤  
hour:min 24-hour clock

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)****Generated On: 18 Sep 2014 07:49:14**

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

- Was smoking satisfying? ☒ 6
- Did cigarettes taste good? ☐
- Did you enjoy the sensation in your throat and chest? ☐
- Did smoking calm you down? ☐
- Did smoking make you feel more awake? ☐
- Did smoking make you feel less irritable? ☐
- Did smoking help you concentrate? ☐
- Did smoking reduce your hunger for food? ☐
- Did smoking make you dizzy? ☐
- Did smoking make you nauseous? ☐
- Did smoking immediately relieve your craving for a cigarette? ☐
- Did you enjoy smoking? ☐

Response

- Not at all ☒ 7
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Modifier Cigarette Evaluation Questionnaire		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6 QSTEST	\$200		1 = Was smoking satisfying?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Did cigarettes taste good?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Did you enjoy the sensation in your throat and chest?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Did smoking calm you down?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Did smoking make you feel more awake?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Did smoking make you feel less irritable?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Did smoking help you concentrate ?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = Did smoking reduce your hunger for food?		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = Did smoking make you dizzy?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Did smoking make you nauseous?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

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

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Did smoking immediately relieve your craving for a cigarette?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = Did you enjoy smoking?		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Was smoking satisfying?	QSTEST
				2: Did cigarettes taste good?	
				3: Did you enjoy the sensation in your throat and chest?	
				4: Did smoking calm you down?	
				5: Did smoking make you feel more awake?	
				6: Did smoking make you feel less irritable?	
				7: Did smoking help you concentrate?	
				8: Did smoking reduce your hunger for food?	
				9: Did smoking make you dizzy?	
				10: Did smoking make you nauseous?	
PROD 08.000 (MAIN) SP 28JUL14 (640)				11: Did smoking immediately relieve your craving for a cigarette?	



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ QSORRES	1		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		QSORRES



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Cough Assessment (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Type Cough Assessment **1**

Was paper questionnaire used?

No **2**  
Yes

Reason not done

**3**

Date of assessment  
DD/MMM/YYYY

Fixed Unit: **4**  
DD/MMM/YYYY

Time of assessment

Fixed Unit: **5**  
hour:min 24-hour clock

Have you experienced a regular need to cough e.g.  
coughing several times in the last 24 hrs?

Yes **6**  
No  
Abandoned

If YES, please answer the following questions:

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

**8**



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Cough Assessment (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

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

Very mild ☒ 9  
Mild ☐  
Moderate ☐  
Severe ☐  
Very severe ☐  
Abandoned ☐  
Not Applicable ☐

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

Rarely ☒ 10  
Sometimes ☐  
Fairly often ☐  
Often ☐  
Almost always ☐  
Abandoned ☐  
Not Applicable ☐

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

No sputum ☒ 11  
A moderate amount of sputum ☐  
A large amount of sputum ☐  
A very large amount of sputum ☐  
Abandoned ☐  
Not Applicable ☐

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

12



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Cough Assessment (Paper)****Generated On: 18 Sep 2014 07:49:14**


	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Cough Assessment		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSDAT	dd MMM YYYY				QSDAT
⑤	QSTIM	HH:nn				QSTIM
⑥	QS_COUGH 8 _ORRES			1 = Yes 2 = No -1 = Abandoned		QS_COUGH _ORRES
⑧	QS_COUGH 8 _ORRES1					QS_COUGH _ORRES1
⑨	QS_COUGH 8 _ORRES2			1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Cough Assessment (Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES2
10 QS_COUGH 8 _ORRES3			1 = Rarely 2 = Sometimes 3 = Fairly often 4 = Often 5 = Almost always -1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES3
11 QS_COUGH 8 _ORRES4			0 = No sputum 1 = A moderate amount of sputum 2 = A large amount of sputum 3 = A very large amount of sputum		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Cough Assessment (Paper)  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned -9 = Not Applicable		QS_COUGH _ORRES4
 QS_COUGH \$200 _ORRES5					QS_COUGH _ORRES5

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)****Generated On: 18 Sep 2014 07:49:14**

Type MNWS ①

Was paper questionnaire used?

No ☐ ②  
Yes ☐

Reason not done

③

Type

Behaviour Rating Scale ④  
Self-ReportDate of assessment  
DD/MMM/YYYYFixed Unit: ⑤  
DD/MMM/YYYY

Time of assessment

Fixed Unit: ⑥  
hour:min 24-hour clock

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



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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

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

**Generated On: 18 Sep 2014 07:49:14**

---

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

---

Result ☒ 9

☐ None

☐ Slight

☐ Mild

☐ Moderate

☐ Severe

☐ Abandoned

---



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		MNWS		QSCAT
②	QSSTAT	\$1		N = No Y = Yes		QSSTAT
③	QSREASND	\$200				QSREASND
④	QSSCAT	\$40		Behaviour Rating Scale Self-Report		QSSCAT
⑤	QSDAT	dd MMM YYYY				QSDAT
⑥	QSTIM	HH:nn				QSTIM



PROD 08.000 (MAIN) SP 28JUL14: Case Book

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

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
QSTEST_M 2 SWS			1 = 1. Angry, irritable, frustrated		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = 2. Anxious, tense		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

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

**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = 3. Depressed Mood, sad		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = 4. Desire or craving to smoke		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

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

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = 5. Difficulty concentrati ng		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = 6. Increased appetite, hungry, weight gain		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = 7. Insomnia, sleep problems, awakening at night		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

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

**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 8. Restless		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = 9. Impatient		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

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

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = 10. Constipation		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = 11. Dizziness		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

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

**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = 12. Coughing		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

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

**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			13 = 13. Dreaming or nightmares		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = 14. Nausea		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = 15. Sore throat		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			1: 1. Angry, irritable, frustrated	QSTEST_M SWS	
			2: 2. Anxious, tense		
			3: 3. Depressed Mood, sad		
			4: 4. Desire or craving to smoke		
			5: 5. Difficulty concentrating		
			6: 6. Increased appetite, hungry, weight gain		
			7: 7. Insomnia, sleep problems, awakening at night		
			8: 8. Restless		
			9: 9. Impatient		
			10: 10. Constipation		
			11: 11. Dizziness		
			12: 12. Coughing		
			13: 13. Dreaming		
PROD 08.000 (MAIN) SP 28JUL14 (640)			or nightmares		501 of 656
			14: 14. Nausea		
			15: 15. Sore throat		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS) (Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 QSORRES_ 1 MSWS			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: LABSTAT results****Generated On: 18 Sep 2014 07:49:14**

Cohort Number	_____	①
Kit Number	_____	②
Vial Number	_____	③
Day Number	_____	④
Sample Collection Date	_____	⑤
Group No.	_____	⑥
Run No.	_____	⑦
Port No.	_____	⑧
Sample ID	_____	⑨
Number of Filters	_____	⑩
Extraction Volume (ml)	_____	⑪
Date of Extraction	_____	⑫
Sample Volume (ml)	_____	⑬
Dilution Volume (ml)	_____	⑭
Total Volume (ml)	_____	⑮



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: LABSTAT results****Generated On: 18 Sep 2014 07:49:14**

Date of analysis (UV)	16
Absolute UV Absorbance Mouthpiece part of the Filter	17
Absolute UV Absorbance 'PLA + HAT' part of the Filter	18
Absolute UV Absorbance Full Filter	19
Normalized UV Absorbance Mouthpiece part of the Filter	20
Normalized UV Absorbance 'PLA + HAT' part of the Filter	21
Normalized UV Absorbance Full Filter	22
Date of analysis (Nicotine)	23
Nicotine Amount Mouthpiece part of the Filter (mg/ml)	24
Nicotine Amount 'PLA + HAT' part of the Filter (mg/ml)	25
Nicotine Amount Full Filter (mg/ml)	26
Nicotine Amount Mouthpiece part of the Filter (mg/filter)	27
Nicotine Amount 'PLA + HAT' part of the Filter (mg/filter)	28
Nicotine Amount Full Filter (mg/filter)	29
Comments	30

**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

Form: LABSTAT results

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LSCOHORT	2				LSCOHORT
②	LSKITNO	\$5				LSKITNO
③	LSVIALNO	2				LSVIALNO
④	LSDAY	2				LSDAY
⑤	LSSAMPDT	dd MMM YYYY				LSSAMPDT
⑥	LSGRP	2				LSGRP
⑦	LSRUN	2				LSRUN
⑧	LSPORT	2				LSPORT
⑨	LSSAMPID	10				LSSAMPID
⑩	LSFILTNO	1				LSFILTNO
⑪	LSEXVOL	2				LSEXVOL
⑫	LSEXDAT	dd MMM YYYY				LSEXDAT
⑬	LSSAMPVOL5.2					LSSAMPVOL

**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

Form: LABSTAT results

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
14	LSDILVOL	5.2				LSDILVOL
15	LSVOL	5.2				LSVOL
16	LSANALDAT	dd MMM YYYY				LSANALDAT
17	LSORRES1	\$6				LSORRES1
18	LSORRES2	\$6				LSORRES2
19	LSORRES3	\$6				LSORRES3
20	LSORRES4	\$6				LSORRES4
21	LSORRES5	\$6				LSORRES5
22	LSORRES6	\$6				LSORRES6
23	LSNICDAT	dd MMM YYYY				LSNICDAT
24	LSORRES7	\$6				LSORRES7
25	LSORRES8	\$6				LSORRES8
26	LSORRES9	\$6				LSORRES9

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: LABSTAT results****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
27	LSORRES10	\$6				LSORRES10
28	LSORRES11	\$6				LSORRES11
29	LSORRES12	\$6				LSORRES12
30	LSCOM	\$200				LSCOM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Biomarker(Blood)****Generated On: 18 Sep 2014 07:49:14**

Sample type	_____	①
Sample Barcode	_____	②
Analyte	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Planned time point (Hour)	_____	⑨
Day of Visit	_____	⑩
Celerion Study Number	_____	⑪
Date of Collection	_____	⑫
Timepoint-minutes	_____	⑬
Urine Start Day	_____	⑭
Urine End Day	_____	⑮

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Biomarker(Blood)****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCSPEC	\$40				PCSPEC
②	PCREFID	\$40				PCREFID
③	PCTEST	\$40				PCTEST
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCTPTNUM	\$20				PCTPTNUM
⑩	PCVSTNUM	\$10				PCVSTNUM
⑪	STUDYNM	\$40				STUDYNM
⑫	PCACTNUM	\$20				PCACTNUM
⑬	PCTPMNUM	\$10				PCTPMNUM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Biomarker(Blood)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Biomarker(Urine)****Generated On: 18 Sep 2014 07:49:14**



Sample type	_____	①
Sample Barcode	_____	②
Analyte	_____	③
Result	_____	④
Result Unit	_____	⑤
Lab Status	_____	⑥
Sample comment	_____	⑦
Detection method	_____	⑧
Planned time point (Hour)	_____	⑨
Day of Visit	_____	⑩
Celerion Study Number	_____	⑪
Date of Collection	_____	⑫
Timepoint-minutes	_____	⑬
Urine Start Day	_____	⑭
Urine End Day	_____	⑮



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Biomarker(Urine)****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	PCSPEC	\$40				PCSPEC
②	PCREFID	\$40				PCREFID
③	PCTEST	\$40				PCTEST
④	PCORRES	\$40				PCORRES
⑤	PCORRESU	\$40				PCORRESU
⑥	PCSTAT	\$40				PCSTAT
⑦	PCREASND	\$200				PCREASND
⑧	PCMETHOD	\$20				PCMETHOD
⑨	PCTPTNUM	\$20				PCTPTNUM
⑩	PCVSTNUM	\$10				PCVSTNUM
⑪	STUDYNM	\$40				STUDYNM
⑫	PCACTNUM	\$20				PCACTNUM
⑬	PCTPMNUM	\$10				PCTPMNUM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Biomarker(Urine)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 PCTPSNUM	\$20				PCTPSNUM
 PCTPENUM	\$20				PCTPENUM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab-BU****Generated On: 18 Sep 2014 07:49:14**

Test Category	<input type="text"/>	1
Date of Sample Collection	<input type="text"/>	2
Date (BU)	<input type="text"/>	3
Blood Sample time(BU)	<input type="text"/>	4
Urine Sample time(BU)	<input type="text"/>	5
Time of Blood Sample Collection	<input type="text"/>	6
Time of Urine Sample Collection	<input type="text"/>	7
Test Name	<input type="text"/>	8
Result	<input type="text"/>	9
Text Result	<input type="text"/>	10
Unit	<input type="text"/>	11
Lower limit	<input type="text"/>	12
Upper limit	<input type="text"/>	13
Flag	Out of Reference Range <input type="checkbox"/>	14
	Low <input type="checkbox"/>	
	High <input type="checkbox"/>	

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab-BU****Generated On: 18 Sep 2014 07:49:14**

Clinically Significant?

No ☐ 15  
Yes ☐

Comment

16

Result Category

17

Text Result Code

18

Reference Value Category

19

Timepoint(COHB)

20

Material Code

21

Chyle Comment Code

22

Chyle Comment English

23

Hemolysis Comment Code

24

Hemolysis Comment English

25

Specimen Comment Code 1

26

Specimen English Comment 1

27

Specimen Comment Code 2

28

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab-BU****Generated On: 18 Sep 2014 07:49:14**Specimen English Comment 2 29Result Supplementary Comment Code 1 30Result Supplementary English Comment Code 1 31Result Supplementary Comment Code 2 32Result Supplementary English Comment Code 2 33Accession No. 34

Please document clinically relevant abnormalities in the AE form

H\_NOW (Derived): 35Derived Form name 36

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab-BU****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBCAT_1	\$80				LBCAT_1
②	LBDAT_1	yyyy MMM dd				LBDAT_1
③	LBDAT_BU	\$11				LBDAT_BU
④	LBTIM_1_B U	4				LBTIM_1_B U
⑤	LBTIM_2_B U	4				LBTIM_2_B U
⑥	LBTIM_1	HH:nn				LBTIM_1
⑦	LBTIM_2	HH:nn				LBTIM_2
⑧	LBSPEC	\$200				LBSPEC
⑨	LBORRES	\$40				LBORRES
⑩	LBORRESN	\$40				LBORRESN
⑪	LBSTRESU	\$40				LBSTRESU
⑫	LBORNRLO	\$20				LBORNRLO



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Lab-BU

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
15 LBORNRHI	\$20				LBORNRHI
16 LBFL	\$1		! = Out of Reference Range L = Low H = High		LBFL
15 LBCLINSIG	\$1		N = No Y = Yes		LBCLINSIG
16 LBCOM	\$200				LBCOM
17 LBRESCAT	\$1				LBRESCAT
18 LBRESCODE	\$3				LBRESCODE
19 LBREFCAT	\$1				LBREFCAT
20 LBTPT	\$100				LBTPT
21 LBSPECIME	\$100				LBSPECIME
N					N
22 LBCHCODE	\$3				LBCHCODE

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab-BU****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
23	LBCHCOM	\$40				LBCHCOM
24	LBHECODE	\$3				LBHECODE
25	LBHECOM	\$40				LBHECOM
26	LBSPCODE1	\$3				LBSPCODE1
27	LBSPCOM1	\$40				LBSPCOM1
28	LBSPCODE2	\$3				LBSPCODE2
29	LBSPCOM2	\$40				LBSPCOM2
30	LBSUCODE 1	\$3				LBSUCODE 1
31	LBSUCOM1	\$40				LBSUCOM1
32	LBSUCODE 2	\$3				LBSUCODE 2
33	LBSUCOM2	\$40				LBSUCOM2
34	LBACCNO	\$12				LBACCNO



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab-BU****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
36	H_NOW	dd MMM YYYY hh:nn:ss				H_NOW
37	F_NAME	\$40				F_NAME

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Type	Product Use	①
Date of completion DD/MMM/YYYY		②
Time of completion hh:mm		③
Date the questionnaire was completed for DD/MMM/YYYY		④



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)  
Generated On: 18 Sep 2014 07:49:14

What tobacco/nicotine product did you use today?

- THS 2.2 ☒ 5
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- Abandoned ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Product use diary(Paper)

Generated On: 18 Sep 2014 07:49:14

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

How many THS 2.2 tobacco sticks did you use today? \_\_\_\_\_ 6

How many CC/ roll-your-own did you smoke today? \_\_\_\_\_ 7



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Product use diary(Paper)

Generated On: 18 Sep 2014 07:49:14

What NRT product did you used today?

- Nicotine Inhaler ☒ 8
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐



Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch	<input type="radio"/>
Nicotine Gum and Nicotine Patch	<input type="radio"/>
Nicotine Inhaler, Nicotine Gum and Nicotine Patch	<input type="radio"/>
Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch	<input type="radio"/>
Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch	<input type="radio"/>
Nicotine Lozenge and Nicotine Patch	<input type="radio"/>
Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch	<input type="radio"/>
Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch	<input type="radio"/>
Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch	<input type="radio"/>
Nicotine Gum, Nicotine Lozenge and Nicotine Patch	<input type="radio"/>
Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch	<input type="radio"/>
Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch	<input type="radio"/>
Nicotine Inhaler and Other NRT Product	<input type="radio"/>
Nicotine Nasal Spray and Other NRT Product	<input type="radio"/>
Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product	<input type="radio"/>



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

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



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

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

How many times did you use an inhaler today? \_\_\_\_\_ 9

How many times did you use a nasal spray today? \_\_\_\_\_ 10

How many gums did you use today? \_\_\_\_\_ 11

How many lozenges did you use today? \_\_\_\_\_ 12

How many patches did you use today? \_\_\_\_\_ 13

How many times did you use other NRT products today  
not listed previously? \_\_\_\_\_ 14





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)**  
**Generated On: 18 Sep 2014 07:49:14**

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☒ 15
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

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

16



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

**Form: Product use diary(Paper)**

**Generated On: 18 Sep 2014 07:49:14**

How many cigars/cigarillos did you smoke today? \_\_\_\_\_ 17

How many times did you smoke a pipe today? \_\_\_\_\_ 18

How many times did you use a tobacco product today  
not listed previously? \_\_\_\_\_ 19

How many times did you use an electronic cigarette  
today? \_\_\_\_\_ 20

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Product Use		QSCAT
②	EXDATE	dd MMM YYYY				EXDATE
③	EXTIME	HH:nn				EXTIME
④	EXDATE_1	dd MMM YYYY				EXDATE_1
⑤	EXPROD	8		1 = THS 2.2 2 = CC 4 = NRT 8 = Other tobacco product 16 = Electronic cigarette 32 = None of the above -1 = Abandoned 3 = THS 2.2 and CC 5 = THS 2.2 and NRT		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = CC and NRT 7 = THS 2.2, CC and NRT 9 = THS 2.2 and Other tobacco product 10 = CC and Other tobacco product 12 = NRT and Other tobacco product 13 = THS 2.2, NRT and Other tobacco product 14 = CC, NRT and Other tobacco product 15 = THS 2.2, CC, NRT and Other tobacco product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			17 = THS 2.2 and Electronic cigarette 18 = CC and Electronic cigarette 20 = NRT and Electronic cigarette 21 = THS 2.2, NRT and Electronic cigarette 22 = CC, NRT and Electronic cigarette 23 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette 24 = Other tobacco product and Electronic cigarette		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			25 = THS 2.2, Other tobacco product and Electronic cigarette 26 = CC, Other tobacco product and Electronic cigarette 27 = THS 2.2, CC, Other tobacco product and Electronic cigarette 28 = NRT, Other tobacco product and Electronic cigarette 29 = THS 2.2, NRT, Other tobacco product and Electronic cigarette		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			30 = CC, NRT, Other tobacco product and Electronic cigarette 31 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		EXPROD
⑥ THSNUM	8				THSNUM
⑦ CCNUM	8				CCNUM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
Ⓜ NRTPROD	8		1 = Nicotine Inhaler 2 = Nicotine Nasal Spray 4 = Nicotine Gum 8 = Nicotine Lozenge 16 = Nicotine Patch 32 = Other NRT Product -1 = Abandoned -9 = Not Applicable 3 = Nicotine Inhaler and Nicotine Nasal Spray		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Nicotine Inhaler and Nicotine Gum		
			6 = Nicotine Nasal Spray and Nicotine Gum		
			7 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Gum		
			9 = Nicotine Inhaler and Nicotine Lozenge		
			10 = Nicotine Nasal Spray and Nicotine Lozenge		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Lozenge		
			12 = Nicotine Gum and Nicotine Lozenge		
			13 = Nicotine Inhaler, Nicotine Gum and Nicotine Lozenge		
			14 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		
			17 = Nicotine Inhaler and Nicotine Patch		
			18 = Nicotine Nasal Spray and Nicotine Patch		
			19 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = Nicotine Gum and Nicotine Patch		
			21 = Nicotine Inhaler, Nicotine Gum and Nicotine Patch		
			22 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		
			23 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			24 = Nicotine Lozenge and Nicotine Patch		
			25 = Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch		
			26 = Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		
			27 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			28 = Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			29 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			30 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			31 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			33 = Nicotine Inhaler and Other NRT Product		
			34 = Nicotine Nasal Spray and Other NRT Product		
			35 = Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			36 = Nicotine Gum and Other NRT Product		
			37 = Nicotine Inhaler, Nicotine Gum and Other NRT Product		
			38 = Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		
			39 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			40 = Nicotine Lozenge and Other NRT Product		
			41 = Nicotine Inhaler, Nicotine Lozenge and Other NRT Product		
			42 = Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		
			43 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			44 = Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			45 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			46 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			47 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			48 = Nicotine Patch and Other NRT Product		
			49 = Nicotine Inhaler, Nicotine Patch and Other NRT Product		
			50 = Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			51 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Patch and Other NRT Product: 52 = Nicotine Gum,Nicotin e Patch and Other NRT Product: 53 = Nicotine Inhaler, Nicotine Gum,Nicotin e Patch and Other NRT Product:		NRTPROD

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9	INHFREQ	8				INHFREQ
10	NASPFREQ	8				NASPFREQ
11	GUMFREQ	8				GUMFREQ
12	LOZFREQ	8				LOZFREQ
13	PATFREQ	8				PATFREQ
14	OTHNRTRF EQ	8				OTHNRTRF EQ
15	OTHPROD	8		1 = Chewable/S mokeless Tobacco 2 = Cigars/Cigar illos 4 = Pipe 8 = Other Tobacco Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		
			-9 = Not Applicable		
			3 = Chewable/S mokeless Tobacco and Cigars/Cigar illos		
			5 = Chewable/S mokeless Tobacco and Pipe		
			6 = Cigars/Cigar illos and Pipe		
			7 = Chewable/S mokeless Tobacco, Cigars/Cigar illos and Pipe		
			9 = Chewable/S mokeless Tobacco and Other Tobacco Product		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Cigars/Cigar illos and Other Tobacco Product: 11 = Chewable/S mokeless Tobacco and Cigars/Cigar illos and Other Tobacco Product: 12 = Pipe and Other Tobacco Product: 13 = Chewable/S mokeless Tobacco, Pipe and Other Tobacco Product: 14 = Cigars/Cigar illos, Pipe and Other Tobacco Product:		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Product use diary(Paper)****Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Chewable/S mokeless Tobacco, Cigars/Cigar illos, Pipe and Other Tobacco Product		OTHPROD
16 TOBFREQ	8				TOBFREQ
17 CIGFREQ	8				CIGFREQ
18 PIPFREQ	8				PIPFREQ
19 TOBNFREQ	8				TOBNFREQ
20 ECNUM	8				ECNUM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU\_CCLS****Generated On: 18 Sep 2014 07:49:14**

Actual Collection Date \_\_\_\_\_ ①

Transmission Type \_\_\_\_\_ Cumulative ☐ ②  
Incremental ☐

Subject ID or Number \_\_\_\_\_ ③

Subject Sex \_\_\_\_\_ ④

Subject Date of Birth \_\_\_\_\_ ⑤

Visit Name \_\_\_\_\_ ⑥

Visit Type \_\_\_\_\_ Scheduled ☐ ⑦  
Unscheduled ☐

Accession ID \_\_\_\_\_ ⑧

Actual Collection Time \_\_\_\_\_ ⑨

Specimen Condition \_\_\_\_\_ ⑩

Battery ID \_\_\_\_\_ ⑪

Battery Name \_\_\_\_\_ ⑫

Lab Test ID \_\_\_\_\_ ⑬

Lab Test Name \_\_\_\_\_ ⑭

PROD 08.000 (MAIN) SP  
28JUL14 (640)

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU\_CCLS****Generated On: 18 Sep 2014 07:49:14**

Test ID \_\_\_\_\_ 15

Test Status \_\_\_\_\_ 16  
Done ☐  
Not Performed (Pending) ☐  
Cancelled ☐

Reported Text Result \_\_\_\_\_ 17

Reported Numeric Result \_\_\_\_\_ 18

Reference Range low \_\_\_\_\_ 19

Reference Range high \_\_\_\_\_ 20

Range Units \_\_\_\_\_ 21

Conventional Text Result \_\_\_\_\_ 22

Conventional Numeric Result \_\_\_\_\_ 23

Conventional Reference Range Low \_\_\_\_\_ 24

Conventional Reference Range High \_\_\_\_\_ 25

Conventional Units \_\_\_\_\_ 26

SI Text Result \_\_\_\_\_ 27

SI Numeric Result \_\_\_\_\_ 28

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU\_CCLS****Generated On: 18 Sep 2014 07:49:14**SI Reference Range Low  29SI Reference Range High  30SI Units  31

Reported Result Type

Coded ☐ 37

Numeric ☐

Text ☐

Greater Than (quantifiable limit) ☐

Less Than (quantifiable limit) ☐

Range ☐

Alert Flag

Low Panic ☐ 33

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐

Clinically Significant?

No ☐ 34

Yes ☐

Comment  35

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU\_CCLS****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBDT	yyyy mm dd				LBDT
②	TRMTYP	\$1		C = Cumulative I = Incremental		TRMTYP
③	SUBJID	\$20				SUBJID
④	SEX_CCLS	\$1				SEX_CCLS
⑤	BRTHDTM	yyyy mm dd				BRTHDTM
⑥	VISITNUM	\$20				VISITNUM
⑦	VISITTYP	\$1		S = Scheduled U = Unschedule d		VISITTYP
⑧	ACCSNNUM	\$20				ACCSNNUM
⑨	LBTM	HH:nn				LBTM



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Lab\_BU\_CCLS

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	SPECCND	\$200				SPECCND
11	BATTRID	\$20				BATTRID
12	BATTRNAM	\$40				BATTRNAM
13	LABTESTCD	\$20				LABTESTCD
14	LBTEST	\$100				LBTEST
15	TSTCD	\$20				TSTCD
16	TSTSTAT	\$1		D = Done N = Not Performed (Pending) X = Cancelled		TSTSTAT
17	RPTRESC	\$200				RPTRESC
18	RPTRESN	20.3				RPTRESN
19	RPTNRLO	\$40				RPTNRLO
20	RPTNRHI	\$20				RPTNRHI

PROD 08.000 (MAIN) SP  
28JUL14 (640)

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PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Lab\_BU\_CCLS

Generated On: 18 Sep 2014 07:49:14




	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21	RPTU	\$20				RPTU
22	CNVRESC	\$200				CNVRESC
23	CNVRESN	20.3				CNVRESN
24	CNVNRLO	\$40				CNVNRLO
25	CNVNRHI	\$40				CNVNRHI
26	CNVU	\$20				CNVU
27	SIRESC	\$200				SIRESC
28	SIRESN	20.3				SIRESN
29	SINRLO	\$40				SINRLO
30	SINRHI	\$40				SINRHI
31	SIU	\$20				SIU
32	RPTRTYP	\$1		C = Coded N = Numeric		



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Lab\_BU\_CCLS

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			T = Text G = Greater Than (quantifiable limit) L = Less Than (quantifiable limit) R = Range		RPTRTYP
 ALRTFL	\$2		LP = Low Panic LT = Low Telephone L = Low H = High HT = High Telephone HP = High Panic		ALRTFL
 LBCLINSIG	\$1		N = No Y = Yes		LBCLINSIG
 LBCOM	\$200				LBCOM

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU Risk markers****Generated On: 18 Sep 2014 07:49:14**

Actual Collection Date \_\_\_\_\_ ①

Transmission Type \_\_\_\_\_ Cumulative ☐ ②  
Incremental ☐

Subject ID or Number \_\_\_\_\_ ③

Subject Sex \_\_\_\_\_ ④

Subject Date of Birth \_\_\_\_\_ ⑤

Visit ID or Number \_\_\_\_\_ ⑥

Visit Type \_\_\_\_\_ Scheduled ☐ ⑦  
Unscheduled ☐

Accession ID \_\_\_\_\_ ⑧

Actual Collection Time \_\_\_\_\_ ⑨

Specimen Condition \_\_\_\_\_ ⑩

Battery ID \_\_\_\_\_ ⑪

Battery Name \_\_\_\_\_ ⑫

Lab Test ID \_\_\_\_\_ ⑬

Test ID \_\_\_\_\_ ⑭



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU Risk markers****Generated On: 18 Sep 2014 07:49:14**Lab Test Name 15Test Status 16  
Done ☐  
Not Performed (Pending) ☐  
Cancelled ☐Reported Text Result 17Reported Numeric Result 18Reference Range low 19Reference Range high 20Range Units 21Conventional Text Result 22Conventional Numeric Result 23Conventional Reference Range Low 24Conventional Reference Range High 25Conventional Units 26SI Text Result 27SI Reference Range Low 28

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU Risk markers****Generated On: 18 Sep 2014 07:49:14**SI Reference Range High  29SI Units  30

Reported Result Type

Coded ☐ 31

Numeric ☐

Text ☐

Greater Than (quantifiable limit) ☐

Less Than (quantifiable limit) ☐

Range ☐

Alert Flag

Low Panic ☐ 37

Low Telephone ☐

Low ☐

High ☐

High Telephone ☐

High Panic ☐

SI Numeric Result  38

**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

Form: Lab\_BU Risk markers

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	LBDT	yyyy mm dd				LBDT
②	TRMTYP	\$1		C = Cumulative I = Incremental		TRMTYP
③	SUBJID	\$20				SUBJID
④	SEX_CCLS	\$1				SEX_CCLS
⑤	BRTHDTM	yyyy mm dd				BRTHDTM
⑥	VISITNUM	\$20				VISITNUM
⑦	VISITTYP	\$1		S = Scheduled U = Unschedule d		VISITTYP
⑧	ACCSNNUM	\$20				ACCSNNUM
⑨	LBTM	HH:nn				LBTM



## PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Lab\_BU Risk markers

Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10	SPECCND	\$200				SPECCND
11	BATTRID	\$20				BATTRID
12	BATTRNAM	\$40				BATTRNAM
13	LABTESTCD	\$20				LABTESTCD
14	TSTCD	\$20				TSTCD
15	LBTEST	\$100				LBTEST
16	TSTSTAT	\$1		D = Done N = Not Performed (Pending) X = Cancelled		TSTSTAT
17	RPTRESC	\$200				RPTRESC
18	RPTRESN	20.3				RPTRESN
19	RPTNRLO	\$40				RPTNRLO
20	RPTNRHI	\$20				RPTNRHI



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Lab\_BU Risk markers****Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
21	RPTU	\$20				RPTU
22	CNVRESC	\$200				CNVRESC
23	CNVRESN	20.3				CNVRESN
24	CNVNRLO	\$40				CNVNRLO
25	CNVNRHI	\$40				CNVNRHI
26	CNVU	\$20				CNVU
27	SIRESC	\$200				SIRESC
28	SINRLO	\$40				SINRLO
29	SINRHI	\$40				SINRHI
30	SIU	\$20				SIU
31	RPTRTYP	\$1		C = Coded N = Numeric T = Text G = Greater Than (quantifiable limit)		

**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

Form: Lab\_BU Risk markers

Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			L = Less Than (quantifiable limit) R = Range		RPTRTYP
 ALRTFL	\$2		LP = Low Panic LT = Low Telephone L = Low H = High HT = High Telephone HP = High Panic		ALRTFL
 SIRESN	20.3				SIRESN



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Cough Assessment (Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Type Cough Assessment **1**

Date of assessment  
DD/MM/YYYY

Fixed Unit: **2**  
DD/MM/YYYY

Timepoint

Baseline (Day 0) **3**  
Day 1 ☐  
Day 2 ☐  
Day 3 ☐  
Day 4 ☐  
Day 5 ☐  
Day 6 ☐  
Day 30 ☐  
Day 60 ☐  
Day 90 ☐

Time of assessment

Fixed Unit: **4**  
hour:min 24-hour clock

Have you experienced a regular need to cough e.g.  
coughing several times in the last 24 hrs?

Yes ☐ **5**  
No ☐  
Abandoned ☐

If YES, please answer the following questions:

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

**7**



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Cough Assessment (Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

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

Very mild ☒ 8  
Mild ☐  
Moderate ☐  
Severe ☐  
Very severe ☐  
Abandoned ☐  
Not Applicable ☐

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

Rarely ☒ 9  
Sometimes ☐  
Fairly often ☐  
Often ☐  
Almost always ☐  
Abandoned ☐  
Not Applicable ☐

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

No sputum ☒ 10  
A moderate amount of sputum ☐  
A large amount of sputum ☐  
A very large amount of sputum ☐  
Abandoned ☐  
Not Applicable ☐

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

11

12





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Cough Assessment (Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Cough Assessment		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT1	\$20		DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY6 = Day 6 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT1
④	QSTIM	HH:nn				QSTIM
⑤	QS_COUGH 8 _ORRES			1 = Yes		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Cough Assessment (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = No -1 = Abandoned		QS_COUGH_ORRES
7 QS_COUGH 8_ORRES1					QS_COUGH_ORRES1
8 QS_COUGH 8_ORRES2			1 = Very mild 2 = Mild 3 = Moderate 4 = Severe 5 = Very severe -1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES2
9 QS_COUGH 8_ORRES3			1 = Rarely 2 = Sometimes 3 = Fairly often 4 = Often 5 = Almost always -1 = Abandoned -9 = Not Applicable		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Cough Assessment (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
					QS_COUGH_ORRES3
10 QS_COUGH 8_ORRES4			0 = No sputum 1 = A moderate amount of sputum 2 = A large amount of sputum 3 = A very large amount of sputum -1 = Abandoned -9 = Not Applicable		QS_COUGH_ORRES4
11 QS_COUGH \$200_ORRES5					QS_COUGH_ORRES5
12 D_F_NAME \$40_QS					D_F_NAME_QS

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper) <Unscheduled>****Generated On: 18 Sep 2014 07:49:14**Type MNWS **1**Type Behaviour Rating Scale **2**  
Self-ReportDate of assessment DD/MM/YYYY Fixed Unit: **3**  
DD/MM/YYYYTimepoint Baseline (Day 0) **4**  
Day 1  
Day 2  
Day 3  
Day 4  
Day 5  
Day 6  
Day 30  
Day 60  
Day 90Time of assessment Fixed Unit: **5**  
hour:min 24-hour clock

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



PROD 08.000 (MAIN) SP 28JUL14: Case Book

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

Generated On: 18 Sep 2014 07:49:14

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

Result

- 
- None ☒ 8
- Slight ☐
- Mild ☐
- Moderate ☐
- Severe ☐
- Abandoned ☐
- 
- 9
-



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		MNWS		QSCAT
②	QSSCAT	\$40		Behaviour Rating Scale Self-Report		QSSCAT
③	QSDAT	dd MMM YYYY				QSDAT
④	QSTPT2	\$20		DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY6 = Day 6 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT2



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 QSTIM	HH:nn				QSTIM



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)  
(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑦ QSTEST_M 2 SWS			1 = 1, Angry, irritable, frustrated		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = 2. Anxious, tense		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = 3, Depressed Mood, sad		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = 4, Desire or craving to smoke		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = 5. Difficulty concentrati ng		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = 6. Increased appetite, hungry, weight gain		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = 7. Insomnia, sleep problems, awakening at night		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = 8, Restless		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = 9, Impatient		





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = 10. Constipation		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = 11. Dizziness		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = 12. Coughing		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			13 = 13. Dreaming or nightmares		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = 14, Nausea		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)**  
**(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = 15. Sore throat		





PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)  
(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: 1. Angry, irritable, frustrated 2: 2. Anxious, tense 3: 3. Depressed Mood, sad 4: 4. Desire or craving to smoke 5: 5. Difficulty concentrating 6: 6. Increased appetite, hungry, weight gain 7: 7. Insomnia, sleep problems, awakening at night 8: 8. Restless 9: 9. Impatient 10: 10. Constipation 11: 11. Dizziness 12: 12. Coughing 13: 13. Dreaming or nightmares 14: 14. Nausea 15: 15. Sore throat	
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PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)  
(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSORRES_ 1 MSWS			1 = None 2 = Slight 3 = Mild 4 = Moderate 5 = Severe -1 = Abandoned		QSORRES_ MSWS
 D_F_NAME \$40 _QS					D_F_NAME _QS





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Type	Product Use	①
Date of completion DD/MM/YYYY		②
Timepoint	Discharge	③
	Day 30	
	Day 60	
	Day 90	
Time of completion hh:mm		④
Date the questionnaire was completed for DD/MM/YYYY		⑤



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

What tobacco/nicotine product did you use today?

- THS 2.2 ☒ 6
- CC ☐
- NRT ☐
- Other tobacco product ☐
- Electronic cigarette ☐
- None of the above ☐
- Abandoned ☐
- THS 2.2 and CC ☐
- THS 2.2 and NRT ☐
- CC and NRT ☐
- THS 2.2, CC and NRT ☐
- THS 2.2 and Other tobacco product ☐
- CC and Other tobacco product ☐
- NRT and Other tobacco product ☐
- THS 2.2, NRT and Other tobacco product ☐
- CC, NRT and Other tobacco product ☐
- THS 2.2, CC, NRT and Other tobacco product ☐
- THS 2.2 and Electronic cigarette ☐
- CC and Electronic cigarette ☐
- NRT and Electronic cigarette ☐
- THS 2.2, NRT and Electronic cigarette ☐
- CC, NRT and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐
- Other tobacco product and Electronic cigarette ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
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- THS 2.2, Other tobacco product and Electronic cigarette ☐
- CC, Other tobacco product and Electronic cigarette ☐
- THS 2.2, CC, Other tobacco product and Electronic cigarette ☐
- NRT, Other tobacco product and Electronic cigarette ☐
- THS 2.2, NRT, Other tobacco product and Electronic cigarette ☐
- CC, NRT, Other tobacco product and Electronic cigarette ☐
- THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette ☐

How many THS 2.2 tobacco sticks did you use today? \_\_\_\_\_ ⑦

How many CC/ roll-your-own did you smoke today? \_\_\_\_\_ ⑧



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
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What NRT product did you used today?

- Nicotine Inhaler ☒ 9
- Nicotine Nasal Spray ☐
- Nicotine Gum ☐
- Nicotine Lozenge ☐
- Nicotine Patch ☐
- Other NRT Product ☐
- Abandoned ☐
- Not Applicable ☐
- Nicotine Inhaler and ☐
- Nicotine Nasal Spray ☐
- Nicotine Inhaler and ☐
- Nicotine Gum ☐
- Nicotine Nasal Spray and ☐
- Nicotine Gum ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Gum ☐
- Nicotine Inhaler and ☐
- Nicotine Lozenge ☐
- Nicotine Nasal Spray and ☐
- Nicotine Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray and Nicotine ☐
- Lozenge ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Gum and Nicotine Lozenge ☐
- Nicotine Nasal Spray, ☐
- Nicotine Gum and Nicotine ☐
- Lozenge ☐
- Nicotine Inhaler, Nicotine ☐
- Nasal Spray, Nicotine Gum ☐
- and Nicotine Lozenge ☐
- Nicotine Inhaler and ☐
- Nicotine Patch ☐
- Nicotine Nasal Spray and ☐
- Nicotine Patch ☐



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Form: Product use diary(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

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



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

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



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

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

How many times did you use an inhaler today? \_\_\_\_\_ 10

How many times did you use a nasal spray today? \_\_\_\_\_ 11

How many gums did you use today? \_\_\_\_\_ 12

How many lozenges did you use today? \_\_\_\_\_ 13

How many patches did you use today? \_\_\_\_\_ 14

How many times did you use other NRT products today  
not listed previously? \_\_\_\_\_ 15





PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

What other tobacco product did you used today?

- Chewable/Smokeless Tobacco ☒ 16
- Cigars/Cigarillos ☐
- Pipe ☐
- Other Tobacco Product ☐
- Abandoned ☐
- Not Applicable ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos ☐
- Chewable/Smokeless Tobacco and Pipe ☐
- Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos and Pipe ☐
- Chewable/Smokeless Tobacco and Other Tobacco Product ☐
- Cigars/Cigarillos and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco and Cigars/Cigarillos and Other Tobacco Product ☐
- Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Pipe and Other Tobacco Product ☐
- Cigars/Cigarillos, Pipe and Other Tobacco Product ☐
- Chewable/Smokeless Tobacco, Cigars/Cigarillos, Pipe and Other Tobacco Product ☐

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

17





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
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How many cigars/cigarillos did you smoke today? \_\_\_\_\_ 18

How many times did you smoke a pipe today? \_\_\_\_\_ 19

How many times did you use a tobacco product today  
not listed previously? \_\_\_\_\_ 20

How many times did you use an electronic cigarette  
today? \_\_\_\_\_ 21

\_\_\_\_\_ 22



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Product Use		QSCAT
②	EXDATE	dd MMM YYYY				EXDATE
③	QSTPT3	\$20		DISCHARGE = Discharge DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT3
④	EXTIME	HH:nn				EXTIME
⑤	EXDATE_1	dd MMM YYYY				EXDATE_1
⑥	EXPROD	8		1 = THS 2.2 2 = CC 4 = NRT 8 = Other tobacco product		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			16 = Electronic cigarette 32 = None of the above -1 = Abandoned 3 = THS 2.2 and CC 5 = THS 2.2 and NRT 6 = CC and NRT 7 = THS 2.2, CC and NRT 9 = THS 2.2 and Other tobacco product 10 = CC and Other tobacco product 12 = NRT and Other tobacco product 13 = THS 2.2, NRT and Other tobacco product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			14 = CC, NRT and Other tobacco product 15 = THS 2.2, CC, NRT and Other tobacco product 17 = THS 2.2 and Electronic cigarette 18 = CC and Electronic cigarette 20 = NRT and Electronic cigarette 21 = THS 2.2, NRT and Electronic cigarette 22 = CC, NRT and Electronic cigarette		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			23 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette 24 = Other tobacco product and Electronic cigarette 25 = THS 2.2, Other tobacco product and Electronic cigarette 26 = CC, Other tobacco product and Electronic cigarette 27 = THS 2.2, CC, Other tobacco product and Electronic cigarette 28 = NRT, Other tobacco product and Electronic cigarette		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			29 = THS 2.2, NRT, Other tobacco product and Electronic cigarette 30 = CC, NRT, Other tobacco product and Electronic cigarette 31 = THS 2.2, CC, NRT, Other tobacco product and Electronic cigarette		EXPROD
7 THSNUM	8				THSNUM
8 CCNUM	8				CCNUM



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
9 NRTPROD	8		1 = Nicotine Inhaler 2 = Nicotine Nasal Spray 4 = Nicotine Gum 8 = Nicotine Lozenge 16 = Nicotine Patch 32 = Other NRT Product -1 = Abandoned -9 = Not Applicable 3 = Nicotine Inhaler and Nicotine Nasal Spray		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Nicotine Inhaler and Nicotine Gum		
			6 = Nicotine Nasal Spray and Nicotine Gum		
			7 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Gum		
			9 = Nicotine Inhaler and Nicotine Lozenge		
			10 = Nicotine Nasal Spray and Nicotine Lozenge		





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**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Lozenge		
			12 = Nicotine Gum and Nicotine Lozenge		
			13 = Nicotine Inhaler, Nicotine Gum and Nicotine Lozenge		
			14 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Lozenge		
			17 = Nicotine Inhaler and Nicotine Patch		
			18 = Nicotine Nasal Spray and Nicotine Patch		
			19 = Nicotine Inhaler, Nicotine Nasal Spray and Nicotine Patch		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			20 = Nicotine Gum and Nicotine Patch		
			21 = Nicotine Inhaler, Nicotine Gum and Nicotine Patch		
			22 = Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		
			23 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Nicotine Patch		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			24 = Nicotine Lozenge and Nicotine Patch		
			25 = Nicotine Inhaler, Nicotine Lozenge and Nicotine Patch		
			26 = Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		
			27 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Nicotine Patch		

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			28 = Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			29 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			30 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
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Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			31 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Nicotine Patch		
			33 = Nicotine Inhaler and Other NRT Product		
			34 = Nicotine Nasal Spray and Other NRT Product		
			35 = Nicotine Inhaler, Nicotine Nasal Spray and Other NRT Product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			36 = Nicotine Gum and Other NRT Product		
			37 = Nicotine Inhaler, Nicotine Gum and Other NRT Product		
			38 = Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		
			39 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum and Other NRT Product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			40 = Nicotine Lozenge and Other NRT Product		
			41 = Nicotine Inhaler, Nicotine Lozenge and Other NRT Product		
			42 = Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		
			43 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Lozenge and Other NRT Product		

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			44 = Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			45 = Nicotine Inhaler, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			46 = Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			47 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Gum, Nicotine Lozenge and Other NRT Product		
			48 = Nicotine Patch and Other NRT Product		
			49 = Nicotine Inhaler, Nicotine Patch and Other NRT Product		
			50 = Nicotine Nasal Spray, Nicotine Patch and Other NRT Product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			51 = Nicotine Inhaler, Nicotine Nasal Spray, Nicotine Patch and Other NRT Product: 52 = Nicotine Gum,Nicotin e Patch and Other NRT Product: 53 = Nicotine Inhaler, Nicotine Gum,Nicotin e Patch and Other NRT Product:		NRTPROD



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Product use diary(Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
10 INHFREQ	8				INHFREQ
11 NASPFREQ	8				NASPFREQ
12 GUMFREQ	8				GUMFREQ
13 LOZFREQ	8				LOZFREQ
14 PATFREQ	8				PATFREQ
15 OTHNRTFR EQ	8				OTHNRTFR EQ
16 OTHPROD	8		1 = Chewable/S mokeless Tobacco 2 = Cigars/Cigar illos 4 = Pipe 8 = Other Tobacco Product		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			-1 = Abandoned		
			-9 = Not Applicable		
			3 = Chewable/S mokeless Tobacco and Cigars/Cigar illos		
			5 = Chewable/S mokeless Tobacco and Pipe		
			6 = Cigars/Cigar illos and Pipe		
			7 = Chewable/S mokeless Tobacco, Cigars/Cigar illos and Pipe		
			9 = Chewable/S mokeless Tobacco and Other Tobacco Product		

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**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Cigars/Cigar illos and Other Tobacco Product: 11 = Chewable/S mokeless Tobacco and Cigars/Cigar illos and Other Tobacco Product: 12 = Pipe and Other Tobacco Product: 13 = Chewable/S mokeless Tobacco, Pipe and Other Tobacco Product: 14 = Cigars/Cigar illos, Pipe and Other Tobacco Product:		



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Product use diary(Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			15 = Chewable/S mokeless Tobacco, Cigars/Cigar illos, Pipe and Other Tobacco Product		OTHPROD
17 TOBFREQ	8				TOBFREQ
18 CIGFREQ	8				CIGFREQ
19 PIPFREQ	8				PIPFREQ
20 TOBNFREQ	8				TOBNFREQ
21 ECNUM	8				ECNUM
22 D_F_NAME_QS	\$40				D_F_NAME_QS

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 18 Sep 2014 07:49:14**

Type Questionnaire on smoking urges **1**

Date of assessment **2**

DD/MMM/YYYY

Timepoint Baseline (Day -1) **3**

Baseline (Day 0) ☐

Day 1 ☐

Day 2 ☐

Day 3 ☐

Day 4 ☐

Day 5 ☐

Day 30 ☐

Day 60 ☐

Day 90 ☐

Time of assessment **4**

hour:min 24-hour clock

1. I have a desire for a cigarette right now Strongly disagree **5**

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>****Generated On: 18 Sep 2014 07:49:14**

---

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

Strongly disagree ☒ 6

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

3. If it were possible I would probably smoke now

Strongly disagree ☒ 7

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

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

Strongly disagree ☒ 8

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---



---

**PROD 08.000 (MAIN) SP 28JUL14: Case Book**

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

**Generated On: 18 Sep 2014 07:49:14**

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5. All I want right now is a cigarette

Strongly disagree ☐ 9

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

6. I have an urge for a cigarette

Strongly disagree ☐ 10

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

---

7. A cigarette would taste good now

Strongly disagree ☐ 11

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐



PROD 08.000 (MAIN) SP 28JUL14: Case Book

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

Generated On: 18 Sep 2014 07:49:14

8. I would do almost anything for a cigarette now

Strongly disagree ☐ 17

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

9. Smoking would make me less depressed

Strongly disagree ☐ 13

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

10. I am going to smoke as soon as possible

Strongly disagree ☐ 14

Disagree ☐

Somewhat disagree ☐

Do not agree or disagree ☐

Somewhat agree ☐

Agree ☐

Strongly agree ☐

Abandoned ☐

15



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Questionnaire on smoking urges		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT4	\$20		BASELINE = Baseline (Day -1) DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT4
④	QSTIM	HH:nn				QSTIM



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 QSORRES_ 8 1			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 1
6 QSORRES_ 8 2			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 2
⑦ QSORRES_ 8 3			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 3



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
8 QSORRES_ 8 4			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 4
9 QSORRES_ 8 5			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 5
10 QSORRES_ 8 6			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 6






PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
QSORRES_ 8 7			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 7
QSORRES_ 8 8			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree		





PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 8
 QSORRES_ 9			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 9



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Questionnaire on smoking urges (QSU) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 QSORRES_ 8 10			1 = Strongly disagree 2 = Disagree 3 = Somewhat disagree 4 = Do not agree or disagree 5 = Somewhat agree 6 = Agree 7 = Strongly agree -1 = Abandoned		QSORRES_ 10
 D_F_NAME \$40 _QS					D_F_NAME _QS



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**  
**Generated on: 28 Sep 2014 07:49:14**

Type Modifier Cigarette Evaluation Questionnaire ①

Date of assessment Fixed Unit: ②  
DD/MMM/YYYY DD/MMM/YYYY

Timepoint Baseline (Day -1) ③  
Baseline (Day 0)  
Day 1  
Day 2  
Day 3  
Day 4  
Day 5  
Day 30  
Day 60  
Day 90

Time of assessment Fixed Unit: ④  
hour:min 24-hour clock



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on: 28 Jul 2014 07:49:14

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

- Was smoking satisfying? ☒ 5
- Did cigarettes taste good? ☐
- Did you enjoy the sensation in your throat and chest? ☐
- Did smoking calm you down? ☐
- Did smoking make you feel more awake? ☐
- Did smoking make you feel less irritable? ☐
- Did smoking help you concentrate? ☐
- Did smoking reduce your hunger for food? ☐
- Did smoking make you dizzy? ☐
- Did smoking make you nauseous? ☐
- Did smoking immediately relieve your craving for a cigarette? ☐
- Did you enjoy smoking? ☐

Response

- Not at all ☒ 6
- Very little ☐
- Little ☐
- Moderately ☐
- A lot ☐
- Quite a lot ☐
- Extremely ☐
- Abandoned ☐

**PROD 08.000 (MAIN) SP 28JUL14: Case Book****Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)**

Generated on 28 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		Modifier Cigarette Evaluation Questionnaire		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT5	\$20		BASELINE = Baseline (Day -1) DAY0 = Baseline (Day 0) DAY1 = Day 1 DAY2 = Day 2 DAY3 = Day 3 DAY4 = Day 4 DAY5 = Day 5 DAY30 = Day 30 DAY60 = Day 60 DAY90 = Day 90		QSTPT5
④	QSTIM	HH:nn				QSTIM



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
5 QSTEST	\$200		1 = Was smoking satisfying?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Did cigarettes taste good?		





PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			3 = Did you enjoy the sensation in your throat and chest?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
(Generated on 18 Sep 2014 07:49:14)

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			4 = Did smoking calm you down?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			5 = Did smoking make you feel more awake?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
(Generated on 28 Sep 2014 07:49:14)

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			6 = Did smoking make you feel less irritable?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			7 = Did smoking help you concentrate?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			8 = Did smoking reduce your hunger for food?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			9 = Did smoking make you dizzy?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			10 = Did smoking make you nauseous?		





PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			11 = Did smoking immediately relieve your craving for a cigarette?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
(Generated on 28 Sep 2014 07:49:14)

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			12 = Did you enjoy smoking?		



PROD 08.000 (MAIN) SP 28JUL14: Case Book

Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)

Generated on 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
				1: Was smoking satisfying? 2: Did cigarettes taste good? 3: Did you enjoy the sensation in your throat and chest? 4: Did smoking calm you down? 5: Did smoking make you feel more awake? 6: Did smoking make you feel less irritable? 7: Did smoking help you concentrate? 8: Did smoking reduce your hunger for food? 9: Did smoking make you dizzy? 10: Did smoking make you nauseous? 11: Did smoking immediately relieve your craving for a cigarette?	QSTEST
PROD 08.000 (MAIN) SP 28JUL14 (640)					650 of 656



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: Modifier Cigarette Evaluation Questionnaire (mCEQ)  
Generated on 28 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
⑥ QSORRES	1		1 = Not at all 2 = Very little 3 = Little 4 = Moderately 5 = A lot 6 = Quite a lot 7 = Extremely -1 = Abandoned		QSORRES
⑦ D_F_NAME_QS	\$40				D_F_NAME_QS



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Type FTND **1**

Date of assessment Fixed Unit: **2**  
DD/MMM/YYYY DD/MMM/YYYY

Timepoint Screening **3**  
Day 90

Time of assessment Fixed Unit: **4**  
hour:min 24-hour clock

1. How soon after you wake up do you smoke your first cigarette? 31-60 minutes **5**  
6-30 minutes  
Within 5 minutes  
Abandoned  
After 60 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden? Yes **6**  
No  
Abandoned

3. Which cigarette would you hate most to give up? The first in the morning **7**  
Any other  
Abandoned



**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

4. How many cigarettes per day do you smoke? 10 or less ☒ 8  
11-20 ☐  
21-30 ☐  
31 or more ☐  
Abandoned ☐

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day? Yes ☒ 9  
No ☐  
Abandoned ☐

6. Do you smoke even if you are so ill that you are in bed most of the day? Yes ☒ 10  
No ☐  
Abandoned ☐

11



PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	QSCAT	\$40		FTND		QSCAT
②	QSDAT	dd MMM YYYY				QSDAT
③	QSTPT6	\$20		SCREEN = Screening DAY90 = Day 90		QSTPT6
④	QSTIM	HH:nn				QSTIM
⑤	QS_FTND_ ORRES_1	8		1 = 31-60 minutes 2 = 6-30 minutes 3 = Within 5 minutes -1 = Abandoned 0 = After 60 minutes		QS_FTND_ ORRES_1
⑥	QS_FTND_ ORRES_2	8		1 = Yes 2 = No -1 = Abandoned		QS_FTND_ ORRES_2




PROD 08.000 (MAIN) SP 28JUL14: Case Book  
Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>  
Generated On: 18 Sep 2014 07:49:14

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
7 QS_FTND_ 8 ORRES_3			1 = The first in the morning 0 = Any other -1 = Abandoned		QS_FTND_ ORRES_3
8 QS_FTND_ 8 ORRES_4			0 = 10 or less 1 = 11-20 2 = 21-30 3 = 31 or more -1 = Abandoned		QS_FTND_ ORRES_4
9 QS_FTND_ 8 ORRES_5			1 = Yes 2 = No -1 = Abandoned		QS_FTND_ ORRES_5
10 QS_FTND_ 8 ORRES_6			1 = Yes 2 = No -1 = Abandoned		QS_FTND_ ORRES_6





**PROD 08.000 (MAIN) SP 28JUL14: Case Book**  
**Form: FTND Questionnaire (FTND) (Paper)<Unscheduled>**  
**Generated On: 18 Sep 2014 07:49:14**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 D_F_NAME_QS	\$40				D_F_NAME_QS



Subject Case Report Forms

PROD 04.000 (SITE) SP 28JUL14 - Case Book

Signature Prompt: I hereby confirm that all data is accurate to the best of my knowledge.



**PROD 04.000 (SITE) SP 28JUL14: Case Book**


**Form: Subject (Site level)**

**Generated On: 18 Sep 2014 07:47:55**

Subject (site level)



**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Subject (Site level)****Generated On: 18 Sep 2014 07:47:55**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
 SUBJ_DUM MY	\$4				SUBJ_DUM MY

**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:47:55**

Cohort	<input type="text"/>	①
Subject	<input type="text"/>	②
Assessment	<input type="text"/>	③
Visit	<div>Screen Failure <input type="checkbox"/></div> <div>Screening <input type="checkbox"/></div> <div>Admission (Day -2) <input type="checkbox"/></div> <div>Baseline (Day -1) <input type="checkbox"/></div> <div>Baseline (Day 0) <input type="checkbox"/></div> <div>Day 1 <input type="checkbox"/></div> <div>Day 2 <input type="checkbox"/></div> <div>Day 3 <input type="checkbox"/></div> <div>Day 4 <input type="checkbox"/></div> <div>Day 5 <input type="checkbox"/></div> <div>Day 6 <input type="checkbox"/></div> <div>Discharge <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>	④
Other, Specify	<input type="text"/>	⑤
Timepoint	<input type="text"/>	⑥
Description of Deviation	<input type="text"/>	⑦
Date Deviation Occurred	<input type="text"/>	⑧
DD/MM/YYYY	<input type="text"/>	

**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:47:55**Date Deviation Reported 9

DD/MMM/YYYY

Date Deviation Ended 10

DD/MMM/YYYY

Resolution of the Deviation 11

Source of the Deviation

CRA 12Site personnel ☐Sponsor ☐CRO ☐Labs ☐IXRS ☐ePRO ☐Deviation Category 13Violation ☐Mis-randomization ☐Mis-use of product ☐Concomitant medication ☐Time deviation ☐Time missing ☐Assessment missing ☐Deviation Type 14Major ☐Minor ☐If Major, Evaluation Category 15Evaluable ☐Non Evaluable ☐

**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:47:55**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	COHORT	\$200				COHORT
②	SUBJ	\$4				SUBJ
③	ASSESS	\$200				ASSESS
④	PDVIS	2		1 = Screen Failure 2 = Screening 3 = Admission (Day -2) 4 = Baseline (Day -1) 5 = Baseline (Day 0) 6 = Day 1 7 = Day 2 8 = Day 3 9 = Day 4 10 = Day 5 11 = Day 6 12 = Discharge 13 = Other		PDVIS
⑤	PDVISSPEC	\$200				PDVISSPEC

**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:47:55**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
6	PDTPT	\$200				PDTPT
7	PDDESC	\$200				PDDESC
8	PDSTDT	dd MMM YYYY				PDSTDT
9	PDRPDT	dd MMM YYYY				PDRPDT
10	PDENDT	dd MMM YYYY				PDENDT
11	PDRES	\$200				PDRES
12	PDSOR	\$200		1 = CRA 2 = Site personnel 3 = Sponsor 4 = CRO 5 = Labs 6 = IXRS 7 = ePRO		PDSOR
13	PDCAT	2		1 = Violation		



**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Deviation Form****Generated On: 18 Sep 2014 07:47:55**

Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
			2 = Mis-random ization 3 = Mis-use of product 4 = Concomitan t medication 5 = Time deviation 6 = Time missing 7 = Assessment missing		PDCAT
12 PDTyp	2		1 = Major 2 = Minor		PDTyp
13 PDEVAL	2		1 = Evaluable 2 = Non Evaluable		PDEVAL

**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Site Accountability****Generated On: 18 Sep 2014 07:47:55**

Date of batch dispensed	_____	①
Batch number	_____	②
Category	Received <input type="checkbox"/> ③ Returned <input type="checkbox"/>	
Batch Expiration Date (only for received event) DD/MMM/YYYY	_____	④
Number of packs received	_____	⑤
Number of unused packs returned	_____	⑥
Number of unused sticks returned	_____	⑦

**PROD 04.000 (SITE) SP 28JUL14: Case Book****Form: Site Accountability****Generated On: 18 Sep 2014 07:47:55**

	Field Name	Data Type	Units	Values	Pre-Filled Values	Include Field OID
①	ACCDAT	dd MMM YYYY				ACCDAT
②	BATCHNO	\$10				BATCHNO
③	ACC_CAT	1		1 = Received 2 = Returned		ACC_CAT
④	BATCHDAT	dd MMM YYYY				BATCHDAT
⑤	PACREC	4				PACREC
⑥	ACCPACK	4				ACCPACK
⑦	ACCSTICK	6				ACCSTICK



16.1.2.2 Subject Questionnaire English

16.1.2.2.1 Socio-Economic Questionnaire



## SES Questionnaire Japan-English version

Q1. In total, including yourself, how many people live in your household? PLEASE TYPE IN NUMBER NEXT TO EACH ITEM BELOW	
1	<input type="checkbox"/> total number of people living in the household <input type="text"/>
2	<input type="checkbox"/> prefer not to say
Q2. What is the highest level of education you have attained or are currently attending? PLEASE SELECT ONE ANSWER ONLY	
1	<input type="checkbox"/> Elementary school / Junior high school
2	<input type="checkbox"/> Senior high school
3	<input type="checkbox"/> College
4	<input type="checkbox"/> University / Postgraduate
5	<input type="checkbox"/> Prefer not to say
Q3. How many income earners are in your household?	
1	<input type="checkbox"/> None – all are unemployed
2	<input type="checkbox"/> Just one income earner
3	<input type="checkbox"/> Two or more income earners
<Those who have one or more income earners>	
Q4. What is your occupation? PLEASE SELECT ONE ANSWER ONLY	
1	<input type="checkbox"/> General white collar
2	<input type="checkbox"/> Professional/ technical worker
3	<input type="checkbox"/> General blue collar
4	<input type="checkbox"/> Working in service industry
5	<input type="checkbox"/> Manager (kacho or above)
6	<input type="checkbox"/> Director/president (30 employees or more)
7	<input type="checkbox"/> Proprietor (29 employees or less)
8	<input type="checkbox"/> Professional/technical worker (Lawyer, Accountant, Professor etc)
9	<input type="checkbox"/> Farming/forestry/fishing
10	<input type="checkbox"/> Shop keeper
11	<input type="checkbox"/> Part-time worker (More than one day per week)
12	<input type="checkbox"/> Student
13	<input type="checkbox"/> Housewife (Including part-time less than one day per week)
14	<input type="checkbox"/> Unemployed
15	<input type="checkbox"/> Others



<Those who have one or more income earners>

Q5a. What is your approximate MONTHLY household income from all sources before tax? PLEASE SELECT ONE ANSWER ONLY

- 1 ☐ Below 100,000 yen
- 2 ☐ 100,000 yen – 199,999 yen
- 3 ☐ 200,000 yen – 299,999 yen
- 4 ☐ 300,000 yen – 399,999 yen
- 5 ☐ 400,000 yen – 499,999 yen
- 6 ☐ 500,000 yen – 599,999 yen
- 7 ☐ 600,000 yen – 699,999 yen
- 8 ☐ 700,000 yen – 799,999 yen
- 9 ☐ 800,000 yen – 899,999 yen
- 10 ☐ 900,000 yen – 999,999 yen
- 11 ☐ 1,000,000 yen or above
- 12 ☐ Don't know
- 13 ☐ Prefer not to say

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

[ASK IF CODES 12 or 13 SELECTED AT Q5a]

Q5b. Would your MONTHLY household income be over or under 800,000 yen? PLEASE SELECT ONE ANSWER ONLY

- 1 ☐ Under 800,000yen
- 2 ☐ 800,000yen or more
- 3 ☐ Don't know
- 4 ☐ Prefer not to say



#### 16.1.2.2.2 Cough Assessment – Visual Analogue Scale Questionnaire



Cough assessment

Have you experienced a regular need to cough e.g. coughing several times in the last 24 hrs?

YES / NO

If YES, please answer the following questions:

First Question: Cough Impact Scale

How much is your cough bothering you?

VAS: Not Bothering Me at All -----Extremely Bothersome

Second Question: Cough Intensity Scale:

How intense is your cough?

1 = very mild - 2 = mild - 3 = moderate - 4 = severe - 5 = very severe

Third Question: Cough Frequency Scale:

How frequently do you normally have to cough each day?

1 = rarely - 2 = sometimes - 3 = fairly often - 4 = often - 5 = almost always

Fourth Question: Sputum Production

To what extent do you produce sputum when coughing?

0 = no sputum - 1 = a moderate amount of sputum - 2 = a large amount of sputum - 3 = a very large amount of sputum

Fifth Question:

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





#### 16.1.2.2.3 Fagerström-Nicotine-Dependence-Test

**Fagerstrom Test for Nicotine Dependence \***

1. How soon after you wake up do you smoke your first cigarette?
  - Within 5 minutes (3)
  - 6-30 minutes (2)
  - 31-60 minutes (1)
  - After 60 minutes (0)
2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g. in church, at the library, cinema, etc.?
  - Yes (1)
  - No (0)
3. Which cigarette would you hate most to give up?
  - The first one in the morning (1)
  - All others (0)
4. How many cigarettes/day do you smoke?
  - 10 or less (0)
  - 11-20 (1)
  - 21-30 (2)
  - 31 or more (3)
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?
  - Yes (1)
  - No (0)
6. Do you smoke if you are so ill that you are in bed most of the day?
  - Yes (1)
  - No (0)

\* Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. British Journal of Addictions 1991;86:1119-27



#### 16.1.2.2.4 Modified Cigarette Evaluation Questionnaire





Modified Cigarette Evaluation Questionnaire						
5. Did smoking make you feel more awake?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Did smoking make you feel less irritable?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Did smoking help you concentrate?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Did smoking reduce your hunger for food?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Did smoking make you dizzy?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Did smoking make you nauseous?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Modified Cigarette Evaluation Questionnaire						
11. Did smoking immediately relieve your craving for a cigarette?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Did you enjoy smoking?						
Not at all	Very little	Little	Moderately	A lot	Quite a lot	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



#### 16.1.2.2.5 Questionnaire on Smoking Urges



Questionnaire on smoking urges (QSU)						
<div>Date and time of assessment (24-hour clock)<div><div><div></div><div></div></div><div>/</div><div><div></div><div></div></div><div>/</div><div><div></div><div></div><div></div><div></div></div><div>/</div><div><div></div><div></div><div></div><div></div><div></div><div></div></div></div><div><div></div><div></div></div><div>:</div><div><div></div><div></div></div><div>hour</div><div>min</div></div> <div><input type="checkbox"/> Tick if same as visit date</div>						
1. I have a desire for a cigarette right now						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Nothing would be better than smoking a cigarette right now						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. If it were possible I would probably smoke now						
Strongly disagree						Strongly agree
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>





Questionnaire on smoking urges (QSU)						
4. I could control things better right now if I could smoke						
<b>Strongly disagree</b>						<b>Strongly agree</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. All I want right now is a cigarette						
<b>Strongly disagree</b>						<b>Strongly agree</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I have an urge for a cigarette						
<b>Strongly disagree</b>						<b>Strongly agree</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. A cigarette would taste good now						
<b>Strongly disagree</b>						<b>Strongly agree</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I would do almost anything for a cigarette now						
<b>Strongly disagree</b>						<b>Strongly agree</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Questionnaire on smoking urges (QSU)						
9. Smoking would make me less depressed						
<b>Strongly disagree</b>						<b>Strongly agree</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I am going to smoke as soon as possible						
<b>Strongly disagree</b>						<b>Strongly agree</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



#### 16.1.2.2.6 Human Smoking Topography Questionnaire



How do you agree with the following sentences/affirmations :

1. The smoking of the conventional cigarettes/products is different with the device.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

If you agree or strongly agree, please describe :

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

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

If you disagree or strongly disagree, please describe :

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

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

If you agree or strongly agree, please describe :

4. The device is easy to use.

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

If you disagree or strongly disagree, please describe :

5. Your smoking is disturbed by the device

- ☐ Strongly agree
- ☐ Agree
- ☐ Neither agree nor disagree
- ☐ Disagree
- ☐ Strongly disagree

If you agree or strongly agree, please describe :



#### 16.1.2.2.7 Minnesota Nicotine Withdrawal Scale Questionnaire



CRF Id : QS.QS.003\_01

[Study identifier] [Site Identifier] [Unique Subject Identifier]

<b>&lt;VISIT&gt;</b>					
<b>Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)</b>					
<b>Behavior Rating Scale Self-Report</b>					
Date and time of assessment (24-hour clock) <input type="checkbox"/> Tick if same as visit date					
<div><div><div><div></div><div></div></div><div>D D</div></div><div>/</div><div><div><div></div><div></div><div></div><div></div></div><div>M M M</div></div><div>/</div><div><div><div></div><div></div><div></div><div></div><div></div><div></div></div><div>Y Y Y Y Y</div></div></div> <div><div><div></div><div></div></div><div>hour</div></div> <div>:</div> <div><div><div></div><div></div></div><div>min</div></div>					



CRF Id : QS.QS.003\_01

[Study identifier] [Site Identifier] [Unique Subject Identifier]

<VISIT>					
Minnesota Nicotine Dependence/Withdrawal Scale (MNWS)					
Behavior Rating Scale Self-Report					
12. Coughing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Dreaming or nightmares	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Nausea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Sore throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart Rate	_____				bpm
Weight	_____				Kg



### 16.1.2.3 Subject Questionnaire Local Language

#### 16.1.2.3.1 Socio-Economic Questionnaire





## SES Questionnaire Japan- Japanese version

Q1. ご自身も含めて、世帯と一緒に暮らす人の数は何人ですか。（以下の各項目の隣に半角数字で）	
1 <input type="checkbox"/>	自分の世帯と一緒に暮らす人の数 <input type="text"/>
2 <input type="checkbox"/>	回答を控える
Q2. これまでに取得した、あるいは現在取得中の最高学歴をお答えください。回答は一つだけ選択してください。（ひとつだけ）	
1 <input type="checkbox"/>	小学校/中学校
2 <input type="checkbox"/>	高校/旧制中学校
3 <input type="checkbox"/>	短大/高等専門学校
4 <input type="checkbox"/>	大学/大学院
5 <input type="checkbox"/>	回答を控える
Q3. あなたの世帯には所得を得ている方が何人いますか	
1 <input type="checkbox"/>	いない－全員無職
2 <input type="checkbox"/>	所得者一人
3 <input type="checkbox"/>	所得者二人以上
Q4. あなたの職業をお知らせ下さい。回答は一つだけ選択してください。（ひとつだけ）	
1 <input type="checkbox"/>	営業職・事務職・教師
2 <input type="checkbox"/>	専門職・技術職
3 <input type="checkbox"/>	労務職・販売職
4 <input type="checkbox"/>	サービス職
5 <input type="checkbox"/>	課長以上の管理職
6 <input type="checkbox"/>	会社役員・取締役（従業員30人以上）
7 <input type="checkbox"/>	商工自営（従業員29人以下）
8 <input type="checkbox"/>	高度な専門的職業（弁護士／会計士／大学教授など）
9 <input type="checkbox"/>	農林漁業
10 <input type="checkbox"/>	商店勤務・家族従業者
11 <input type="checkbox"/>	パート・アルバイト（週に一日以上）
12 <input type="checkbox"/>	学生
13 <input type="checkbox"/>	専業主婦（週に1日未満のパートも含む）
14 <input type="checkbox"/>	無職
15 <input type="checkbox"/>	その他



＜世帯に所得者がいる方＞

Q5a. あなたの世帯の総月間所得は、税引き前でおおよそどれくらいですか？回答は一つだけ選択してください。（ひとつだけ）

- 1 ☐ 100,000 円未満
- 2 ☐ 100,000 円 から 199,999 円
- 3 ☐ 200,000 円 から 299,999 円
- 4 ☐ 300,000 円 から 399,999 円
- 5 ☐ 400,000 円 から 499,999 円
- 6 ☐ 500,000 円 から 599,999 円
- 7 ☐ 600,000 円 から 699,999 円
- 8 ☐ 700,000 円 から 799,999 円
- 9 ☐ 800,000 円 から 899,999 円
- 10 ☐ 900,000 円 から 999,999 円
- 11 ☐ 1,000,000 円以上
- 12 ☐ わからない
- 13 ☐ 回答を控える

＜世帯に所得者がいる方＞

[Q5aで12、13が挙げった場合聞く]

Q5b. あなたの世帯総月間所得は、80万円以上ですか、未満ですか？ 回答は一つだけ選択してください。（ひとつだけ）

- 1 ☐ 80万円未満
- 2 ☐ 80万円以上
- 3 ☐ わからない
- 4 ☐ 回答を控える



#### 16.1.2.3.2 Cough Assessment – Visual Analogue Scale



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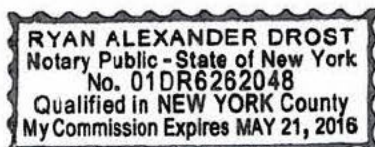
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Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

Signature, Notary Public



Stamp, Notary Public



咳の評価

過去 24 時間に、日常的に(例えば、数回)咳をしましたか？

はい／いいえ

「はい」の場合、以下の質問にお答えください：

第 1 問：咳の影響のスケール

あなたは咳によってどのくらい悩まされていますか？

VAS(視覚的アナログ尺度)：全く悩まされていない-----非常に悩まされている

第 2 問：咳の激しさのスケール：

あなたの咳はどのくらい激しいですか？

1 = 非常に軽い    2 = 軽い    3 = 中程度    4 = 激しい    5 = 非常に激しい

第 3 問：咳の頻度のスケール：

あなたは毎日通常どのくらいの頻度で咳をしますか？

1 = まれ    2 = 時々    3 = やや頻繁に    4 = 頻繁に    5 = ほとんど常に

第 4 問：痰の分泌

咳をする時に、どのくらい痰が出ますか？

0 = 痰は出ない    1 = 中程度の量の痰    2 = 大量の痰    3 = 非常に大量の痰

第 5 問：

あなたの咳について他に気が付いたことがあれば書いてください。(自由回答式の質問)




#### 16.1.2.3.3 Fagerström-Nicotine-Dependence-Test




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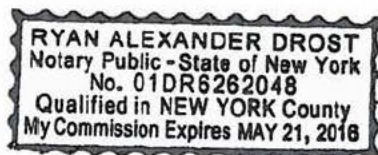
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Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

  
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**ファガストローム ニコチン依存度テスト\***

喫煙は「ただの習慣」ですか、それともあなたは中毒になっていますか？このテストを受けて、あなたのニコチン依存のレベルを知ってください。

1. 起床後何分で最初の喫煙をしますか？
  - ◆ 61分以降 (0)
  - ◆ 31～60分 (1)
  - ◆ 6～30分 (2)
  - ◆ 5分以内 (3)
2. 喫煙が禁じられている場所でタバコを吸わないでいることがつらいと感じますか？
  - ◆ いいえ (0)
  - ◆ はい (1)
3. 喫煙の中でどれが一番やめにくいですか？
  - ◆ 朝の最初の1本 (1)
  - ◆ それ以外 (0)
4. あなたは1日に何本タバコを吸いますか？
  - ◆ 10本以下 (0)
  - ◆ 11～20本 (1)
  - ◆ 21～30本 (2)
  - ◆ 31本以上 (3)
5. 他の時間帯より起床後数時間内に多く喫煙しますか？
  - ◆ いいえ (0)
  - ◆ はい (1)
6. ほとんど1日中寝込んでいるような病気の時でも喫煙しますか？
  - ◆ いいえ (0)
  - ◆ はい (1)

\* Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. British Journal of Addictions 1991;86:1119-27



**ファガストローム ニコチン依存度テスト (続き)**

あなたのスコア: \_\_\_\_\_

あなたのニコチン依存度:

0～2 非常に低い依存度	6～7 高い依存度
3～4 低い依存度	8～10 非常に高い依存度
5 中程度の依存度	

5点未満のスコア:「あなたのニコチン依存度はまだ低レベルです。依存度が高くなる前に今すぐ適切な処置を行うべきです。」

5点のスコア:「あなたのニコチン依存度は中レベルです。すぐに止めないとニコチン依存度が高くなり、ひどい中毒症状を起こします。今すぐ適切な処置を行い、ニコチン依存を断ってください。」

7点を超えるスコア:「あなたのニコチン依存度は高レベルです。あなたは喫煙をコントロールできていません。喫煙があなたをコントロールしているのです！ やめることを決心したら、中毒を克服するのを手助けするニコチン置換療法または他の薬について医師に相談することをお勧めします。」



#### 16.1.2.3.4 Modified Cigarette Evaluation Questionnaire



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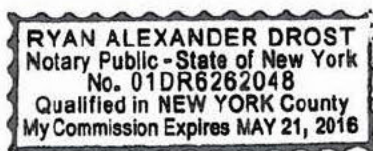
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Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

Signature, Notary Public



Stamp, Notary Public



## 改訂版タバコ評価質問票(mCEQ)

評価の日時  
(24 時間制) /  /   
日 日 月 月 年 年 年 年 :   
時 分☐ 来院日と同じ場  
合はチェックマ  
ークを入れてくだ  
さい

本質問票を前回記入してから喫煙した場合は、タバコを吸ってどのように感じたかを最も表しているものにチェックマークを付けてください。

1. タバコを吸って満足した。

全く あてはま らない	ほとんど あてはま らない	少し あてはま る	まあまあ あてはま る	とても あてはま る	かなり あてはま る	極めて あてはま る
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. タバコの味はおいしかった。

全く あてはま らない	ほとんど あてはま らない	少し あてはま る	まあまあ あてはま る	とても あてはま る	かなり あてはま る	極めて あてはま る
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. 喉や胸への刺激を堪能した。

全く あてはま らない	ほとんど あてはま らない	少し あてはま る	まあまあ あてはま る	とても あてはま る	かなり あてはま る	極めて あてはま る
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. タバコを吸ったら気持ちが落ち着いた。

全く あてはま らない	ほとんど あてはま らない	少し あてはま る	まあまあ あてはま る	とても あてはま る	かなり あてはま る	極めて あてはま る
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



改訂版タバコ評価質問票 (mCEQ)							
5. タバコを吸ったらより頭が冴えた感じになった。							
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. タバコを吸ったらイライラ感が少なくなった。							
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. タバコを吸ったら集中しやすくなった。							
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. タバコを吸ったら食欲が低下した。							
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. タバコを吸ったらめまいがした。							
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. タバコを吸ったら吐き気がした。							
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



改訂版タバコ評価質問票 (mCEQ)						
11. タバコを吸ったら、タバコを吸いたい気持ちがすぐにおさまった。						
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. タバコを吸って楽しかった。						
全く あてはま らない	ほとんど あてはま らない	少し あてはまる	まあまあ あてはまる	とても あてはまる	かなり あてはまる	極めて あてはまる
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



#### 16.1.2.3.5 Questionnaire on Smoking Urges

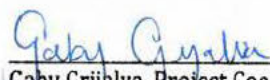




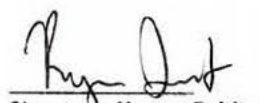
TRANSPERFECT

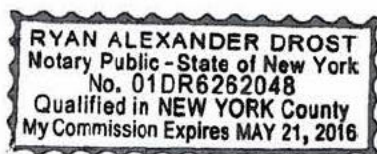
City of New York, State of New York, County of New York

I, Gaby Grijalva, hereby certify that the following is, to the best of my knowledge and belief, a true and accurate translation of the document titled "QSU-brief United Kingdom (English)\_Final\_Clean" from English into Japan (Japanese) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 5 adult smokers, final proofreading, and formatting.

  
Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

  
Signature, Notary Public



Stamp, Notary Public





## 喫煙衝動に関する質問票(QSU)

評価の日時 (24 時間制)	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="checkbox"/> 来院日と同じ場合はチェックマークを入れてください
	日 月 年	
	<input type="text"/> : <input type="text"/>	
	時 分	

1. 今タバコを吸いたいと思っている	
全く同意しない	強く同意する
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

2. 今、一番したいことはタバコを吸うことである	
全く同意しない	強く同意する
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

3. 今タバコが吸えるのであれば、吸うと思う	
全く同意しない	強く同意する
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>



喫煙衝動に関する質問票(QSU)							
4. 今タバコが吸えれば、もっとうまく物事に対処できる							
全く同意し ない							強く同意 する
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. 今欲しいものはタバコだけだ							
全く同意し ない							強く同意 する
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. とてもタバコが吸いたい							
全く同意し ない							強く同意 する
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. 今タバコを吸ったらおいしいだろうと思う							
全く同意し ない							強く同意 する
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. 今タバコのためなら、たいていのことはする							
全く同意し ない							強く同意 する
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



喫煙衝動に関する質問票(QSU)						
9. タバコを吸ったら憂鬱さが軽減するだろう						
全く同意し ない						強く同意 する
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. 私はできるだけすぐタバコを吸うつもりである						
全く同意し ない						強く同意 する
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



#### 16.1.2.3.6 Human Smoking Topography Questionnaire



以下の文章/記述にどの程度同意しますか。あてはまるものに印をつけてください。

1. デバイスを使用した場合、従来のタバコまたは試験製品の喫煙は違ったものになる。

- ☐ 強く同意する  
☐ 同意する  
☐ どちらでもない  
☐ 同意しない  
☐ 全く同意しない

「同意しない」または「全く同意しない」と答えた場合は、説明を記入してください。

---

2. デバイスを使用した場合の喫煙は、使用しない場合と同じくらい楽しめる。

- ☐ 強く同意する  
☐ 同意する  
☐ どちらでもない  
☐ 同意しない  
☐ 全く同意しない

「同意しない」または「全く同意しない」と答えた場合は、説明を記入してください。

---

3. デバイスを使用した場合、従来のタバコまたは試験製品の味は違ったものになる。

- ☐ 強く同意する  
☐ 同意する  
☐ どちらでもない  
☐ 同意しない  
☐ 全く同意しない

「同意する」または「強く同意する」と答えた場合は、説明を記入してください。

---

4. デバイスの使い方は簡単である。

- ☐ 強く同意する  
☐ 同意する  
☐ どちらでもない  
☐ 同意しない  
☐ 全く同意しない

「同意しない」または「全く同意しない」と答えた場合は、説明を記入してください。

---

5. デバイスは喫煙に支障を来たす。

- ☐ 強く同意する  
☐ 同意する  
☐ どちらでもない  
☐ 同意しない  
☐ 全く同意しない

「同意する」または「強く同意する」と答えた場合は、説明を記入してください。

---



#### 16.1.2.3.7 Minnesota Nicotine Withdrawal Scale Questionnaire



TRANSPERFECT

City of New York, State of New York, County of New York

I, Gaby Grijalva, hereby certify that the following is, to the best of my knowledge and belief, a true and accurate translation of the document titled "MNWS ENG SELF" from English into Japan (Japanese) following Covance's process of concept definition, Dual Forward Translation, Reconciliation, Back Translation, Resolution, Covance cognitive interviewing with 5 adult smokers, final proofreading, and formatting.

Gaby Grijalva, Project Coordinator

Sworn to before me this  
Wednesday, May 15, 2013

Signature, Notary Public



Stamp, Notary Public

**ミネソタニコチン依存／離脱スケール(Minnesota Nicotine Dependence/Withdrawal Scale, MNWS)****自己記入式行動評価尺度**

評価の日時  
(24時間制)

☐ 来院日と同じ場合はチェックマークを入れてください

日 日 / 月 月 / 年 年 年 年

時 分

下記の各項目に対して、あなたがこの 24 時間にどのように感じていたか、  
当てはまるものにチェックマークを入れてください。

	全くない	わずかに ある	軽度	中程度	重度
1. 怒り、怒りっぽさ、イライラ感	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. 不安、神経質	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. 落ち込んだ感じや悲しみ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. タバコを吸いたいという欲求 や欲望	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. 集中しにくさ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. 食欲の増進、空腹感、体重 の増加	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. 不眠、睡眠障害、夜中に目 が覚めること	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. 落ち着きのなさ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. 短気	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. 便秘	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. 目まい	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>





ミネソタニコチン依存／離脱スケール(Minnesota Nicotine Dependence/Withdrawal Scale, MNWS)					
自己記入式行動評価尺度					
12. 咳	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. 夢または悪夢	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. 吐き気	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. 喉の痛み	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
心拍数	_____				bpm (拍/分)
体重	_____				Kg



16.1.2.4 Subject Smoking Diary English



What tobacco/nicotine product  
did you use today?

☐ THS 2.2

How many THS 2.2 tobacco sticks did  
you use today?

☐ CC

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

☐ NRT

What NRT product did you used  
today?

☐ nicotine  
inhaler

how many times did you use an inhaler  
today

☐ nicotine nasal  
spray

how many times did you use a nasal spray  
today

☐ nicotine gum

how many gums did you use today

☐ nicotine lozenge

how many lozenges did you use today

☐ nicotine patch

how many patches did you use today

☐ other NRT product

how many times did you use other NRT  
products today not listed previously



- |   |   |
|---|---|
| <input type="checkbox"/> Other tobacco product      | What other tobacco product did you smoked today?                        |
| <input type="checkbox"/> chewable/smokeless tobacco | how many times did you use chewable/smokeless tobacco today             |
| <input type="checkbox"/> cigars/cigarillos          | how many cigars/cigarillos did you smoke today                          |
| <input type="checkbox"/> pipe                       | how many time did you smoke a pipe today                                |
| <input type="checkbox"/> other tobacco product      | how many time did you use a tobacco product today not listed previously |
| <input type="checkbox"/> electronic cigaretie       | How many times did you use an electronic cigarette today ?              |
| <input type="checkbox"/> None of the above          |   |



16.1.2.5 Subject Smoking Diary Local Language



PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

(b) (4)

## Diary Translation Acceptance Document

Study Code: PM2953

Language: jaJP (Japanese Japan)

Document File Name: PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

Document ID: 9A0AC4F7679CE1E79A90870F78FC38A3

### Instructions

On the following pages compare the base language (English) screen on the left to the translated language screen on the right. Ensure that the translated screen is an accurate representation of the information on the English screen then indicate whether or not you approve the translation.

1A. Review the English screen.

1B. Review the translated screen.

2. Is the translation correct? Highlight either Yes or No.

Approval: YES NO  
SECRET TRANSLATOR NAME:  
SHARED IVT: S

For each screen pair (usually one per page):

1. Compare the English and translated screens. **Review the translated screen** to verify that it is correct including:
  - Clear accurate translation  
→ When reviewing DTA version 1 **note only critical errors**. Stylistic changes and rewriting are not appropriate.
  - Correct translated text placement
  - Appropriate formatting of translated text (line breaks boldface italics etc.)
2. On the Approval line (under the screen pictures) **indicate whether or not you approve the screen** translation:
  - For **correct** translation and formatting: Highlight **Yes**.
  - For translation or formatting **errors**: Highlight **No**.  
→ When reviewing DTA version 2 or higher please confirm that the corrections to DTA version 1 (or the previous version) were implemented correctly if correct highlight **Yes** to approve the screens. No changes to previously approved text will be considered.

### Additional Guidance for Reviewing Screens

- To accommodate longer translated text the formatting on the translated screen may differ from the English screen. This is acceptable.
- Screens may appear in the document in a different order than they appear in the software.

**After you review all the screens, follow the instructions on the last page of this document.**



PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

1.

<p>What tobacco / nicotine product did you use today?</p> <ul style="list-style-type: none"><li><input type="checkbox"/> THS 2.2</li><li><input type="checkbox"/> Conventional Cigarette</li><li><input type="checkbox"/> NRT</li><li><input type="checkbox"/> Other Tobacco Product</li><li><input type="checkbox"/> Electronic Cigarette</li><li><input type="checkbox"/> None of the above</li></ul>	<p>今日どのタバコ／ニコチン製品を使用しましたか?</p> <ul style="list-style-type: none"><li><input type="checkbox"/> THS 2.2</li><li><input type="checkbox"/> 従来のタバコ</li><li><input type="checkbox"/> ニコチン置換療法 (Nicotine Replacement Therapy, NRT)</li><li><input type="checkbox"/> 他のタバコ製品</li><li><input type="checkbox"/> 電子タバコ</li><li><input type="checkbox"/> 上記のどれでもない</li></ul>
---	--

9:57  
?

9:57  
?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 1, 2, 3, 4, 5, 6, 7

YES NO









PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

2.

<p>How many THS 2.2 tobacco sticks did you use today?</p> <p></p>	<p>今日、何本のTHS 2.2 タバコスティックを使用 しましたか?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)  
Script Translator Line: 8

YES NO







PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

3.

<p>How many conventional cigarettes / roll-your-own cigarettes did you smoke today?</p> <p></p>	<p>今日、何本の従来のタバコ ／手巻きタバコを吸 いましたか?</p> <p></p>
---	---

9:57 ? 9:57 ?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 9

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc



DTA Translations jaJP

Version 1

4.

What NRT product did you use today?	今日どのNRT製品を使用しましたか?
<input type="checkbox"/> Nicotine Inhaler	<input type="checkbox"/> ニコチン吸入剤
<input type="checkbox"/> Nicotine Nasal Spray	<input type="checkbox"/> ニコチン鼻腔スプレー
<input type="checkbox"/> Nicotine Gum	<input type="checkbox"/> ニコチンガム
<input type="checkbox"/> Nicotine Lozenge	<input type="checkbox"/> ニコチンドロップ
<input type="checkbox"/> Nicotine Patch	<input type="checkbox"/> ニコチンパッチ
<input type="checkbox"/> Other NRT Product	<input type="checkbox"/> 他のNRT製品

 9:57 ? 

 9:57 ? 

Do you approve the screen? (Highlight one.)  
Script Translator Line: 10, 11, 12, 13, 14, 15, 16

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

5.

<p>How many times did you use an inhaler today?</p> <p></p>	<p>今日、吸入剤を何回使用しましたか?</p> <p></p>
--	--

9:57 ? 9:57 ?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 17

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

6.

<p>How many times did you use a nasal spray today?</p> <p></p>	<p>今日、鼻腔スプレーを何回使用しましたか?</p> <p></p>
---	---

9:57 ? 9:57 ?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 18

YES NO









PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

7.

<p>How many pieces of gum did you chew today?</p> <p></p>	<p>今日、何個のガム をかみましたか?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)  
Script Translator Line: 19

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

8.

<p>How many lozenges did you use today?</p> <p></p>	<p>今日、何個のドロップを使用しましたか?</p> <p></p>
--	--

9:57 ? 9:57 ?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 20

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

9.

<p>How many patches did you use today?</p> <p></p>	<p>今日、何個のパッチ を使用しましたか?</p> <p></p>
---	--

9:57 ? 9:57 ?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 21

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

10.

<p>How many times did you use other NRT products today not listed previously?</p> <p> <input type="text"/></p>	<p>今日、前に記載されていない 他のNRT製品を何回使用 しましたか?</p> <p> <input type="text"/></p>
---	---

9:57 ? 9:57 ?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 22

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

11.

<p>What other tobacco product did you use today?</p> <p><input type="checkbox"/> Chewable / Smokeless Tobacco</p> <p><input type="checkbox"/> Cigars / Cigarillos</p> <p><input type="checkbox"/> Pipe</p> <p><input type="checkbox"/> Other Tobacco Product</p>	<p>今日、他のどのタバコ製品を使用しましたか?</p> <p><input type="checkbox"/> チュアブル／無煙タバコ</p> <p><input type="checkbox"/> 葉巻／シガリロ</p> <p><input type="checkbox"/> キセル</p> <p><input type="checkbox"/> 他のタバコ製品</p>
--	--

Navigation bar: Left arrow, 9:57, Right arrow, Left arrow, 9:57, Right arrow

Do you approve the screen? (Highlight one.)  
Script Translator Line: 23, 24, 25, 26, 27

YES NO



PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

12.

<p>How many times did you use chewable / smokeless tobacco today?</p> <p>▲ <input type="text"/></p>	<p>今日、チュアブル／無 煙タバコを何回使用 しましたか？</p> <p>▲ <input type="text"/></p>
---	--

Navigation bar: Left arrow, 9:57, ?, Right arrow, Left arrow, 9:57, ?, Right arrow

Do you approve the screen? (Highlight one.)  
Script Translator Line: 28

YES NO











PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

13.

<p>How many cigars / cigarillos did you smoke today?</p> <p></p>	<p>今日、何本の葉巻／シガリロ を吸いましたか?</p> <p></p>
<p> 9:57  </p>	<p> 9:57  </p>

Do you approve the screen? (Highlight one.)  
Script Translator Line: 29

YES NO









PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

14.

<p>How many times did you smoke a pipe today?</p> <p></p>	<p>今日、キセルを何回 吸いましたか?</p> <p></p>
<p> 9:57 ? </p>	<p> 9:57 ? </p>

Do you approve the screen? (Highlight one.)  
Script Translator Line: 30

YES NO









PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

15.

<p>How many times did you use a tobacco product today not listed previously?</p> <p> <input type="text"/></p>	<p>今日、前に記載されていない タバコ製品を何回使用 しましたか?</p> <p> <input type="text"/></p>
--	---

9:57 ?   9:57 ?  

Do you approve the screen? (Highlight one.)  
Script Translator Line: 31

YES NO





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

16.

<p>How many times did you use an electronic cigarette today?</p> <p></p>	<p>今日、電子タバコを何 回使用しましたか?</p> <p></p>
--	--

9:57 ? 9:57 ?

Do you approve the screen? (Highlight one.)  
Script Translator Line: 32

YES NO



PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

### DTA Review Summary

Now that you have reviewed and approved or rejected each screen in the DTA, please work through the steps below to complete the DTA review process.

#### Review Results

Were all the screen translations approved? Please highlight one: **Yes** No

#### → If Yes

1. **Save a copy** of the reviewed DTA for your records.
2. **Email a copy** of the reviewed DTA to your translation company project coordinator.

<b>Reviewer Name</b> (printed): <u>Gaby Grijalva</u>
<b>Reviewer Signature:</b> <u>Gaby Grijalva</u>
<b>Review Completion Date</b> (dd MON yyyy): <u>25 JUN 2013</u>

#### → If No

1. In the table below, **list each screen that was not approved** (where you marked **No** on the approval line), enter the incorrect text or problem (such as a formatting error), then enter the correction.

Screen Number	Incorrect Text or Formatting	Correct Text or Formatting	Translation Vendor – Agree or Disagree*
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

\*Please use the "**Translation Vendor – Agree or Disagree**" column only for verifying Secondary Reviewer revisions.

2. If you are a Linguist, please **email** a copy of the reviewed DTA to your translation company project coordinator and they will return the reviewed DTA to **(b)**

OR

If you are a Secondary Reviewer, such as an **(b)** client or assessment author, please **email** a copy of the reviewed DTA to **(b) (4)**





PM2953 DiaryPRO ZRHM-REXA-07-JP, YVDM-REXA-14-JP  
PM2953\_DiaryPRO\_DTA\_ProductUse\_jaJP\_v1.doc

DTA Translations jaJP

Version 1

#### DTA Revision History

Name	Modifications	Date	Version
Matthew Carulli	Initial DTA Creation	21 Jun 2013	1