	Vertex Pharmaceuticals Incorporated Controlled Document
	Title: eCRF and Schedule of Events Approval

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Protocol	Version of eCRF and Schedule of Events	Version Date of eCRF and Schedule of Events
VX14-661-108	3.0	14JAN2016

Role	Approval
Primary Clinical Data Manager	Signature: <u><i>Dominic Hue</i></u> Date: <u>17 JAN 2016</u> Print Name: Dominic Hue
Clinical Operations Study Lead	Signature: <u><i>Gina Carbone</i></u> Date: <u>17 MAR 2017</u> Print Name: Gina Carbone
Clinical Pharmacologist <input checked="" type="checkbox"/> N/A, specify reason: Change only extended year codelist	Signature: _____ Date: _____ Print Name: _____
Medical Director <input checked="" type="checkbox"/> N/A, specify reason: Change only extended year codelist	Signature: _____ Date: _____ Print Name: _____
Primary Medical Coder <input checked="" type="checkbox"/> N/A, specify reason: Change only extended year codelist	Signature: _____ Date: _____ Print Name: _____
SDTM Owner <input checked="" type="checkbox"/> N/A, specify reason: Change only extended year codelist	Signature: _____ Date: _____ Print Name: _____
Study Biostatistician <input checked="" type="checkbox"/> N/A, specify reason: Change only extended year codelist	Signature: _____ Date: _____ Print Name: _____
Study Statistical Programmer <input checked="" type="checkbox"/> N/A, specify reason: Change only extended year codelist	Signature: _____ Date: _____ Print Name: _____
<div style="border: 1px solid black; padding: 2px; font-size: small;"> This document is the property of Vertex Pharmaceuticals Incorporated and may not be duplicated, copied, altered, or removed from the company without prior approval of Quality Assurance. </div> Other, Specify Role: WI-0187a t 1.2 <input checked="" type="checkbox"/> N/A	Signature: _____ Date: _____ Print Name: _____

Annotated Study Book for Study Design: VX14-661-108

Study Design Version: 3.0

Sponsor: Vertex Pharmaceuticals, Inc.

Protocol: VX14-661-108

VX14661108

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January 14, 2016 10:08AM

Time and Events Schedule For Study Design: VX14-661-108

Element	Assessment	CRF	System		VX661_108														
			INFScreening (INFScreening) [S]	INFEnrollment (INFEnrollment) [S]	Screening (Day -28 to Day-1) (Screening) [S]	Week 1/Day 1 (Day 1) [S]	Week 2/Day 15 (Day 15) [S]	Week 4/Day 29 (Week 4) [S]	Week 8/Day 57 (Week 8) [S]	Safety Eval/Week 12 (Week 12) [S]	Week 17/Day 113 (Week 17) [S]	Week 18/Day 127 (Week 18) [S]	Week 20/Day 141 (Week 20) [S]	Week 24/Day 169 (Week 24) [S]	Early termination (ET) [S]	Safety Follow-Up (FUP) [S]	LOGS (LOGS) [S]	TERM (TERM) [S]	Unscheduled (UNS) [U/R]
	Visit Start Hours		0	0	0	24	384	1056	2400	4416	7272	10296	13656	17688	18408	18576	18912	19584	19585
1	SYSTEM SCREENING	INFSCR	1																
2	SYSTEM ENROLLMENT	INFENR		1															
3	DATE OF VISIT	DOV			1	1	1	1	1	1	1	1	1	1	1	1			1
4	RANDOMIZATION	RAND			2														
5	DEMOGRAPHY	DM			3														
6	INCLUSION AND EXCLUSION	IE			4														
7	INFORMED CONSENT AND ASSENT	ICA			5														
8	SUPPLEMENTAL INFORMED CONSENT AND ASSENT	ICAS			6														
9	CYSTIC FIBROSIS GENOTYPING	GENO			7														
10	MEDICAL HISTORY	MH			8														
11	HOSPITALIZATION AND CLINIC VISIT HISTORY	HCHX			9														
12	OPHTHALMOLOGY HISTORY	OH			10														
13	VITAL SIGNS - WITH AGE	VS			11														
14	QUESTIONNAIRES	QUES			12	4		4	3	4	4		4	3	3	3			5-DF
15	CFQ-R FOR ADOLESCENTS AND ADULTS - English (US)	CFQR-AA			13-DF	5-DF		5-DF	4-DF	5-DF	5-DF		5-DF	4-DF	4-DF	4-DF			6-DF
16	CFQ-R FOR PARENTS/CAREGIVERS - English (US)	CFQR-PC			14-DF	6-DF		6-DF	6-DF	6-DF	7-DF		7-DF	5-DF	6-DF	6-DF			7-DF
17	CFQ-R FOR CHILDREN AGES 12 AND 13 - English (US)	CFQR-CH			15-DF	7-DF		7-DF	5-DF	7-DF	6-DF		6-DF	6-DF	5-DF	5-DF			8-DF
18	12-ITEM SHORT FORM HEALTH SURVEY	SF-12			16	8		8	7	8	8		8	7	7	7			9-DF
19	PHYSICAL EXAM	PE			17														
20	OPHTHALMOLOGY EXAM	OE			18										9	9			
21	BRONCHODILATOR	BRON			19	10	5	12	10	9	10	5	12	10	11	10			13-DF
22	RESPIRATORY MICROBIOLOGY	RMICRO			20														
23	VITAL SIGNS - WITHOUT AGE	VS2				2	2	2	2	2	2	2	2	2	2	2			3-DF
24	URINE PREGNANCY TEST	UPREG				3-DF	3-DF	3-DF		3-DF	3-DF	3-DF	3-DF						4-DF
25	STUDY DRUG ADMINISTRATION	SDA				9	4	11			9	4	11						10-DF
26	DOSES BEFORE PK SAMPLING	DOSEPK						9	8				9	8	8				11-DF
27	PK SAMPLE COLLECTION	PK1						10	9				10	9	10	8			
28	STATUS	STATUS															1		
29	ADVERSE EVENTS	AE															2-DF-RF		
30	PRIOR AND CONCOMITANT MEDICATIONS	CM															3-DF-RF		
31	NON-PHARMACOLOGICAL TREATMENTS OR PROCEDURES	NT															4-DF-RF		
32	SINOPULMONARY SIGNS & SYMPTOMS FOR ANTIBIOTICS	SS															5-DF-RF		
33	UNPLANNED HOSPITALIZATIONS	UHOSP															6-DF-RF		
34	PLANNED HOSPITALIZATIONS	PHOSP															7-DF-RF		
35	OUTPATIENT SICK VISITS	OSV															8-DF-RF		
36	STUDY DRUG INTERRUPTIONS	INTER															9-DF		
37	RECONSENT AND RE-ASSENT	RICA															10		
38	SUPPLEMENTAL RECONSENT AND RE-ASSENT	RICAS															11		
39	DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 1	DOSEL																1	
40	DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 2	DOSEL2																2	
41	END OF DOSING	ENDDOSE																3	
42	END OF STUDY	ENDSTUDY																4	
43	ROLLOVER TO EXTENSION STUDY	RO																5	
44	UNSCHEDULED	UNSCHED																	2
45	PK SAMPLE COLLECTION UNSCHEDULED	PK2																	12-DF-RF

Key: [S] = Scheduled Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
C = Common Form DF = Dynamic Form RF = Repeating Form

Key: [S] = Scheduled Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit
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Annotated Study Book for Study Design: VX14-661-108

Study Design Version: 3.0

Sponsor: Vertex Pharmaceuticals, Inc.

Protocol: VX14-661-108

VX14661108

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January 14, 2016 10:05AM

DN

VX14-661-108: System Screening (INFSCR) [INFSCR]	
1. Subject Initials <i>[read-only]</i> [REDACTED]	[SUBJINIT] A3
2. Date of Birth <i>[read-only]</i> [REDACTED]	[BRTH_DAT] Req <input type="button" value="v"/> (1900-2005)
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

Study Object Descriptions: System Screening		
Type	RefName	Description
Form	INFSCR	System Screening
Item	SUBJINIT	'---' will be sent from IVRS system
Item	BRTH_DAT	DOB mapped to DM form

RDE Analytics: RD_INFSCR		
Data Variable RefName	RD Column Name	Column Data Type
SUBJINIT	SUBJINIT	VARCHAR2
	SUBJINIT_ND	VARCHAR2
BRTH_DAT	BRTH_DAT_DTS	VARCHAR2
	BRTH_DAT_ND	VARCHAR2

VX14-661-108: System Enrollment (INFENR) [INFENR]

1. Subject ID *(read-only)*

✓

SU

[SUBJID]

A11

Key: [✓] = Source verification required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: System Enrollment		
Type	RefName	Description
Form	INFENR	System Enrollment
Item	SUBJID	Subject ID is mapped to RAND form

RDE Analytics: RD_INFENR		
Data Variable RefName	RD Column Name	Column Data Type
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2

Codelist Values Tables: DATE OF VISIT					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clDOVCHK	String	DOV entered in error	E	clIDOVCHK	VISERROR

VX14-661-108: RANDOMIZATION (RAND) [RAND]

1. Subject ID *[read-only]*

✓ [Subject ID]

[SUBJID]

A11

2. Date of Randomization *[read-only]*

✓

S

[RANDDT]

Req / Req / Req (2015-2020)

Key: [✓] = Source verification required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: RANDOMIZATION		
Type	RefName	Description
Item	SUBJID	Subject ID is mapped to RAND form

RDE Analytics: RD_RAND		
Data Variable RefName	RD Column Name	Column Data Type
SUBJID	SUBJID	VARCHAR2
	SUBJID_ND	VARCHAR2
RANDDT	RANDDT	DATE
	RANDDT_DTS	VARCHAR2
	RANDDT_ND	VARCHAR2

file:///C:/Users/kmalsick/AppData/Local/Apps/2.0/9ATPEO2Z.DB1/B72KY8PM.AGZ/orac...769 040cb68c7390ff6f 0002.0001 1a75c9af89f12f2b/HtmlResources/AnnotatedStudybook.html

1/14/2016

VX14-661-108: DEMOGRAPHY

(DM) [DM]

1.*

Date of birth *[read-only]*

BR

[BRTHDAT]

Req ☐ (1900-2005)

2.*

Sex

SE

[SEX]

[A:M] ☐ Male

[A:F] ☐ [CHILDPOT]

Female

Is the subject a woman of childbearing potential?

SU

[A:N] ☐ [NOCHILDP]

No

Reason not of childbearing potential:

SU

[A:POSTMENOPAUSAL] ☐ Postmenopausal

[A:PREMENARCHAL] ☐ Premenarchal

[A:OTHER, SPECIFY] ☐ [NOCHILDS]

Other, specify: A40

3.*

Ethnicity

ET

[ETHNIC]

[A:HISPANIC OR LATINO] ☐ H

[A:NOT HISPANIC OR LATINO] ☐ Not Hispanic or Latino

[A:NOT COLLECTED PER LOCAL REGULATIONS] ☐ Not Collected per Local Regulations

SU

US

4.*

Race

RA

[RACE]

[A:WHITE] ☐ White

[A:BLACK OR AFRICAN AMERICAN] ☐ Black or African American

[A:ASIAN] ☐ Asian

[A:AMERICAN INDIAN OR ALASKA NATIVE] ☐ American Indian or Alaska Native

[A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER] ☐ Native Hawaiian or Other Pacific Islander

[A:NOT COLLECTED PER LOCAL REGULATIONS] ☐ Not Collected per Local Regulations

[A:OTHER, SPECIFY] ☐ [RACE_SP]

Other, specify: A45

Key: [*] = Item is required [✓] = Source verification required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: DEMOGRAPHY

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
Sex	String	Male	M	MALE	SEX
		Female, is subject of childbearing potential	F	FEMALE	
ciYESNO	String	Yes	Y	ciYES	CHILDPOT
		No	N	ciNO	
NOCHILDPDC	String	Surgical Procedure	SURGICAL PROCEDURE	SURGPROC	NOCHILDP
		Postmenopausal	POSTMENOPAUSAL	POSTMEN	
		Premenarchal	PREMENARCHAL	PREMEN	
		Other, specify:	OTHER, SPECIFY	OtherSP	
ETHNICPDC	String	Hispanic or Latino	HISPANIC OR LATINO	HISPLAT	ETHNIC
		Not Hispanic or Latino	NOT HISPANIC OR LATINO	NOTHISPLAT	
		Not Collected per Local Regulations	NOT COLLECTED PER LOCAL REGULATIONS	NOTCOLL	
RACEPDC	String	White	WHITE	WHITE	RACE
		Black or African American	BLACK OR AFRICAN AMERICAN	BLACK	

		Asian	ASIAN	ASIAN	
		American Indian or Alaska Native	AMERICAN INDIAN OR ALASKA NATIVE	AIorAN	
		Native Hawaiian or Other Pacific Islander	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NWorPI	
		Not Collected per Local Regulations	NOT COLLECTED PER LOCAL REGULATIONS	NOTCOLL	
		Other	OTHER, SPECIFY	Other	

RDE Analytics: RD_DM		
Data Variable RefName	RD Column Name	Column Data Type
BRTHDAT	BRTHDAT_DTS	VARCHAR2
	BRTHDAT_ND	VARCHAR2
SEX	SEX_C	VARCHAR2
	SEX	VARCHAR2
	SEX_ND	VARCHAR2
SEX - CHILD POT	CHILDPOT_C	VARCHAR2
	CHILDPOT	VARCHAR2
SEX - NOCHILDP	NOCHILDP_C	VARCHAR2
	NOCHILDP	VARCHAR2
SEX - NOCHILDS	NOCHILDS	VARCHAR2
ETHNIC	ETHNIC_C	VARCHAR2
	ETHNIC	VARCHAR2
	ETHNIC_ND	VARCHAR2
RACE	RACE_C	VARCHAR2
	RACE	VARCHAR2
	RACE_ND	VARCHAR2
RACE - RACE_SP	RACE_SP	VARCHAR2

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	IEYN
		No	N	cliNO	
IEUNMETPDC	String	EXCLUSION 1	EXCLUSION 1	IEUNMETEX1	IEUNMET
		EXCLUSION 2	EXCLUSION 2	IEUNMETEX2	
		EXCLUSION 3	EXCLUSION 3	IEUNMETEX3	
		EXCLUSION 4	EXCLUSION 4	IEUNMETEX4	
		EXCLUSION 5	EXCLUSION 5	IEUNMETEX5	
		EXCLUSION 6	EXCLUSION 6	IEUNMETEX6	
		EXCLUSION 7	EXCLUSION 7	IEUNMETEX7	
		EXCLUSION 8	EXCLUSION 8	IEUNMETEX9	
		EXCLUSION 9	EXCLUSION 9	IEUNMETEX8	
		EXCLUSION 10	EXCLUSION 10	IEUNMETEX10	
		EXCLUSION 11	EXCLUSION 11	IEUNMETEX11	
		EXCLUSION 12	EXCLUSION 12	IEUNMETEX12	
		EXCLUSION 13	EXCLUSION 13	IEUNMETEX13	
		EXCLUSION 14	EXCLUSION 14	IEUNMETEX14	
		INCLUSION 1	INCLUSION 1	IEUNMETIN1	
		INCLUSION 2	INCLUSION 2	IEUNMETIN2	
		INCLUSION 3	INCLUSION 3	IEUNMETIN3	
		INCLUSION 4	INCLUSION 4	IEUNMETIN4	
		INCLUSION 5	INCLUSION 5	IEUNMETIN5	
		INCLUSION 6	INCLUSION 6	IEUNMETIN6	

		INCLUSION 7	INCLUSION 7	IEUNMETIN7	
		INCLUSION 8	INCLUSION 8	IEUNMETIN8	
		INCLUSION 9	INCLUSION 9	IEUNMETIN9	

RDE Analytics: RD_IE		
Data Variable RefName	RD Column Name	Column Data Type
IEYN	IEYN_C	VARCHAR2
	IEYN	VARCHAR2
	IEYN_ND	VARCHAR2
RD_IE_IE_R1		
IESPID	IESPID	NUMBER
	IESPID_ND	VARCHAR2
IEUNMET	IEUNMET_C	VARCHAR2
	IEUNMET	VARCHAR2
	IEUNMET_ND	VARCHAR2
IEUNMETF	IEUNMETF	VARCHAR2
	IEUNMETF_ND	VARCHAR2

VX14-661-108: INFORMED CONSENT AND ASSENT (ICA) [ICA]

On this page, record the **original** informed consent/assent. If the subject or caregiver signed a revised informed consent/assent **after** the original, record that on the Reconsent page.

Enter the **protocol version** the consent/assent corresponds to. Do **not** enter the version of the ICF itself.

1.*
✓

Date of **written** informed CONSENT
[REDACTED] CONSENT]

[ICA_DAT]
Req [dropdown] / Req [dropdown] / Req [dropdown] (2015-2020)

2.*
✓

[REDACTED] DS
[REDACTED] SU

[A:CAREGIVER] [IA_YN]
Caregiver
Did the subject provide ASSENT?
[REDACTED] SU
Date of ASSENT
[REDACTED] SU
[A:N] [dropdown]

3.*
✓

Protocol version to which this consent/assent corresponds (please enter in the format 1.0 , 2.0, etc.)
[REDACTED] DS

[ICAPROTV]
xx.x

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: INFORMED CONSENT AND ASSENT					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliSUBJCAREGV	String	Subject	SUBJECT	cliSUBJECT	ICSUBCG
		Caregiver	CAREGIVER	cliCAREGIVER	
cliYESNO	String	Yes	Y	cliYES	IA_YN
		No	N	cliNO	

RDE Analytics: RD_ICA		
Data Variable RefName	RD Column Name	Column Data Type
ICA_DAT	ICA_DAT	DATE
	ICA_DAT_DTS	VARCHAR2
	ICA_DAT_ND	VARCHAR2
ICSUBCG	ICSUBCG_C	VARCHAR2
	ICSUBCG	VARCHAR2
	ICSUBCG_ND	VARCHAR2
ICSUBCG - IA_YN	IA_YN_C	VARCHAR2
	IA_YN	VARCHAR2
ICSUBCG - IAS_DAT	IAS_DAT	DATE
	IAS_DAT_DTS	VARCHAR2
ICAPROTV	ICAPROTV	FLOAT
	ICAPROTV_ND	VARCHAR2

VX14-661-108: SUPPLEMENTAL INFORMED CONSENT AND ASSENT (ICAS) [ICAS]

DS original informed consent/assent to the supplemental assessments. If the subject or caregiver signed a revised informed consent/assent to the supplemental assessments **after** the original consent, record that on the Supplemental Reconsent and Re-assent page.

Enter the **protocol version** the consent/assent corresponds to. Do **not** enter the version of the ICF itself.

<div>1.* Did the subject or caregiver consent to DNA Sample A?</div> <div><div>✓</div><div>DS</div></div>	<div><div>[ICA1_YN]</div><div>[A:Y] <input checked="" type="radio"/> [ICA1_YN2]</div><div>Yes</div><div>[IC1_DAT]</div><div>Date of written informed consent to DNA Sample A</div><div>DS 2015-2020)</div><div>[IC1SUBCG]</div><div>Informed CONSENT provided by:</div><div>US</div><div>[A:CAREGIVER] <input checked="" type="radio"/> [IA1_YN]</div><div>Caregiver</div><div>Did the subject provide ASSENT to DNA Sample A?</div><div>US</div><div>Yes</div><div>Date of ASSENT to DNA Sample A</div><div>US</div><div>[A:N] <input type="radio"/> No</div></div>
---	---

If consent/assent was provided, please complete item 2 below.

<div>2. Protocol version to which this consent/assent corresponds (please enter in the format 1.0, 2.0, etc.)</div> <div><div>✓</div><div>DS</div></div>	<div><div>[ICA1PRTV]</div><div>xx.x</div></div>
<div>3.* Did the subject or caregiver consent to DNA Sample B?</div> <div><div>✓</div><div>DS</div></div>	<div><div>[ICA2_YN]</div><div>[A:Y] <input checked="" type="radio"/> [ICA2_YN2]</div><div>Yes</div><div>[IC2_DAT]</div><div>Date of written informed consent to DNA Sample B</div><div>DS 2015-2020)</div><div>[IC2SUBCG]</div><div>Informed CONSENT provided by:</div><div>[A:SUBJECT] <input checked="" type="radio"/> Subject</div><div>[A:CAREGIVER] <input type="radio"/> [IA2_YN]</div><div>Caregiver</div><div>Did the subject provide ASSENT to DNA Sample B?</div><div>US</div><div>Yes</div><div>Date of ASSENT to DNA Sample B</div><div>US</div><div>[A:N] <input type="radio"/> No</div></div>

If consent/assent was provided, please complete item 4 below.

<div>4. Protocol version to which this consent/assent corresponds (please enter in the format 1.0, 2.0, etc.)</div> <div><div>✓</div><div>[Protocol version]</div></div>	<div><div>[ICA2PRTV]</div><div>xx.x</div></div>
<div>5.* Did the subject or caregiver consent to Nasal brushing?</div> <div><div>✓</div><div>DS</div></div>	<div><div>[ICA3_YN]</div><div>[A:Y] <input checked="" type="radio"/> [ICA3_YN2]</div><div>Yes</div><div>[IC3_DAT]</div><div>Date of written informed consent to Nasal brushing</div><div>DS 2015-2020)</div><div>[IC3SUBCG]</div><div>Informed CONSENT provided by:</div></div>

		<div><div>[A:SUBJECT] <input type="checkbox"/> Subject</div><div>[A:CAREGIVER] <input type="checkbox"/> [IA3_YN] Caregiver</div><div>Did the subject provide ASSENT to Nasal brushing?</div><div>[A:Y] <input type="checkbox"/> [IAS3_DAT] Yes</div><div>Date of ASSENT to Nasal brushing</div><div>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2015-2020)</div><div>[A:N] <input type="checkbox"/> No</div></div>
If consent/assent was provided, please complete item 6 below.		
6. <input checked="" type="checkbox"/> [Protocol version]	[ICA3PRTV] <input type="text" value="xx.x"/>	
Key: [<input checked="" type="checkbox"/>] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Codelist Values Tables: SUPPLEMENTAL INFORMED CONSENT AND ASSENT					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	ICA1_YN, IA1_YN, ICA2_YN, IA2_YN, ICA3_YN, IA3_YN
		No	N	cliNO	
ICSUBCGRDC	String	Subject	SUBJECT	ICSUB	IC1SUBCG, IC2SUBCG, IC3SUBCG
		Caregiver	CAREGIVER	ICCG	

RDE Analytics: RD_ICAS		
Data Variable RefName	RD Column Name	Column Data Type
ICA1_YN	ICA1_YN_C	VARCHAR2
	ICA1_YN	VARCHAR2
	ICA1_YN_ND	VARCHAR2
ICA1_YN - IC1_DAT	IC1_DAT	DATE
	IC1_DAT_DTS	VARCHAR2
ICA1_YN - IC1SUBCG	IC1SUBCG_C	VARCHAR2
	IC1SUBCG	VARCHAR2
ICA1_YN - IA1_YN	IA1_YN_C	VARCHAR2
	IA1_YN	VARCHAR2
ICA1_YN - IAS1_DAT	IAS1_DAT	DATE
	IAS1_DAT_DTS	VARCHAR2
ICA1PRTV	ICA1PRTV	FLOAT
	ICA1PRTV_ND	VARCHAR2
ICA2_YN	ICA2_YN_C	VARCHAR2
	ICA2_YN	VARCHAR2
	ICA2_YN_ND	VARCHAR2
ICA2_YN - IC2_DAT	IC2_DAT	DATE
	IC2_DAT_DTS	VARCHAR2

ICA2_YN - IC2SUBCG	IC2SUBCG_C	VARCHAR2
	IC2SUBCG	VARCHAR2
ICA2_YN - IA2_YN	IA2_YN_C	VARCHAR2
	IA2_YN	VARCHAR2
ICA2_YN - IAS2_DAT	IAS2_DAT	DATE
	IAS2_DAT_DTS	VARCHAR2
ICA2PRTV	ICA2PRTV	FLOAT
	ICA2PRTV_ND	VARCHAR2
ICA3_YN	ICA3_YN_C	VARCHAR2
	ICA3_YN	VARCHAR2
	ICA3_YN_ND	VARCHAR2
ICA3_YN - IC3_DAT	IC3_DAT	DATE
	IC3_DAT_DTS	VARCHAR2
ICA3_YN - IC3SUBCG	IC3SUBCG_C	VARCHAR2
	IC3SUBCG	VARCHAR2
ICA3_YN - IA3_YN	IA3_YN_C	VARCHAR2
	IA3_YN	VARCHAR2
ICA3_YN - IAS3_DAT	IAS3_DAT	DATE
	IAS3_DAT_DTS	VARCHAR2
ICA3PRTV	ICA3PRTV	FLOAT
	ICA3PRTV_ND	VARCHAR2

VX14-661-108: CYSTIC FIBROSIS GENOTYPING (GENO) [GENO]

1.	Genotype for Mutation 1	<div>ns</div>	[GNFMT]	<div>A25</div>
2.	Genotype for Mutation 2 <i>[read-only]</i>	<div>ns</div>	[GNSMT]	<div>A25</div>
3. ✓	Genotype for Mutation 3	<div>ns</div>	[GNTMT]	<div>A50</div>

Key: [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_GENO		
Data Variable RefName	RD Column Name	Column Data Type
GNFMT	GNFMT	VARCHAR2
	GNFMT_ND	VARCHAR2
GNSMT	GNSMT	VARCHAR2
	GNSMT_ND	VARCHAR2
GNTMT	GNTMT	VARCHAR2
	GNTMT_ND	VARCHAR2

VX14-661-108: MEDICAL HISTORY (MH) [MH]

Record the subject's significant medical history, baseline signs/symptoms and any baseline *cystic fibrosis signs/symptoms* present before signed ICF.

Do **not** include:

- cystic fibrosis
- remote (> 1 year ago) minor procedures (e.g. wisdom tooth extraction, bunionectomy, inguinal hernia repair), except sterilization
- remote trauma (> 1 year ago) without residual significance or whose only residual significance is cosmetic (e.g. healed lacerations, burns, or minor fractures)
- dates, outcomes, durations, or family medical history

Record one condition or procedure per line.

1.* ✓	Does the subject have any significant medical history? <div style="background-color: yellow; border: 1px solid black; padding: 2px; display: inline-block;">N O</div>	[MHYN] [A:Y] <input type="radio"/> Yes [A:N] <input checked="" type="radio"/> No
2. ✓	Line #	Condition
		Cont. when ICF signed?

Medical History Entry [MH_R1]

If yes, select Add Entry to add each condition below.

2.1	Line # [read-only] [Line #]	[MHSPID] N3
2.2* ✓	Abnormality/Condition [Condition]	[MHTERM] A200
2.3* ✓	Continuing when ICF signed? [Cont. when ICF signed?]	[MHONGO] [A:Y] <input type="radio"/> Yes [A:N] <input checked="" type="radio"/> No
2.4	Mapped Abnormality/Condition [hidden] [Mapped Condition]	[MHVERBATIM] A200
2.5	Dictionary Name and Version [hidden] [MedDRA Ver.]	[VMEDDRA] A200
2.6	Lowest Level Term Name [hidden] [LLT Name]	[LLT_NAME] A200
2.7	Lowest Level Term Code [hidden] [LLT Code]	[LLT_CODE] A200
2.8	Preferred Term Name [hidden] [PT Name]	[MHDECOD] A200

2.9	Preferred Term Code <i>[hidden]</i> [PT Code]	[PT_CODE] A200
2.10	High Level Term Name <i>[hidden]</i> [HLT Name]	[HLT_NAME] A200
2.11	High Level Term Code <i>[hidden]</i> [HLT Code]	[HLT_CODE] A200
2.12	High Level Group Term Name <i>[hidden]</i> [HLGT Name]	[HLGTNAME] A200
2.13	High Level Group Term Code <i>[hidden]</i> [HLGT Code]	[HLGTCODE] A200
2.14	System Organ Class Name <i>[hidden]</i> [SOC Name]	[MHBODSYS] A200
2.15	System Organ Class Code <i>[hidden]</i> [SOC Code]	[SOC_CODE] A200

Key: [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: MEDICAL HISTORY		
Type	RefName	Description
Item	MHSPID	Line # will be calculated as a sequential number upon submission of the form.

Codelist Values Tables: MEDICAL HISTORY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	MHYN, MHONGO
		No	N	cliNO	

Coding Summary: MEDICAL HISTORY		
Verbatim RefName: MHTERM		
Dictionary: MedDRA Verbatim Type: DISEASE		

Coding Item RefName	Level	Level Type
MHBODSYS	System Organ Class	Term
SOC_CODE	System Organ Class	Code
HLGTNAME	High Level Group Term	Term
HLGTCODE	High Level Group Term	Code
HLT_NAME	High Level Term	Term
HLT_CODE	High Level Term	Code
MHDECOD	Preferred Term	Term
PT_CODE	Preferred Term	Code
LLT_NAME	Low Level Term	Term
LLT_CODE	Low Level Term	Code
VMEDDRA	Dictionary	Term

RDE Analytics: RD_MH		
Data Variable RefName	RD Column Name	Column Data Type
MHYN	MHYN_C	VARCHAR2
	MHYN	VARCHAR2
	MHYN_ND	VARCHAR2
RD_MH_MH_R1		
MHSPID	MHSPID	NUMBER
	MHSPID_ND	VARCHAR2
MHTERM	MHTERM	VARCHAR2
	MHTERM_ND	VARCHAR2
MHONGO	MHONGO_C	VARCHAR2
	MHONGO	VARCHAR2
	MHONGO_ND	VARCHAR2
MHVERBATIM	MHVERBATIM	VARCHAR2
	MHVERBATIM_ND	VARCHAR2
VMEDDRA	VMEDDRA	VARCHAR2
	VMEDDRA_ND	VARCHAR2
LLT_NAME	LLT_NAME	VARCHAR2
	LLT_NAME_ND	VARCHAR2
LLT_CODE	LLT_CODE	VARCHAR2
	LLT_CODE_ND	VARCHAR2
MHDECOD	MHDECOD	VARCHAR2
	MHDECOD_ND	VARCHAR2
PT_CODE	PT_CODE	VARCHAR2
	PT_CODE_ND	VARCHAR2
HLT_NAME	HLT_NAME	VARCHAR2
	HLT_NAME_ND	VARCHAR2
HLT_CODE	HLT_CODE	VARCHAR2
	HLT_CODE_ND	VARCHAR2
HLGTNAME	HLGTNAME	VARCHAR2

	HLGTNAME_ND	VARCHAR2
HLGTCODE	HLGTCODE	VARCHAR2
	HLGTCODE_ND	VARCHAR2
MHBODSYS	MHBODSYS	VARCHAR2
	MHBODSYS_ND	VARCHAR2
SOC_CODE	SOC_CODE	VARCHAR2
	SOC_CODE_ND	VARCHAR2

Codelist Values Tables: HOSPITALIZATION AND CLINIC VISIT HISTORY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cIYESNO	String	Yes	Y	cIYES	HCHXANTIB
		No	N	cIINO	

file:///C:/Users/kmalsick/AppData/Local/Apps/2.0/9A1PEO2Z.DB1/B72KY8PM.AGZ/orac...769 040cb68c7390ff6f 0002.0001 1a75c9af89f12f2b/HtmlResources/AnnotatedStudybook.html 1/14/2016

	HCHXUPOTNUM_ND	VARCHAR2
HCHXSVNUM	HCHXSVNUM	NUMBER
	HCHXSVNUM_ND	VARCHAR2
HCHXANTIB	HCHXANTIB_C	VARCHAR2
	HCHXANTIB	VARCHAR2
	HCHXANTIB_ND	VARCHAR2
HCHXANTIB - ANTIBNEW	ANTIBNEW	NUMBER
HCHXANTIB - ANTIBHOSP	ANTIBHOSP	NUMBER
HCHXANTIB - ANTIBIV	ANTIBIV	NUMBER

VX14-661-108: OPHTHALMOLOGY HISTORY (OH) [OH]		
1.* ✓	Does the subject have a history of treatment with steroids (oral/IV/inhaled/nasal/ocular)? [History of treatment with steroids]	[STERHX] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
2.* ✓	Has the subject had prolonged (≥ 2 weeks) continuous use of steroids (oral/IV/inhaled/nasal/ocular)? [Prolonged continuous use of steroids?]	[STERUSE] [A:Y] <input type="radio"/> [STERUSEY] Yes [STERDUR] Please check the longest duration of continuous treatment [A:2 WEEKS - < 3 MONTHS] <input type="radio"/> 2 weeks - < 3 months [A:3 - 6 MONTHS] <input type="radio"/> 3 - 6 months [A:> 6 MONTHS] <input type="radio"/> > 6 months [STERFREQ] Please check the frequency of continuous treatment [A:DAILY] <input type="radio"/> Daily dosing [A:EVERY OTHER DAY] <input type="radio"/> Every other day [A:OTHER] <input type="radio"/> [STERUSESP] Other, specify: <input type="text" value="A200"/> [A:N] <input type="radio"/> No
3.* ✓	Has the subject had any prior ophthalmologic examinations? [Any prior ophthalmologic examinations?]	[OPEXAM] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
4.* ✓	Has the subject had any prior cataract diagnosis? [Any prior cataract diagnosis?]	[CATRACTS] [A:Y] <input type="radio"/> [CATRACTSCMP] Yes [CATRACTSL] Left Eye [A:Y] <input type="radio"/> [CATDATL] Yes Date of diagnosis Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1930-2020) [A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown [CATRACTSR] Right Eye [A:Y] <input type="radio"/> [CATDATR] Yes Date of diagnosis Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1930-2020) [A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown [A:N] <input type="radio"/> No
5.* ✓	Does the subject have a history of trauma to the eye requiring medical or surgical treatment? [History of trauma?]	[EYETRHX] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
6.* ✓	Does the subject require corrective lenses (i.e., glasses or contacts) [Require corrective lenses?]	[CORRENS] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown
7.* ✓	Does the subject wear protective eyewear (i.e., sunglasses or prescription glasses) when exposed to extreme sunlight [Wear protective eyewear]	[EYEWEAR] [A:ALWAYS] <input type="radio"/> Always [A:SOMETIMES] <input type="radio"/> Sometimes

		<p>[A:NEVER] <input type="radio"/> Never</p>
8.* ✓	Does the subject have a family history (blood relatives) of: [Family History]	<p>[GLAUCGRP] [GLAUCHX] Glaucoma</p> <p>[A:Y] <input type="radio"/> [GLAUGRP] Yes [GLAUCHXAGE] Age at diagnosis (years) <input type="text" value="A3"/></p> <p>[GLAUCHXUNK] [A:U] <input type="radio"/> Unknown</p> <p>[GLAUCHXTYPE] Type [A:NARROW ANGLE] <input type="radio"/> Narrow Angle [A:OPEN ANGLE] <input type="radio"/> Open Angle [A:OTHER] <input type="radio"/> [GLAUCHXSP] Type Other <input type="text" value="A200"/></p> <p>[A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown</p> <p>[CATHX] Cataracts</p> <p>[A:Y] <input type="radio"/> [CATGRP] Yes [CONCATHXYX] Age at diagnosis (years) <input type="text" value="A3"/></p> <p>[CONCATHXUNK] [A:U] <input type="radio"/> Unknown</p> <p>[CONCATHX] Congenital cataracts [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown</p> <p>[A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown</p>
9.* ✓	What is the subject's eye color? [Subject's eye color]	<p>[EYECLR]</p> <p>[A:BLUE] <input type="radio"/> Blue [A:BROWN] <input type="radio"/> Brown [A:GREEN/HAZEL] <input type="radio"/> Green/Hazel [A:OTHER] <input type="radio"/> [EYECLRSP] Other, specify: <input type="text" value="A40"/></p>
10.* ✓	Has the subject had in-home exposure to second hand smoke? [In-home exposure to second hand smoke]	<p>[HM2NDSMK]</p> <p>[A:Y] <input type="radio"/> [HMSSMKCMP] Yes [HMYRSSMK] What is the total number of years of exposure? <input type="text" value="N2"/> years^[b]</p> <p>[HMYRSSMKUNK] [A:U] <input type="radio"/> Unknown</p> <p>[A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown</p>
11.*	Retinopathy of prematurity	[RETINO]

✓	[Retinopathy of prematurity]	<p>[A:Y] <input type="radio"/> [RETINOTR] Yes Treatment needed [A:LASER THERAPY] <input type="radio"/> Laser therapy [A:CRYOTHERAPY] <input type="radio"/> Cryotherapy [A:OTHER] <input type="radio"/> [RETINOTRSP] Other, specify: A200</p> <p>[A:N] <input type="radio"/> No</p>
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Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit
 Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: OPHTHALMOLOGY HISTORY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
ciYESNO	String	Yes	Y	cliYES	STERHX, STERUSE, OPEXAM, CATRACTS, EYETRHX, RETINO
		No	N	cliNO	
ciOHDURATION	String	2 weeks - < 3 months	2 WEEKS - < 3 MONTHS	cli2WKS	STERDUR
		3 - 6 months	3 - 6 MONTHS	cli3MOS	
		> 6 months	> 6 MONTHS	cli6MOS	
ciOHFREQ	String	Daily dosing	DAILY	cliOHDaily	STERFREQ
		Every other day	EVERY OTHER DAY	cliOHEOD	
		Other	OTHER	cliOHOTH	
ciYESNOUNK	String	Yes	Y	cliYES	CATRACTSL, CATRACTSR, CORRENS, GLAUCHX, HM2NDSMK
		No	N	cliNO	
		Unknown	U	cliUNK	
ciOHEXPOSED	String	Always	ALWAYS	cliAlways	EYEWEAR
		Sometimes	SOMETIMES	cliSometimes	
		Never	NEVER	cliNever	
cliUNK	String	Unknown	U	cliUNK	GLAUCHXUNK, CONCATHXUNK, HMYRSMKUNK
ciOHTYPE	String	Narrow Angle	NARROW ANGLE	cliNarrow	GLAUCHXTYPE
		Open Angle	OPEN ANGLE	cliOpen	
		Other	OTHER	cliTypeOth	
ciCATARACTS	String	Yes	Y	cliYES	CATHX, CONCATHX
		No	N	cliNO	
		Unknown	U	cliUNK	
cliEYECOLOR	String	Blue	BLUE	cliBLUE	EYECLR
		Brown	BROWN	cliBROWN	
		Green/Hazel	GREEN/HAZEL	cliGREEN	
		Other	OTHER	cliEYEOTHER	
ciOHRETTX	String	Laser therapy	LASER THERAPY	cliLaser	RETINOTR

		Cryotherapy	CRYOTHERAPY	cliCryo	
		Other	OTHER	cliRETTXO	

RDE Analytics: RD_OH		
Data Variable RefName	RD Column Name	Column Data Type
STERHX	STERHX_C	VARCHAR2
	STERHX	VARCHAR2
	STERHX_ND	VARCHAR2
STERUSE	STERUSE_C	VARCHAR2
	STERUSE	VARCHAR2
	STERUSE_ND	VARCHAR2
STERUSE - STERDUR	STERDUR_C	VARCHAR2
	STERDUR	VARCHAR2
STERUSE - STERFREQ	STERFREQ_C	VARCHAR2
	STERFREQ	VARCHAR2
STERUSE - STERUSESP	STERUSESP	VARCHAR2
OPEXAM	OPEXAM_C	VARCHAR2
	OPEXAM	VARCHAR2
	OPEXAM_ND	VARCHAR2
CATRACTS	CATRACTS_C	VARCHAR2
	CATRACTS	VARCHAR2
	CATRACTS_ND	VARCHAR2
CATRACTS - CATRACTSL	CATRACTSL_C	VARCHAR2
	CATRACTSL	VARCHAR2
CATRACTS - CATDATL	CATDATL	DATE
	CATDATL_DTS	VARCHAR2
	CATDATL_DTR	VARCHAR2
CATRACTS - CATRACTSR	CATRACTSR_C	VARCHAR2
	CATRACTSR	VARCHAR2
CATRACTS - CATDATR	CATDATR	DATE
	CATDATR_DTS	VARCHAR2
	CATDATR_DTR	VARCHAR2
EYETRHX	EYETRHX_C	VARCHAR2
	EYETRHX	VARCHAR2
	EYETRHX_ND	VARCHAR2
CORRENS	CORRENS_C	VARCHAR2
	CORRENS	VARCHAR2
	CORRENS_ND	VARCHAR2
EYEWEAR	EYEWEAR_C	VARCHAR2
	EYEWEAR	VARCHAR2
	EYEWEAR_ND	VARCHAR2
GLAUCGRP	GLAUCGRP_ND	VARCHAR2
GLAUCGRP - GLAUCHX	GLAUCHX_C	VARCHAR2

	GLAUCHX	VARCHAR2
GLAUCGRP - GLAUCHXAGE	GLAUCHXAGE	VARCHAR2
GLAUCGRP - GLAUCHXUNK	GLAUCHXUNK_C	VARCHAR2
	GLAUCHXUNK	VARCHAR2
GLAUCGRP - GLAUCHXTYPE	GLAUCHXTYPE_C	VARCHAR2
	GLAUCHXTYPE	VARCHAR2
GLAUCGRP - GLAUCHXSP	GLAUCHXSP	VARCHAR2
GLAUCGRP - CATHX	CATHX_C	VARCHAR2
	CATHX	VARCHAR2
GLAUCGRP - CONCATHXYX	CONCATHXYX	VARCHAR2
GLAUCGRP - CONCATHXUNK	CONCATHXUNK_C	VARCHAR2
	CONCATHXUNK	VARCHAR2
GLAUCGRP - CONCATHX	CONCATHX_C	VARCHAR2
	CONCATHX	VARCHAR2
EYECLR	EYECLR_C	VARCHAR2
	EYECLR	VARCHAR2
	EYECLR_ND	VARCHAR2
EYECLR - EYECLRSP	EYECLRSP	VARCHAR2
HM2NDSMK	HM2NDSMK_C	VARCHAR2
	HM2NDSMK	VARCHAR2
	HM2NDSMK_ND	VARCHAR2
HM2NDSMK - HMYRSSMK	HMYRSSMK	NUMBER
	HMYRSSMK_U	VARCHAR2
HM2NDSMK - HMYRSSMKUNK	HMYRSSMKUNK_C	VARCHAR2
	HMYRSSMKUNK	VARCHAR2
RETINO	RETINO_C	VARCHAR2
	RETINO	VARCHAR2
	RETINO_ND	VARCHAR2
RETINO - RETINOTR	RETINOTR_C	VARCHAR2
	RETINOTR	VARCHAR2
RETINO - RETINOTRSP	RETINOTRSP	VARCHAR2

1.*

✓

Date of Assessment

[VSDAT]

Req ☐ / Req ☐ / Req ☐ (2015-2020)

2.*

✓

Age

[AGEGRP]

3.*

✓

Height

[HEIGHT]

4.*

✓

Weight

[WEIGHT]

5.*

✓

Blood Pressure

[PRESSURE]

6.*

✓

7.*

✓

Pulse Rate

[PULSE]

8.*

✓

Respiration Rate

[RESP]

9.*

✓

Oxygen Saturation

[O2SAT]

Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_VS		
Data Variable RefName	RD Column Name	Column Data Type
VSDAT	VSDAT	DATE
	VSDAT_DTS	VARCHAR2
	VSDAT_ND	VARCHAR2
AGEGRP	AGEGRP_ND	VARCHAR2
AGEGRP - AGEYR	AGEYR	NUMBER
	AGEYR_U	VARCHAR2
AGEGRP - AGEMTH	AGEMTH	NUMBER
	AGEMTH_U	VARCHAR2
HEIGHT	HEIGHT	NUMBER
	HEIGHT_N	NUMBER
	HEIGHT_U	VARCHAR2
	HEIGHT_NU	VARCHAR2
	HEIGHT_ND	VARCHAR2
WEIGHT	WEIGHT	NUMBER
	WEIGHT_N	NUMBER
	WEIGHT_U	VARCHAR2
	WEIGHT_NU	VARCHAR2
	WEIGHT_ND	VARCHAR2

file:///C:/Users/kmalsick/AppData/Local/Apps/2.0/9ATPEO2Z.DB1/B72KY8PM.AGZ/orac...769 040cb68c7390ff6f 0002.0001 1a75c9af89f12f2b/HtmlResources/AnnotatedStudybook.html

1/14/2016

PRESSURE	PRESSURE_ND	VARCHAR2
PRESSURE - SYSBP	SYSBP	NUMBER
	SYSBP_U	VARCHAR2
PRESSURE - DIABP	DIABP	NUMBER
	DIABP_U	VARCHAR2
TEMP	TEMP	FLOAT
	TEMP_N	FLOAT
	TEMP_U	VARCHAR2
	TEMP_NU	VARCHAR2
	TEMP_ND	VARCHAR2
PULSE	PULSE	NUMBER
	PULSE_U	VARCHAR2
	PULSE_ND	VARCHAR2
RESP	RESP	NUMBER
	RESP_U	VARCHAR2
	RESP_ND	VARCHAR2
O2SAT	O2SAT	NUMBER
	O2SAT_U	VARCHAR2
	O2SAT_ND	VARCHAR2

VX14-661-108: QUESTIONNAIRES (QUES) [QUES]

CFQ-R Type [QUES_S1]

1.*
✓

Please select the appropriate type of CFQ-R questionnaire(s) that were completed based on the subject's age at the Day 1 visit (check all that apply).
[Appropriate CFQ-R]

[CFQRTYPE]
[A:CFQR-AA] ☐ CFQ-R for Adolescents and Adults
[A:CFQR-PC] ☐ CFQ-R for Parents/Caregivers
[A:CFQR-CH] ☐ CFQ-R for Children Ages 12 and 13

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: QUESTIONNAIRES		
Type	RefName	Description
Form	QUES	This form will trigger the correct CFQRs based on the answer to Item #1

Codelist Values Tables: QUESTIONNAIRES					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CFQRTYPE_CL	String	CFQ-R for Adolescents and Adults	CFQR-AA	CFQRAA	CFQRTYPE
		CFQ-R for Parents/Caregivers	CFQR-PC	CFQRPC	
		CFQ-R for Children Ages 12 and 13	CFQR-CH	CFQRCH	

RDE Analytics: RD_QUES		
Data Variable RefName	RD Column Name	Column Data Type
CFQRTYPE	CFQRTYPE_ND	VARCHAR2
CFQRTYPE - CFQ-R for Adolescents and Adults	CFQRTYPE_CFQRAA_C	VARCHAR2
	CFQRTYPE_CFQRAA	VARCHAR2
CFQRTYPE - CFQ-R for Parents/Caregivers	CFQRTYPE_CFQRPC_C	VARCHAR2
	CFQRTYPE_CFQRPC	VARCHAR2
CFQRTYPE - CFQ-R for Children Ages 12 and 13	CFQRTYPE_CFQRCH_C	VARCHAR2
	CFQRTYPE_CFQRCH	VARCHAR2

VX14-661-108: CFQ-R FOR ADOLESCENTS AND ADULTS - English (US) (CFQR-AA) [CFQRAA_E]									
Section II. Quality of Life [sctQOL1]									
Please check the box indicating the answer. During the past two weeks , to what extent have you had difficulty:									
1. ✓	1. Performing vigorous activities such as running or playing sports [Vigorous activities such as running or playing sports]	[QAA_1] [A:A LOT OF DIFFICULTY]	<input type="radio"/> A lot of difficulty	[A:SOME DIFFICULTY]	<input type="radio"/> Some difficulty	[A:A LITTLE DIFFICULTY]	<input type="radio"/> A little difficulty	[A:NO DIFFICULTY]	<input type="radio"/> No difficulty
2. ✓	2. Walking as fast as others [Walking as fast as others]	[QAA_2] [A:A LOT OF DIFFICULTY]	<input type="radio"/> A lot of difficulty	[A:SOME DIFFICULTY]	<input type="radio"/> Some difficulty	[A:A LITTLE DIFFICULTY]	<input type="radio"/> A little difficulty	[A:NO DIFFICULTY]	<input type="radio"/> No difficulty
3. ✓	3. Carrying or lifting heavy things such as books, groceries, or school bags [Carrying or lifting heavy things]	[QAA_3] [A:A LOT OF DIFFICULTY]	<input type="radio"/> A lot of difficulty	[A:SOME DIFFICULTY]	<input type="radio"/> Some difficulty	[A:A LITTLE DIFFICULTY]	<input type="radio"/> A little difficulty	[A:NO DIFFICULTY]	<input type="radio"/> No difficulty
4. ✓	4. Climbing one flight of stairs [Climbing one flight of stairs]	[QAA_4] [A:A LOT OF DIFFICULTY]	<input type="radio"/> A lot of difficulty	[A:SOME DIFFICULTY]	<input type="radio"/> Some difficulty	[A:A LITTLE DIFFICULTY]	<input type="radio"/> A little difficulty	[A:NO DIFFICULTY]	<input type="radio"/> No difficulty
5. ✓	5. Climbing stairs as fast as others [Climbing stairs as fast as others]	[QAA_5] [A:A LOT OF DIFFICULTY]	<input type="radio"/> A lot of difficulty	[A:SOME DIFFICULTY]	<input type="radio"/> Some difficulty	[A:A LITTLE DIFFICULTY]	<input type="radio"/> A little difficulty	[A:NO DIFFICULTY]	<input type="radio"/> No difficulty
During the past two weeks, indicate how often:									
6. ✓	6. You felt well [Felt well]	[QAA_6] [A:ALWAYS]	<input type="radio"/> Always	[A:OFTEN]	<input type="radio"/> Often	[A:SOMETIMES]	<input type="radio"/> Sometimes	[A:NEVER]	<input type="radio"/> Never
7. ✓	7. You felt worried [Felt worried]	[QAA_7] [A:ALWAYS]	<input type="radio"/> Always	[A:OFTEN]	<input type="radio"/> Often	[A:SOMETIMES]	<input type="radio"/> Sometimes	[A:NEVER]	<input type="radio"/> Never
8. ✓	8. You felt useless [Felt useless]	[QAA_8] [A:ALWAYS]	<input type="radio"/> Always	[A:OFTEN]	<input type="radio"/> Often	[A:SOMETIMES]	<input type="radio"/> Sometimes	[A:NEVER]	<input type="radio"/> Never
9. ✓	9. You felt tired [Felt tired]	[QAA_9] [A:ALWAYS]	<input type="radio"/> Always	[A:OFTEN]	<input type="radio"/> Often	[A:SOMETIMES]	<input type="radio"/> Sometimes	[A:NEVER]	<input type="radio"/> Never
10. ✓	10. You felt energetic [Felt energetic]	[QAA_10] [A:ALWAYS]	<input type="radio"/> Always	[A:OFTEN]	<input type="radio"/> Often	[A:SOMETIMES]	<input type="radio"/> Sometimes	[A:NEVER]	<input type="radio"/> Never
11. ✓	11. You felt exhausted [Felt exhausted]	[QAA_11] [A:ALWAYS]	<input type="radio"/> Always	[A:OFTEN]	<input type="radio"/> Often	[A:SOMETIMES]	<input type="radio"/> Sometimes	[A:NEVER]	<input type="radio"/> Never
12. ✓	12. You felt sad [Felt sad]	[QAA_12] [A:ALWAYS]	<input type="radio"/> Always	[A:OFTEN]	<input type="radio"/> Often	[A:SOMETIMES]	<input type="radio"/> Sometimes	[A:NEVER]	<input type="radio"/> Never
Please select the number indicating the answer. Thinking about the state of your health over the last two weeks :									
13. ✓	13. To what extent do you have difficulty walking? [Extent do you have difficulty walking]	[QAA_13] [A:1] <input type="radio"/> 1. You can walk a long time without getting tired [A:2] <input type="radio"/> 2. You can walk a long time but you get tired [A:3] <input type="radio"/> 3. You cannot walk a long time because you get tired quickly [A:4] <input type="radio"/> 4. You avoid walking whenever possible because it's too tiring for you							
14. ✓	14. How do you feel about eating? [Feel about eating]	[QAA_14] [A:1] <input type="radio"/> 1. Just thinking about food makes you feel sick [A:2] <input type="radio"/> 2. You never enjoy eating [A:3] <input type="radio"/> 3. You are sometimes able to enjoy eating [A:4] <input type="radio"/> 4. You are always able to enjoy eating							
15. ✓	15. To what extent do your treatments make your daily life more difficult? [Extent do your treatments make your daily life more difficult]	[QAA_15] [A:1] <input type="radio"/> 1. Not at all [A:2] <input type="radio"/> 2. A little [A:3] <input type="radio"/> 3. Moderately							

		[A:4] <input type="radio"/> 4. A lot
16. ✓	16. How much time do you currently spend each day on your treatments? [Spend each day on your treatments]	[QAA_16] [A:1] <input type="radio"/> 1. A lot [A:2] <input type="radio"/> 2. Some [A:3] <input type="radio"/> 3. A little [A:4] <input type="radio"/> 4. Not very much
17. ✓	17. How difficult is it for you to do your treatments (including medications) each day? [Difficult is it for you to do your treatments each day]	[QAA_17] [A:1] <input type="radio"/> 1. Not at all [A:2] <input type="radio"/> 2. A little [A:3] <input type="radio"/> 3. Moderately [A:4] <input type="radio"/> 4. Very
18. ✓	18. How do you think your health is now? [Think your health is now]	[QAA_18] [A:1] <input type="radio"/> 1. Excellent [A:2] <input type="radio"/> 2. Good [A:3] <input type="radio"/> 3. Fair [A:4] <input type="radio"/> 4. Poor
Please select the answer. Thinking about your health during the past two weeks , indicate the extent to which each sentence is true or false:		
19. ✓	19. I have trouble recovering after physical effort [Trouble recovering after physical effort]	[QAA_19] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
20. ✓	20. I have to limit vigorous activities such as running or playing sports [Limit vigorous activities such as running or playing sports]	[QAA_20] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
21. ✓	21. I have to force myself to eat [Force myself to eat]	[QAA_21] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
22. ✓	22. I have to stay at home more than I want to [Stay at home more than I want]	[QAA_22] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
23. ✓	23. I feel comfortable discussing my illness with others [Feel comfortable discussing my illness with others]	[QAA_23] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
24. ✓	24. I think I am too thin [Think I am too thin]	[QAA_24] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
25. ✓	25. I think I look different from others my age [Look different from others my age]	[QAA_25] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
26. ✓	26. I feel bad about my physical appearance [Feel bad about my physical appearance]	[QAA_26] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
27. ✓	27. People are afraid that I may be contagious [People are afraid that I may be contagious]	[QAA_27] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
28. ✓	28. I get together with my friends a lot [I get together with my friends a lot]	[QAA_28] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
29. ✓	29. I think my coughing bothers others [Think my coughing bothers others]	[QAA_29] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
30. ✓	30. I feel comfortable going out at night [Feel comfortable going out at night]	[QAA_30] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false

31. ✓	31. I often feel lonely [I often feel lonely]	[QAA_31] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
32. ✓	32. I feel healthy [I feel healthy]	[QAA_32] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
33. ✓	33. It is difficult to make plans for the future (for example, going to college, getting married, advancing in a job, etc.) [It is difficult to make plans for the future]	[QAA_33] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
34. ✓	34. I lead a normal life [I lead a normal life]	[QAA_34] [A:VERY TRUE] <input type="radio"/> Very true [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat true [A:SOMEWHAT FALSE] <input type="radio"/> Somewhat false [A:VERY FALSE] <input type="radio"/> Very false
Section III. School, Work, or Daily Activities [sctACTIVITY]		
<i>Questions 35 through 38 are about school, work, or other daily tasks.</i>		
35. ✓	35. To what extent did you have trouble keeping up with your schoolwork, professional work, or other daily activities during the past two weeks ? [Trouble keeping up with your schoolwork, professional work, or other daily activities]	[QAA_35] [A:1] <input type="radio"/> 1. You have had no trouble keeping up [A:2] <input type="radio"/> 2. You have managed to keep up but it's been difficult [A:3] <input type="radio"/> 3. You have been behind [A:4] <input type="radio"/> 4. You have not been able to do these activities at all
36. ✓	36. How often were you absent from school, work, or unable to complete daily activities during the last two weeks because of your illness or other treatments? [How often were you absent from school, work, or unable to complete daily activities]	[QAA_36] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
37. ✓	37. How often does CF get in the way of meeting your school, work, or personal goals? [How often CF in the way of meeting your school, work, or personal goals?]	[QAA_37] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
38. ✓	38. How often does CF interfere with getting out of the house to run errands such as shopping or going to the bank? [How often does CF interfere with getting out of the house to run errands]	[QAA_38] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
Section IV. Symptom Difficulties [sctSYMPTOMS1]		
<i>Please select the answer.</i> Indicate how you have been feeling during the past two weeks :		
39. ✓	39. Have you had trouble gaining weight? [Trouble gaining weight]	[QAA_39] [A:A GREAT DEAL] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:A LITTLE] <input type="radio"/> A little [A:NOT AT ALL] <input type="radio"/> Not at all
40. ✓	40. Have you been congested? [Been congested]	[QAA_40] [A:A GREAT DEAL] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:A LITTLE] <input type="radio"/> A little [A:NOT AT ALL] <input type="radio"/> Not at all
41. ✓	41. Have you been coughing during the day? [Been coughing during the day]	[QAA_41] [A:A GREAT DEAL] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:A LITTLE] <input type="radio"/> A little [A:NOT AT ALL] <input type="radio"/> Not at all
42. ✓	42. Have you had to cough up mucus? [Cough up mucus?]	[QAA_42] [A:A GREAT DEAL] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:A LITTLE] <input type="radio"/> A little [A:NOT AT ALL] <input type="radio"/> Not at all (Go to Question 44)
43. ✓	43. Has your mucus been mostly: [Your mucus been mostly:]	[QAA_43] [A:CLEAR] <input type="radio"/> Clear [A:CLEAR TO YELLOW] <input type="radio"/> Clear to yellow [A:YELLOWISH-GREEN] <input type="radio"/> Yellowish-green [A:GREEN WITH TRACES OF BLOOD] <input type="radio"/> Green with traces of blood [A:DON'T KNOW] <input type="radio"/> Don't know
<i>How often during the past two weeks:</i>		
44. ✓	44. Have you been wheezing? [Been wheezing]	[QAA_44] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
45. ✓	45. Have you had trouble breathing? [Trouble breathing]	[QAA_45] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
46. ✓	46. Have you woken up during the night because you were coughing? [Woken up because you were coughing]	[QAA_46] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never

47. ✓	47. Have you had problems with gas? [Problems with gas]	[QAA_47] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
48. ✓	48. Have you had diarrhea? [Had diarrhea]	[QAA_48] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
49. ✓	49. Have you had abdominal pain? [Had abdominal pain]	[QAA_49] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
50. ✓	50. Have you had eating problems? [Had eating problems]	[QAA_50] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
Key: [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Codelist Values Tables: CFQ-R FOR ADOLESCENTS AND ADULTS - English (US)

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
QAA1_5CL	String	A lot of difficulty	A LOT OF DIFFICULTY	QSQ1_5S1	QAA_1, QAA_2, QAA_3, QAA_4, QAA_5
		Some difficulty	SOME DIFFICULTY	QSQ1_5S2	
		A little difficulty	A LITTLE DIFFICULTY	QSQ1_5S3	
		No difficulty	NO DIFFICULTY	QSQ1_5S4	
QAA6_12CL	String	Always	ALWAYS	QSQ6_12S1	QAA_6, QAA_7, QAA_8, QAA_9, QAA_10, QAA_11, QAA_12, QAA_36, QAA_37, QAA_38, QAA_44, QAA_45, QAA_46, QAA_47, QAA_48, QAA_49, QAA_50
		Often	OFTEN	QSQ6_12S2	
		Sometimes	SOMETIMES	QSQ6_12S3	
		Never	NEVER	QSQ6_12S4	
QAA13CL	String	1. You can walk a long time without getting tired	1	QSQ13S1	QAA_13
		2. You can walk a long time but you get tired	2	QSQ13S2	
		3. You cannot walk a long time because you get tired quickly	3	QSQ13S3	
		4. You avoid walking whenever possible because it's too tiring for you	4	QSQ13S4	
QAA14CL	String	1. Just thinking about food makes you feel sick	1	QSQ14S1	QAA_14
		2. You never enjoy eating	2	QSQ14S2	
		3. You are sometimes able to enjoy eating	3	QSQ14S3	
		4. You are always able to enjoy eating	4	QSQ14S4	
QAA15CL	String	1. Not at all	1	QSQ15S1	QAA_15
		2. A little	2	QSQ15S2	
		3. Moderately	3	QSQ15S3	
		4. A lot	4	QSQ15S4	
QAA16CL	String	1. A lot	1	QSQ16S1	QAA_16
		2. Some	2	QSQ16S2	
		3. A little	3	QSQ16S3	
		4. Not very much	4	QSQ16S4	

QAA17CL	String	1. Not at all	1	QSQ17S1	QAA_17
		2. A little	2	QSQ17S2	
		3. Moderately	3	QSQ17S3	
		4. Very	4	QSQ17S4	
QAA18CL	String	1. Excellent	1	QSQ18S1	QAA_18
		2. Good	2	QSQ18S2	
		3. Fair	3	QSQ18S3	
		4. Poor	4	QSQ18S4	
QAA19_34CL	String	Very true	VERY TRUE	QSQ19_34S1	QAA_19, QAA_20, QAA_21, QAA_22, QAA_23, QAA_24, QAA_25, QAA_26, QAA_27, QAA_28, QAA_29, QAA_30, QAA_31, QAA_32, QAA_33, QAA_34
		Somewhat true	SOMEWHAT TRUE	QSQ19_34S2	
		Somewhat false	SOMEWHAT FALSE	QSQ19_34S3	
		Very false	VERY FALSE	QSQ19_34S4	
QAA35CL	String	1. You have had no trouble keeping up	1	QSQ35S1	QAA_35
		2. You have managed to keep up but it's been difficult	2	QSQ35S2	
		3. You have been behind	3	QSQ35S3	
		4. You have not been able to do these activities at all	4	QSQ35S4	
QAAQ39_42CL	String	A great deal	A GREAT DEAL	QSQ39_42S1	QAA_39, QAA_40, QAA_41
		Somewhat	SOMEWHAT	QSQ39_42S2	
		A little	A LITTLE	QSQ39_42S3	
		Not at all	NOT AT ALL	QSQ39_42S4	
QAAQ42CL	String	A great deal	A GREAT DEAL	QSQ39_42S1	QAA_42
		Somewhat	SOMEWHAT	QSQ39_42S2	
		A little	A LITTLE	QSQ39_42S3	
		Not at all (Go to Question 44)	NOT AT ALL	QSQ42S4	
QAA43CL	String	Clear	CLEAR	QSQ43S1	QAA_43
		Clear to yellow	CLEAR TO YELLOW	QSQ43S2	
		Yellowish-green	YELLOWISH-GREEN	QSQ43S3	
		Green with traces of blood	GREEN WITH TRACES OF BLOOD	QSQ43S4	
		Don't know	DON'T KNOW	QSQ43S5	

RDE Analytics: RD_CFQRAA_E		
Data Variable RefName	RD Column Name	Column Data Type
QAA_1	QAA_1_C	VARCHAR2
	QAA_1	VARCHAR2
	QAA_1_ND	VARCHAR2
QAA_2	QAA_2_C	VARCHAR2

	QAA_2	VARCHAR2
	QAA_2_ND	VARCHAR2
QAA_3	QAA_3_C	VARCHAR2
	QAA_3	VARCHAR2
	QAA_3_ND	VARCHAR2
QAA_4	QAA_4_C	VARCHAR2
	QAA_4	VARCHAR2
	QAA_4_ND	VARCHAR2
QAA_5	QAA_5_C	VARCHAR2
	QAA_5	VARCHAR2
	QAA_5_ND	VARCHAR2
QAA_6	QAA_6_C	VARCHAR2
	QAA_6	VARCHAR2
	QAA_6_ND	VARCHAR2
QAA_7	QAA_7_C	VARCHAR2
	QAA_7	VARCHAR2
	QAA_7_ND	VARCHAR2
QAA_8	QAA_8_C	VARCHAR2
	QAA_8	VARCHAR2
	QAA_8_ND	VARCHAR2
QAA_9	QAA_9_C	VARCHAR2
	QAA_9	VARCHAR2
	QAA_9_ND	VARCHAR2
QAA_10	QAA_10_C	VARCHAR2
	QAA_10	VARCHAR2
	QAA_10_ND	VARCHAR2
QAA_11	QAA_11_C	VARCHAR2
	QAA_11	VARCHAR2
	QAA_11_ND	VARCHAR2
QAA_12	QAA_12_C	VARCHAR2
	QAA_12	VARCHAR2
	QAA_12_ND	VARCHAR2
QAA_13	QAA_13_C	VARCHAR2
	QAA_13	VARCHAR2
	QAA_13_ND	VARCHAR2
QAA_14	QAA_14_C	VARCHAR2
	QAA_14	VARCHAR2
	QAA_14_ND	VARCHAR2
QAA_15	QAA_15_C	VARCHAR2
	QAA_15	VARCHAR2
	QAA_15_ND	VARCHAR2
QAA_16	QAA_16_C	VARCHAR2
	QAA_16	VARCHAR2

	QAA_16_ND	VARCHAR2
QAA_17	QAA_17_C	VARCHAR2
	QAA_17	VARCHAR2
	QAA_17_ND	VARCHAR2
QAA_18	QAA_18_C	VARCHAR2
	QAA_18	VARCHAR2
	QAA_18_ND	VARCHAR2
QAA_19	QAA_19_C	VARCHAR2
	QAA_19	VARCHAR2
	QAA_19_ND	VARCHAR2
QAA_20	QAA_20_C	VARCHAR2
	QAA_20	VARCHAR2
	QAA_20_ND	VARCHAR2
QAA_21	QAA_21_C	VARCHAR2
	QAA_21	VARCHAR2
	QAA_21_ND	VARCHAR2
QAA_22	QAA_22_C	VARCHAR2
	QAA_22	VARCHAR2
	QAA_22_ND	VARCHAR2
QAA_23	QAA_23_C	VARCHAR2
	QAA_23	VARCHAR2
	QAA_23_ND	VARCHAR2
QAA_24	QAA_24_C	VARCHAR2
	QAA_24	VARCHAR2
	QAA_24_ND	VARCHAR2
QAA_25	QAA_25_C	VARCHAR2
	QAA_25	VARCHAR2
	QAA_25_ND	VARCHAR2
QAA_26	QAA_26_C	VARCHAR2
	QAA_26	VARCHAR2
	QAA_26_ND	VARCHAR2
QAA_27	QAA_27_C	VARCHAR2
	QAA_27	VARCHAR2
	QAA_27_ND	VARCHAR2
QAA_28	QAA_28_C	VARCHAR2
	QAA_28	VARCHAR2
	QAA_28_ND	VARCHAR2
QAA_29	QAA_29_C	VARCHAR2
	QAA_29	VARCHAR2
	QAA_29_ND	VARCHAR2
QAA_30	QAA_30_C	VARCHAR2
	QAA_30	VARCHAR2
	QAA_30_ND	VARCHAR2

QAA_31	QAA_31_C	VARCHAR2
	QAA_31	VARCHAR2
	QAA_31_ND	VARCHAR2
QAA_32	QAA_32_C	VARCHAR2
	QAA_32	VARCHAR2
	QAA_32_ND	VARCHAR2
QAA_33	QAA_33_C	VARCHAR2
	QAA_33	VARCHAR2
	QAA_33_ND	VARCHAR2
QAA_34	QAA_34_C	VARCHAR2
	QAA_34	VARCHAR2
	QAA_34_ND	VARCHAR2
QAA_35	QAA_35_C	VARCHAR2
	QAA_35	VARCHAR2
	QAA_35_ND	VARCHAR2
QAA_36	QAA_36_C	VARCHAR2
	QAA_36	VARCHAR2
	QAA_36_ND	VARCHAR2
QAA_37	QAA_37_C	VARCHAR2
	QAA_37	VARCHAR2
	QAA_37_ND	VARCHAR2
QAA_38	QAA_38_C	VARCHAR2
	QAA_38	VARCHAR2
	QAA_38_ND	VARCHAR2
QAA_39	QAA_39_C	VARCHAR2
	QAA_39	VARCHAR2
	QAA_39_ND	VARCHAR2
QAA_40	QAA_40_C	VARCHAR2
	QAA_40	VARCHAR2
	QAA_40_ND	VARCHAR2
QAA_41	QAA_41_C	VARCHAR2
	QAA_41	VARCHAR2
	QAA_41_ND	VARCHAR2
QAA_42	QAA_42_C	VARCHAR2
	QAA_42	VARCHAR2
	QAA_42_ND	VARCHAR2
QAA_43	QAA_43_C	VARCHAR2
	QAA_43	VARCHAR2
	QAA_43_ND	VARCHAR2
QAA_44	QAA_44_C	VARCHAR2
	QAA_44	VARCHAR2
	QAA_44_ND	VARCHAR2
QAA_45	QAA_45_C	VARCHAR2

	QAA_45	VARCHAR2
	QAA_45_ND	VARCHAR2
QAA_46	QAA_46_C	VARCHAR2
	QAA_46	VARCHAR2
	QAA_46_ND	VARCHAR2
QAA_47	QAA_47_C	VARCHAR2
	QAA_47	VARCHAR2
	QAA_47_ND	VARCHAR2
QAA_48	QAA_48_C	VARCHAR2
	QAA_48	VARCHAR2
	QAA_48_ND	VARCHAR2
QAA_49	QAA_49_C	VARCHAR2
	QAA_49	VARCHAR2
	QAA_49_ND	VARCHAR2
QAA_50	QAA_50_C	VARCHAR2
	QAA_50	VARCHAR2
	QAA_50_ND	VARCHAR2

VX14-661-108: CFQ-R FOR PARENTS/CAREGIVERS - English (US) (CFQR-PC) [CFQRPC_E]**Section II. Quality of Life [sctQOL1PC]**

Please indicate how your child has been feeling during the past two weeks by checking the box matching your response.
To what extent has your child had difficulty:

1. ✓	1. Performing vigorous activities such as running or playing sports [Vigorous activities such as running or playing sports]	[QPC_1] [A:A LOT OF DIFFICULTY] <input type="radio"/> A lot of difficulty [A:SOME DIFFICULTY] <input type="radio"/> Some difficulty [A:A LITTLE DIFFICULTY] <input type="radio"/> A little difficulty [A:NO DIFFICULTY] <input type="radio"/> No difficulty
2. ✓	2. Walking as fast as others [Walking as fast as others]	[QPC_2] [A:A LOT OF DIFFICULTY] <input type="radio"/> A lot of difficulty [A:SOME DIFFICULTY] <input type="radio"/> Some difficulty [A:A LITTLE DIFFICULTY] <input type="radio"/> A little difficulty [A:NO DIFFICULTY] <input type="radio"/> No difficulty
3. ✓	3. Climbing stairs as fast as others [Climbing stairs as fast as others]	[QPC_3] [A:A LOT OF DIFFICULTY] <input type="radio"/> A lot of difficulty [A:SOME DIFFICULTY] <input type="radio"/> Some difficulty [A:A LITTLE DIFFICULTY] <input type="radio"/> A little difficulty [A:NO DIFFICULTY] <input type="radio"/> No difficulty
4. ✓	4. Carrying or lifting heavy objects such as books, a school bag or backpack [Carrying or lifting heavy objects]	[QPC_4] [A:A LOT OF DIFFICULTY] <input type="radio"/> A lot of difficulty [A:SOME DIFFICULTY] <input type="radio"/> Some difficulty [A:A LITTLE DIFFICULTY] <input type="radio"/> A little difficulty [A:NO DIFFICULTY] <input type="radio"/> No difficulty
5. ✓	5. Climbing several flights of stairs [Climbing several flights of stairs]	[QPC_5] [A:A LOT OF DIFFICULTY] <input type="radio"/> A lot of difficulty [A:SOME DIFFICULTY] <input type="radio"/> Some difficulty [A:A LITTLE DIFFICULTY] <input type="radio"/> A little difficulty [A:NO DIFFICULTY] <input type="radio"/> No difficulty

Please select the answer matching your response.

During the past **two weeks**, indicate how often your child:

6. ✓	6. Seemed happy [Seemed happy]	[QPC_6] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
7. ✓	7. Seemed worried [Seemed worried]	[QPC_7] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
8. ✓	8. Seemed tired [Seemed tired]	[QPC_8] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
9. ✓	9. Seemed short-tempered [Seemed short-tempered]	[QPC_9] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
10. ✓	10. Seemed well [Seemed well]	[QPC_10] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
11. ✓	11. Seemed grouchy [Seemed grouchy]	[QPC_11] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
12. ✓	12. Seemed energetic [Seemed energetic]	[QPC_12] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
13. ✓	13. Was absent or late for school or other activities because of his/her illness or treatments [Absent or late for school or other activities]	[QPC_13] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never

Please select the answer. Please choose only one answer for each question.

Thinking about the state of your child's health over the **past two weeks**, indicate the extent to which:

14. ✓	14. Your child participated in sports and other physical activities, such as gym class [Your child participated in sports and other physical activities, such as gym class]	[QPC_14] [A:1] <input type="radio"/> 1. Has not participated in physical activities [A:2] <input type="radio"/> 2. Has participated less than usual in sports [A:3] <input type="radio"/> 3. Has participated as much as usual but with some difficulty [A:4] <input type="radio"/> 4. Has been able to participate in physical activities without any difficulty
15. ✓	15. Your child has difficulty walking [Your child has difficulty walking]	[QPC_15] [A:1] <input type="radio"/> 1. He or she can walk a long time without getting tired [A:2] <input type="radio"/> 2. He or she can walk a long time but gets tired [A:3] <input type="radio"/> 3. He or she cannot walk a long time because he or she gets tired quickly [A:4.] <input type="radio"/> 4. He or she avoids walking whenever possible because it's too tiring for him or her

Please select the answer that matches your response to these questions.

Thinking about your child's state of health during the past **two weeks**, indicate the extent to which each sentence is true or false for your child:

16. ✓	16. My child has trouble recovering after physical effort [Trouble recovering after physical effort]	[QPC_16] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
17. ✓	17. Mealtimes are a struggle [Mealtimes are a struggle]	[QPC_17] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
18. ✓	18. My child's treatments get in the way or his or her activities [Get in the way or his or her activities]	[QPC_18] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
19. ✓	19. My child feels small compared to other kids the same age [Feels small compared to other kids the same age]	[QPC_19] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
20. ✓	20. My child feels physically different from other kids the same age [Feels physically different from other kids the same age]	[QPC_20] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
21. ✓	21. My child thinks he/she is too thin [Too thin]	[QPC_21] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
22. ✓	22. My child feels healthy [Feels healthy]	[QPC_22] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
23. ✓	23. My child tends to be withdrawn [Tends to be withdrawn]	[QPC_23] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
24. ✓	24. My child leads a normal life [Leads a normal life]	[QPC_24] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
25. ✓	25. My child has less fun than usual [Less fun than usual]	[QPC_25] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
26. ✓	26. My child has trouble getting along with others [Trouble getting along with others]	[QPC_26] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
27. ✓	27. My child has trouble concentrating [Trouble concentrating]	[QPC_27] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
28. ✓	28. My child is able to keep up with his/her school work or summer activities (e.g.camp) [Keep up with his/her school work or summer activities]	[QPC_28] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
29. ✓	29. My child is not doing as well as usual in school or summer activities (e.g.camp) [Not doing as well as usual in school or summer activities]	[QPC_29] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false
30. ✓	30. My child spends a lot of time on his/her treatments everyday [Spends a lot of time on his/her treatments everyday]	[QPC_30] [A:VTRUE] <input type="radio"/> Very true [A:STRUE] <input type="radio"/> Somewhat true [A:SFALSE] <input type="radio"/> Somewhat false [A:VFALSE] <input type="radio"/> Very false

Please select the answer. Please choose only one answer for each question.

31. ✓	31. How difficult is it for your child to do his/her treatments (including medications) each day? [Difficult to do his/her treatments (including medications) each day]	[QPC_31] [A:NOT AT ALL] <input type="radio"/> Not at all [A:LITTLE] <input type="radio"/> A little [A:MODERATE] <input type="radio"/> Moderately [A:VERY] <input type="radio"/> Very
32. ✓	32. How do you think your child's health is now? [Think your child's health is now]	[QPC_32] [A:EXCELLENT] <input type="radio"/> Excellent [A:GOOD] <input type="radio"/> Good [A:FAIR] <input type="radio"/> Fair [A:POOR] <input type="radio"/> Poor

Section III. Symptom Difficulties [sctSYMPTOMSPC1]

The next set of questions is designed to determine the frequency with which your child has certain respiratory difficulties, such as coughing or shortness of breath.

Please indicate how your child has been feeling during the past **two weeks**:

33. ✓	33. My child had trouble gaining weight [Trouble gaining weight]	[QPC_33] [A:GREAT] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:ALITTLE] <input type="radio"/> A little [A:NOT] <input type="radio"/> Not at all
34. ✓	34. My child was congested [Been congested]	[QPC_34] [A:GREAT] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:ALITTLE] <input type="radio"/> A little [A:NOT] <input type="radio"/> Not at all
35. ✓	35. My child coughed during the day [Been coughing during the day]	[QPC_35] [A:GREAT] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:ALITTLE] <input type="radio"/> A little [A:NOT] <input type="radio"/> Not at all

36. ✓	36. My child had to cough up mucus [Cough up mucus]	[QPC_36] [A:GREAT] <input type="radio"/> A great deal [A:SOMEWHAT] <input type="radio"/> Somewhat [A:ALITTLE] <input type="radio"/> A little [A:NOT] <input type="radio"/> Not at all (Go to Question 38)
37. ✓	37. My child's mucus has been mostly: [Mucus been mostly:]	[QPC_37] [A:1] <input type="radio"/> Clear [A:2] <input type="radio"/> Clear to yellow [A:3] <input type="radio"/> Yellowish-green [A:4] <input type="radio"/> Green with traces of blood [A:5] <input type="radio"/> Don't know
During the past two weeks :		
38. ✓	38. My child wheezed [Been wheezing]	[QPC_38] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
39. ✓	39. My child had trouble breathing [Trouble breathing]	[QPC_39] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
40. ✓	40. My child woke up during the night because he/she was coughing [Woken up because coughing]	[QPC_40] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
41. ✓	41. My child had gas [Problems with gas]	[QPC_41] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
42. ✓	42. My child had diarrhea [Had diarrhea]	[QPC_42] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
43. ✓	43. My child had abdominal pain [Had abdominal pain]	[QPC_43] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
44. ✓	44. My child has had eating problems [Had eating problems]	[QPC_44] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
Key: [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Study Object Descriptions: CFQ-R FOR PARENTS/CAREGIVERS - English (US)

Type	RefName	Description
Form	CFQRPC_E	Dynamic for subjects 12 and 13 at Day-14

Codelist Values Tables: CFQ-R FOR PARENTS/CAREGIVERS - English (US)

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
QAA1_5CL	String	A lot of difficulty	A LOT OF DIFFICULTY	QSQ1_5S1	QPC_1, QPC_2, QPC_3, QPC_4, QPC_5
		Some difficulty	SOME DIFFICULTY	QSQ1_5S2	
		A little difficulty	A LITTLE DIFFICULTY	QSQ1_5S3	
		No difficulty	NO DIFFICULTY	QSQ1_5S4	
QAA6_12CL_2	String	Always	ALWAYS	QSQ6_12S1_2	QPC_6, QPC_7, QPC_8, QPC_9, QPC_10, QPC_11, QPC_12, QPC_13, QPC_38, QPC_39, QPC_40, QPC_41, QPC_42, QPC_43, QPC_44
		Often	OFTEN	QSQ6_12S2_2	
		Sometimes	SOMETIMES	QSQ6_12S3_2	
		Never	NEVER	QSQ6_12S4_2	
QPC14CL	String	1. Has not participated in physical activities	1	QPC14S1	QPC_14
		2. Has participated less than usual in sports	2	QPC14S2	
		3. Has participated as much as usual but with some difficulty	3	QPC14S3	

		4. Has been able to participate in physical activities without any difficulty	4	QPC14S4	
QSQ15CL	String	1. He or she can walk a long time without getting tired	1	QPC15S1	QPC_15
		2. He or she can walk a long time but gets tired	2	QPC15S2	
		3. He or she cannot walk a long time because he or she gets tired quickly	3	QPC15S3	
		4. He or she avoids walking whenever possible because it's too tiring for him or her	4.	QPC15S4	
QAA19_34CL_2	String	Very true	VTRUE	QSQ19_34S1_2	QPC_16, QPC_17, QPC_18, QPC_19, QPC_20, QPC_21, QPC_22, QPC_23, QPC_24, QPC_25, QPC_26, QPC_27, QPC_28, QPC_29, QPC_30
		Somewhat true	STRUE	QSQ19_34S2_2	
		Somewhat false	SFALSE	QSQ19_34S3_2	
		Very false	VFALSE	QSQ19_34S4_2	
QPC31CL	String	Not at all	NOT AT ALL	QPC31S1	QPC_31
		A little	LITTLE	QPC31S2	
		Moderately	MODERATE	QPC31S3	
		Very	VERY	QPC31S4	
QPC32CL	String	Excellent	EXCELLENT	QPC32S1	QPC_32
		Good	GOOD	QPC32S2	
		Fair	FAIR	QPC32S3	
		Poor	POOR	QPC32S4	
QPC33_37CL	String	A great deal	GREAT	QPC33_37S1	QPC_33, QPC_34, QPC_35
		Somewhat	SOMEWHAT	QPC33_37S2	
		A little	ALITTLE	QPC33_37S3	
		Not at all	NOT	QPC33_37S4	
QPC36CL	String	A great deal	GREAT	QPC36S1	QPC_36
		Somewhat	SOMEWHAT	QPC36S2	
		A little	ALITTLE	QPC36S3	
		Not at all (Go to Question 38)	NOT	QPC36S4	
QAA43CL_2	String	Clear	1	QSQ43S1_2	QPC_37
		Clear to yellow	2	QSQ43S2_2	
		Yellowish-green	3	QSQ43S3_2	
		Green with traces of blood	4	QSQ43S4_2	
		Don't know	5	QSQ43S5_2	

RDE Analytics: RD_CFQRPC_E		
Data Variable RefName	RD Column Name	Column Data Type
QPC_1	QPC_1_C	VARCHAR2
	QPC_1	VARCHAR2
	QPC_1_ND	VARCHAR2
QPC_2	QPC_2_C	VARCHAR2

	QPC_2	VARCHAR2
	QPC_2_ND	VARCHAR2
QPC_3	QPC_3_C	VARCHAR2
	QPC_3	VARCHAR2
	QPC_3_ND	VARCHAR2
QPC_4	QPC_4_C	VARCHAR2
	QPC_4	VARCHAR2
	QPC_4_ND	VARCHAR2
QPC_5	QPC_5_C	VARCHAR2
	QPC_5	VARCHAR2
	QPC_5_ND	VARCHAR2
QPC_6	QPC_6_C	VARCHAR2
	QPC_6	VARCHAR2
	QPC_6_ND	VARCHAR2
QPC_7	QPC_7_C	VARCHAR2
	QPC_7	VARCHAR2
	QPC_7_ND	VARCHAR2
QPC_8	QPC_8_C	VARCHAR2
	QPC_8	VARCHAR2
	QPC_8_ND	VARCHAR2
QPC_9	QPC_9_C	VARCHAR2
	QPC_9	VARCHAR2
	QPC_9_ND	VARCHAR2
QPC_10	QPC_10_C	VARCHAR2
	QPC_10	VARCHAR2
	QPC_10_ND	VARCHAR2
QPC_11	QPC_11_C	VARCHAR2
	QPC_11	VARCHAR2
	QPC_11_ND	VARCHAR2
QPC_12	QPC_12_C	VARCHAR2
	QPC_12	VARCHAR2
	QPC_12_ND	VARCHAR2
QPC_13	QPC_13_C	VARCHAR2
	QPC_13	VARCHAR2
	QPC_13_ND	VARCHAR2
QPC_14	QPC_14_C	VARCHAR2
	QPC_14	VARCHAR2
	QPC_14_ND	VARCHAR2
QPC_15	QPC_15_C	VARCHAR2
	QPC_15	VARCHAR2
	QPC_15_ND	VARCHAR2
QPC_16	QPC_16_C	VARCHAR2
	QPC_16	VARCHAR2

	QPC_16_ND	VARCHAR2
QPC_17	QPC_17_C	VARCHAR2
	QPC_17	VARCHAR2
	QPC_17_ND	VARCHAR2
QPC_18	QPC_18_C	VARCHAR2
	QPC_18	VARCHAR2
	QPC_18_ND	VARCHAR2
QPC_19	QPC_19_C	VARCHAR2
	QPC_19	VARCHAR2
	QPC_19_ND	VARCHAR2
QPC_20	QPC_20_C	VARCHAR2
	QPC_20	VARCHAR2
	QPC_20_ND	VARCHAR2
QPC_21	QPC_21_C	VARCHAR2
	QPC_21	VARCHAR2
	QPC_21_ND	VARCHAR2
QPC_22	QPC_22_C	VARCHAR2
	QPC_22	VARCHAR2
	QPC_22_ND	VARCHAR2
QPC_23	QPC_23_C	VARCHAR2
	QPC_23	VARCHAR2
	QPC_23_ND	VARCHAR2
QPC_24	QPC_24_C	VARCHAR2
	QPC_24	VARCHAR2
	QPC_24_ND	VARCHAR2
QPC_25	QPC_25_C	VARCHAR2
	QPC_25	VARCHAR2
	QPC_25_ND	VARCHAR2
QPC_26	QPC_26_C	VARCHAR2
	QPC_26	VARCHAR2
	QPC_26_ND	VARCHAR2
QPC_27	QPC_27_C	VARCHAR2
	QPC_27	VARCHAR2
	QPC_27_ND	VARCHAR2
QPC_28	QPC_28_C	VARCHAR2
	QPC_28	VARCHAR2
	QPC_28_ND	VARCHAR2
QPC_29	QPC_29_C	VARCHAR2
	QPC_29	VARCHAR2
	QPC_29_ND	VARCHAR2
QPC_30	QPC_30_C	VARCHAR2
	QPC_30	VARCHAR2
	QPC_30_ND	VARCHAR2

QPC_31	QPC_31_C	VARCHAR2
	QPC_31	VARCHAR2
	QPC_31_ND	VARCHAR2
QPC_32	QPC_32_C	VARCHAR2
	QPC_32	VARCHAR2
	QPC_32_ND	VARCHAR2
QPC_33	QPC_33_C	VARCHAR2
	QPC_33	VARCHAR2
	QPC_33_ND	VARCHAR2
QPC_34	QPC_34_C	VARCHAR2
	QPC_34	VARCHAR2
	QPC_34_ND	VARCHAR2
QPC_35	QPC_35_C	VARCHAR2
	QPC_35	VARCHAR2
	QPC_35_ND	VARCHAR2
QPC_36	QPC_36_C	VARCHAR2
	QPC_36	VARCHAR2
	QPC_36_ND	VARCHAR2
QPC_37	QPC_37_C	VARCHAR2
	QPC_37	VARCHAR2
	QPC_37_ND	VARCHAR2
QPC_38	QPC_38_C	VARCHAR2
	QPC_38	VARCHAR2
	QPC_38_ND	VARCHAR2
QPC_39	QPC_39_C	VARCHAR2
	QPC_39	VARCHAR2
	QPC_39_ND	VARCHAR2
QPC_40	QPC_40_C	VARCHAR2
	QPC_40	VARCHAR2
	QPC_40_ND	VARCHAR2
QPC_41	QPC_41_C	VARCHAR2
	QPC_41	VARCHAR2
	QPC_41_ND	VARCHAR2
QPC_42	QPC_42_C	VARCHAR2
	QPC_42	VARCHAR2
	QPC_42_ND	VARCHAR2
QPC_43	QPC_43_C	VARCHAR2
	QPC_43	VARCHAR2
	QPC_43_ND	VARCHAR2
QPC_44	QPC_44_C	VARCHAR2
	QPC_44	VARCHAR2
	QPC_44_ND	VARCHAR2

VX14-661-108: CFQ-R FOR CHILDREN AGES 12 AND 13 - English (US) (CFQR-CH) [CFQRCH_E]								
Section II. Quality of Life [sctQOL1CH_1]								
Please check the box matching your response. In the past two weeks :								
1. ✓	1. You were able to walk as fast as others [Walking as fast as others]	[QCH01_1] [A:VERY TRUE] <input checked="" type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True						
2. ✓	2. You were able to climb stairs as fast as others [Climb stairs as fast as other]	[QCH02_1] [A:VERY TRUE] <input checked="" type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True						
3. ✓	3. You were able to run, jump, and climb as you wanted [Run, jump, and climb as you wanted]	[QCH03_1] [A:VERY TRUE] <input checked="" type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True						
4. ✓	4. You were able to run as quickly and as long as others [Run as quickly and as long as others]	[QCH04_1] [A:VERY TRUE] <input checked="" type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True						
5. ✓	5. You were able to participate in sports you enjoy (e.g., swimming, soccer, dancing or others) [Able to participate in sports you enjoy]	[QCH05_1] [A:VERY TRUE] <input checked="" type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True						
6. ✓	6. You had difficulty carrying or lifting heavy things such as your books, your school bag, or a backpack [Difficulty carrying or lifting heavy things]	[QCH06_1] [A:VERY TRUE] <input checked="" type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True						
Please check the box matching your response. And during these past two weeks , indicate how often:								
7. ✓	7. You felt tired [Felt tired]	[QCH07_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
8. ✓	8. You felt mad [Felt mad]	[QCH08_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
9. ✓	9. You felt grouchy [Felt grouchy]	[QCH09_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
10. ✓	10. You felt worried [Felt worries]	[QCH10_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
11. ✓	11. You felt sad [Felt sad]	[QCH11_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
12. ✓	12. You had trouble falling asleep [Trouble falling asleep]	[QCH12_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
13. ✓	13. You had bad dreams or nightmares [Bad dreams or nightmares]	[QCH13_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
14. ✓	14. You felt good about yourself [Felt good about yourself]	[QCH14_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
15. ✓	15. You had trouble eating [Trouble eating]	[QCH15_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
16. ✓	16. You had to stop fun activities to do your treatments [Stop fun activities to do your treatments]	[QCH16_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
17. ✓	17. You were pushed to eat [Pushed to eat]	[QCH17_1] [A:ALWAYS] <input checked="" type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never						
Please check the box matching your response. During the past two weeks :								
18. ✓	18. You were able to do all of your treatments [Do all of your treatments]	[QCH18_1] [A:VERY TRUE] <input checked="" type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True						

19. ✓	19. You enjoyed eating [Enjoyed eating]	[QCH19] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
20. ✓	20. You got together with friends a lot [Got together with your friends a lot]	[QCH20] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
21. ✓	21. You stayed at home more than you wanted to [Stayed at home more than you wanted to]	[QCH21] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
22. ✓	22. You felt comfortable sleeping away from home (at a friend or family member's house or elsewhere) [Comfortable sleeping away from home]	[QCH22] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
23. ✓	23. You felt left out [Felt left out]	[QCH23] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
24. ✓	24. You often invited friends to your house [Often invited friends to your house]	[QCH24] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
25. ✓	25. You were teased by other children [Teased by other children]	[QCH25] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
26. ✓	26. You felt comfortable discussing your illness with others (friends, teachers) [Comfortable discussing your illness with others]	[QCH26] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
27. ✓	27. You thought you were too short [Too short]	[QCH27] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
28. ✓	28. You thought you were too thin [Too thin]	[QCH28] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
29. ✓	29. You thought you were physically different from others your age [Physically different from others your age]	[QCH29] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
30. ✓	30. Doing your treatments bothered you [Doing your treatments bothered you]	[QCH30] [A:VERY TRUE] <input type="radio"/> Very True [A:MOSTLY TRUE] <input type="radio"/> Mostly True [A:SOMEWHAT TRUE] <input type="radio"/> Somewhat True [A:NOT AT ALL TRUE] <input type="radio"/> Not at all True
Please check the box matching your response. Let us know how often in the past two weeks :		
31. ✓	31. You coughed during the day [Coughed during the day]	[QCH31] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
32. ✓	32. You woke up during the night because you were coughing [Woke up during the night because you were coughing]	[QCH32] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
33. ✓	33. You had to cough up mucus [Cough up mucus]	[QCH33] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
34. ✓	34. You had trouble breathing [Trouble breathing]	[QCH34] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
35. ✓	35. Your stomach hurt [Stomach hurt]	[QCH35] [A:ALWAYS] <input type="radio"/> Always [A:OFTEN] <input type="radio"/> Often [A:SOMETIMES] <input type="radio"/> Sometimes [A:NEVER] <input type="radio"/> Never
Key: [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Codelist Values Tables: CFQ-R FOR CHILDREN AGES 12 AND 13 - English (US)

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName

QSchTFCL_1	String	Very True	VERY TRUE	QSch1SVT_1	QCH01_1, QCH02_1, QCH03_1, QCH04_1, QCH05_1, QCH06_1, QCH18_1, QCH19, QCH20, QCH21, QCH22, QCH23, QCH24, QCH25, QCH26, QCH27, QCH28, QCH29, QCH30
		Mostly True	MOSTLY TRUE	QSch1SST_1	
		Somewhat True	SOMEWHAT TRUE	QSch1SSF_1	
		Not at all True	NOT AT ALL TRUE	QSch1SVF_1	
QSch2CL	String	Always	ALWAYS	QSch2S1	QCH07_1, QCH08_1, QCH09_1, QCH10_1, QCH11_1, QCH12_1, QCH13_1, QCH14_1, QCH15_1, QCH16_1, QCH17_1, QCH31, QCH32, QCH33, QCH34, QCH35
		Often	OFTEN	QSch2S2	
		Sometimes	SOMETIMES	QSch2S3	
		Never	NEVER	QSch2S4	

RDE Analytics: RD_CFQRCH_E		
Data Variable RefName	RD Column Name	Column Data Type
QCH01_1	QCH01_1_C	VARCHAR2
	QCH01_1	VARCHAR2
	QCH01_1_ND	VARCHAR2
QCH02_1	QCH02_1_C	VARCHAR2
	QCH02_1	VARCHAR2
	QCH02_1_ND	VARCHAR2
QCH03_1	QCH03_1_C	VARCHAR2
	QCH03_1	VARCHAR2
	QCH03_1_ND	VARCHAR2
QCH04_1	QCH04_1_C	VARCHAR2
	QCH04_1	VARCHAR2
	QCH04_1_ND	VARCHAR2
QCH05_1	QCH05_1_C	VARCHAR2
	QCH05_1	VARCHAR2
	QCH05_1_ND	VARCHAR2
QCH06_1	QCH06_1_C	VARCHAR2
	QCH06_1	VARCHAR2

	QCH06_1_ND	VARCHAR2
QCH07_1	QCH07_1_C	VARCHAR2
	QCH07_1	VARCHAR2
	QCH07_1_ND	VARCHAR2
QCH08_1	QCH08_1_C	VARCHAR2
	QCH08_1	VARCHAR2
	QCH08_1_ND	VARCHAR2
QCH09_1	QCH09_1_C	VARCHAR2
	QCH09_1	VARCHAR2
	QCH09_1_ND	VARCHAR2
QCH10_1	QCH10_1_C	VARCHAR2
	QCH10_1	VARCHAR2
	QCH10_1_ND	VARCHAR2
QCH11_1	QCH11_1_C	VARCHAR2
	QCH11_1	VARCHAR2
	QCH11_1_ND	VARCHAR2
QCH12_1	QCH12_1_C	VARCHAR2
	QCH12_1	VARCHAR2
	QCH12_1_ND	VARCHAR2
QCH13_1	QCH13_1_C	VARCHAR2
	QCH13_1	VARCHAR2
	QCH13_1_ND	VARCHAR2
QCH14_1	QCH14_1_C	VARCHAR2
	QCH14_1	VARCHAR2
	QCH14_1_ND	VARCHAR2
QCH15_1	QCH15_1_C	VARCHAR2
	QCH15_1	VARCHAR2
	QCH15_1_ND	VARCHAR2
QCH16_1	QCH16_1_C	VARCHAR2
	QCH16_1	VARCHAR2
	QCH16_1_ND	VARCHAR2
QCH17_1	QCH17_1_C	VARCHAR2
	QCH17_1	VARCHAR2
	QCH17_1_ND	VARCHAR2
QCH18_1	QCH18_1_C	VARCHAR2
	QCH18_1	VARCHAR2
	QCH18_1_ND	VARCHAR2
QCH19	QCH19_C	VARCHAR2
	QCH19	VARCHAR2
	QCH19_ND	VARCHAR2
QCH20	QCH20_C	VARCHAR2
	QCH20	VARCHAR2
	QCH20_ND	VARCHAR2

QCH21	QCH21_C	VARCHAR2
	QCH21	VARCHAR2
	QCH21_ND	VARCHAR2
QCH22	QCH22_C	VARCHAR2
	QCH22	VARCHAR2
	QCH22_ND	VARCHAR2
QCH23	QCH23_C	VARCHAR2
	QCH23	VARCHAR2
	QCH23_ND	VARCHAR2
QCH24	QCH24_C	VARCHAR2
	QCH24	VARCHAR2
	QCH24_ND	VARCHAR2
QCH25	QCH25_C	VARCHAR2
	QCH25	VARCHAR2
	QCH25_ND	VARCHAR2
QCH26	QCH26_C	VARCHAR2
	QCH26	VARCHAR2
	QCH26_ND	VARCHAR2
QCH27	QCH27_C	VARCHAR2
	QCH27	VARCHAR2
	QCH27_ND	VARCHAR2
QCH28	QCH28_C	VARCHAR2
	QCH28	VARCHAR2
	QCH28_ND	VARCHAR2
QCH29	QCH29_C	VARCHAR2
	QCH29	VARCHAR2
	QCH29_ND	VARCHAR2
QCH30	QCH30_C	VARCHAR2
	QCH30	VARCHAR2
	QCH30_ND	VARCHAR2
QCH31	QCH31_C	VARCHAR2
	QCH31	VARCHAR2
	QCH31_ND	VARCHAR2
QCH32	QCH32_C	VARCHAR2
	QCH32	VARCHAR2
	QCH32_ND	VARCHAR2
QCH33	QCH33_C	VARCHAR2
	QCH33	VARCHAR2
	QCH33_ND	VARCHAR2
QCH34	QCH34_C	VARCHAR2
	QCH34	VARCHAR2
	QCH34_ND	VARCHAR2
QCH35	QCH35_C	VARCHAR2

	QCH35	VARCHAR2
	QCH35_ND	VARCHAR2

VX14-661-108: 12-ITEM SHORT FORM HEALTH SURVEY (SF-12) [SF12]	
12-item Short Form Health Survey [SF12_S1]	
This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. <i>Thank you for completing this survey!</i>	
For each of the following questions, please make a selection that best describes your answer.	
1. <input checked="" type="checkbox"/> 1. In general, would you say your health is: [In general, would you say your health is:]	[SF12_1] [A:EXCELLENT] <input type="radio"/> Excellent [A:VERY GOOD] <input type="radio"/> Very good [A:GOOD] <input type="radio"/> Good [A:FAIR] <input type="radio"/> Fair [A:POOR] <input type="radio"/> Poor
2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?	
2. <input checked="" type="checkbox"/> 2a. <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf [Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf]	[SF12_2a] [A:LIMITED A LOT] <input type="radio"/> Yes, limited a lot [A:LIMITED A LITTLE] <input type="radio"/> Yes, limited a little [A:NOT LIMITED] <input type="radio"/> No, not limited at all
3. <input checked="" type="checkbox"/> 2b. Climbing several flights of stairs [Climbing several flights of stairs]	[SF12_2b] [A:LIMITED A LOT] <input type="radio"/> Yes, limited a lot [A:LIMITED A LITTLE] <input type="radio"/> Yes, limited a little [A:NOT LIMITED] <input type="radio"/> No, not limited at all
3. During the <u>past week</u> , how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>	
4. <input checked="" type="checkbox"/> 3a. <u>Accomplished less</u> than you would like [Accomplished less than you would like]	[SF12_3a] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
5. <input checked="" type="checkbox"/> 3b. Were limited in the <u>kind</u> of work or other activities [Were limited in the kind of work or other activities]	[SF12_3b] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
4. During the <u>past week</u> , how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?	
6. <input checked="" type="checkbox"/> 4a. <u>Accomplished less</u> than you would like [Accomplished less than you would like]	[SF12_4a] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
7. <input checked="" type="checkbox"/> 4b. Did work or other activities <u>less carefully than usual</u> [Did work or other activities less carefully than usual]	[SF12_4b] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
8. <input checked="" type="checkbox"/> 5. During the <u>past week</u> , how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)? [During the past week, how much did pain interfere with your normal work?]	[SF12_5] [A:NOT AT ALL] <input type="radio"/> Not at all [A:A LITTLE BIT] <input type="radio"/> A little bit [A:MODERATELY] <input type="radio"/> Moderately [A:QUITE A BIT] <input type="radio"/> Quite a bit [A:EXTREMELY] <input type="radio"/> Extremely
6. These questions are about how you feel and how things have been with you <u>during the past week</u> . For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past week</u> ...	
9. <input checked="" type="checkbox"/> 6a. Have you felt calm and peaceful? [Have you felt calm and peaceful?]	[SF12_6a] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
10. <input checked="" type="checkbox"/> 6b. Did you have a lot of energy? [Did you have a lot of energy?]	[SF12_6b] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
11. <input checked="" type="checkbox"/> 6c. Have you felt downhearted and depressed? [Have you felt downhearted and depressed?]	[SF12_6c] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
12. <input checked="" type="checkbox"/> 7. During the <u>past week</u> , how much of the time has your <u>physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?</u> [7. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities?]	[SF12_7] [A:ALL OF THE TIME] <input type="radio"/> All of the time [A:MOST OF THE TIME] <input type="radio"/> Most of the time [A:SOME OF THE TIME] <input type="radio"/> Some of the time [A:A LITTLE OF THE TIME] <input type="radio"/> A little of the time [A:NONE OF THE TIME] <input type="radio"/> None of the time
Key: [<input checked="" type="checkbox"/>] = Source verification required	

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: 12-ITEM SHORT FORM HEALTH SURVEY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
SF12_1_CL	String	Excellent	EXCELLENT	SF12_1_1	SF12_1
		Very good	VERY GOOD	SF12_1_2	
		Good	GOOD	SF12_1_3	
		Fair	FAIR	SF12_1_4	
		Poor	POOR	SF12_1_5	
SF12_2_CL	String	Yes, limited a lot	LIMITED A LOT	SF12_2_1	SF12_2a, SF12_2b
		Yes, limited a little	LIMITED A LITTLE	SF12_2_2	
		No, not limited at all	NOT LIMITED	SF12_2_3	
SF12_S3_CL	String	All of the time	ALL OF THE TIME	SF12_3_1	SF12_3a, SF12_3b, SF12_4a, SF12_4b, SF12_6a, SF12_6b, SF12_6c, SF12_7
		Most of the time	MOST OF THE TIME	SF12_3_2	
		Some of the time	SOME OF THE TIME	SF12_3_3	
		A little of the time	A LITTLE OF THE TIME	SF12_3_4	
		None of the time	NONE OF THE TIME	SF12_3_5	
SF12_5_CL	String	Not at all	NOT AT ALL	SF12_5_1	SF12_5
		A little bit	A LITTLE BIT	SF12_5_2	
		Moderately	MODERATELY	SF12_5_3	
		Quite a bit	QUITE A BIT	SF12_5_4	
		Extremely	EXTREMELY	SF12_5_5	

RDE Analytics: RD_SF12		
Data Variable RefName	RD Column Name	Column Data Type
SF12_1	SF12_1_C	VARCHAR2
	SF12_1	VARCHAR2
	SF12_1_ND	VARCHAR2
SF12_2a	SF12_2A_C	VARCHAR2
	SF12_2A	VARCHAR2
	SF12_2A_ND	VARCHAR2
SF12_2b	SF12_2B_C	VARCHAR2
	SF12_2B	VARCHAR2
	SF12_2B_ND	VARCHAR2
SF12_3a	SF12_3A_C	VARCHAR2
	SF12_3A	VARCHAR2
	SF12_3A_ND	VARCHAR2
SF12_3b	SF12_3B_C	VARCHAR2
	SF12_3B	VARCHAR2
	SF12_3B_ND	VARCHAR2
SF12_4a	SF12_4A_C	VARCHAR2
	SF12_4A	VARCHAR2

	SF12_4A_ND	VARCHAR2
SF12_4b	SF12_4B_C	VARCHAR2
	SF12_4B	VARCHAR2
	SF12_4B_ND	VARCHAR2
SF12_5	SF12_5_C	VARCHAR2
	SF12_5	VARCHAR2
	SF12_5_ND	VARCHAR2
SF12_6a	SF12_6A_C	VARCHAR2
	SF12_6A	VARCHAR2
	SF12_6A_ND	VARCHAR2
SF12_6b	SF12_6B_C	VARCHAR2
	SF12_6B	VARCHAR2
	SF12_6B_ND	VARCHAR2
SF12_6c	SF12_6C_C	VARCHAR2
	SF12_6C	VARCHAR2
	SF12_6C_ND	VARCHAR2
SF12_7	SF12_7_C	VARCHAR2
	SF12_7	VARCHAR2
	SF12_7_ND	VARCHAR2

VX14-661-108: PHYSICAL EXAM (PE) [PE]		
1.* ✓	Date of physical exam [Date of physical exam]	[PEDAT] Req <input type="text"/> / Req <input type="text"/> (2015-2020)
2.* ✓	Head, Neck & Thyroid [Head, Neck & Thyroid]	[HNT] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [HNTC] Abnormal, Description of Abnormality A200 [A:NOT DONE] <input type="radio"/> Not Done
3.* ✓	Eyes, Ears, Nose & Throat [Eyes, Ears, Nose & Throat]	[EENT] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [EENTC] Abnormal, Description of Abnormality A200 [A:NOT DONE] <input type="radio"/> Not Done
4.* ✓	Respiratory [Respiratory]	[RESPSYS] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [RESPSYSC] Abnormal, Description of Abnormality A200 [A:NOT DONE] <input type="radio"/> Not Done
5.* ✓	Cardiovascular [Cardiovascular]	[CV] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [CVC] Abnormal, Description of Abnormality A200 [A:NOT DONE] <input type="radio"/> Not Done
6.* ✓	Lymph Nodes [Lymph Nodes]	[LYMPHN] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [LYMPHNC] Abnormal, Description of Abnormality A200 [A:NOT DONE] <input type="radio"/> Not Done
7.* ✓	Abdomen [Abdomen]	[ABDOMEN] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [ABDOMENC] Abnormal, Description of Abnormality A200

		<p>[A:NOT DONE] <input type="radio"/> Not Done</p>
8.* ✓	Skin [Skin]	<p>[SKIN] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [SKINC] Abnormal, Description of Abnormality A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
9.* ✓	Musculoskeletal [Musculoskeletal]	<p>[MUSCSKEL] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [MUSCSKELC] Abnormal, Description of Abnormality A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
10.* ✓	Neurological [Neurological]	<p>[NEURO] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [NEUROC] Abnormal, Description of Abnormality A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
11.* ✓	Anorectal [Anorectal]	<p>[ANOREC] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [ANORECC] Abnormal, Description of Abnormality A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
12.* ✓	Genital [Genital]	<p>[GENIT] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [GENITC] Abnormal, Description of Abnormality A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
13.* ✓	Breast [Breast]	<p>[BREASTS] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [BREASTSC] Abnormal, Description of Abnormality A200</p>

		<div>[A:NOT DONE] <input type="checkbox"/> Not Done</div>
14.* ✓	Other [Other]	<div><div>[OTHER]</div><div>[A:ABNORMAL] <input type="checkbox"/> [OTHERC]</div><div>Abnormal, Description of Abnormality</div><div>A200</div><div>[A:NOT DONE] <input type="checkbox"/> Not Done</div></div>
<div>Key: [*] = Item is required [✓] = Source verification required</div> <div>Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</div>		

Codelist Values Tables: PHYSICAL EXAM					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cINORABNND	String	Normal	NORMAL	cliNORMAL	HNT, EENT, RESPSYS, CV, LYMPHN, ABDOMEN, SKIN, MUSCSKEL, NEURO, ANOREC, GENIT, BREASTS
		Abnormal	ABNORMAL	cliABNORMAL	
		Not Done	NOT DONE	cliNOTDONE	
cIABNND	String	Abnormal	ABNORMAL	cliABNORMAL	OTHER
		Not Done	NOT DONE	cliNOTDONE	

RDE Analytics: RD_PE		
Data Variable RefName	RD Column Name	Column Data Type
PEDAT	PEDAT	DATE
	PEDAT_DTS	VARCHAR2
	PEDAT_ND	VARCHAR2
HNT	HNT_C	VARCHAR2
	HNT	VARCHAR2
	HNT_ND	VARCHAR2
HNT - HNTC	HNTC	VARCHAR2
EENT	EENT_C	VARCHAR2
	EENT	VARCHAR2
	EENT_ND	VARCHAR2
EENT - EENTC	EENTC	VARCHAR2
RESPSYS	RESPSYS_C	VARCHAR2
	RESPSYS	VARCHAR2
	RESPSYS_ND	VARCHAR2
RESPSYS - RESPSYSC	RESPSYSC	VARCHAR2
CV	CV_C	VARCHAR2
	CV	VARCHAR2
	CV_ND	VARCHAR2

CV - CVC	CVC	VARCHAR2
LYMPHN	LYMPHN_C	VARCHAR2
	LYMPHN	VARCHAR2
	LYMPHN_ND	VARCHAR2
LYMPHN - LYMPHNC	LYMPHNC	VARCHAR2
ABDOMEN	ABDOMEN_C	VARCHAR2
	ABDOMEN	VARCHAR2
	ABDOMEN_ND	VARCHAR2
ABDOMEN - ABDOMENC	ABDOMENC	VARCHAR2
SKIN	SKIN_C	VARCHAR2
	SKIN	VARCHAR2
	SKIN_ND	VARCHAR2
SKIN - SKINC	SKINC	VARCHAR2
MUSCSKEL	MUSCSKEL_C	VARCHAR2
	MUSCSKEL	VARCHAR2
	MUSCSKEL_ND	VARCHAR2
MUSCSKEL - MUSCSKELC	MUSCSKELC	VARCHAR2
NEURO	NEURO_C	VARCHAR2
	NEURO	VARCHAR2
	NEURO_ND	VARCHAR2
NEURO - NEUROC	NEUROC	VARCHAR2
ANOREC	ANOREC_C	VARCHAR2
	ANOREC	VARCHAR2
	ANOREC_ND	VARCHAR2
ANOREC - ANORECC	ANORECC	VARCHAR2
GENIT	GENIT_C	VARCHAR2
	GENIT	VARCHAR2
	GENIT_ND	VARCHAR2
GENIT - GENITC	GENITC	VARCHAR2
BREASTS	BREASTS_C	VARCHAR2
	BREASTS	VARCHAR2
	BREASTS_ND	VARCHAR2
BREASTS - BREASTSC	BREASTSC	VARCHAR2
OTHER	OTHER_C	VARCHAR2
	OTHER	VARCHAR2
	OTHER_ND	VARCHAR2
OTHER - OTHERC	OTHERC	VARCHAR2

VX14-661-108: OPHTHALMOLOGY EXAM (OE) [OE]		
1.* ✓	Date of examination [Date of examination]	[OEDAT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2014-2020)
2.* ✓	Best corrected distance visual acuity [Best corrected distance visual acuity]	[VISACTY] [A:FEET] <input type="radio"/> [VISACTYCMP] Feet [VISACTYL] Left Eye (OS): 20/ <input type="text" value="N3"/> [VISACTYR] Right Eye (OD): 20/ <input type="text" value="N3"/> [VISACTYFBOTH_CMP] Both Eyes (OU): 20/ [VISACTYFBOTH] <input type="text" value="N3"/> [VISACTYFND] [A:Not Done] <input type="radio"/> Not Done [A:METERS] <input type="radio"/> [VISACTY1CMP] Meters [VISACTY1L] Left Eye (OS): 6/ <input type="text" value="N3"/> [VISACTY1R] Right Eye (OD): 6/ <input type="text" value="N3"/> [VISACTYMBOTH_CMP] Both Eyes (OU): 6/ [VISACTYMBOTH] <input type="text" value="N3"/> [VISACTYMND] [A:Not Done] <input type="radio"/> Not Done
3.* ✓	Refraction Left Eye [Refraction Left Eye]	[REFRAL] [REFRALD] Was left eye treated with a cycloplegic agent prior to performing refraction? [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [REFRALM] Method [A:AUTOREFRA] <input type="radio"/> Auto-refraction [A:OPHTHAL] <input type="radio"/> Ophthalmoscopy [A:OTHER, SPECIFY] <input type="radio"/> [LREFRASP] Other, specify: <input type="text" value="A200"/>
4.* ✓	Refraction Left Eye Results - Spherical [Refraction Left Eye Results - Spherical]	[REFSPHERL] [SPHERICALU] Spherical [A:+] <input type="radio"/> + [A:-] <input type="radio"/> - [SPHERICAL] <input type="text" value="xx.xx"/> [SPHERICALND] [A:ND] <input type="radio"/> [SPHERICALNDSP_CMP] Not Done [SPHERICALNDSP] Specify reason: <input type="text" value="A200"/>

		[A:U] <input type="radio"/> Unknown
5.* ✓	Refraction Left Eye Results - Cylindrical [Refraction Left Eye Results - Cylindrical]	<p>[REFCYLNL] [CYLINDU] Cylindrical</p> <p>[A:+] <input type="radio"/> + [A:-] <input type="radio"/> -</p> <p>[CYLIND] xx.xx</p> <p>[CYLINDND] [A:ND] <input type="radio"/> [CYLINDNDSP_CMP] Not Done [CYLINDNDSP] Specify reason: A200</p> <p>[A:U] <input type="radio"/> Unknown</p>
6.* ✓	Refraction Left Eye Results - Axis [Refraction Left Eye Results - Axis]	<p>[REFRLAXIS] [AXIS] Axis N3</p> <p>[AXISND] [A:ND] <input type="radio"/> [AXISNDSP_CMP] Not Done [AXISNDSP] Specify reason: A200</p> <p>[A:U] <input type="radio"/> Unknown</p>
7.* ✓	Refraction Right Eye [Refraction Right Eye]	<p>[REFRAR] [REFRARD] Was right eye treated with a cycloplegic agent prior to performing refraction? [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No</p> <p>[REFRARM] Method [A:AUTOREFRA] <input type="radio"/> Auto-refraction [A:OPHTHAL] <input type="radio"/> Ophthalmoscopy [A:OTHER, SPECIFY] <input type="radio"/> [RREFRASP] Other, specify: A200</p>
8.* ✓	Refraction Right Eye Results - Spherical [Refraction Right Eye Results - Spherical]	<p>[REFSPHERR] [SPHERICALRU] Spherical</p> <p>[A:+] <input type="radio"/> + [A:-] <input type="radio"/> -</p> <p>[SPHERICALR] xx.xx</p> <p>[SPHERICALRND] [A:ND] <input type="radio"/> [SPHERICALRNDSP_CMP] Not Done [SPHERICALRNDSP] Specify reason</p>

		<div>A200</div> <div>[A:U] <input type="radio"/> Unknown</div>
9.* ✓	Refraction Right Eye Results - Cylindrical [Refraction Right Eye Results - Cylindrical]	<div>[REFCYLNR]</div> <div>[CYLINDRU]</div> <div>Cylindrical</div> <div>[A:+] <input type="radio"/> + [A:-] <input type="radio"/> -</div> <div>[CYLINDR]</div> <div>xx.xx</div> <div>[CYLINDRND]</div> <div>[A:ND] <input type="radio"/> [CYLINDRNDSP_CMP]</div> <div>Not Done</div> <div>[CLYNDRICALRNDSP]</div> <div>Specify reason:</div> <div>A200</div> <div>[A:U] <input type="radio"/> Unknown</div>
10.* ✓	Refraction Right Eye Results - Axis [Refraction Right Eye Results - Axis]	<div>[REFRRAXIS]</div> <div>[AXISR]</div> <div>Axis</div> <div>N3</div> <div>[AXISRND]</div> <div>[A:ND] <input type="radio"/> [AXISRNDSP_CMP]</div> <div>Not Done</div> <div>[AXISRNDSP]</div> <div>Specify reason:</div> <div>A200</div> <div>[A:U] <input type="radio"/> Unknown</div>
SLIT LAMP EXAM - LEFT EYE [OE_S2]		
11.* ✓	Was the left eye dilated prior to slit lamp exam? [Was the left eye dilated prior to slit lamp exam?]	<div>[DILATEDL]</div> <div>[A:Y] <input type="radio"/> Yes</div> <div>[A:N] <input type="radio"/> No</div>
12.	Left Lens - deleted [hidden] [Left Lens - deleted]	<div>[LENSL]</div> <div>[A:NORMAL] <input type="radio"/> Normal</div> <div>[A:ABNORMAL] <input type="radio"/> [ABNMLCMP]</div> <div>Abnormal - deleted</div> <div>[OPLYN]</div> <div>Opacity? - deleted</div> <div>[A:Y] <input type="radio"/> [OPLYCMP]</div> <div>Yes - deleted</div> <div>[OPLYTYPE]</div> <div>Opacity type: - deleted</div> <div>[A:CATARACT RELATED] <input type="radio"/> Cataract related</div> <div>[A:NON-CATARACT RELATED] <input type="radio"/> Non-cataract related</div> <div>[A:UNKNOWN] <input type="radio"/> Unknown</div> <div>[OPLY]</div> <div>Is opacity congenital, non-progressive and not visually significant? - deleted</div> <div>[A:Y] <input type="radio"/> Yes</div> <div>[A:N] <input type="radio"/> No</div>

		<div style="text-align: right;"> <input type="radio"/> No </div> <p>[CATLYN] Cataracts? - deleted</p> <p>[CATL] Yes Cataracts Location of Cataracts: <i>(check all that apply)</i> - deleted</p> <p>[A:NUCLEAR] <input type="checkbox"/> Nuclear [A:CORTICAL] <input type="checkbox"/> Cortical [A:LAMELLAR] <input type="checkbox"/> Lamellar [A:ANTERIOR] <input type="checkbox"/> [CATLANT] Anterior - deleted [A:POLAR] <input type="checkbox"/> Polar [A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular</p> <p>[A:POSTERIOR] <input type="checkbox"/> [CATLPOST] Posterior - deleted [A:POLAR] <input type="checkbox"/> Polar [A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular</p> <p>[A:OTHER, SPECIFY] <input type="checkbox"/> [CATLSP] Other, specify: - deleted <div style="border: 1px solid black; padding: 2px;">A40</div></p> <div style="text-align: right;"> <input type="radio"/> No </div>
13.* ✓	Left Lens - Opacity? [Left Lens - Opacity?]	<p>[OPLYN1] [A:Y] <input type="radio"/> [OPLYN1CMP] Yes [OPLYTYPE1] Opacity type: [A:CATARACT RELATED] <input type="radio"/> Cataract related [A:NON-CATARACT RELATED] <input type="radio"/> Non-cataract related [A:UNKNOWN] <input type="radio"/> Unknown</p> <p>[OPLYCS1] Is opacity clinically significant? [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown</p> <div style="text-align: right;"> <input type="radio"/> No </div>
14.* ✓	Left Lens - Cataract? [Left Lens - Cataract?]	<p>[CATLYN1] [A:Y] <input type="radio"/> [CATLYN1CMP] Yes [CATL1] Location of Cataracts: <i>(check all that apply)</i> [A:NUCLEAR] <input type="checkbox"/> Nuclear [A:CORTICAL] <input type="checkbox"/> Cortical [A:LAMELLAR] <input type="checkbox"/> Lamellar [A:ANTERIOR] <input type="checkbox"/> [CATLANT1CMP] Anterior [A:POLAR] <input type="checkbox"/> Polar [A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular</p> <p>[A:POSTERIOR] <input type="checkbox"/> [CATLPOST1CMP] Posterior [CATLPOST1] Polar</p>

		<p>[A:POLAR] <input type="checkbox"/></p> <p>[A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular</p> <p>[A:OTHER, SPECIFY] <input type="checkbox"/></p> <p>[CATLSP1CMP]</p> <p>Other</p> <p>[CATLSP1]</p> <p>Specify: <input type="text" value="A40"/></p> <p>[CATLYCS1]</p> <p>Is cataract clinically significant?</p> <p>[A:Y] <input type="radio"/> Yes</p> <p>[A:N] <input type="radio"/> No</p> <p>[A:U] <input type="radio"/> Unknown</p> <p>[A:N] <input type="radio"/> No</p>
SLIT LAMP EXAM - RIGHT EYE [OE_S3]		
15.* ✓	Was the right eye dilated prior to slit lamp exam? [Was the right eye dilated prior to slit lamp exam?]	<p>[DILATEDR]</p> <p>[A:Y] <input type="radio"/> Yes</p> <p>[A:N] <input type="radio"/> No</p>
16.	Right Lens - deleted [hidden] [Right Lens - deleted]	<p>[LENSR]</p> <p>[A:NORMAL] <input type="radio"/> Normal</p> <p>[A:ABNORMAL] <input type="radio"/> [ABNMRCMP]</p> <p>Abnormal - deleted</p> <p>[OPRYN]</p> <p>Opacity? - deleted</p> <p>[A:Y] <input type="radio"/> [OPRYCMP]</p> <p>Yes - deleted</p> <p>[OPRYTYPE]</p> <p>Opacity type: - deleted</p> <p>[A:CATARACT-RELATED] <input type="radio"/> Cataract related</p> <p>[A:NON-CATARACT-RELATED] <input type="radio"/> Non-cataract related</p> <p>[A:UNKNOWN] <input type="radio"/> Unknown</p> <p>[OPRY]</p> <p>Is opacity congenital, non-progressive and not visually significant? - deleted</p> <p>[A:Y] <input type="radio"/> Yes</p> <p>[A:N] <input type="radio"/> No</p> <p>[A:N] <input type="radio"/> No</p> <p>[CATRYN]</p> <p>Cataracts? - deleted</p> <p>[A:Y] <input type="radio"/> [CATR]</p> <p>Yes</p> <p>Location of Cataract: (check all that apply) - deleted</p> <p>[A:NUCLEAR] <input type="checkbox"/> Nuclear</p> <p>[A:CORTICAL] <input type="checkbox"/> Cortical</p> <p>[A:LAMELLAR] <input type="checkbox"/> Lamellar</p> <p>[A:ANTERIOR] <input type="checkbox"/> [CATRANT]</p> <p>Anterior - deleted</p> <p>[A:POLAR] <input type="checkbox"/> Polar</p> <p>[A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular</p> <p>[A:POSTERIOR] <input type="checkbox"/> [CATRPOST]</p> <p>Posterior - deleted</p> <p>[A:POLAR] <input type="checkbox"/> Polar</p> <p>[A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular</p> <p>[A:OTHER, SPECIFY] <input type="checkbox"/> [CATRSP]</p> <p>Other, specify: - deleted <input type="text"/></p>

		<div>[A:N] <input type="radio"/> No</div> <div>A40</div>
17.* ✓	Right Lens - Opacity? [Right Lens - Opacity?]	<div>[OPRYN1] [A:Y] <input type="radio"/> [OPRYN1CMP] Yes [OPRYTYPE1] Opacity type: [A:CATARACT RELATED] <input type="radio"/> Cataract related [A:NON-CATARACT RELATED] <input type="radio"/> Non-cataract related [A:UNKNOWN] <input type="radio"/> Unknown [OPRYCS1] Is opacity clinically significant? [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown [A:N] <input type="radio"/> No</div>
18.* ✓	Right Lens - Cataract [Right Lens - Cataract]	<div>[CATRYN1] [A:Y] <input type="radio"/> [CATRYN1CMP] Yes [CATR1] Location of Cataracts: (check all that apply) [A:NUCLEAR] <input type="checkbox"/> Nuclear [A:CORTICAL] <input type="checkbox"/> Cortical [A:LAMELLAR] <input type="checkbox"/> Lamellar [A:ANTERIOR] <input type="checkbox"/> [CATRANT1CMP] Anterior [CATRANT1] [A:POLAR] <input type="checkbox"/> Polar [A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular [A:POSTERIOR] <input type="checkbox"/> [CATRPOST1CMP] Posterior [CATRPOST1] [A:POLAR] <input type="checkbox"/> Polar [A:SUBCAPSULAR] <input type="checkbox"/> Subcapsular [A:OTHER, SPECIFY] <input type="checkbox"/> [CATRSP1CMP] Other [CATRSP1] Specify: A40 [CATRYCS1] Is cataract clinically significant? [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [A:U] <input type="radio"/> Unknown [A:N] <input type="radio"/> No</div>
<div>Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</div>		

Study Object Descriptions: OPHTHALMOLOGY EXAM		
Type	RefName	Description
Form	OE	Subsequent Exam

Codelist Values Tables: OPHTHALMOLOGY EXAM

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cVISACTY	String	Feet	FEET	cliFeet	VISACTY
		Meters	METERS	cliMeters	
clNotDone	String	Not Done	Not Done	clNotDone1	VISACTYFND, VISACTYMND
cliYESNO	String	Yes	Y	cliYES	REFRALD, REFRARD, DILATEDL, OPLYN, OPLY, CATLYN, OPLYN1,
		No	N	cliNO	CATLYN1, DILATEDR, OPRYN, OPRY, CATRYN, OPRYN1, CATRYN1
cIOEMETHOD	String	Auto-refraction	AUTOREFRA	citmAUTOREF	REFRALM, REFRARM
		Ophthalmoscopy	OPHTHAL	citmOPHTHAL	
		Other	OTHER, SPECIFY	cliOtherSP	
cIOEOSNEG	String	+	+	cliSPHEREPOS	SPHERICALU, CYLINDU, SPHERICALRU, CYLINDRU
		-	-	cliSPHERENEG	
cIND	String	Not Done	ND	cliND	SPHERICALND, CYLINDND, AXISND, SPHERICALRND, CYLINDRND, AXISRND
		Unknown	U	cliUNK	
cINORMABN	String	Normal	NORMAL	cliNORMAL	LENSL, LENSR
		Abnormal	ABNORMAL	cliABNORMAL	
cIOPLYTYPE	String	Cataract related	CATARACT RELATED	cIOPLYTYPE1	OPLYTYPE, OPRYTYPE
		Non-cataract related	NON-CATARACT RELATED	cIOPLYTYPE2	
		Unknown	UNKNOWN	cIOPLYTYPE3	
cICATARACT	String	Nuclear	NUCLEAR	cliNuclear	CATL, CATR
		Cortical	CORTICAL	cliCortical	
		Lamellar	LAMELLAR	cliLamellar	
		Anterior	ANTERIOR	cliAnterior	
		Posterior	POSTERIOR	cliPosterior	
		Other	OTHER, SPECIFY	cliCataractOther	
CATLOC	String	Polar	POLAR	cICATLANT1	CATLANT, CATLPOST, CATRANT, CATRPOST
		Subcapsular	SUBCAPSULAR	cICATLANT2	
cIOPTYPE1	String	Cataract related	CATARACT RELATED	clitmOPTYPE1	OPLYTYPE1, OPRYTYPE1
		Non-cataract related	NON-CATARACT RELATED	clitmOPTYPE2	
		Unknown	UNKNOWN	clitmOPTYPE3	
cliYESNOUNK	String	Yes	Y	cliYES	OPLYCS1, CATLYCS1, OPRYCS1,
		No	N	cliNO	

		Unknown	U	cliUNK	CATRYCS1
cICATARACT1	String	Nuclear	NUCLEAR	cliNuclear	CATL1, CATR1
		Cortical	CORTICAL	cliCortical	
		Lamellar	LAMELLAR	cliLamellar	
		Anterior	ANTERIOR	cliAnterior	
		Posterior	POSTERIOR	cliPosterior	
		Other	OTHER, SPECIFY	cliCataractOther	
cICATLOC1	String	Polar	POLAR	cICATLANT1	CATLANT1, CATLPOST1, CATRANT1, CATRPOST1
		Subcapsular	SUBCAPSULAR	cICATLANT2	

RDE Analytics: RD_OE		
Data Variable RefName	RD Column Name	Column Data Type
OEDAT	OEDAT	DATE
	OEDAT_DTS	VARCHAR2
	OEDAT_DTR	VARCHAR2
	OEDAT_ND	VARCHAR2
VISACTY	VISACTY_C	VARCHAR2
	VISACTY	VARCHAR2
	VISACTY_ND	VARCHAR2
VISACTY - VISACTYL	VISACTYL	NUMBER
VISACTY - VISACTYR	VISACTYR	NUMBER
VISACTY - VISACTYFBOTH	VISACTYFBOTH	NUMBER
VISACTY - VISACTYFND	VISACTYFND_C	VARCHAR2
	VISACTYFND	VARCHAR2
VISACTY - VISACTY1L	VISACTY1L	NUMBER
VISACTY - VISACTY1R	VISACTY1R	NUMBER
VISACTY - VISACTYMBOTH	VISACTYMBOTH	NUMBER
VISACTY - VISACTYMND	VISACTYMND_C	VARCHAR2
	VISACTYMND	VARCHAR2
REFRAL	REFRAL_ND	VARCHAR2
REFRAL - REFRALD	REFRALD_C	VARCHAR2
	REFRALD	VARCHAR2
REFRAL - REFRALM	REFRALM_C	VARCHAR2
	REFRALM	VARCHAR2
REFRAL - LREFRASP	LREFRASP	VARCHAR2
REFSPHERL	REFSPHERL_ND	VARCHAR2
REFSPHERL - SPHERICALU	SPHERICALU_C	VARCHAR2
	SPHERICALU	VARCHAR2
REFSPHERL - SPHERICAL	SPHERICAL	FLOAT
REFSPHERL - SPHERICALND	SPHERICALND_C	VARCHAR2
	SPHERICALND	VARCHAR2
REFSPHERL - SPHERICALNDSP	SPHERICALNDSP	VARCHAR2

REFCYLNL	REFCYLNL_ND	VARCHAR2
REFCYLNL - CYLINDU	CYLINDU_C	VARCHAR2
	CYLINDU	VARCHAR2
REFCYLNL - CYLIND	CYLIND	FLOAT
REFCYLNL - CYLINDND	CYLINDND_C	VARCHAR2
	CYLINDND	VARCHAR2
REFCYLNL - CYLINDNDSP	CYLINDNDSP	VARCHAR2
REFRLAXIS	REFRLAXIS_ND	VARCHAR2
REFRLAXIS - AXIS	AXIS	NUMBER
REFRLAXIS - AXISND	AXISND_C	VARCHAR2
	AXISND	VARCHAR2
REFRLAXIS - AXISNDSP	AXISNDSP	VARCHAR2
REFRAR	REFRAR_ND	VARCHAR2
REFRAR - REFRARD	REFRARD_C	VARCHAR2
	REFRARD	VARCHAR2
REFRAR - REFRARM	REFRARM_C	VARCHAR2
	REFRARM	VARCHAR2
REFRAR - RREFRASP	RREFRASP	VARCHAR2
REFSPHERR	REFSPHERR_ND	VARCHAR2
REFSPHERR - SPHERICALRU	SPHERICALRU_C	VARCHAR2
	SPHERICALRU	VARCHAR2
REFSPHERR - SPHERICALR	SPHERICALR	FLOAT
REFSPHERR - SPHERICALRND	SPHERICALRND_C	VARCHAR2
	SPHERICALRND	VARCHAR2
REFSPHERR - SPHERICALRNDSP	SPHERICALRNDSP	VARCHAR2
REFCYLNR	REFCYLNR_ND	VARCHAR2
REFCYLNR - CYLINDRU	CYLINDRU_C	VARCHAR2
	CYLINDRU	VARCHAR2
REFCYLNR - CYLINDR	CYLINDR	FLOAT
REFCYLNR - CYLINDRND	CYLINDRND_C	VARCHAR2
	CYLINDRND	VARCHAR2
REFCYLNR - CLYNDRICALRNDSP	CLYNDRICALRNDSP	VARCHAR2
REFRRAXIS	REFRRAXIS_ND	VARCHAR2
REFRRAXIS - AXISR	AXISR	NUMBER
REFRRAXIS - AXISRND	AXISRND_C	VARCHAR2
	AXISRND	VARCHAR2
REFRRAXIS - AXISRNDSP	AXISRNDSP	VARCHAR2
DILATEDL	DILATEDL_C	VARCHAR2
	DILATEDL	VARCHAR2
	DILATEDL_ND	VARCHAR2
LENSL	LENSL_C	VARCHAR2
	LENSL	VARCHAR2
	LENSL_ND	VARCHAR2

LENSL - OPLYN	OPLYN_C	VARCHAR2
	OPLYN	VARCHAR2
LENSL - OPLYTYPE	OPLYTYPE_C	VARCHAR2
	OPLYTYPE	VARCHAR2
LENSL - OPLY	OPLY_C	VARCHAR2
	OPLY	VARCHAR2
LENSL - CATLYN	CATLYN_C	VARCHAR2
	CATLYN	VARCHAR2
LENSL - Nuclear	CATL_CLINUCLEAR_C	VARCHAR2
	CATL_CLINUCLEAR	VARCHAR2
LENSL - Cortical	CATL_CLICORTICAL_C	VARCHAR2
	CATL_CLICORTICAL	VARCHAR2
LENSL - Lamellar	CATL_CLILAMELLAR_C	VARCHAR2
	CATL_CLILAMELLAR	VARCHAR2
LENSL - Anterior	CATL_CATLANT_C	VARCHAR2
	CATL_CATLANT	VARCHAR2
LENSL - Polar	CATLANT_CLCATLANT1_C	VARCHAR2
	CATLANT_CLCATLANT1	VARCHAR2
LENSL - Subcapsular	CATLANT_CLCATLANT2_C	VARCHAR2
	CATLANT_CLCATLANT2	VARCHAR2
LENSL - Posterior	CATL_CATLPOST_C	VARCHAR2
	CATL_CATLPOST	VARCHAR2
LENSL - Polar	CATLPOST_CLCATLANT1_C	VARCHAR2
	CATLPOST_CLCATLANT1	VARCHAR2
LENSL - Subcapsular	CATLPOST_CLCATLANT2_C	VARCHAR2
	CATLPOST_CLCATLANT2	VARCHAR2
LENSL - Other	CATL_CATLSP_C	VARCHAR2
	CATL_CATLSP	VARCHAR2
LENSL - CATLSP	CATLSP	VARCHAR2
OPLYN1	OPLYN1_C	VARCHAR2
	OPLYN1	VARCHAR2
	OPLYN1_ND	VARCHAR2
OPLYN1 - OPLYTYPE1	OPLYTYPE1_C	VARCHAR2
	OPLYTYPE1	VARCHAR2
OPLYN1 - OPLYCS1	OPLYCS1_C	VARCHAR2
	OPLYCS1	VARCHAR2
CATLYN1	CATLYN1_C	VARCHAR2
	CATLYN1	VARCHAR2
	CATLYN1_ND	VARCHAR2
CATLYN1 - Nuclear	CATL1_CLINUCLEAR_C	VARCHAR2
	CATL1_CLINUCLEAR	VARCHAR2
CATLYN1 - Cortical	CATL1_CLICORTICAL_C	VARCHAR2
	CATL1_CLICORTICAL	VARCHAR2

CATLYN1 - Lamellar	CATL1_CLILAMELLAR_C	VARCHAR2
	CATL1_CLILAMELLAR	VARCHAR2
CATLYN1 - Anterior	CATL1_CATLANT1CMP_C	VARCHAR2
	CATL1_CATLANT1CMP	VARCHAR2
CATLYN1 - Polar	CATLANT1_CLCATLANT1_C	VARCHAR2
	CATLANT1_CLCATLANT1	VARCHAR2
CATLYN1 - Subcapsular	CATLANT1_CLCATLANT2_C	VARCHAR2
	CATLANT1_CLCATLANT2	VARCHAR2
CATLYN1 - Posterior	CATL1_CATLPOST1CMP_C	VARCHAR2
	CATL1_CATLPOST1CMP	VARCHAR2
CATLYN1 - Polar	CATLPOST1_CLCATLANT1_C	VARCHAR2
	CATLPOST1_CLCATLANT1	VARCHAR2
CATLYN1 - Subcapsular	CATLPOST1_CLCATLANT2_C	VARCHAR2
	CATLPOST1_CLCATLANT2	VARCHAR2
CATLYN1 - Other	CATL1_CATLSP1CMP_C	VARCHAR2
	CATL1_CATLSP1CMP	VARCHAR2
CATLYN1 - CATLSP1	CATLSP1	VARCHAR2
CATLYN1 - CATLYCS1	CATLYCS1_C	VARCHAR2
	CATLYCS1	VARCHAR2
DILATEDR	DILATEDR_C	VARCHAR2
	DILATEDR	VARCHAR2
	DILATEDR_ND	VARCHAR2
LENSR	LENSR_C	VARCHAR2
	LENSR	VARCHAR2
	LENSR_ND	VARCHAR2
LENSR - OPRYN	OPRYN_C	VARCHAR2
	OPRYN	VARCHAR2
LENSR - OPRYTYPE	OPRYTYPE_C	VARCHAR2
	OPRYTYPE	VARCHAR2
LENSR - OPRY	OPRY_C	VARCHAR2
	OPRY	VARCHAR2
LENSR - CATRYN	CATRYN_C	VARCHAR2
	CATRYN	VARCHAR2
LENSR - Nuclear	CATR_CLINUCLEAR_C	VARCHAR2
	CATR_CLINUCLEAR	VARCHAR2
LENSR - Cortical	CATR_CLICORTICAL_C	VARCHAR2
	CATR_CLICORTICAL	VARCHAR2
LENSR - Lamellar	CATR_CLILAMELLAR_C	VARCHAR2
	CATR_CLILAMELLAR	VARCHAR2
LENSR - Anterior	CATR_CATRANT_C	VARCHAR2
	CATR_CATRANT	VARCHAR2
LENSR - Polar	CATRANT_CLCATLANT1_C	VARCHAR2
	CATRANT_CLCATLANT1	VARCHAR2

LENSR - Subcapsular	CATRANT_CLCATLANT2_C	VARCHAR2
	CATRANT_CLCATLANT2	VARCHAR2
LENSR - Posterior	CATR_CATRPOST_C	VARCHAR2
	CATR_CATRPOST	VARCHAR2
LENSR - Polar	CATRPOST_CLCATLANT1_C	VARCHAR2
	CATRPOST_CLCATLANT1	VARCHAR2
LENSR - Subcapsular	CATRPOST_CLCATLANT2_C	VARCHAR2
	CATRPOST_CLCATLANT2	VARCHAR2
LENSR - Other	CATR_CATRSP_C	VARCHAR2
	CATR_CATRSP	VARCHAR2
LENSR - CATRSP	CATRSP	VARCHAR2
OPRYN1	OPRYN1_C	VARCHAR2
	OPRYN1	VARCHAR2
	OPRYN1_ND	VARCHAR2
OPRYN1 - OPRYTYPE1	OPRYTYPE1_C	VARCHAR2
	OPRYTYPE1	VARCHAR2
OPRYN1 - OPRYCS1	OPRYCS1_C	VARCHAR2
	OPRYCS1	VARCHAR2
CATRYN1	CATRYN1_C	VARCHAR2
	CATRYN1	VARCHAR2
	CATRYN1_ND	VARCHAR2
CATRYN1 - Nuclear	CATR1_CLINUCLEAR_C	VARCHAR2
	CATR1_CLINUCLEAR	VARCHAR2
CATRYN1 - Cortical	CATR1_CLICORTICAL_C	VARCHAR2
	CATR1_CLICORTICAL	VARCHAR2
CATRYN1 - Lamellar	CATR1_CLILAMELLAR_C	VARCHAR2
	CATR1_CLILAMELLAR	VARCHAR2
CATRYN1 - Anterior	CATR1_CATRANT1CMP_C	VARCHAR2
	CATR1_CATRANT1CMP	VARCHAR2
CATRYN1 - Polar	CATRANT1_CLCATLANT1_C	VARCHAR2
	CATRANT1_CLCATLANT1	VARCHAR2
CATRYN1 - Subcapsular	CATRANT1_CLCATLANT2_C	VARCHAR2
	CATRANT1_CLCATLANT2	VARCHAR2
CATRYN1 - Posterior	CATR1_CATRPOST1CMP_C	VARCHAR2
	CATR1_CATRPOST1CMP	VARCHAR2
CATRYN1 - Polar	CATRPOST1_CLCATLANT1_C	VARCHAR2
	CATRPOST1_CLCATLANT1	VARCHAR2
CATRYN1 - Subcapsular	CATRPOST1_CLCATLANT2_C	VARCHAR2
	CATRPOST1_CLCATLANT2	VARCHAR2
CATRYN1 - Other	CATR1_CATRSP1CMP_C	VARCHAR2
	CATR1_CATRSP1CMP	VARCHAR2
CATRYN1 - CATRSP1	CATRSP1	VARCHAR2
CATRYN1 - CATRYCS1	CATRYCS1_C	VARCHAR2

	CATRYCS1	VARCHAR2
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VX14-661-108: BRONCHODILATOR (BRON) [BRON]

✓ CM bronchodilator within 24 hours prior to any spirometry assessment(s) at this visit? ✓ SU	[BRONYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
---	--

Line #	Medication Name	Bronchodilator Date	Bronchodilator Stop Time
2. ✓	CM	CM	CM

Bronchodilator Entry [BRON_R1]

2.1	Line # [read-only] CM	[BRONNo] N3
2.2* ✓	Medication Name [Medication Name] CM	[BRON_MED] A200
2.3* ✓	Bronchodilator Date [Bronchodilator Date] CM	[BRONDAT] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
2.4* ✓	Bronchodilator Stop Time [Bronchodilator Stop Time] CM	[BRONTIM] Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock
2.5	Mapped Medication Name [hidden] CM	[BRONVERBATIM] A200
2.6	Dictionary Name and Version [hidden] SU	[VWHODRUG] A200
2.7	Drug name [hidden] SU	[DRUGNAME] A200
2.8	Drug code [hidden] SU	[DRUGCODE] A200
2.9	Preferred Name [hidden] CM	[BRONDECOD] A200
2.10	Preferred Code [hidden] SU	[PREFCODE] A200
2.11	Ingredient List [hidden] SU	[ING_LIST]

A200

Key: [✓] = Source verification required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: BRONCHODILATOR

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	BRONYN
		No	N	cliNO	

Coding Summary: BRONCHODILATOR

Verbatim RefName: BRON_MED

Dictionary: WHODD Verbatim Type: MEDPROD

Coding Item RefName	Level	Level Type
BRONDECOD	Preferred Name	Term
PREFCODE	Preferred Name	Code
ING_LIST	Ingredients	AdditionalInfo
DRUGNAME	Trade Name	Term
DRUGCODE	Trade Name	Code
VWHODRUG	Dictionary	Term

RDE Analytics: RD_BRON

Data Variable RefName	RD Column Name	Column Data Type
BRONYN	BRONYN_C	VARCHAR2
	BRONYN	VARCHAR2
	BRONYN_ND	VARCHAR2
RD_BRON_BRON_R1		
BRONNo	BRONNO	NUMBER
	BRONNO_ND	VARCHAR2
BRON_MED	BRON_MED	VARCHAR2
	BRON_MED_ND	VARCHAR2
BRONDAT	BRONDAT	DATE
	BRONDAT_DTS	VARCHAR2
	BRONDAT_ND	VARCHAR2
BRONTIM	BRONTIM	DATE
	BRONTIM_TMS	VARCHAR2
	BRONTIM_ND	VARCHAR2
BRONVERBATIM	BRONVERBATIM	VARCHAR2
	BRONVERBATIM_ND	VARCHAR2
VWHODRUG	VWHODRUG	VARCHAR2
	VWHODRUG_ND	VARCHAR2
DRUGNAME	DRUGNAME	VARCHAR2
	DRUGNAME_ND	VARCHAR2

DRUGCODE	DRUGCODE	VARCHAR2
	DRUGCODE_ND	VARCHAR2
BRONDECOD	BRONDECOD	VARCHAR2
	BRONDECOD_ND	VARCHAR2
PREFCODE	PREFCODE	VARCHAR2
	PREFCODE_ND	VARCHAR2
ING_LIST	ING_LIST	VARCHAR2
	ING_LIST_ND	VARCHAR2

VX14-661-108: RESPIRATORY MICROBIOLOGY (RMICRO) [RMICRO]

<p>1.* ✓ Has the subject tested positive to any respiratory pathogen in the past TWO YEARS? [Subject test positive?]</p>	<p>[RM] [A:Y] <input checked="" type="radio"/> [RM1] <input type="checkbox"/> Yes</p> <p>[A:ASPERGILLUS (ANY SPECIES)] <input type="checkbox"/> [ASPANY] <input type="checkbox"/> Aspergillus (any species) How many times did the subject test positive in the past TWO years? [A:1] <input type="radio"/> 1 [A:2] <input type="radio"/> 2 or more</p> <p>[A:ALCALIGENES (ACHROMOBACTER) XYLOSOXIDANS] <input type="checkbox"/> [ALCMANY] <input type="checkbox"/> Alcaligenes (Achromobacter) xylosoxidans How many times did the subject test positive in the past TWO years? [A:1] <input type="radio"/> 1 [A:2] <input type="radio"/> 2 or more</p> <p>[A:BURKHOLDERIA SPECIES] <input type="checkbox"/> [RM3] <input type="checkbox"/> Burkholderia species, specify: [A:CEPACIA] <input type="checkbox"/> [RM3BCCMP] <input type="checkbox"/> B. cepacia [RM3BCEP] How many times did the subject test positive in the past TWO years? [A:1] <input type="radio"/> 1 [A:2] <input type="radio"/> 2 or more</p> <p>[A:MULTIVORANS] <input type="checkbox"/> B. multivorans [A:CENOCEPACIA] <input type="checkbox"/> [RM3BCENCMP] <input type="checkbox"/> B. cenocepacia [RM3BCEN] How many times did the subject test positive in the past TWO years? [A:1] <input type="radio"/> 1 [A:2] <input type="radio"/> 2 or more</p> <p>[A:STABILIS] <input type="checkbox"/> B. stabilis [A:VIETNAMENSIS] <input type="checkbox"/> B. vietnamensis [A:DOLOSA] <input type="checkbox"/> [RM3BDOLCMP] <input type="checkbox"/> B. dolosa [RM3BDOL] How many times did the subject test positive in the past TWO years? [A:1] <input type="radio"/> 1 [A:2] <input type="radio"/> 2 or more</p> <p>[A:AMBIFRIA] <input type="checkbox"/> B. ambifria [A:ANTHINA] <input type="checkbox"/> B. anthina [A:PYRROCINIA] <input type="checkbox"/> B. pyrrocinia</p> <p>[A:ESCHERICHIA COLI (E. COLI)] <input type="checkbox"/> Escherichia coli (E. coli) [A:HAEMOPHILUS INFLUENZAE] <input type="checkbox"/> Haemophilus influenzae [A:KLEBSIELLA (ANY SPECIES)] <input type="checkbox"/> Klebsiella (any species)</p> <p>[A:NON-TUBERCULOSIS MYCOBACTERIUM (NTM)] <input type="checkbox"/> [RM4] <input type="checkbox"/> Non-tuberculosis mycobacterium (NTM), specify species: [A:M. AVIUM COMPLEX] <input type="checkbox"/> M. avium complex [A:M. KANSASII] <input type="checkbox"/> M. kansasii [A:M. SIMIAE] <input type="checkbox"/> M. simiae [A:M. ABSCESSUS] <input type="checkbox"/> [RM4MABSCMP] <input type="checkbox"/> M. abscessus [RM4MABSC] How many times did the subject test positive in the past TWO years?</p>
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Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	RM
		No	N	cliNO	
clRMFINDINGS	String	Aspergillus (any species)	ASPERGILLUS (ANY SPECIES)	cliAspergillus	RM1
		Alcaligenes (Achromobacter) xylosoxidans	ALCALIGENES (ACHROMOBACTER) XYLOSOXIDANS	cliAlcaligenes	

		Burkholderia species	BURKHOLDERIA SPECIES	cliBurkholderia	
		Escherichia coli (E. coli)	ESCHERICHIA COLI (E. COLI)	cliEscherichia	
		Haemophilus influenzae	HAEMOPHILUS INFLUENZAE	cliHaemophilus	
		Klebsiella (any species)	KLEBSIELLA (ANY SPECIES)	cliKlebsiella	
		Non-tuberculosis mycobacterium (NTM)	NON-TUBERCULOSIS MYCOBACTERIUM (NTM)	cliINontuberculosis	
		Pseudomonas aeruginosa, Non specific	PSEUDOMONAS AERUGINOSA	cliPseudomonas	
		Pseudomonas aeruginosa, Dry, Non-mucoid	PSEUDOMONAS NON MUC	cliPseudomonasNonMuc	
		Pseudomonas aeruginosa, Mucoid	PSEUDOMONAS MUC	cliPseudoMucoid	
		Other pseudomonas species	OTHER PSEUDOMONAS	cliOtherPseudSpec	
		Staphylococcus aureus, methicillin sensitive (MSSA)	STAPHYLOCOCCUS AUREUS, METHICILLIN SENSITIVE (MSSA)	cliStaphylococcus	
		Methicillin resistant staph aureus (MRSA)	METHICILLIN RESISTANT STAPH AUREUS (MRSA)	cliMRSA	
		Staphylococcus aureus (except MRSA) Non specific	STAPHYLOCOCCUS AUREUS (EXCEPT MSRA) NON SPECIFIC	cliMRSAstaphylNonSpecific	
		Stenotrophomonas (Xanthomonas) maltophilia	STENOTROPHOMONAS (XANTHOMONAS) MALTOPHILIA	cliStenotrophomonas	
		Other gram negative (e.g., Burkholderia gladioli)	OTHER GRAM NEGATIVE	cliOthergram	
cINOSPOS	String	1	1	cliOne	ASPMANY, ALCMANY, RM3BCEP, RM3BCEN, RM3BDOL, RM4MABSC, RM5PSNON, RM6PSDRY, RM7PSMUC, RM8MSSA, RM9MRSA, RM10STPH
		2 or more	2	cliTwoorMore	
cIBURKSPEC	String	B. cepacia	CEPACIA	cliCepacia	RM3
		B. multivorans	MULTIVORANS	climultivorans	
		B. cenocepacia	CENOCEPACIA	clicenocepacia	
		B. stabilis	STABILIS	clistabilis	
		B. vietnamensis	VIETNAMENSIS	clivietnamensis	
		B. dolosa	DOLOSA	clidolosa	
		B. ambifria	AMBIFRIA	cliambifria	
		B. anthina	ANTHINA	clianthina	
		B. pyrrocinia	PYRROCINIA	clipyrrocinia	
cINONTUBSP	String	M. avium complex	M. AVIUM COMPLEX	cliMavium	RM4
		M. kansasii	M. KANSASII	cliKansasii	
		M. simiae	M. SIMAE	cliSimiae	
		M. abscessus	M. ABSCESSUS	cliAbscessus	
		M. chelonae	M. CHELONAE	cliChelonae	
		M. fortuitum	M. FORTUITUM	cliFortu	
		Other NTM Species	OTHER NTM SPECIES	cliOthNTMSpecies	

RDE Analytics: RD_RMICRO		
Data Variable RefName	RD Column Name	Column Data Type
RM	RM_C	VARCHAR2
	RM	VARCHAR2

	RM_ND	VARCHAR2
RM - Aspergillus (any species)	RM1_ASPMANY_C	VARCHAR2
	RM1_ASPMANY	VARCHAR2
RM - ASPMANY	ASPMANY_C	VARCHAR2
	ASPMANY	VARCHAR2
RM - Alcaligenes (Achromobacter) xylooxidans	RM1_ALCMANY_C	VARCHAR2
	RM1_ALCMANY	VARCHAR2
RM - ALCMANY	ALCMANY_C	VARCHAR2
	ALCMANY	VARCHAR2
RM - Burkholderia species	RM1_RM3_C	VARCHAR2
	RM1_RM3	VARCHAR2
RM - B. cepacia	RM3_RM3BCCMP_C	VARCHAR2
	RM3_RM3BCCMP	VARCHAR2
RM - RM3BCEP	RM3BCEP_C	VARCHAR2
	RM3BCEP	VARCHAR2
RM - B. multivorans	RM3_CLIMULTIVORANS_C	VARCHAR2
	RM3_CLIMULTIVORANS	VARCHAR2
RM - B. cenocepacia	RM3_RM3BCENCMP_C	VARCHAR2
	RM3_RM3BCENCMP	VARCHAR2
RM - RM3BCEN	RM3BCEN_C	VARCHAR2
	RM3BCEN	VARCHAR2
RM - B. stabilis	RM3_CLISTABILIS_C	VARCHAR2
	RM3_CLISTABILIS	VARCHAR2
RM - B. vietnamensis	RM3_CLIVIETNAMENSIS_C	VARCHAR2
	RM3_CLIVIETNAMENSIS	VARCHAR2
RM - B. dolosa	RM3_RM3BDOLCMP_C	VARCHAR2
	RM3_RM3BDOLCMP	VARCHAR2
RM - RM3BDOL	RM3BDOL_C	VARCHAR2
	RM3BDOL	VARCHAR2
RM - B. ambifria	RM3_CLIAMBIFRIA_C	VARCHAR2
	RM3_CLIAMBIFRIA	VARCHAR2
RM - B. anthina	RM3_CLIANTHINA_C	VARCHAR2
	RM3_CLIANTHINA	VARCHAR2
RM - B. pyrrocinia	RM3_CLIPYRROCINIA_C	VARCHAR2
	RM3_CLIPYRROCINIA	VARCHAR2
RM - Escherichia coli (E. coli)	RM1_CLIESCHERICHIA_C	VARCHAR2
	RM1_CLIESCHERICHIA	VARCHAR2
RM - Haemophilus influenzae	RM1_CLIHAEMOPHILUS_C	VARCHAR2
	RM1_CLIHAEMOPHILUS	VARCHAR2
RM - Klebsiella (any species)	RM1_CLIiklebsiella_C	VARCHAR2
	RM1_CLIiklebsiella	VARCHAR2
RM - Non-tuberculosis mycobacterium (NTM)	RM1_RM4_C	VARCHAR2
	RM1_RM4	VARCHAR2

RM - M. avium complex	RM4_CLIMAVIUM_C	VARCHAR2
	RM4_CLIMAVIUM	VARCHAR2
RM - M. kansasii	RM4_CLIKANSASII_C	VARCHAR2
	RM4_CLIKANSASII	VARCHAR2
RM - M. simiae	RM4_CLISIMIAE_C	VARCHAR2
	RM4_CLISIMIAE	VARCHAR2
RM - M. abscessus	RM4_RM4MABSCMP_C	VARCHAR2
	RM4_RM4MABSCMP	VARCHAR2
RM - RM4MABSC	RM4MABSC_C	VARCHAR2
	RM4MABSC	VARCHAR2
RM - M. chelonae	RM4_CLICHELONAE_C	VARCHAR2
	RM4_CLICHELONAE	VARCHAR2
RM - M. fortuitum	RM4_CLIFORTU_C	VARCHAR2
	RM4_CLIFORTU	VARCHAR2
RM - Other NTM Species	RM4_CLIOTHNTMSPECIES_C	VARCHAR2
	RM4_CLIOTHNTMSPECIES	VARCHAR2
RM - Pseudomonas aeruginosa, Non specific	RM1_RM5PSNONCMP_C	VARCHAR2
	RM1_RM5PSNONCMP	VARCHAR2
RM - RM5PSNON	RM5PSNON_C	VARCHAR2
	RM5PSNON	VARCHAR2
RM - Pseudomonas aeruginosa, Dry, Non-mucoid	RM1_RM6PSDRYCMP_C	VARCHAR2
	RM1_RM6PSDRYCMP	VARCHAR2
RM - RM6PSDRY	RM6PSDRY_C	VARCHAR2
	RM6PSDRY	VARCHAR2
RM - Pseudomonas aeruginosa, Mucoid	RM1_RM7PSMUCCMP_C	VARCHAR2
	RM1_RM7PSMUCCMP	VARCHAR2
RM - RM7PSMUC	RM7PSMUC_C	VARCHAR2
	RM7PSMUC	VARCHAR2
RM - Other pseudomonas species	RM1_CLIOTHERPSEUDSPEC_C	VARCHAR2
	RM1_CLIOTHERPSEUDSPEC	VARCHAR2
RM - Staphylococcus aureus, methicillin sensitive (MSSA)	RM1_RM8MSSACMP_C	VARCHAR2
	RM1_RM8MSSACMP	VARCHAR2
RM - RM8MSSA	RM8MSSA_C	VARCHAR2
	RM8MSSA	VARCHAR2
RM - Methicillin resistant staph aureus (MRSA)	RM1_RM9MRSACMP_C	VARCHAR2
	RM1_RM9MRSACMP	VARCHAR2
RM - RM9MRSA	RM9MRSA_C	VARCHAR2
	RM9MRSA	VARCHAR2
RM - Staphylococcus aureus (except MRSA) Non specific	RM1_RM10STPHCMP_C	VARCHAR2
	RM1_RM10STPHCMP	VARCHAR2
RM - RM10STPH	RM10STPH_C	VARCHAR2
	RM10STPH	VARCHAR2
RM - Stenotrophomonas (Xanthomonas) maltophilia	RM1_CLISTENOTROPHOMONAS_C	VARCHAR2

	RM1_CLISTENOTROPHOMONAS	VARCHAR2
RM - Other gram negative (e.g., Burkholderia gladioli)	RM1_CLIOTHERGRAM_C	VARCHAR2
	RM1_CLIOTHERGRAM	VARCHAR2

VX14-661-108: VITAL SIGNS - WITHOUT AGE (VS2) [VS2]

1.*

✓

Date of Assessment

VS

[VSDAT]

Req / Req / Req (2015-2020)

2.*

✓

Height

VS

[HEIGHT2]

3.*

✓

Weight

VS

[WEIGHT]

4.*

✓

Blood Pressure

VS

VS

[PRESSURE]

BP]

mmHg[b]

5.*

✓

Temperature

VS

VS

Fahrenheit

6.*

✓

Pulse Rate

VS

[PULSE]

7.*

✓

Respiration Rate

VS

[RESP]

8.*

✓

Oxygen Saturation

VS

[O2SAT]

Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

RDE Analytics: RD_VS2		
Data Variable RefName	RD Column Name	Column Data Type
VSDAT	VSDAT	DATE
	VSDAT_DTS	VARCHAR2
	VSDAT_ND	VARCHAR2
HEIGHT2	HEIGHT2	NUMBER
	HEIGHT2_N	NUMBER
	HEIGHT2_U	VARCHAR2
	HEIGHT2_NU	VARCHAR2
	HEIGHT2_ND	VARCHAR2
WEIGHT	WEIGHT	NUMBER
	WEIGHT_N	NUMBER
	WEIGHT_U	VARCHAR2
	WEIGHT_NU	VARCHAR2
	WEIGHT_ND	VARCHAR2
PRESSURE	PRESSURE_ND	VARCHAR2
PRESSURE - SYSBP	SYSBP	NUMBER
	SYSBP_U	VARCHAR2
PRESSURE - DIABP	DIABP	NUMBER
	DIABP_U	VARCHAR2
TEMP	TEMP	FLOAT
	TEMP_N	FLOAT

file:///C:/Users/kmalsick/AppData/Local/Apps/2.0/9ATPEO2Z.DB1/B72KY8PM.AGZ/orac...769_040cb68c7390ff6f_0002.0001_1a75c9af89f12f2b/HtmlResources/AnnotatedStudybook.html

1/14/2016

	TEMP_U	VARCHAR2
	TEMP_NU	VARCHAR2
	TEMP_ND	VARCHAR2
PULSE	PULSE	NUMBER
	PULSE_U	VARCHAR2
	PULSE_ND	VARCHAR2
RESP	RESP	NUMBER
	RESP_U	VARCHAR2
	RESP_ND	VARCHAR2
O2SAT	O2SAT	NUMBER
	O2SAT_U	VARCHAR2
	O2SAT_ND	VARCHAR2

RDE Analytics: RD_UPREG		
Data Variable RefName	RD Column Name	Column Data Type
CHILDPO2	CHILDPO2_C	VARCHAR2
	CHILDPO2	VARCHAR2
	CHILDPO2_ND	VARCHAR2
CHILDPO2 - ULBDAT	ULBDAT	DATE
	ULBDAT_DTS	VARCHAR2
CHILDPO2 - ULBORRES	ULBORRES_C	VARCHAR2
	ULBORRES	VARCHAR2

VX14-661-108: STUDY DRUG ADMINISTRATION (SDA) [SDA]

[REDACTED] ATION [SDA_S1]	
<div>1.* ✓ Was VX661/ivacaftor study drug taken in the <u>morning</u> in clinic? [Was VX661/ivacaftor study drug taken in the morning in clinic?]</div>	<div>[SDAVX661770] [A:Y] <input checked="" type="radio"/> [SDAVX661770CMP] Yes [DOSEDATVX661770] VX661/ivacaftor Dose date [REDACTED] (2015-2020) [DOSETIMVX661770] VX661/ivacaftor Dose time [REDACTED] ock [DOSETABVX661770] # of VX661/ivacaftor Tablets Taken [REDACTED] SU [MLAMYNVX661770] Was study drug taken with food? [REDACTED] SU [A:N] <input checked="" type="radio"/> No [A:N] <input checked="" type="radio"/> No</div>
<div>2.* ✓ Was ivacaftor study drug taken in the <u>morning</u> in clinic? [Was ivacaftor study drug taken in the morning in clinic?]</div>	<div>[SDAVX770] [A:Y] <input checked="" type="radio"/> [SDAVX770CMP] Yes [DOSEDATVX770] Ivacaftor Dose date [REDACTED] (2015-2020) [DOSETIMVX770] Ivacaftor Dose time [REDACTED] ock [DOSETABVX770] Ivacaftor Tablets Taken [REDACTED] SU [MLAMYNVX770] Was study drug taken with food? [A:Y] <input checked="" type="radio"/> Yes [A:N] <input checked="" type="radio"/> No [A:N] <input checked="" type="radio"/> No</div>
Ivacaftor Afternoon Dose [SDA_S2]	
<div>3. ✓ Was ivacaftor study drug taken in the <u>afternoon</u> in clinic? [Afternoon ivacaftor study drug taken]</div>	<div>[SDAVX770P] [A:Y] <input checked="" type="radio"/> [SDAVX770PCMP] Yes [DOSEDATVX770P] Ivacaftor Dose date Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2013-2020) [DOSETIMVX770P] Ivacaftor Dose time Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock [DOSETABVX770P] Ivacaftor Tablets Taken [REDACTED] [MLAMYNVX770P] Was study drug taken with food? [A:Y] <input checked="" type="radio"/> Yes [A:N] <input checked="" type="radio"/> No</div>

[A:N]  No

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: STUDY DRUG ADMINISTRATION					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	SDAVX661770, MLAMYNVX661770, SDAVX770, MLAMYNVX770, SDAVX770P
		No	N	cliNO	
QAAC_YN	String	Yes	Y	QAAC_YES	MLAMYNVX770P
		No	N	QAAC_NO	

RDE Analytics: RD_SDA		
Data Variable RefName	RD Column Name	Column Data Type
SDAVX661770	SDAVX661770_C	VARCHAR2
	SDAVX661770	VARCHAR2
	SDAVX661770_ND	VARCHAR2
SDAVX661770 - DOSEDATVX661770	DOSEDATVX661770	DATE
	DOSEDATVX661770_DTS	VARCHAR2
SDAVX661770 - DOSETIMVX661770	DOSETIMVX661770	DATE
	DOSETIMVX661770_TMS	VARCHAR2
SDAVX661770 - DOSETABVX661770	DOSETABVX661770	NUMBER
SDAVX661770 - MLAMYNVX661770	MLAMYNVX661770_C	VARCHAR2
	MLAMYNVX661770	VARCHAR2
SDAVX770	SDAVX770_C	VARCHAR2
	SDAVX770	VARCHAR2
	SDAVX770_ND	VARCHAR2
SDAVX770 - DOSEDATVX770	DOSEDATVX770	DATE
	DOSEDATVX770_DTS	VARCHAR2
SDAVX770 - DOSETIMVX770	DOSETIMVX770	DATE
	DOSETIMVX770_TMS	VARCHAR2
SDAVX770 - DOSETABVX770	DOSETABVX770	NUMBER
SDAVX770 - MLAMYNVX770	MLAMYNVX770_C	VARCHAR2
	MLAMYNVX770	VARCHAR2
SDAVX770P	SDAVX770P_C	VARCHAR2
	SDAVX770P	VARCHAR2
	SDAVX770P_ND	VARCHAR2
SDAVX770P - DOSEDATVX770P	DOSEDATVX770P	DATE
	DOSEDATVX770P_DTS	VARCHAR2
SDAVX770P - DOSETIMVX770P	DOSETIMVX770P	DATE
	DOSETIMVX770P_TMS	VARCHAR2
SDAVX770P - DOSETABVX770P	DOSETABVX770P	NUMBER

SDAVX770P - MLAMYNVX770P	MLAMYNVX770P_C	VARCHAR2
	MLAMYNVX770P	VARCHAR2

VX14-661-108: DOSES BEFORE PK SAMPLING (DOSEPK) [DOSEPK]

EX [Redacted] Drug taken two days prior to the PK sampling. If any of the doses were missed, enter item-level comment of "not done" for date and time of dose(s) missed.

VX661/IVACAFITOR DOSE 1 - MORNING DOSE [DOSEPK_S1]

1.* ✓	Date of VX661/ivacaftor Drug Administration [Date of VX661/ivacaftor Drug Administration]	[VX661770DAT1] Req [v] / Req [v] / Req [v] (2015-2020)
2.* ✓	Time of VX661/ivacaftor Drug Administration [Time of VX661/ivacaftor Drug Administration]	[VX661770TIM1] Req [v] : Req [v] 24-hour clock
3.* ✓	# of VX661/ivacaftor Tablets Taken [# of VX661/ivacaftor Tablets Taken]	[VX661770TABTK1] N1
	Was VX661/ivacaftor study drug taken with food? [Was VX661/ivacaftor study drug taken with food?]	[VX661770MLYN1] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No

IVACAFITOR DOSE 1 - MORNING DOSE [DOSEPK_S2]

5.* ✓	Date of ivacaftor Drug Administration [Date of ivacaftor Drug Administration]	[VX770DAT1] Req [v] / Req [v] / Req [v] (2015-2020)
6.* ✓	Time of ivacaftor Drug Administration [Time of ivacaftor Drug Administration]	[VX770TIM1] Req [v] : Req [v] 24-hour clock
7.* ✓	# of ivacaftor Tablets Taken [# of ivacaftor Tablets Taken]	[VX770TABTK1] N4
8.* ✓	Was ivacaftor study drug taken with food? [Was ivacaftor study drug taken with food?]	[VX770MLYN1] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No

IVACAFITOR DOSE 1 - AFTERNOON DOSE [DOSEPK_S5]

9.* ✓	Date of ivacaftor Drug Administration [Date of ivacaftor Drug Administration]	[VX770DAT1P] Req [v] / Req [v] / Req [v] (2015-2020)
10.* ✓	Time of ivacaftor Drug Administration [Time of ivacaftor Drug Administration]	[VX770TIM1P] Req [v] : Req [v] 24-hour clock
11.* ✓	# of ivacaftor Tablets Taken [# of ivacaftor Tablets Taken]	[VX770TABTK1P] N4
12.* ✓	Was ivacaftor study drug taken with food? [Was ivacaftor study drug taken with food?]	[VX770MLYN1P] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No

VX661/IVACAFITOR DOSE 2 - MORNING DOSE [DOSEPK_S3]

13.* ✓	Date of VX661/ivacaftor Drug Administration [Date of VX661/ivacaftor Drug Administration]	[VX661770DAT2] Req [v] / Req [v] / Req [v] (2015-2020)
14.* ✓	Time of VX661/ivacaftor Drug Administration [Time of VX661/ivacaftor Drug Administration]	[VX661770TIM2] Req [v] : Req [v] 24-hour clock
15.* ✓	# of VX661/ivacaftor Tablets Taken [# of VX661/ivacaftor Tablets Taken]	[VX661770TABTK2] N1
16.* ✓	Was VX661/ivacaftor study drug taken with food? [Was VX661/ivacaftor study drug taken with food?]	[VX661770MLYN2] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No

IVACAFITOR DOSE 2 - MORNING DOSE [DOSEPK_S4]

17.* ✓	Date of ivacaftor Drug Administration [Date of ivacaftor Drug Administration]	[VX770DAT2] Req [v] / Req [v] / Req [v] (2015-2020)
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
18.* ✓	Time of ivacaftor Drug Administration [Time of ivacaftor Drug Administration]	[VX770TIM2] Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock
19.* ✓	# of ivacaftor Tablets Taken [# of ivacaftor Tablets Taken]	[VX770TABTK2] <input type="text" value="N4"/>
20.* ✓	Was ivacaftor study drug taken with food? [Was ivacaftor study drug taken with food?]	[VX770MLYN2] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
IVACAFTOR DOSE 2 - AFTERNOON DOSE [DOSEPK_S6]		
21.* ✓	Date of ivacaftor Drug Administration [Date of ivacaftor Drug Administration]	[VX770DAT2P] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
22.* ✓	Time of ivacaftor Drug Administration [Time of ivacaftor Drug Administration]	[VX770TIM2P] Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock
23.* ✓	# of ivacaftor Tablets Taken [# of ivacaftor Tablets Taken]	[VX770TABTK2P] <input type="text" value="N4"/>
24.* ✓	Was ivacaftor study drug taken with food? [Was ivacaftor study drug taken with food?]	[VX770MLYN2P] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Codelist Values Tables: DOSES BEFORE PK SAMPLING					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	VX661770MLYN1, VX770MLYN1,
		No	N	cliNO	VX661770MLYN2, VX770MLYN2
QAAC_YN	String	Yes	Y	QAAC_YES	VX770MLYN1P, VX770MLYN2P
		No	N	QAAC_NO	

RDE Analytics: RD_DOSEPK		
Data Variable RefName	RD Column Name	Column Data Type
VX661770DAT1	VX661770DAT1	DATE
	VX661770DAT1_DTS	VARCHAR2
	VX661770DAT1_ND	VARCHAR2
VX661770TIM1	VX661770TIM1	DATE
	VX661770TIM1_TMS	VARCHAR2
	VX661770TIM1_ND	VARCHAR2
VX661770TABTK1	VX661770TABTK1	NUMBER
	VX661770TABTK1_ND	VARCHAR2
VX661770MLYN1	VX661770MLYN1_C	VARCHAR2
	VX661770MLYN1	VARCHAR2
	VX661770MLYN1_ND	VARCHAR2
VX770DAT1	VX770DAT1	DATE
	VX770DAT1_DTS	VARCHAR2
	VX770DAT1_ND	VARCHAR2

VX770TIM1	VX770TIM1	DATE
	VX770TIM1_TMS	VARCHAR2
	VX770TIM1_ND	VARCHAR2
VX770TABTK1	VX770TABTK1	NUMBER
	VX770TABTK1_ND	VARCHAR2
VX770MLYN1	VX770MLYN1_C	VARCHAR2
	VX770MLYN1	VARCHAR2
	VX770MLYN1_ND	VARCHAR2
VX770DAT1P	VX770DAT1P	DATE
	VX770DAT1P_DTS	VARCHAR2
	VX770DAT1P_ND	VARCHAR2
VX770TIM1P	VX770TIM1P	DATE
	VX770TIM1P_TMS	VARCHAR2
	VX770TIM1P_ND	VARCHAR2
VX770TABTK1P	VX770TABTK1P	NUMBER
	VX770TABTK1P_ND	VARCHAR2
VX770MLYN1P	VX770MLYN1P_C	VARCHAR2
	VX770MLYN1P	VARCHAR2
	VX770MLYN1P_ND	VARCHAR2
VX661770DAT2	VX661770DAT2	DATE
	VX661770DAT2_DTS	VARCHAR2
	VX661770DAT2_ND	VARCHAR2
VX661770TIM2	VX661770TIM2	DATE
	VX661770TIM2_TMS	VARCHAR2
	VX661770TIM2_ND	VARCHAR2
VX661770TABTK2	VX661770TABTK2	NUMBER
	VX661770TABTK2_ND	VARCHAR2
VX661770MLYN2	VX661770MLYN2_C	VARCHAR2
	VX661770MLYN2	VARCHAR2
	VX661770MLYN2_ND	VARCHAR2
VX770DAT2	VX770DAT2	DATE
	VX770DAT2_DTS	VARCHAR2
	VX770DAT2_ND	VARCHAR2
VX770TIM2	VX770TIM2	DATE
	VX770TIM2_TMS	VARCHAR2
	VX770TIM2_ND	VARCHAR2
VX770TABTK2	VX770TABTK2	NUMBER
	VX770TABTK2_ND	VARCHAR2
VX770MLYN2	VX770MLYN2_C	VARCHAR2
	VX770MLYN2	VARCHAR2
	VX770MLYN2_ND	VARCHAR2
VX770DAT2P	VX770DAT2P	DATE
	VX770DAT2P_DTS	VARCHAR2

	VX770DAT2P_ND	VARCHAR2
VX770TIM2P	VX770TIM2P	DATE
	VX770TIM2P_TMS	VARCHAR2
	VX770TIM2P_ND	VARCHAR2
VX770TABTK2P	VX770TABTK2P	NUMBER
	VX770TABTK2P_ND	VARCHAR2
VX770MLYN2P	VX770MLYN2P_C	VARCHAR2
	VX770MLYN2P	VARCHAR2
	VX770MLYN2P_ND	VARCHAR2

VX14-661-108: PK SAMPLE COLLECTION (PK1) [PK1]		
1.* ✓	Collection Date [Collection Date]	[PRE_DT] Req  / Req  / Req  (2015-2020)
2.* ✓	Actual Time [Actual Time]	[PRE_TM] Req  : Req  24-hour clock
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_PK1		
Data Variable RefName	RD Column Name	Column Data Type
PRE_DT	PRE_DT	DATE
	PRE_DT_DTS	VARCHAR2
	PRE_DT_ND	VARCHAR2
PRE_TM	PRE_TM	DATE
	PRE_TM_TMS	VARCHAR2
	PRE_TM_ND	VARCHAR2

VX14-661-108: STATUS (STATUS) [STATUS]	
ADVERSE EVENTS [STATUS_S1]	
1. Has the subject had any adverse events during the protocol-specific collection period? ✓ [AE during collection period]	[AEYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
PRIOR AND CONCOMITANT MEDICATIONS [STATUS_S2]	
2. Has the subject taken medication during the protocol-specified collection period? ✓ [Medication during collection period]	[CMYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
NON-PHARMACOLOGICAL TREATMENTS OR PROCEDURES [STATUS_S3]	
3. Has the subject had any non-pharmacological treatments or therapeutic procedures during the protocol-specified collection period? ✓ [Non-pharmacological treatments during the collection period]	[NT_YN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
SINOPULMONARY SIGNS & SYMPTOMS [STATUS_S4]	
4. Did the subject have 4 or more signs or symptoms of pulmonary exacerbation during the protocol-specified collection period? ✓ [Did the subject have 4 or more signs or symptoms of pulmonary exacerbation?]	[SSSSYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
UNPLANNED HOSPITALIZATION [STATUS_S5]	
5. Has the subject had an unplanned hospitalization during the protocol-specified collection period? ✓ [Unplanned hospitalization?]	[UPLANYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
PLANNED HOSPITALIZATION [STATUS_S6]	
6. Has the subject had a planned hospitalization during the protocol-specified collection period? ✓ [Planned hospitalization?]	[PLANYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
OUTPATIENT SICK VISITS [STATUS_S7]	
7. Has the subject had any Outpatient Sick Visits during the protocol-specified collection period? ✓ [Has the subject had any Outpatient Sick Visits during the protocol specified collection period?]	[OSYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
STUDY DRUG INTERRUPTIONS [STATUS_S8]	
8. Has the subject had any study drug interruptions during the protocol-specified collection period? ✓ [Has the subject had any study drug interruptions during the protocol-specified collection period?]	[INTERYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
Key: [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

Codelist Values Tables: STATUS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	AEYN, CMYN, NT_YN, SSSSYN, UPLANYN, PLANYN, OSYN, INTERYN
		No	N	cliNO	

RDE Analytics: RD_STATUS

Data Variable RefName	RD Column Name	Column Data Type
AEYN	AEYN_C	VARCHAR2
	AEYN	VARCHAR2
	AEYN_ND	VARCHAR2
CMYN	CMYN_C	VARCHAR2
	CMYN	VARCHAR2
	CMYN_ND	VARCHAR2
NT_YN	NT_YN_C	VARCHAR2
	NT_YN	VARCHAR2
	NT_YN_ND	VARCHAR2
SSSSYN	SSSSYN_C	VARCHAR2
	SSSSYN	VARCHAR2
	SSSSYN_ND	VARCHAR2
UPLANYN	UPLANYN_C	VARCHAR2
	UPLANYN	VARCHAR2
	UPLANYN_ND	VARCHAR2
PLANYN	PLANYN_C	VARCHAR2
	PLANYN	VARCHAR2
	PLANYN_ND	VARCHAR2
OSYN	OSYN_C	VARCHAR2
	OSYN	VARCHAR2
	OSYN_ND	VARCHAR2
INTERYN	INTERYN_C	VARCHAR2
	INTERYN	VARCHAR2
	INTERYN_ND	VARCHAR2

VX14-661-108: ADVERSE EVENTS (AE) - Repeating Form [AE]

#	Line #	Adverse Event	Serious?	Start Date	Stop Date	Relationship to Study Drug Regimen	VX661/ivacaftor Action Taken	Ivacaftor Action Taken	Severity	Outcome	TX Required?
1.		AE		AE			AE		SU		
1.	Line # [read-only]	AE		AE					SU		
2.*		Adverse Event [Adverse Event]								AE	
										AE	
3.*		Is AE Serious?									
4.*		Start Date [Start Date]									
5.		Stop Date [Stop Date]									
6.*		Relationship to study drug regimen [Relationship to Study Drug Regimen]									
7.*		VX661/ivacaftor Action Taken [VX661/ivacaftor Action Taken]									
8.*		Ivacaftor Action Taken [Ivacaftor Action Taken]									
9.*		Severity [Severity]									
10.		Outcome [Outcome]									
11.*		Treatment Required?									

12.	<p>Mapped Adverse Event [hidden]</p> <p>[Mapped] AE</p> <p>AE</p>	<p>[AEVERBATIM]</p> <p>A200</p>
13.	<p>Dictionary Name and Version [hidden]</p> <p>SU</p>	<p>[VMEDDRA]</p>
14.	<p>Lowest Level Term Name [hidden]</p> <p>AE</p>	<p>[LLT_NAME]</p> <p>A200</p>
15.	<p>Lowest Level Term Code [hidden]</p> <p>AE</p>	<p>[LLT_CODE]</p> <p>A200</p>
16.	<p>Preferred Term Name [hidden]</p> <p>AE</p>	<p>[AEDECOD]</p> <p>A200</p>
17.	<p>Preferred Term Code [hidden]</p> <p>AE</p>	<p>[PT_CODE]</p> <p>A200</p>
18.	<p>High Level Term Name [hidden]</p> <p>AE</p>	<p>[HLT_NAME]</p> <p>A200</p>
19.	<p>High Level Term Code [hidden]</p> <p>AE</p>	<p>[HLT_CODE]</p> <p>A200</p>
20.	<p>High Level Group Term Name [hidden]</p> <p>AE</p>	<p>[HLGTNAME]</p> <p>A200</p>
21.	<p>High Level Group Term Code [hidden]</p> <p>AE</p>	<p>[HLGTCODE]</p> <p>A200</p>
22.	<p>System Organ Class Name [hidden]</p> <p>AE</p> <p>AE</p>	<p>[AEBODSYS]</p> <p>A200</p>

23.	System Organ Class Code <i>[hidden]</i> [SOC Code]	<div><div>[SOC_CODE]</div><div>A200</div></div>
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Key: [✓] = Source verification required [🔑] = Key item

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: ADVERSE EVENTS		
Type	RefName	Description
Form	AE	Form dynamic based on STATUS
Item	AESPID	Line # will be calculated as a sequential number upon submission of the form.

Keys (navigation)/Uniqueness: ADVERSE EVENTS		
Item	Unique	Order #
AE (Repeating form)		
AE_S1		
AETERM	None	1
AESTDAT	None	2

Codelist Values Tables: ADVERSE EVENTS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cIYESNO	String	Yes	Y	cliYES	AESER, AECONTRT
		No	N	cliNO	
AERELTRDC	String	Not Related	NOT RELATED	NOTRELATED	AEREL
		Unlikely Related	UNLIKELY RELATED	UNLIKELYRELATED	
		Possibly Related	POSSIBLY RELATED	POSSIBLYRELATED	
		Related	RELATED	RELATED	
AEACNRDC	String	Dose Not Changed	DOSE NOT CHANGED	DOSENOTCHANGED	AEACN661770, AEACN770
		Dose Reduced	DOSE REDUCED	DOSEREDUCED	
		Drug Interrupted	DRUG INTERRUPTED	DRUGINTERRUPTED	
		Drug Withdrawn	DRUG WITHDRAWN	DRUGWITHDRAWN	
		Not Applicable	NOT APPLICABLE	NOTAPPLICABLE	
AESEVRDC	String	Mild	MILD	MILD	AESEV
		Moderate	MODERATE	MODERATE	
		Severe	SEVERE	SEVERE_1	
		Life threatening	LIFE THREATENING	LIFETHREATENING	
AEOUTRDC	String	Recovered/Resolved	RECOVERED/RESOLVED	RECOVEREDRESOLVED	AEOUT
		Not Recovered/Not Resolved	NOT RECOVERED/NOT RESOLVED	NOTRECOVNOTRESOL	
		Recovered/Resolved with Sequelae	RECOVERED/RESOLVED WITH SEQUELAE	RECOVEREDWSEQ	
		Fatal	FATAL	FATAL	
		Unknown	UNKNOWN	UNKNOWN	

Coding Summary: ADVERSE EVENTS

Verbatim RefName: AETERM Dictionary: MedDRA Verbatim Type: AE		
Coding Item RefName	Level	Level Type
AEBODSYS	System Organ Class	Term
SOC_CODE	System Organ Class	Code
HLGTNAME	High Level Group Term	Term
HLGTCODE	High Level Group Term	Code
HLT_NAME	High Level Term	Term
HLT_CODE	High Level Term	Code
AEDECOD	Preferred Term	Term
PT_CODE	Preferred Term	Code
LLT_NAME	Low Level Term	Term
LLT_CODE	Low Level Term	Code
VMEDDRA	Dictionary	Term

RDE Analytics: RD_AE		
Data Variable RefName	RD Column Name	Column Data Type
AESPID	AESPID	NUMBER
	AESPID_ND	VARCHAR2
AETERM	AETERM	VARCHAR2
	AETERM_ND	VARCHAR2
AESER	AESER_C	VARCHAR2
	AESER	VARCHAR2
	AESER_ND	VARCHAR2
AESTDAT	AESTDAT	DATE
	AESTDAT_DTS	VARCHAR2
	AESTDAT_DTR	VARCHAR2
	AESTDAT_ND	VARCHAR2
AEENDAT	AEENDAT	DATE
	AEENDAT_DTS	VARCHAR2
	AEENDAT_DTR	VARCHAR2
	AEENDAT_ND	VARCHAR2
AEREL	AEREL_C	VARCHAR2
	AEREL	VARCHAR2
	AEREL_ND	VARCHAR2
AEACN661770	AEACN661770_C	VARCHAR2
	AEACN661770	VARCHAR2
	AEACN661770_ND	VARCHAR2
AEACN770	AEACN770_C	VARCHAR2
	AEACN770	VARCHAR2
	AEACN770_ND	VARCHAR2
AESEV	AESEV_C	VARCHAR2
	AESEV	VARCHAR2

	AESEV_ND	VARCHAR2
AEOUT	AEOUT_C	VARCHAR2
	AEOUT	VARCHAR2
	AEOUT_ND	VARCHAR2
AECONTRT	AECONTRT_C	VARCHAR2
	AECONTRT	VARCHAR2
	AECONTRT_ND	VARCHAR2
AEVERBATIM	AEVERBATIM	VARCHAR2
	AEVERBATIM_ND	VARCHAR2
VMEDDRA	VMEDDRA	VARCHAR2
	VMEDDRA_ND	VARCHAR2
LLT_NAME	LLT_NAME	VARCHAR2
	LLT_NAME_ND	VARCHAR2
LLT_CODE	LLT_CODE	VARCHAR2
	LLT_CODE_ND	VARCHAR2
AEDECOD	AEDECOD	VARCHAR2
	AEDECOD_ND	VARCHAR2
PT_CODE	PT_CODE	VARCHAR2
	PT_CODE_ND	VARCHAR2
HLT_NAME	HLT_NAME	VARCHAR2
	HLT_NAME_ND	VARCHAR2
HLT_CODE	HLT_CODE	VARCHAR2
	HLT_CODE_ND	VARCHAR2
HLGTNAME	HLGTNAME	VARCHAR2
	HLGTNAME_ND	VARCHAR2
HLGTCODE	HLGTCODE	VARCHAR2
	HLGTCODE_ND	VARCHAR2
AEBODSYS	AEBODSYS	VARCHAR2
	AEBODSYS_ND	VARCHAR2
SOC_CODE	SOC_CODE	VARCHAR2
	SOC_CODE_ND	VARCHAR2

VX14-661-108: PRIOR AND CONCOMITANT MEDICATIONS (CM) - Repeating Form [CM]

#	Line #	Medication Name	Start date	Stop date or Continuing?	Route	Indication(s)
1						
Record anything that is applied, ingested, imbibed, infused, injected, inhaled, swished, or instilled to produce a therapeutic effect during the protocol-specified collection period						
1.	Line # [read-only]					
2.*	Medication Name [Medication Name]					
3.*	Start date [Start date]					
4.	Stop date [Stop date or Continuing?]					
5.*	Route [Route]					
6.*	Indication(s) [Indication(s)]					
7.	Mapped Route [hidden]					
8.	Mapped Medication Name [hidden]					
9.	Mapped Route Text [hidden]					

10.	Mapped Indication(s) [hidden] NO	[MAPCMINDC] A120
11.	Dictionary Name and Version [hidden] SU	[VWHODRUG] A200
12.	Drug name [hidden] SU	[DRUGNAME] A200
13.	Drug code [hidden] SU	[DRUGCODE] A200
14.	Preferred Name [hidden] CM	[CMDECOD] A200
15.	Preferred Code [hidden] SU	[PREFCODE] A200
16.	Ingredient List [hidden] SU	[ING_LIST] A200

Key: [✓] = Source verification required [K] = Key item
Note: Associated form = SINOPULMONARY SIGNS & SYMPTOMS FOR ANTIBIOTICS.
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: PRIOR AND CONCOMITANT MEDICATIONS

Type	RefName	Description
Item	CMSPID	Line # will be calculated as a sequential number upon submission of the form.

Keys (navigation)/Uniqueness: PRIOR AND CONCOMITANT MEDICATIONS

Item	Unique	Order #
CM (Repeating form)		
CM_S1		
CMTRT	None	1
CMSTDAT	None	2

Codelist Values Tables: PRIOR AND CONCOMITANT MEDICATIONS

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Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CMEN_DTRDC	String	Stop date	Stop date	CMstop	CMONGO
		Continuing at Follow-Up visit?	Continuing	Continuing	
CMROUTERDC	String	Oral	ORAL	ORAL	CMROUTE
		Intramuscular	INTRAMUSCULAR	INTRAMUSCULAR	
		Inhaled	INHALED	INHALED	
		Intravenous	INTRAVENOUS	INTRAVENOUS	
		Intravenous Bolus	INTRAVENOUS BOLUS	INTRAVENOUSBOLUS	
		Topical	TOPICAL	TOPICAL	
		Subcutaneous	SUBCUTANEOUS	SUBCUTANEOUS	
		Sublingual	SUBLINGUAL	SUBLINGUAL	
CMDOSFRM_RDC	String	Other, specify:	OTHER, SPECIFY	OtherSP	CMDOSFRM
		Nebulized	NEBULIZED	NEBULIZED	
		MDI	MDI	MDI	
		DPI (Dry Powder Inhalation)	DPI	DPI	

Coding Summary: PRIOR AND CONCOMITANT MEDICATIONS		
Verbatim RefName: CMTRT Dictionary: WHODD Verbatim Type: MEDPROD		
Coding Item RefName	Level	Level Type
CMDECOD	Preferred Name	Term
PREFCODE	Preferred Name	Code
ING_LIST	Ingredients	AdditionalInfo
DRUGNAME	Trade Name	Term
DRUGCODE	Trade Name	Code
VWHODRUG	Dictionary	Term
Context Item RefName	Context Meaning	
TXTRoute	Route Of Administration	
CMINDC	Indication	

RDE Analytics: RD_CM		
Data Variable RefName	RD Column Name	Column Data Type
CMSPID	CMSPID	NUMBER
	CMSPID_ND	VARCHAR2
CMTRT	CMTRT	VARCHAR2
	CMTRT_ND	VARCHAR2
CMSTDAT	CMSTDAT	DATE
	CMSTDAT_DTS	VARCHAR2
	CMSTDAT_DTR	VARCHAR2
	CMSTDAT_ND	VARCHAR2
CMONGO	CMONGO_C	VARCHAR2
	CMONGO	VARCHAR2
	CMONGO_ND	VARCHAR2

CMONGO - CMENDAT	CMENDAT	DATE
	CMENDAT_DTS	VARCHAR2
	CMENDAT_DTR	VARCHAR2
CMROUTE	CMROUTE_C	VARCHAR2
	CMROUTE	VARCHAR2
	CMROUTE_ND	VARCHAR2
CMROUTE - CMDOSFRM	CMDOSFRM_C	VARCHAR2
	CMDOSFRM	VARCHAR2
CMROUTE - CMROUTESP	CMROUTESP	VARCHAR2
CMINDC	CMINDC	VARCHAR2
	CMINDC_ND	VARCHAR2
TXTRROUTE	TXTRROUTE	VARCHAR2
	TXTRROUTE_ND	VARCHAR2
CMVERBATIM	CMVERBATIM	VARCHAR2
	CMVERBATIM_ND	VARCHAR2
MAPTXTRROUTE	MAPTXTRROUTE	VARCHAR2
	MAPTXTRROUTE_ND	VARCHAR2
MAPCMINDC	MAPCMINDC	VARCHAR2
	MAPCMINDC_ND	VARCHAR2
VWHODRUG	VWHODRUG	VARCHAR2
	VWHODRUG_ND	VARCHAR2
DRUGNAME	DRUGNAME	VARCHAR2
	DRUGNAME_ND	VARCHAR2
DRUGCODE	DRUGCODE	VARCHAR2
	DRUGCODE_ND	VARCHAR2
CMDECOD	CMDECOD	VARCHAR2
	CMDECOD_ND	VARCHAR2
PREFCODE	PREFCODE	VARCHAR2
	PREFCODE_ND	VARCHAR2
ING_LIST	ING_LIST	VARCHAR2
	ING_LIST_ND	VARCHAR2

VX14-661-108: NON-PHARMACOLOGICAL TREATMENTS OR PROCEDURES (NT) - Repeating Form [NT]					
#	Line #	Treatment or Procedure	Start Date	Stop Date or Continuing?	Indication(s)
1					
Record all non-pharmacological treatments and therapeutic procedures during the protocol-specified collection period. Examples are physical therapy, surgery, plaster casts, etc.					
1.	Line # <i>[read-only]</i> [Line #]		[NTSPID] <input type="text" value="N3"/>		
2.*	Name of Treatment or Procedure [Treatment or Procedure]		[NTNAME] <input type="text" value="A120"/>		
3.*	Start Date [Start Date]		[NTSTDAT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (1945-2020)		
4.	Stop Date [Stop Date or Continuing?]		[NTONGO] <i>[A:Stop Date]</i> <input type="button" value="v"/> [NTENDAT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> (2015-2020) <i>[A:Continuing]</i> <input type="button" value="v"/> Continuing at Follow-Up visit?		
5.*	Indication(s) [Indication(s)]		[NTINDC] <input type="text" value="A120"/>		
6.	Mapped Name of Treatment or Procedure <i>[hidden]</i> [Mapped Treatment or Procedure]		[NTVERBATIM] <input type="text" value="A120"/>		
7.	Dictionary Name and Version <i>[hidden]</i> [MedDRA Ver.]		[VMEDDRA] <input type="text" value="A200"/>		
8.	Lowest Level Term Name <i>[hidden]</i> [LLT Name]		[LLT_NAME] <input type="text" value="A200"/>		
9.	Lowest Level Term Code <i>[hidden]</i> [LLT Code]		[LLT_CODE] <input type="text" value="A200"/>		
10.	Preferred Term Name <i>[hidden]</i> [PT Name]		[NTDECOD] <input type="text" value="A200"/>		
11.	Preferred Term Code <i>[hidden]</i> [PT Code]		[PT_CODE] <input type="text" value="A200"/>		
12.	High Level Term Name <i>[hidden]</i>		[HLT_NAME] <input type="text"/>		

	[HLT Name]	A200
13.	High Level Term Code [hidden] [HLT Code]	[HLT_CODE] A200
14.	High Level Group Term Name [hidden] [HLGT Name]	[HLGTNAME] A200
15.	High Level Group Term Code [hidden] [HLGT Code]	[HLGTCODE] A200
16.	System Organ Class Name [hidden] [SOC Name]	[NTBODSYS] A200
17.	System Organ Class Code [hidden] [SOC Code]	[SOC_CODE] A200

Key: [✓] = Source verification required [🔑] = Key item
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: NON-PHARMACOLOGICAL TREATMENTS OR PROCEDURES		
Type	RefName	Description
Form	NT	Dynamic form based on STATUS
Item	NTSPID	Line # will be calculated as a sequential number upon submission of the form.

Keys (navigation)/Uniqueness: NON-PHARMACOLOGICAL TREATMENTS OR PROCEDURES		
Item	Unique	Order #
NT (Repeating form)		
NT_S1		
NTNAME	None	1
NTSTDAT	None	2

Codelist Values Tables: NON-PHARMACOLOGICAL TREATMENTS OR PROCEDURES					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
NTEN_DTRDC	String	Stop Date	Stop Date	StopDate	NTONGO
		Continuing at Follow-Up visit?	Continuing	CTContinuing	

Coding Summary: NON-PHARMACOLOGICAL TREATMENTS OR PROCEDURES		
Verbatim RefName: NTNAME Dictionary: MedDRA Verbatim Type: DISEASE		
Coding Item RefName	Level	Level Type
NTBODSYS	System Organ Class	Term
SOC_CODE	System Organ Class	Code
HLGTNAME	High Level Group Term	Term
HLGTCODE	High Level Group Term	Code
HLT_NAME	High Level Term	Term
HLT_CODE	High Level Term	Code
NTDECOD	Preferred Term	Term
PT_CODE	Preferred Term	Code
LLT_NAME	Low Level Term	Term
LLT_CODE	Low Level Term	Code
VMEDDRA	Dictionary	Term

RDE Analytics: RD_NT		
Data Variable RefName	RD Column Name	Column Data Type
NTSPID	NTSPID	NUMBER
	NTSPID_ND	VARCHAR2
NTNAME	NTNAME	VARCHAR2
	NTNAME_ND	VARCHAR2
NTSTDAT	NTSTDAT	DATE
	NTSTDAT_DTS	VARCHAR2
	NTSTDAT_DTR	VARCHAR2
	NTSTDAT_ND	VARCHAR2
NTONGO	NTONGO_C	VARCHAR2
	NTONGO	VARCHAR2
	NTONGO_ND	VARCHAR2
NTONGO - NTENDAT	NTENDAT	DATE
	NTENDAT_DTS	VARCHAR2
	NTENDAT_DTR	VARCHAR2
NTINDC	NTINDC	VARCHAR2
	NTINDC_ND	VARCHAR2
NTVERBATIM	NTVERBATIM	VARCHAR2
	NTVERBATIM_ND	VARCHAR2
VMEDDRA	VMEDDRA	VARCHAR2
	VMEDDRA_ND	VARCHAR2
LLT_NAME	LLT_NAME	VARCHAR2
	LLT_NAME_ND	VARCHAR2
LLT_CODE	LLT_CODE	VARCHAR2
	LLT_CODE_ND	VARCHAR2
NTDECOD	NTDECOD	VARCHAR2

	NTDECOD_ND	VARCHAR2
PT_CODE	PT_CODE	VARCHAR2
	PT_CODE_ND	VARCHAR2
HLT_NAME	HLT_NAME	VARCHAR2
	HLT_NAME_ND	VARCHAR2
HLT_CODE	HLT_CODE	VARCHAR2
	HLT_CODE_ND	VARCHAR2
HLGTNAME	HLGTNAME	VARCHAR2
	HLGTNAME_ND	VARCHAR2
HLGTCODE	HLGTCODE	VARCHAR2
	HLGTCODE_ND	VARCHAR2
NTBODSYS	NTBODSYS	VARCHAR2
	NTBODSYS_ND	VARCHAR2
SOC_CODE	SOC_CODE	VARCHAR2
	SOC_CODE_ND	VARCHAR2

VX14-661-108: SINOPULMONARY SIGNS & SYMPTOMS FOR ANTIBIOTICS (SS) - Repeating Form [SS]					
Sinopulmonary signs/symptoms		Start date	End date or Continuing?	Subject Hospitalized?	Hospitalization
1. Line # (read-only)		[SSSPID] N3			
2.* Sinopulmonary signs/symptoms [Sinopulmonary signs/symptoms]		[SSSS] [A:CHSP] Change in sputum [A:HEMOP] [A:INCOUGH] Increased cough [A:INDYSP] [A:FATIGUE] [A:INCTEMP] [A:ANOREX] [A:SINUSP] [A:SINUSD] [A:PECHEST] [A:DECPULMON] [A:RADIOG]		SU SU SU SU SU SU SU SU SU SU SU SU	
3.* Start date of antibiotic course		[SSSTDAT] Req/Unk / Req/Unk		SU	
4.* End date of antibiotic course		[SSONGO] [A:End date] [A:Continuing]		SU	
5.* Was the subject hospitalized?		[SSHSYN] [A:Y] Yes [A:N] No		SU	
6. Hospitalization start date			Hospitalization end date		
Hospitalization Entry [SS_S2]					
6.1* Hospitalization start date [Hospitalization start date]		[UHSTDAT] Req/Unk / Req/Unk / Req/Unk (2015-2020)			
6.2* Hospitalization end date [Hospitalization end date]		[UHEN DAT] Req/Unk / Req/Unk / Req/Unk (2015-2020)			
Key: [*] = Item is required [✓] = Source verification required Note: Associated form = PRIOR AND CONCOMITANT MEDICATIONS. Note: Source verification critical settings made in InForm will override any settings made in Central Designer.					

Codelist Values Tables: SINOPULMONARY SIGNS & SYMPTOMS FOR ANTIBIOTICS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cISSS	String	Change in sputum	CHSP	citmCHSP	SSSS
		New or increased hemoptysis	HEMOP	citmHEMOP	
		Increased cough	INCOUGH	citmINCOUGH	
		Increased dyspnea	INDYSP	citmINDYSP	
		Malaise, fatigue, or lethargy	FATIGUE	citmFATIG	
		Temperature above 38 degrees Celsius	INCTEMP	citmINCTEMP	
		Anorexia or weight loss	ANOREX	citmANOREX	

		Sinus pain or tenderness	SINUSP	citmSINUSP	
		Change in sinus discharge	SINUSD	citmSINUSD	
		Change in physical examination of the chest	PECHEST	citmPECHEST	
		Decrease in pulmonary function by 10%	DECPULMON	citmDECPULM	
		Radiographic changes indicative of pulmonary infection	RADIOG	citmRADIOG	
SSEN_DTRDC	String	End date	End date	clitmENDDT	SSONGO
		Continuing	Continuing	clitmCONTIN	
cliYESNO	String	Yes	Y	cliYES	SSH SYN
		No	N	cliNO	

RDE Analytics: RD_SS		
Data Variable RefName	RD Column Name	Column Data Type
SSSPID	SSSPID	NUMBER
	SSSPID_ND	VARCHAR2
SSSS	SSSS_ND	VARCHAR2
SSSS - Change in sputum	SSSS_CITMCHSP_C	VARCHAR2
	SSSS_CITMCHSP	VARCHAR2
SSSS - New or increased hemoptysis	SSSS_CITMHEMOP_C	VARCHAR2
	SSSS_CITMHEMOP	VARCHAR2
SSSS - Increased cough	SSSS_CITMINCOUGH_C	VARCHAR2
	SSSS_CITMINCOUGH	VARCHAR2
SSSS - Increased dyspnea	SSSS_CITMINDYSP_C	VARCHAR2
	SSSS_CITMINDYSP	VARCHAR2
SSSS - Malaise, fatigue, or lethargy	SSSS_CITMFATIG_C	VARCHAR2
	SSSS_CITMFATIG	VARCHAR2
SSSS - Temperature above 38 degrees Celsius	SSSS_CITMINCTEMP_C	VARCHAR2
	SSSS_CITMINCTEMP	VARCHAR2
SSSS - Anorexia or weight loss	SSSS_CITMANOREX_C	VARCHAR2
	SSSS_CITMANOREX	VARCHAR2
SSSS - Sinus pain or tenderness	SSSS_CITMSINUSP_C	VARCHAR2
	SSSS_CITMSINUSP	VARCHAR2
SSSS - Change in sinus discharge	SSSS_CITMSINUSD_C	VARCHAR2
	SSSS_CITMSINUSD	VARCHAR2
SSSS - Change in physical examination of the chest	SSSS_CITMPECHEST_C	VARCHAR2
	SSSS_CITMPECHEST	VARCHAR2
SSSS - Decrease in pulmonary function by 10%	SSSS_CITMDECPULM_C	VARCHAR2
	SSSS_CITMDECPULM	VARCHAR2
SSSS - Radiographic changes indicative of pulmonary infection	SSSS_CITMRADIOG_C	VARCHAR2
	SSSS_CITMRADIOG	VARCHAR2
SSSTDAT	SSSTDAT	DATE
	SSSTDAT_DTS	VARCHAR2
	SSSTDAT_DTR	VARCHAR2
	SSSTDAT_ND	VARCHAR2

SSONGO	SSONGO_C	VARCHAR2
	SSONGO	VARCHAR2
	SSONGO_ND	VARCHAR2
SSONGO - SSENDAT	SSENDAT	DATE
	SSENDAT_DTS	VARCHAR2
	SSENDAT_DTR	VARCHAR2
SSH SYN	SSH SYN_C	VARCHAR2
	SSH SYN	VARCHAR2
	SSH SYN_ND	VARCHAR2
RD_SS_SS_S2		
UHSTDAT	UHSTDAT	DATE
	UHSTDAT_DTS	VARCHAR2
	UHSTDAT_DTR	VARCHAR2
	UHSTDAT_ND	VARCHAR2
UHENDAT	UHENDAT	DATE
	UHENDAT_DTS	VARCHAR2
	UHENDAT_DTR	VARCHAR2
	UHENDAT_ND	VARCHAR2

Codelist Values Tables: UNPLANNED HOSPITALIZATIONS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
UHEN_DTRDC	String	End date	End date	clitmENDDT	UHONGO
		Continuing	Continuing	clitmCONTIN	
clUHREAS	String	Pancreatitis	PANCREATITIS	cliPancreatitis	UHREAS
		Distal Intestinal Obstructive Syndrome	DISTAL INTESTINAL OBSTRUCTIVE SYNDROME	cliDIOS	
		Non-protocol defined pulmonary exacerbation	PULMONARY EXACERBATION	cliPulmExac	
		Other CF reason	OTHER CF REASON	cliOTHCF	

file:///C:/Users/kmalsick/AppData/Local/Apps/2.0/9A1PEO2Z.DB1/B72KY8PM.AGZ/orac...769 040cb68c7390ff6f 0002.0001 1a75c9af89f12f2b/HtmlResources/AnnotatedStudybook.html 1/14/2016

	UHENDAT_DTR	VARCHAR2
UHREAS	UHREAS_C	VARCHAR2
	UHREAS	VARCHAR2
	UHREAS_ND	VARCHAR2
UHREAS - UHREASP	UHREASP	VARCHAR2

VX14-661-108: PLANNED HOSPITALIZATIONS (PHOSP) - Repeating Form [PHOSP]			
#	Line #	Hospitalization start date	Hospitalization end date or Continuing?
1			

Please record planned hospitalizations for antibiotics.

1.	Line # <i>[read-only]</i> [Line #]	[PHOSPID] N3
2.* ✓	Hospitalization start date [Hospitalization start date]	[PHSTDAT] Req/Unk / Req/Unk / Req/Unk (2015-2020)
3.* ✓	Hospitalization end date [Hospitalization end date or Continuing?]	[PHONGO] [A:End date] [PHENDAT] Req/Unk / Req/Unk / Req/Unk (2015-2020) [A:Continuing] Continuing

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: PLANNED HOSPITALIZATIONS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
PHEN_DTRDC	String	End date	End date	clitmENDDT	PHONGO
		Continuing	Continuing	clitmCONTIN	

RDE Analytics: RD_PHOSP		
Data Variable RefName	RD Column Name	Column Data Type
PHOSPID	PHOSPID	NUMBER
	PHOSPID_ND	VARCHAR2
PHSTDAT	PHSTDAT	DATE
	PHSTDAT_DTS	VARCHAR2
	PHSTDAT_DTR	VARCHAR2
	PHSTDAT_ND	VARCHAR2
PHONGO	PHONGO_C	VARCHAR2
	PHONGO	VARCHAR2
	PHONGO_ND	VARCHAR2
PHONGO - PHENDAT	PHENDAT	DATE
	PHENDAT_DTS	VARCHAR2
	PHENDAT_DTR	VARCHAR2

VX14-661-108: OUTPATIENT SICK VISITS (OSV) - Repeating Form [OSV]		
#	Line #	Date of visit
1		
OUTPATIENT SICK VISITS [OSV_S1]		
Please record outpatient sick visits for CF related complications (including sinus, lung, pancreas, or gastrointestinal)		
1.	Line # <i>[read-only]</i> [Line #]	[OSVNo] <input type="text" value="N3"/>
2.* ✓	Date of visit [Date of visit]	[OSVDAT] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

RDE Analytics: RD_OSV		
Data Variable RefName	RD Column Name	Column Data Type
OSVNo	OSVNO	NUMBER
	OSVNO_ND	VARCHAR2
OSVDAT	OSVDAT	DATE
	OSVDAT_DTS	VARCHAR2
	OSVDAT_ND	VARCHAR2

VX14-661-108: STUDY DRUG INTERRUPTIONS (INTER) [INTER]				
Line #	Start Date	Stop Date	Reason for Dose Interruption	
EX	EX	EX	EX	
VX661/ivacaftor Study Drug Interruptions Entry [INTER_S1]				
Click Add Entry to create a row for EACH VX661/ivacaftor study drug interruption				
1.1	Line # [read-only] N3	[VX661770INTSPID] N3		
1.2*	Start Date [Start Date]	[VX661770INTSTDAT] Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (2015-2020)		
1.3*	Stop Date [Stop Date]	[VX661770INTONGO] [A:END DATE] <input type="radio"/> [VX661770INTENDAT] Stop Date Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (2015-2020) [A:CONTINUING] <input type="radio"/> Continuing?		
1.4*	Reason for Dose Interruption [Reason for Dose Interruption]	[VX661770REAS] [A:ADVERSE EVENT NONLFT] <input type="radio"/> Adverse Event - Non-Liver Function Test [A:ADVERSE EVENT LFT] <input type="radio"/> Adverse Event - Liver Function Test [A:LIVER FUNCTION TEST] <input type="radio"/> Liver Function Test [A:CONCOMITANT MEDICATION] <input type="radio"/> Prohibited Concomitant Medication [A:NON-COMPLIANCE] <input type="radio"/> Non-compliance [A:OTHER, SPECIFY] <input type="radio"/> [VX661770OTHSP] Other, Specify EX		
Line #	Start Date	Stop Date	Reason for Dose Interruption	
2.				
Ivacaftor Study Drug Interruptions Entry [INTER_S2]				
Click Add Entry to create a row for EACH ivacaftor study drug interruption				
2.1*	Line # [read-only] [Line #]	[VX770INTSPID] N3		
2.2*	Start Date [Start Date]	[VX770INTSTDAT] Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (2015-2020)		
2.3*	Stop Date [Stop Date]	[VX770INTONGO] [A:END DATE] <input type="radio"/> [VX770INTENDAT] Stop Date Req/Unk [v] / Req/Unk [v] / Req/Unk [v] (2015-2020) [A:CONTINUING] <input type="radio"/> Continuing?		
2.4*	Reason for Dose Interruption [Reason for Dose Interruption]	[VX770REAS] [A:ADVERSE EVENT NONLFT] <input type="radio"/> Adverse Event - Non-Liver Function Test [A:ADVERSE EVENT LFT] <input type="radio"/> Adverse Event - Liver Function Test [A:LIVER FUNCTION TEST] <input type="radio"/> Liver Function Test [A:CONCOMITANT MEDICATION] <input type="radio"/> Prohibited Concomitant Medication		

			<div><div>MEDICATION] [A:NON-COMPLIANCE] [A:OTHER, SPECIFY]</div><div><div><input type="radio"/> Non-compliance</div><div><input checked="" type="radio"/> [VX770OTHSP] Other, Specify</div></div><div>A200</div></div>
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Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: STUDY DRUG INTERRUPTIONS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cISTOPCONT	String	End date	END DATE	clitmENDDAT	VX661770INTONGO, VX770INTONGO
		Continuing?	CONTINUING	clitmCONTING	
cIDRUGINTERUPT	String	Adverse Event - Non-Liver Function Test	ADVERSE EVENT NONLFT	cliINTAENLFT	VX661770REAS, VX770REAS
		Adverse Event - Liver Function Test	ADVERSE EVENT LFT	cliINTAELFT	
		Liver Function Test	LIVER FUNCTION TEST	cliINTLFT	
		Prohibited Concomitant Medication	CONCOMITANT MEDICATION	cliINTCM	
		Non-compliance	NON-COMPLIANCE	cliINTNONCOMP	
		Other	OTHER, SPECIFY	Other	

RDE Analytics: RD_INTER		
Data Variable RefName	RD Column Name	Column Data Type
RD_INTER_INTER_S1		
VX661770INTSPID	VX661770INTSPID	NUMBER
	VX661770INTSPID_ND	VARCHAR2
VX661770INTSTDAT	VX661770INTSTDAT	DATE
	VX661770INTSTDAT_DTS	VARCHAR2
	VX661770INTSTDAT_DTR	VARCHAR2
	VX661770INTSTDAT_ND	VARCHAR2
VX661770INTONGO	VX661770INTONGO_C	VARCHAR2
	VX661770INTONGO	VARCHAR2
	VX661770INTONGO_ND	VARCHAR2
VX661770INTONGO - VX661770INTENDAT	VX661770INTENDAT	DATE
	VX661770INTENDAT_DTS	VARCHAR2
	VX661770INTENDAT_DTR	VARCHAR2
VX661770REAS	VX661770REAS_C	VARCHAR2
	VX661770REAS	VARCHAR2
	VX661770REAS_ND	VARCHAR2
VX661770REAS - VX661770OTHSP	VX661770OTHSP	VARCHAR2
RD_INTER_INTER_S2		
VX770INTSPID	VX770INTSPID	NUMBER
	VX770INTSPID_ND	VARCHAR2

VX770INTSTDAT	VX770INTSTDAT	DATE
	VX770INTSTDAT_DTS	VARCHAR2
	VX770INTSTDAT_DTR	VARCHAR2
	VX770INTSTDAT_ND	VARCHAR2
VX770INTONGO	VX770INTONGO_C	VARCHAR2
	VX770INTONGO	VARCHAR2
	VX770INTONGO_ND	VARCHAR2
VX770INTONGO - VX770INTENDAT	VX770INTENDAT	DATE
	VX770INTENDAT_DTS	VARCHAR2
	VX770INTENDAT_DTR	VARCHAR2
VX770REAS	VX770REAS_C	VARCHAR2
	VX770REAS	VARCHAR2
	VX770REAS_ND	VARCHAR2
VX770REAS - VX770OTHSP	VX770OTHSP	VARCHAR2

VX14-661-108: RECONSENT AND RE-ASSENT (RICA) [RICA]

DS

Whether the subject or caregiver signed a revised informed consent/assent **after** the original consent/assent due to a protocol amendment.

Record the original informed consent/assent on the Screening Informed Consent page.

1.*
✓

Did the subject or caregiver re-consent/re-assent at any time?
[Did the subject or caregiver re-consent/re-assent at any time?]

[RICA_YN]

[A:Y] ☐ Yes

[A:N] ☐ No

Line #	Date of CONSENT	Consent Provided by	Protocol Version
2. ✓			

RECONSENT/RE-ASSENT Entry [RICA_R1]

If yes, click Add Entry to create a row for EACH re-consent/re-assent.

Enter the **protocol version** the consent/assent corresponds to. Do **not** enter the version of the ICF itself.

2.1
✓

Line # [read-only]
[Line #]

[RICASPID]

N4

2.2*
✓

Date of **written** informed CONSENT

[RICA_DAT]

Req / Req / Req (2015-2020)

2.3*
✓

Informed CONSENT provided by:

[RICSUBCG]

[A:SUBJECT] ☐ Subject

[A:CAREGIVER] ☐

[RIA_YN]
Caregiver
Did the subject provide ASSENT?

DS

DS

DS

DS

2.4*
✓

Protocol version to which this consent/assent corresponds (please enter in the format 1.0, 2.0, etc.)

[RICAPRTV]

xx.x

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: RECONSENT AND RE-ASSENT					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cIYESNO	String	Yes	Y	cliYES	RICA_YN, RIA_YN
		No	N	cliNO	
cISUBJCAREGV	String	Subject	SUBJECT	cliSUBJECT	RICSUBCG
		Caregiver	CAREGIVER	cliCAREGIVER	

RDE Analytics: RD_RICA		
Data Variable RefName	RD Column Name	Column Data Type
RICA_YN	RICA_YN_C	VARCHAR2
	RICA_YN	VARCHAR2
	RICA_YN_ND	VARCHAR2
RD_RICA_RICA_R1		
RICASPID	RICASPID	NUMBER
	RICASPID_ND	VARCHAR2

file:///C:/Users/kmalsick/AppData/Local/Apps/2.0/9ATPEO2Z.DB1/B72KY8PM.AGZ/orac...769_040cb68c7390ff6f_0002.0001_1a75c9af89f12f2b/HtmlResources/AnnotatedStudybook.html

1/14/2016

RICA_DAT	RICA_DAT	DATE
	RICA_DAT_DTS	VARCHAR2
	RICA_DAT_ND	VARCHAR2
RICSUBCG	RICSUBCG_C	VARCHAR2
	RICSUBCG	VARCHAR2
	RICSUBCG_ND	VARCHAR2
RICSUBCG - RIA_YN	RIA_YN_C	VARCHAR2
	RIA_YN	VARCHAR2
RICSUBCG - RIAS_DAT	RIAS_DAT	DATE
	RIAS_DAT_DTS	VARCHAR2
RICAPRTV	RICAPRTV	FLOAT
	RICAPRTV_ND	VARCHAR2

VX14-661-108: SUPPLEMENTAL RECONSENT AND RE-ASSENT (RICAS) [RICAS]

On this page, indicate whether the subject or caregiver signed a **revised** informed consent/assent **to a supplemental assessment** after the original consent/assent to the supplemental assessment due to a protocol amendment.

Record the original informed consent/assent to the supplemental assessments on the Screening Supplemental Informed Consent page.

1.* ✓	Did the subject or caregiver re-consent/re-assent to a supplemental assessment at any time? [Did subject or caregiver re-consent/re-assent?]	[RICAS_YN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No			
2. ✓	Line #	Assessment	Date of CONSENT	Consent Provided by	Protocol Version

RECONSENT/RE-ASSENT Entry [RICAS_R1]

If yes, click Add Entry to create a row for EACH re-consent.

Enter the **protocol version** the consent/assent corresponds to. Do **not** enter the version of the ICF itself.

2.1 ✓	Line # [read-only] [Line #]	[RICASPID] <input type="text" value="N4"/>
2.2* ✓	Select the assessment: <div><div></div></div>	[RICSTUDY] [A:DNA SAMPLE A] <input type="radio"/> DNA Sample A [A:DNA SAMPLE B] <input type="radio"/> DNA Sample B [A:NASAL BRUSHING] <input type="radio"/> Nasal Brushing
2.3* ✓	Date of written informed CONSENT [Date of CONSENT]	[RICS_DAT] Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
2.4* ✓	Informed CONSENT provided by: [Consent Provided by]	[RICSUBCG] [A:SUBJECT] <input type="radio"/> Subject [A:CAREGIVER] <input type="radio"/> [RIA_YN] Caregiver Did the subject provide ASSENT? [A:Y] <input type="radio"/> [RIAS_DAT] Yes Date of ASSENT Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020) [A:N] <input type="radio"/> No
2.5* ✓	Protocol version to which this consent/assent corresponds (please enter in the format 1.0, 2.0, etc.) [Protocol Version]	[RICAPRTV] <input type="text" value="xx.x"/>

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: SUPPLEMENTAL RECONSENT AND RE-ASSENT					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cIYESNO	String	Yes	Y	cliYES	RICAS_YN, RIA_YN
		No	N	cliNO	
cIASSESSMENTS	String	DNA Sample A	DNA SAMPLE A	cliDNASAMPA	RICSTUDY
		DNA Sample B	DNA SAMPLE B	cliDNASAMPB	
		Nasal Brushing	NASAL BRUSHING	cliNSLBRSH	
cISUBJCAREGV	String	Subject	SUBJECT	cliSUBJECT	RICSUBCG
		Caregiver	CAREGIVER	cliCAREGIVER	

RDE Analytics: RD_RICAS

Data Variable RefName	RD Column Name	Column Data Type
RICAS_YN	RICAS_YN_C	VARCHAR2
	RICAS_YN	VARCHAR2
	RICAS_YN_ND	VARCHAR2
RD_RICAS_RICAS_R1		
RICASPID	RICASPID	NUMBER
	RICASPID_ND	VARCHAR2
RICSTUDY	RICSTUDY_C	VARCHAR2
	RICSTUDY	VARCHAR2
	RICSTUDY_ND	VARCHAR2
RICS_DAT	RICS_DAT	DATE
	RICS_DAT_DTS	VARCHAR2
	RICS_DAT_ND	VARCHAR2
RICSUBCG	RICSUBCG_C	VARCHAR2
	RICSUBCG	VARCHAR2
	RICSUBCG_ND	VARCHAR2
RICSUBCG - RIA_YN	RIA_YN_C	VARCHAR2
	RIA_YN	VARCHAR2
RICSUBCG - RIAS_DAT	RIAS_DAT	DATE
	RIAS_DAT_DTS	VARCHAR2
RICAPRTV	RICAPRTV	FLOAT
	RICAPRTV_ND	VARCHAR2

D

EX

VX14-661-108: DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 1 (DOSEL) [DOSEL]		
1.*	DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 1 [DOSEL_S1]	[VX661770DOSELDAT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
2.*	LAST VX661/ivacaftor Dose Time [DOSEL_S2]	[VX661770DOSELTIM] Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
3.*	Tablets Dispensed [DOSEL_S3]	[VX661770DOSEDISP] N4
4.*	Tablets Returned [DOSEL_S4]	[VX661770DOSERET] N4
5.*	DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 2 (DOSEL) [DOSEL_S1]	[VX770DOSELDAT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
6.*	LAST ivacaftor Dose Time [DOSEL_S2]	[VX770DOSELTIM] Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
7.*	Tablets Dispensed [DOSEL_S3]	[VX770DOSEDISP] N4
8.*	Tablets Returned [DOSEL_S4]	[VX770DOSERET] N4
9.*	Continuing in Treatment Period 1? [DOSEL_S5]	[SDACOMPYNTP1] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 1					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	SDACOMPYNTP1
		No	N	cliNO	

RDE Analytics: RD_DOSEL		
Data Variable RefName	RD Column Name	Column Data Type
VX661770DOSELDAT	VX661770DOSELDAT	DATE
	VX661770DOSELDAT_DTS	VARCHAR2
	VX661770DOSELDAT_DTR	VARCHAR2
	VX661770DOSELDAT_ND	VARCHAR2
VX661770DOSELTIM	VX661770DOSELTIM	DATE
	VX661770DOSELTIM_TMS	VARCHAR2
	VX661770DOSELTIM_TMR	VARCHAR2
	VX661770DOSELTIM_ND	VARCHAR2
VX661770DOSEDISP	VX661770DOSEDISP	NUMBER
	VX661770DOSEDISP_ND	VARCHAR2
VX661770DOSERET	VX661770DOSERET	NUMBER

	VX661770DOSERET_ND	VARCHAR2
VX770DOSELDAT	VX770DOSELDAT	DATE
	VX770DOSELDAT_DTS	VARCHAR2
	VX770DOSELDAT_DTR	VARCHAR2
	VX770DOSELDAT_ND	VARCHAR2
VX770DOSELTIM	VX770DOSELTIM	DATE
	VX770DOSELTIM_TMS	VARCHAR2
	VX770DOSELTIM_TMR	VARCHAR2
	VX770DOSELTIM_ND	VARCHAR2
VX770DOSEDISP	VX770DOSEDISP	NUMBER
	VX770DOSEDISP_ND	VARCHAR2
VX770DOSERET	VX770DOSERET	NUMBER
	VX770DOSERET_ND	VARCHAR2
SDACOMPYNTP1	SDACOMPYNTP1_C	VARCHAR2
	SDACOMPYNTP1	VARCHAR2
	SDACOMPYNTP1_ND	VARCHAR2

D

VX14-661-108: DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 2 (DOSEL2) [DOSEL2]		
1.*	DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 2 [DOSEL2_S1]	[VX661770DOSELDAT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
2.*	LAST ivacaftor Dose Time [DOSEL2_S2]	[VX661770DOSELTIM] Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
3.*	Tablets Dispensed [DOSEL2_S3]	[VX661770DOSEDISP] N4
4.*	Tablets Returned [DOSEL2_S4]	[VX661770DOSERET] N4
5.*	DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 2 [DOSEL2_S2]	[VX770DOSELDAT] Req/Unk <input type="button" value="v"/> / Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> (2015-2020)
6.*	LAST ivacaftor Dose Time [DOSEL2_S2]	[VX770DOSELTIM] Req/Unk <input type="button" value="v"/> : Req/Unk <input type="button" value="v"/> 24-hour clock
7.*	Tablets Dispensed [DOSEL2_S3]	[VX770DOSEDISP] N4
8.*	Tablets Returned [DOSEL2_S4]	[VX770DOSERET] N4
9.*	Missing in Treatment Period 2? [DOSEL2_S5]	[SDACOMPYNTP2] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: DATE OF LAST DOSE STUDY DRUG IN TREATMENT PERIOD 2					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	SDACOMPYNTP2
		No	N	cliNO	

RDE Analytics: RD_DOSEL2		
Data Variable RefName	RD Column Name	Column Data Type
VX661770DOSELDAT	VX661770DOSELDAT	DATE
	VX661770DOSELDAT_DTS	VARCHAR2
	VX661770DOSELDAT_DTR	VARCHAR2
	VX661770DOSELDAT_ND	VARCHAR2
VX661770DOSELTIM	VX661770DOSELTIM	DATE
	VX661770DOSELTIM_TMS	VARCHAR2
	VX661770DOSELTIM_TMR	VARCHAR2
	VX661770DOSELTIM_ND	VARCHAR2
VX661770DOSEDISP	VX661770DOSEDISP	NUMBER
	VX661770DOSEDISP_ND	VARCHAR2
VX661770DOSERET	VX661770DOSERET	NUMBER

	VX661770DOSERET_ND	VARCHAR2
VX770DOSELDAT	VX770DOSELDAT	DATE
	VX770DOSELDAT_DTS	VARCHAR2
	VX770DOSELDAT_DTR	VARCHAR2
	VX770DOSELDAT_ND	VARCHAR2
VX770DOSELTIM	VX770DOSELTIM	DATE
	VX770DOSELTIM_TMS	VARCHAR2
	VX770DOSELTIM_TMR	VARCHAR2
	VX770DOSELTIM_ND	VARCHAR2
VX770DOSEDISP	VX770DOSEDISP	NUMBER
	VX770DOSEDISP_ND	VARCHAR2
VX770DOSERET	VX770DOSERET	NUMBER
	VX770DOSERET_ND	VARCHAR2
SDACOMPYNTP2	SDACOMPYNTP2_C	VARCHAR2
	SDACOMPYNTP2	VARCHAR2
	SDACOMPYNTP2_ND	VARCHAR2

VX14-661-108: END OF DOSING (ENDDOSE) [ENDDOSE]

VX661/ivacaftor Dosing [ENDDOSE_S1]

Complete this page after the subject takes the last dose of each study drug. (Start when the subject stops taking the first drug. Continue to add information as the other drug(s) are stopped.)

On this page, enter the reason the subject stopped DOSING with each drug.

If a subject refuses further dosing **due to AE**, enter the reason as **'Adverse Event'**, not 'Refused further dosing'.

If a subject will not attend further visits, complete both the End of Dosing and End of Study forms now.

<div>1.* Select the PRIMARY reason VX661/ivacaftor DOSING ended</div> <div><div>DS</div><div>DS</div></div>	<div><div><div>[DSEND]</div><div>[A:COMPLETED]</div><div><input type="radio"/></div>Completed</div><div><div>[A:DISCONTINUED]</div><div><input type="radio"/></div>[DSDISC]</div><div>Discontinued, select the one MOST SIGNIFICANT reason:</div><div><div>[A:ADVERSE EVENT]</div><div><input type="radio"/></div>[DSEAE_SP]</div><div>Adverse Event</div><div>Record the adverse event(s) that led to discontinuation of dosing:</div><div><div>DS</div></div></div> <div><div>[A:SUBJECT REFUSED FURTHER DOSING (NOT DUE TO AE)]</div><div><input type="radio"/></div>[DSRD_SP]</div> <div>Subject Refused Further Dosing (Not due to AE)</div> <div>Specify the reason subject refused further dosing:</div> <div><div>DS</div></div>
---	--

[A:LOST TO FOLLOW-UP]

☐

Lost to Follow-Up

[A:DEATH]

☐

Death

[A:DID NOT MEET ELIGIBILITY CRITERIA]

☐

Did Not Meet Eligibility Criteria

[A:NON-COMPLIANCE WITH STUDY DRUG]

☐

Non-Compliance with Study Drug

[A:OTHER NON-COMPLIANCE]

☐

[DSOnc_SP]

Other Non-Compliance

Specify the nature of non-compliance:

DS

[A:PHYSICIAN DECISION]

☐

[DSDPD_SP]

Physician Decision

Specify the reason for the decision:

DS

[A:REQUIRES PROHIBITED MEDICATION]

☐

Requires Prohibited Medication

[A:PREGNANCY (SELF OR PARTNER)]

☐

Pregnancy (Self or Partner)

[A:STUDY TERMINATED BY SPONSOR]

☐

Study Terminated by Sponsor

[A:OTHER]

☐

[DSOTH_SP]

Other. Specify:

DS

[A:NEVER DOSED]

☐

[DSND_SP]

Never dosed, specify reason:

A200

2.* Did ivacaftor dosing end for the same reason as VX661/ivacaftor?

✓

[Did ivacaftor dosing end for the same reason as VX661/ivacaftor?]

[ALL1RSN]

[A:Y] ☐ Yes

[A:N] ☐ **[DSENDI]**

No

Select the PRIMARY reason ivacaftor DOSING ENDED

[A:COMPLETED] ☐ Completed

[A:DISCONTINUED] ☐ **[DSDISCT]**

Discontinued, select the one MOST SIGNIFICANT reason:

[A:ADVERSE
EVENT] ☐ **[DSAE_SPI]**

Adverse Event

Record the adverse event(s) that led to discontinuation of dosing:

A200

[A:SUBJECT
REFUSED
FURTHER
DOSING (NOT
DUE TO AE)] ☐ **[DSRD_SPI]**

Subject Refused Further Dosing (Not due to AE)
Specify the **reason** subject refused further dosing:

A200

[A:LOST TO
FOLLOW-UP] ☐ Lost to Follow-Up

[A:DEATH] ☐ Death

[A:DID NOT
MEET
ELIGIBILITY
CRITERIA] ☐ Did Not Meet Eligibility Criteria

[A:NON-
COMPLIANCE
WITH STUDY
DRUG] ☐ Non-Compliance with Study Drug

[A:OTHER
NON-
COMPLIANCE] ☐ **[DSOncSPI]**
Other Non-Compliance
Specify the **nature** of non-compliance:

A200

[A:PHYSICIAN
DECISION] ☐ **[DSPD_SPI]**

Physician Decision
Specify the **reason** for the decision:

A200

[A:REQUIRES
PROHIBITED
MEDICATION] ☐ Requires Prohibited Medication

[A:PREGNANCY
(SELF OR
PARTNER)] ☐ Pregnancy (Self or Partner)

[A:STUDY
TERMINATED
BY SPONSOR] ☐ Study Terminated by Sponsor

[A:OTHER] ☐ **[DSOTHSPI]**
Other, Specify:

A200

[A:NEVER DOSED]

DSND_SPI

Never dosed, specify reason:

A200

Key: [*] = Item is required [✓] = Source verification required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: END OF DOSING		
Type	RefName	Description
Form	ENDDOSE	Use this version of the form for studies where a subject doses with only one study drug.

Codelist Values Tables: END OF DOSING					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
DSENDERDC	String	Completed	COMPLETED	DSENDERCOM	DSEND, DSENDI
		Discontinued	DISCONTINUED	DSENDERDIS	
		Never dosed	NEVER DOSED	DSENDERNEV	
DSDISCRDC	String	Adverse Event	ADVERSE EVENT	DSAE	DSDISC, DSDISCI
		Subject Refused Further Dosing (Not due to AE)	SUBJECT REFUSED FURTHER DOSING (NOT DUE TO AE)	DSREF	
		Lost to Follow-Up	LOST TO FOLLOW-UP	DSLOSTFU	
		Death	DEATH	DSDEATH	
		Did Not Meet Eligibility Criteria	DID NOT MEET ELIGIBILITY CRITERIA	DSNOTELIG	
		Non-Compliance with Study Drug	NON-COMPLIANCE WITH STUDY DRUG	DSNONCOMP	
		Other Non-Compliance	OTHER NON-COMPLIANCE	DSOTHNONCOMP	
		Physician Decision	PHYSICIAN DECISION	DSMDDECISION	
		Requires Prohibited Medication	REQUIRES PROHIBITED MEDICATION	DSPROHIBMED	
		Pregnancy (Self or Partner)	PREGNANCY (SELF OR PARTNER)	DSPREG	
		Study Terminated by Sponsor	STUDY TERMINATED BY SPONSOR	DSSPONTERM	
		Other	OTHER	DSOTHER	
cliYESNO	String	Yes	Y	cliYES	ALL1RSN
		No	N	cliNO	

RDE Analytics: RD_ENDDOSE		
Data Variable RefName	RD Column Name	Column Data Type
DSEND	DSEND_C	VARCHAR2
	DSEND	VARCHAR2
	DSEND_ND	VARCHAR2
DSEND - DSDISC	DSDISC_C	VARCHAR2
	DSDISC	VARCHAR2
DSEND - DSAE_SP	DSAE_SP	VARCHAR2
DSEND - DSRD_SP	DSRD_SP	VARCHAR2

DSEND - DSONC_SP	DSONC_SP	VARCHAR2
DSEND - DSPD_SP	DSPD_SP	VARCHAR2
DSEND - DSOTH_SP	DSOTH_SP	VARCHAR2
DSEND - DSND_SP	DSND_SP	VARCHAR2
ALL1RSN	ALL1RSN_C	VARCHAR2
	ALL1RSN	VARCHAR2
	ALL1RSN_ND	VARCHAR2
ALL1RSN - DSENDI	DSENDI_C	VARCHAR2
	DSENDI	VARCHAR2
ALL1RSN - DSDISCI	DSDISCI_C	VARCHAR2
	DSDISCI	VARCHAR2
ALL1RSN - DSAE_SPI	DSAE_SPI	VARCHAR2
ALL1RSN - DSRD_SPI	DSRD_SPI	VARCHAR2
ALL1RSN - DSONCSPI	DSONCSPI	VARCHAR2
ALL1RSN - DSPD_SPI	DSPD_SPI	VARCHAR2
ALL1RSN - DSOTHSPI	DSOTHSPI	VARCHAR2
ALL1RSN - DSND_SPI	DSND_SPI	VARCHAR2

VX14-661-108: END OF STUDY (ENDSTUDY) [ENDSTUDY]

Complete this page when the subject has completed the study or is no longer able or willing to participate in the study.

If a subject withdraws consent **due to AE**, enter the reason as 'Adverse Event', not 'Withdrawal of Consent'.

<p>1.* Select the PRIMARY reason for the end of the subject's participation in the STUDY. [Select the PRIMARY reason for the end of the subject's participation in the STUDY.]</p>	<p>[DSEENDS] [A:COMPLETED] <input type="radio"/> Completed [A:DISCONTINUED] <input type="radio"/> [DSDISCS] Discontinued, select the one MOST SIGNIFICANT reason:</p> <p>[A:ADVERSE EVENT] <input type="radio"/> [DSAES_SP] Adverse Event Record the adverse event(s) that led to discontinuation of STUDY: <input type="text" value="A200"/></p> <p>[A:WITHDRAWAL OF CONSENT (NOT DUE TO AE)] <input type="radio"/> [DSWC_SP] Withdrawal of Consent (not due to AE) Specify the reason subject withdrew consent: <input type="text" value="A200"/></p> <p>[A:LOST TO FOLLOW-UP] <input type="radio"/> Lost to Follow-Up [A:DEATH] <input type="radio"/> Death [A:OTHER NON-COMPLIANCE] <input type="radio"/> [DSOINC_SP] Other Non-Compliance Specify the nature of non-compliance: <input type="text" value="A200"/></p> <p>[A:PHYSICIAN DECISION] <input type="radio"/> [DSPD_SP] Physician Decision Specify the reason for the decision: <input type="text" value="A200"/></p> <p>[A:STUDY TERMINATED BY SPONSOR] <input type="radio"/> Study Terminated by Sponsor [A:OTHER] <input type="radio"/> [DSOTH_SP] Other, Specify: <input type="text" value="A200"/></p> <p>[A:NEVER DOSED] <input type="radio"/> [DSND_SP] Never dosed, specify reason: <input type="text" value="A200"/></p>
<p>2.* Date of Completion or Termination of STUDY [Select the date of completion or termination of STUDY]</p>	<p>[DSDAT] Req <input type="text" value="DS"/> / Req <input type="text" value=""/> / Req <input type="text" value=""/> (2015-2020)</p>

Key: [*] = Item is required [✓] = Source verification required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: END OF STUDY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
DSENRDC	String	Completed	COMPLETED	DSENDCOM	DSENDS
		Discontinued	DISCONTINUED	DSENDDIS	
		Never dosed	NEVER DOSED	DSENDNEV	
DSDISC2RDC	String	Adverse Event	ADVERSE EVENT	DSAE	DSDISCS
		Withdrawal of Consent (not due to AE)	WITHDRAWAL OF CONSENT (NOT DUE TO AE)	DSWDRAW	
		Lost to Follow-Up	LOST TO FOLLOW-UP	DSLOSTFU	
		Death	DEATH	DSDEATH	
		Other Non-Compliance	OTHER NON-COMPLIANCE	DSOTHNONCOMP	
		Physician Decision	PHYSICIAN DECISION	DSMDDECISION	
		Study Terminated by Sponsor	STUDY TERMINATED BY SPONSOR	DSSPONTERM	
		Other	OTHER	DSOTHER	

RDE Analytics: RD_ENDSTUDY		
Data Variable RefName	RD Column Name	Column Data Type
DSENDS	DSENDS_C	VARCHAR2
	DSENDS	VARCHAR2
	DSENDS_ND	VARCHAR2
DSENDS - DSDISCS	DSDISCS_C	VARCHAR2
	DSDISCS	VARCHAR2
DSENDS - DSAES_SP	DSAES_SP	VARCHAR2
DSENDS - DSWC_SP	DSWC_SP	VARCHAR2
DSENDS - DSONC_SP	DSONC_SP	VARCHAR2
DSENDS - DSPD_SP	DSPD_SP	VARCHAR2
DSENDS - DSOTH_SP	DSOTH_SP	VARCHAR2
DSENDS - DSND_SP	DSND_SP	VARCHAR2
DSDAT	DSDAT	DATE
	DSDAT_DTS	VARCHAR2
	DSDAT_ND	VARCHAR2

DS

DS

DS

✓

DS

VX14-661-108: ROLLOVER TO EXTENSION STUDY (RO) [RO]

over to the Extension study?
n study?]

[ROYN]
[A:Y] ☐ **[ROARM]**
Yes
[A:OBSERVATIONAL ARM] ☐ Observational Arm
[A:TREATMENT ARM] ☐ Treatment Arm
[A:N] ☐ No

Key: [*] = Item is required [✓] = Source verification required
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Codelist Values Tables: ROLLOVER TO EXTENSION STUDY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	ROYN
		No	N	cliNO	
cliROARM	String	Observational Arm	OBSERVATIONAL ARM	cliROOBS	ROARM
		Treatment Arm	TREATMENT ARM	cliROTX	






RDE Analytics: RD_RO		
Data Variable RefName	RD Column Name	Column Data Type
ROYN	ROYN_C	VARCHAR2
	ROYN	VARCHAR2
	ROYN_ND	VARCHAR2
ROYN - ROARM	ROARM_C	VARCHAR2
	ROARM	VARCHAR2

1.*	Select the procedure(s) performed: [Select the procedure(s) performed:]	<div data-bbox="1073 151 1169 160">[UNSCRFS]</div> <div data-bbox="1073 167 1482 427"> <div data-bbox="1073 167 1339 180">[A:UNSCHVS] Vital Signs</div> <div data-bbox="1073 186 1388 199">[A:UNSCHUPREG] Urine Pregnancy</div> <div data-bbox="1073 206 1434 219">[A:UNSCHCFQR] CFQ-R Questionnaires</div> <div data-bbox="1073 225 1302 238">[A:UNSCHSF-12] SF-12</div> <div data-bbox="1073 245 1474 258">[A:UNSSDA] Study Drug Administration</div> <div data-bbox="1073 264 1272 277">[A:UNSCHPK2] PK</div> <div data-bbox="1073 284 1474 297">[A:UNSCHLAB] Central Laboratory Sample</div> <div data-bbox="1073 303 1444 316">[A:UNSCHSW] Central Sweat Chloride</div> <div data-bbox="1073 323 1283 334">[A:UNSCHECG] ECG</div> <div data-bbox="1073 342 1339 354">[A:UNSCHSP] Spirometry</div> </div>
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliUNSCRFS	String	Vital Signs	UNSCHVS	cliUNSVS	UNSCRFS
		Urine Pregnancy	UNSCHUPREG	cliUNUPREG	
		CFQ-R Questionnaires	UNSCHCFQR	cliUNCFQR	
		SF-12	UNSCHSF-12	cliUNSF12	
		Study Drug Administration	UNSSDA	cliUNSSDA	
		PK	UNSCHPK2	cliUNPK2	
		Central Laboratory Sample	UNSCHLAB	cliUNCLAB	
		Central Sweat Chloride	UNSCHSW	cliUNSW	
		ECG	UNSCHECG	cliUNECEG	
		Spirometry	UNSCHSP	cliUNSPIRO	

Data Variable RefName	RD Column Name	Column Data Type
UNSCRFS	UNSCRFS_ND	VARCHAR2
UNSCRFS - Vital Signs	UNSCRFS_CLIUNSVS_C	VARCHAR2
	UNSCRFS_CLIUNSVS	VARCHAR2
UNSCRFS - Urine Pregnancy	UNSCRFS_CLIUNUPREG_C	VARCHAR2
	UNSCRFS_CLIUNUPREG	VARCHAR2
UNSCRFS - CFQ-R Questionnaires	UNSCRFS_CLIUNCFQR_C	VARCHAR2
	UNSCRFS_CLIUNCFQR	VARCHAR2
UNSCRFS - SF-12	UNSCRFS_CLIUNSF12_C	VARCHAR2
	UNSCRFS_CLIUNSF12	VARCHAR2
UNSCRFS - Study Drug Administration	UNSCRFS_CLIUNSSDA_C	VARCHAR2
	UNSCRFS_CLIUNSSDA	VARCHAR2
UNSCRFS - PK	UNSCRFS_CLIUNPK2_C	VARCHAR2
	UNSCRFS_CLIUNPK2	VARCHAR2
UNSCRFS - Central Laboratory Sample	UNSCRFS_CLIUNCLAB_C	VARCHAR2

	UNSCRFS_CLIUNCLAB	VARCHAR2
UNSCRFS - Central Sweat Chloride	UNSCRFS_CLIUNSW_C	VARCHAR2
	UNSCRFS_CLIUNSW	VARCHAR2
UNSCRFS - ECG	UNSCRFS_CLIUNECG_C	VARCHAR2
	UNSCRFS_CLIUNECG	VARCHAR2
UNSCRFS - Spirometry	UNSCRFS_CLIUNSPIRO_C	VARCHAR2
	UNSCRFS_CLIUNSPIRO	VARCHAR2

VX14-661-108: PK SAMPLE COLLECTION UNSCHEDULED (PK2) - Repeating Form [PK2]			
#	Line #	Collection Date	Actual Time
1			
1.	Line # <i>[read-only]</i> [Line #]		[PKSPID] N3
2.* ✓	Collection Date [Collection Date]		[PKUDT] Req  / Req  / Req  (2015-2020)
3.* ✓	Actual Time [Actual Time]		[PKUTIM] Req  : Req  24-hour clock
Key: [*] = Item is required [✓] = Source verification required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.			

RDE Analytics: RD_PK2		
Data Variable RefName	RD Column Name	Column Data Type
PKSPID	PKSPID	NUMBER
	PKSPID_ND	VARCHAR2
PKUDT	PKUDT	DATE
	PKUDT_DTS	VARCHAR2
	PKUDT_ND	VARCHAR2
PKUTIM	PKUTIM	DATE
	PKUTIM_TMS	VARCHAR2
	PKUTIM_ND	VARCHAR2

InForm Special Properties For Study Design: VX14-661-108			
InForm Special Property	Property Type	Data Object RefName	Data Object Path RefName
Screening	Visit	INFScreening	INFScreening
Enrollment	Visit	INFEnrollment	INFEnrollment
Screening	Form	INFSCR	INFScreening.INFSCR
Enrollment	Form	INFENR	INFEnrollment.INFENR
Patient Identification	Form	RAND	vsSCR.RAND
Study Completion	Form	Unassigned	Unassigned
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Initials (Screening)	Item	SUBJINIT	INFScreening.INFSCR.INFSCR_S1.SUBJINIT
DOB (Screening)	Item	BRTH_DAT	INFScreening.INFSCR.INFSCR_S1.BRTH_DAT
Screening date (Screening)	Item	Unassigned	Unassigned
Patient No. (Enrollment)	Item	SUBJID	vsSCR.RAND.RAND_S1.SUBJID INFEnrollment.INFENR.INFENR_S1.SUBJID
Initials (Patient Identification)	Item	Unassigned	Unassigned
Completion status (Study Completion)	Item	Unassigned	Unassigned
Drop out reason (Study Completion)	Item	Unassigned	Unassigned
DOV (Date of Visit)	Item	VISDAT	vsUNS.DOV.DOV_S1.VISDAT vsET.DOV.DOV_S1.VISDAT vsW17.DOV.DOV_S1.VISDAT vsSCR.DOV.DOV_S1.VISDAT vsW12.DOV.DOV_S1.VISDAT vsW4.DOV.DOV_S1.VISDAT vsW8.DOV.DOV_S1.VISDAT vsD1.DOV.DOV_S1.VISDAT vsW24.DOV.DOV_S1.VISDAT vsW20.DOV.DOV_S1.VISDAT vsW18.DOV.DOV_S1.VISDAT vsFUP.DOV.DOV_S1.VISDAT vsD15.DOV.DOV_S1.VISDAT
Randomization field (Randomization)	Item	Unassigned	Unassigned