

Annotated Study Book for Study Design: VX18-150-104

Study Design Version: 3.0

Sponsor: Vertex Pharmaceuticals, Inc.

Protocol: VX18-150-104


Sponsor Drug Name: VX150

A Phase 2B Randomized, Double-blind, Placebo-controlled, Dose-ranging, Parallel-design Study of the Efficacy and Safety of VX-150 for Acute Pain Following Bunionectomy

Generated by Central Designer TM

January 31, 2019 12:11PM

VX18-150-104: System Screening (INFSCR) [INFSCR]

1.	Subject Initials <i>[read-only]</i> [INITSCR]	[SUBJINIT] A3
2.	Date of Birth <i>[read-only]</i> [DOBSCR]	[BRTH_DAT] (YYYY) Req  (1900-2002)

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	InFormScreening
Section	INFSCR_S1	
Item	SUBJINIT	Populated via IVRS/Bracket in the format '---'
Item	BRTH_DAT	Populated via IVRS/Bracket and mapped to DM form

Data Series Summary: System Screening

Item No.	Data Variable RefName	Mapping RefName	Data Set Alias/RefName	Data Series Alias/RefName	Data Series Type
2.	BRTH_DAT	IsBRTH_DAT	dsBRTH_DAT	dsrBRTH_DAT	DateTime

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

VX18-150-104: System Enrollment (INFENR) [INFENR]		
1.	Subject ID <i>[read-only]</i> [Subject ID]	[SUBJID] <div>A11</div>
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	InForm Enrollment
Section	INFENR_S1	
Item	SUBJID	Populated via IVRS/Bracket onto INFENR form and mapped to RAND form; Format = "XXX-YYY-ZZZ"

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

VX18-150-104: DATE OF VISIT (DOV) [DOV]

1. *	Date of Visit [Date of Visit]	[VISDAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2. *	Check the box if this visit did not occur and was entered in error [Check the box if this visit did not occur and was entered in error]	[VISERROR] [A:E] <input type="checkbox"/> DOV entered in error

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: DATE OF VISIT

Type	RefName	Description
Form	DOV	
Section	DOV_S1	
Item	VISDAT	
Item	VISERROR	

Data Series Summary: DATE OF VISIT

Item No.	Data Variable RefName	Mapping RefName	Data Set Alias/RefName	Data Series Alias/RefName	Data Series Type
1.	VISDAT	IsDOV	dsDOVofallVisits	dSrDOVofAllVisits	DateTime
2.	VISERROR	IsDOV	dsDOVofallVisits	dSrVISERRORofallVisits	Text

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


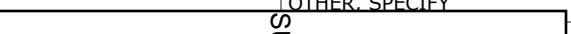
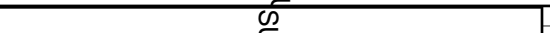

RDE Analytics: RD_DOV








Data Variable RefName	RD Column Name	Column Data Type
VISDAT	VISDAT	DATE
	VISDAT_DTS	VARCHAR2
	VISDAT_ND	VARCHAR2
VISERROR	VISERROR_ND	VARCHAR2
VISERROR - DOV entered in error	VISERROR_CLIDOVCHK_C	VARCHAR2
	VISERROR_CLIDOVCHK	VARCHAR2

VX18-150-104: DEMOGRAPHY (DM) [DM]	
1. ✓	Date of birth [read-only] [Date of birth] <input type="text" value="B"/> [BRTHDAT] (YYYY) (1900-2002)
2.* ✓	Sex [Sex] [SEX] [A:M] <input type="radio"/> Male [A:F] <input type="radio"/> Female [CHILDPO] <input type="radio"/> Is the subject a woman of childbearing potential? [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No [NOCHILDP] <input type="radio"/> Reason not of childbearing potential: [A:SURGICAL PROCEDURE] <input type="radio"/> Surgical [A:OTHER, SPECIFY] <input type="radio"/> [NOCHILDS] Other, specify: A40
3.* ✓	Ethnicity [Ethnicity] <input type="text" value="M"/> [ETHNIC] [A:HISPANIC OR LATINO] <input type="radio"/> Hispanic or Latino [A:NOT HISPANIC OR LATINO] <input type="radio"/> Not Hispanic or Latino [A:NOT COLLECTED PER LOCAL REGULATIONS] <input type="radio"/> Not Collected per Local Regulations
4.* ✓	Race (check all that apply) [Race (check all that apply)] <input type="text" value="R"/> [RACE] [A:WHITE] <input type="checkbox"/> White [A:BLACK OR AFRICAN AMERICAN] <input type="checkbox"/> Black or African American [A:ASIAN] <input type="checkbox"/> Asian [A:AMERICAN INDIAN OR ALASKA NATIVE] <input type="checkbox"/> American Indian or Alaska Native [A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER] <input type="checkbox"/> Native Hawaiian or Other Pacific Islander [A:OTHER, SPECIFY] <input type="checkbox"/> [RACE_SP] Other, specify: A45 [A:NOT COLLECTED PER LOCAL REGULATIONS] <input type="checkbox"/> Not Collected
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: DEMOGRAPHY		
Type	RefName	Description
Form	DM	
Section	DM_S1	
Item	BRTHDAT	Date of birth mapped from INFSCR form; Editable via IVRS/Bracket
Item	SEX	
Item	CHILDPO	
Item	NOCHILDP	
Item	NOCHILDS	
Item	ETHNIC	

Item	RACE	
Item	RACE_SP	

Codelist Values Tables: DEMOGRAPHY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clSex	String	Male	M	cliMALE	SEX 
		Female, is subject of childbearing potential	F	cliFEMALE	
clYESNO	String	Yes	Y	cliYES	CHILDPOT
		No	N	cliNO	
clNOCHILDPDC	String	Surgical Procedure	SURGICAL PROCEDURE	cliSURGPROC	NOCHILDP
		Other, specify: 	OTHER, SPECIFY	cliOtherSP	
clETHNICPDC	String	Hispanic or La 		cliHISPLAT	ETHNIC
		Not Hispanic or Latino	NOT HISPANIC OR LATINO	cliNOTHISPLAT	
		Not Collected per Local Regulations	NOT COLLECTED PER LOCAL REGULATIONS	cliNOTCOLL	
clRACEPDC	String	White	WHITE	cliWHITE	RACE
		Black or African American	BLACK OR AFRICAN AMERICAN	cliBLACK	
		Asian	ASIAN	cliASIAN	
		American Indian or Alaska Native	AMERICAN INDIAN OR ALASKA NATIVE	cliAIorAN	
		Native Hawaiian or Other Pacific Islander	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	cliNWorPI	
		Other	OTHER, SPECIFY	cliOther	
		Not Collected per Local Regulations	NOT COLLECTED PER LOCAL REGULATIONS	cliNOTCOLL	

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_ND	VARCHAR2
SEX - CHILDPOT 	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_ND	VARCHAR2
RACE - White	RACE_CLIWHITE_C	VARCHAR2
	RACE_CLIWHITE	VARCHAR2
RACE - Black or African American	RACE_CLIBLACK_C	VARCHAR2
	RACE_CLIBLACK	VARCHAR2
RACE - Asian	RACE_CLIASIAN_C	VARCHAR2
	RACE_CLIASIAN	VARCHAR2
RACE - American Indian or Alaska Native	RACE_CLIAIORAN_C	VARCHAR2
	RACE_CLIAIORAN	VARCHAR2
RACE - Native Hawaiian or Other Pacific Islander	RACE_CLINWORPI_C	VARCHAR2
	RACE_CLINWORPI	VARCHAR2
RACE - Other	RACE_RACE_SP_C	VARCHAR2
	RACE_RACE_SP	VARCHAR2
RACE - RACE_SP	RACE_SP	VARCHAR2
RACE - Not Collected per Local Regulations	RACE_CLINOTCOLL_C	VARCHAR2
	RACE_CLINOTCOLL	VARCHAR2

VX18-150-104: INFORMED CONSENT (ICA) [ICA]

Record the **original** informed consent/assent to the study and to the supplemental assessment(s). If the subject or his/her legal representative signed a revised informed consent/assent **after** the original, record that on the Reconsent and Re-assent page.

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

Informed Consent [ICA_S1]

1.*
✓

Date of **written** informed consent to the study
[Date of written informed consent to the study]

[IC_DAT] (DD/MM/YYYY)
Req / Req / Req (2018-2020)

2.*
✓

Corresponding **Protocol** Version
[Corresponding **Protocol** Version]

[ICPROTV]

Key: [*] = Item is required [✓] = Source verification required
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Study Object Descriptions: INFORMED CONSENT		
Type	RefName	Description
Form	ICA	
Section	ICA_S1	
Item	IC_DAT	
Item	ICPROTV	

RDE Analytics: RD_ICA		
Data Variable RefName	RD Column Name	Column Data Type
IC_DAT	IC_DAT	DATE
	IC_DAT_DTS	VARCHAR2
	IC_DAT_ND	VARCHAR2
ICPROTV	ICPROTV	FLOAT
	ICPROTV_ND	VARCHAR2

VX18-150-104: INCLUSION AND EXCLUSION (IE) [IE]			
1. ✓	Did the subject meet all inclusion and exclusion criteria? [Did the subject meet all inclusion and exclusion criteria?]	[IEYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No	
2. ✓	Line #	Unmet Inclusion/Exclusion Criterion	How did the subject fail to meet the criterion?
INCLUSION/EXCLUSION Entry [IE_R1]			
If the subject did NOT meet all criteria, click Add Entry to document EACH unmet criterion below.			
2.1	Line # <i>[read-only]</i> [Line #]	[IESPID] <input style="width: 50px;" type="text" value="N3"/>	
2.2* ✓	Unmet Inclusion/Exclusion Criterion [Unmet Inclusion/Exclusion Criterion]	[IEUNMET] [IEUNMETPDC] <input style="width: 50px;" type="button" value="v"/>	
2.3* ✓	How did the subject fail to meet the criterion? [How did the subject fail to meet the criterion?]	[IEUNMETF] <input style="width: 90%; height: 60px;" type="text" value="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: INCLUSION AND EXCLUSION

Type	RefName	Description
Form	IE	
Section	IE_S1	
Item	IEYN	
Section	IE_R1	
Item	IESPID	
Item	IEUNMET	
Item	IEUNMETF	

Codelist Values Tables: INCLUSION AND EXCLUSION

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clYESNO	String	Yes	Y	clYES	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	IEUNMETEX8
	EXCLUSION 9	EXCLUSION 9	IEUNMETEX9
	EXCLUSION 10	EXCLUSION 10	IEUNMETEX10
	EXCLUSION 11	EXCLUSION 11	IEUNMETEX11
	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
	EXCLUSION 12	EXCLUSION 12	IEUNMETEX12
	EXCLUSION 13	EXCLUSION 13	IEUNMETEX13
	EXCLUSION 14	EXCLUSION 14	IEUNMETEX14
	EXCLUSION 15	EXCLUSION 15	IEUNMETEX15
	EXCLUSION 16	EXCLUSION 16	IEUNMETEX16
	EXCLUSION 17	EXCLUSION 17	IEUNMETEX17

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

VX18-150-104: MEDICAL HISTORY (MH) [MH]

Record the subject's significant medical history, baseline signs/symptoms present before signed ICF. Do **not** include:

- remote (> 1 year ago) minor procedures (e.g. wisdom tooth extraction, 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? [Does the subject have any significant medical history?]	[MHYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
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	Line #	Abnormality/Condition	Continuing when ICF signed?
2. ✓			

Medical History Entry [MH_R1]

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

2.1	Line # <i>[read-only]</i> [Line #]	[MHSPID] N3
2.2*	Abnormality/Condition [Abnormality/Condition]	[MHTERM] A200
2.3*	Continuing when ICF signed? [Continuing when ICF signed?]	[MHONGO] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
2.4	Mapped Abnormality/Condition <i>[hidden]</i> [Mapped Abnormality/Condition]	[MHVERBATIM] A200
2.5	Dictionary Name and Version <i>[hidden]</i> [Dictionary Name and Version]	[VMEDDRA] A1500

2.6	Lowest Level Term Name <i>[hidden]</i> [Lowest Level Term Name]	<div>[LLT_NAME] A1500</div>
2.7	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<div>[LLT_CODE] A1500</div>

2.8	Preferred Term Name <i>[hidden]</i> [Preferred Term Name]	<div><div>[MHDECOD] A1500</div></div>
2.9	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<div><div>[PT_CODE] A1500</div></div>

2.10	High Level Term Name <i>[hidden]</i> [High Level Term Name]	<div>[HLT_NAME] A1500</div>
2.11	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<div>[HLT_CODE] A1500</div>

2.12	High Level Group Term Name <i>[hidden]</i> [High Level Group Term Name]	<div><div>[HLGTNAME]</div><div>A1500</div></div>
2.13	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<div><div>[HLGTCODE]</div><div>A1500</div></div>

2.14	System Organ Class Name <i>[hidden]</i> [System Organ Class Name]	[MHBODSYS] A1500
2.15	System Organ Class Code <i>[hidden]</i> [System Organ Class Code]	[SOC_CODE] A1500

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: MEDICAL HISTORY

Type	RefName	Description
Form	MH	
Section	MH_S1	
Item	MHYN	
Section	MH_R1	
Item	MHSPID	Line # will be calculated as a sequential number upon submission of the form.
Item	MHTERM	
Item	MHONGO	
Item	MHVERBATIM	
Item	VMEDDRA	
Item	LLT_NAME	
Item	LLT_CODE	
Item	MHDECOD	
Item	PT_CODE	
Item	HLT_NAME	
Item	HLT_CODE	
Item	HLGTNAME	
Item	HLGTCODE	
Item	MHBODSYS	
Item	SOC_CODE	

Codelist Values Tables: MEDICAL HISTORY

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

VX18-150-104: PHYSICAL EXAM (PE) [PE]		
1.* ✓	Date of physical exam [Date of physical exam]	[PEDAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Head, Neck & Thyroid [Head, Neck & Thyroid]	[HNT] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [HNTCcmp] Abnormal [HNTC] Description of Abnormality: <div style="border: 1px solid black; height: 40px; width: 100%;"></div> 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"/> [EENTCcmp] Abnormal [EENTC] Description of Abnormality: <div style="border: 1px solid black; height: 40px; width: 100%;"></div> A200 [A:NOT DONE] <input type="radio"/> Not Done
4.* ✓	Respiratory [Respiratory]	[RESPSYS] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [RESPSYSCcmp] Abnormal [RESPSYSC] Description of Abnormality: <div style="border: 1px solid black; height: 40px; width: 100%;"></div> A200 [A:NOT DONE] <input type="radio"/> Not Done
5.* ✓	Cardiovascular [Cardiovascular]	[CV] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [CVCcmp] Abnormal [CVC] Description of Abnormality: <div style="border: 1px solid black; height: 40px; width: 100%;"></div> A200 [A:NOT DONE] <input type="radio"/> Not Done

6.* ✓	Lymph Nodes [Lymph Nodes]	<p>[LYMPHN] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input checked="" type="radio"/> [LYMPHNCcmp] Abnormal [LYMPHNC] Description of Abnormality: A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
7.* ✓	Abdomen [Abdomen]	<p>[ABDOMEN] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input checked="" type="radio"/> [ABDOMENCcmp] Abnormal [ABDOMENC] Description of Abnormality: A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
8.* ✓	Skin [Skin]	<p>[SKIN] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input checked="" type="radio"/> [SKINCcmp] Abnormal [SKINC] Description of Abnormality: A200</p> <p>[A:NOT DONE] <input type="radio"/> Not Done</p>
9.* ✓	Musculoskeletal [Musculoskeletal]	<p>[MUSC] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input checked="" type="radio"/> [MUSCCcmp] Abnormal [MUSCC] 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 checked="" type="radio"/> [NEUROCcmp] Abnormal [NEUROC]</p>

		Description of Abnormality: <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
		[A:NOT DONE] <input type="radio"/> Not Done
11.* ✓	Anorectal [Anorectal]	[ANOREC] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [ANORECCcmp] Abnormal [ANORECC] Description of Abnormality: <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
		[A:NOT DONE] <input type="radio"/> Not Done
12.* ✓	Genital [Genital]	[GENIT] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [GENITCcmp] Abnormal [GENITC] Description of Abnormality: <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
		[A:NOT DONE] <input type="radio"/> Not Done
13.* ✓	Breast [Breast]	[BREASTS] [A:NORMAL] <input type="radio"/> Normal [A:ABNORMAL] <input type="radio"/> [BREASTSCcmp] Abnormal [BREASTSC] Description of Abnormality: <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
		[A:NOT DONE] <input type="radio"/> Not Done
14.* ✓	Other [Other]	[OTHER] [A:ABNORMAL] <input type="radio"/> [OTHERCcmp] Abnormal [OTHERC] Description of Abnormality: <div style="border: 1px solid black; height: 50px; width: 100%;"></div>
		[A:NOT DONE] <input type="radio"/> Not Done

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: PHYSICAL EXAM

Type	RefName	Description
Form	PE	
Section	PE_S1	
Item	PEDAT	
Item	HNT	
Item	HNTCcmp	
Item	HNTC	
Item	EENT	
Item	EENTCcmp	
Item	EENTC	
Item	RESPSYS	
Item	RESPSYSCcmp	
Item	RESPSYSC	
Item	CV	
Item	CVCcmp	
Item	CVC	
Item	LYMPHN	
Item	LYMPHNCcmp	
Item	LYMPHNC	
Item	ABDOMEN	
Item	ABDOMENCcmp	
Item	ABDOMENC	
Item	SKIN	
Item	SKINCcmp	
Item	SKINC	
Item	MUSC	
Item	MUSCCcmp	
Item	MUSCC	
Item	NEURO	
Item	NEUROCcmp	
Item	NEUROC	
Item	ANOREC	

Item	ANORECCcmp	
Item	ANORECC	
Item	GENIT	
Item	GENITCcmp	
Item	GENITC	
Item	BREASTS	
Item	BREASTSCcmp	
Item	BREASTSC	
Item	OTHER	
Item	OTHERCcmp	
Item	OTHERC	

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, MUSC, 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
MUSC	MUSC_C	VARCHAR2
	MUSC	VARCHAR2
	MUSC_ND	VARCHAR2
MUSC - MUSCC	MUSCC	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

VX18-150-104: VITAL SIGNS (VS) [VS]

Enter subject's age at time of signed consent/assent.

1.* ✓	Date of Assessment [Date of Assessment]	[VSDAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Age [Age]	[AGEGRP] [VSAGEYR] [VSAGEMTH] <input type="text"/> years ^[b] <input type="text"/> months ^[b]
3.* ✓	Height [Height]	[HEIGHT] <input type="text"/> cm ^[b] <input type="radio"/> in
4.* ✓	Weight [Weight]	[WEIGHT] <input type="text"/> kg ^[b] <input type="radio"/> LB
5.* ✓	Blood Pressure [Blood Pressure]	[PRESSURE] [SYSBP] [DIABP] <input type="text"/> mmHg ^[b] / <input type="text"/> mmHg ^[b]
6.* ✓	Temperature [Temperature]	[TEMP] <input type="text"/> C ^[b] <input type="radio"/> F
7.* ✓	Pulse Rate [Pulse]	[PULSE] <input type="text"/> beats/min ^[b]
8.* ✓	Respiration Rate [Respiration Rate]	[RESP] <input type="text"/> breaths/min ^[b]

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.

Study Object Descriptions: VITAL SIGNS

Type	RefName	Description
Form	VS	
Section	VS_S1	
Item	VSDAT	
Item	AGEGRP	
Item	VSAGEYR	
Item	VSAGEMTH	
Item	HEIGHT	
Item	WEIGHT	
Item	PRESSURE	
Item	SYSBP	
Item	DIABP	
Item	TEMP	
Item	PULSE	

Item	RESP	
------	------	--

Data Series Summary: VITAL SIGNS

Item No.	Data Variable RefName	Mapping RefName	Data Set Alias/RefName	Data Series Alias/RefName	Data Series Type
2.	VSAGEYR	IsAGEYR	dsAGEYR	dsrAGEYR	Integer
	VSAGEMTH	IsAGEYR	dsAGEYR	dsrAGEMONTH	Integer

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 - VSAGEYR	VSAGEYR	NUMBER
	VSAGEYR_U	VARCHAR2
AGEGRP - VSAGEMTH	VSAGEMTH	NUMBER
	VSAGEMTH_U	VARCHAR2
HEIGHT	HEIGHT	FLOAT
	HEIGHT_N	FLOAT
	HEIGHT_U	VARCHAR2
	HEIGHT_NU	VARCHAR2
	HEIGHT_ND	VARCHAR2
WEIGHT	WEIGHT	FLOAT
	WEIGHT_N	FLOAT
	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
	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

VX18-150-104: RANDOMIZATION (RAND) [RAND]		
1.	Subject ID <i>[read-only]</i> [Subject ID]	[SUBJID] A11
2.	Date of Randomization <i>[read-only]</i> [Date of Randomization]	[RANDDT] (DD/MM/YYYY) Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2018-2020)
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Study Object Descriptions: RANDOMIZATION		
Type	RefName	Description
Form	RAND	RANDOMIZATION
Section	RAND_S1	
Item	SUBJID	Populated via IVRS/Bracket onto INFENR form and mapped to RAND form; Format = "XXX-YYY-ZZZ"
Item	RANDDT	Populated via IVRS/Bracket; Editable via IVRS/Bracket

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

VX18-150-104: VITAL SIGNS (VS2) [VS2]		
1.* ✓	Date of Assessment [Date of Assessment]	[VSDAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Blood Pressure [Blood Pressure]	[PRESSURE] [SYSBP] <input type="text"/> mmHg ^[b] / [DIABP] <input type="text"/> mmHg ^[b]
3.* ✓	Temperature [Temperature]	[TEMP] <input type="text"/> °C <input type="radio"/> ^[b] <input type="radio"/> °F
4.* ✓	Pulse Rate [Pulse]	[PULSE] <input type="text"/> beats/min ^[b]
5.* ✓	Respiration Rate [Respiration Rate]	[RESP] <input type="text"/> breaths/min ^[b]
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.		

Study Object Descriptions: VITAL SIGNS

Type	RefName	Description
Form	VS2	
Section	VS2_S1	
Item	VSDAT	
Item	PRESSURE	
Item	SYSBP	
Item	DIABP	
Item	TEMP	
Item	PULSE	
Item	RESP	

RDE Analytics: RD_VS2		
Data Variable RefName	RD Column Name	Column Data Type
VSDAT	VSDAT	DATE
	VSDAT_DTS	VARCHAR2
	VSDAT_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
	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

VX18-150-104: URINE PREGNANCY TEST (UPREG) [UPREG]		
1.* ✓	Date of urine pregnancy test [Date of urine pregnancy test]	[ULBDAT] (DD/MM/YYYY) Req/Unk <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2018-2020)
2.* ✓	Result [Result]	[ULBORRES] [A:NEGATIVE] <input type="radio"/> Negative [A:POSITIVE] <input type="radio"/> Positive
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: URINE PREGNANCY TEST		
Type	RefName	Description
Form	UPREG	
Section	UPREG_S1	
Item	ULBDAT	
Item	ULBORRES	

Codelist Values Tables: URINE PREGNANCY TEST					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cINEGPOS	String	Negative	NEGATIVE	cliNegative	ULBORRES
		Positive	POSITIVE	cliPositive	

RDE Analytics: RD_UPREG		
Data Variable RefName	RD Column Name	Column Data Type
ULBDAT	ULBDAT	DATE
	ULBDAT_DTS	VARCHAR2
	ULBDAT_DTR	VARCHAR2
	ULBDAT_ND	VARCHAR2
ULBORRES	ULBORRES_C	VARCHAR2
	ULBORRES	VARCHAR2
	ULBORRES_ND	VARCHAR2

VX18-150-104: PAIN BLOCK REMOVAL (BLOCK) [BLCK]		
1.* ✓	Enter the date when the pain block was removed: [Enter the date when the pain block was removed]	[BLOCK_DAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Enter the time when the pain block was removed: [Enter the time when the pain block was removed]	[BLOCK_TM] (hh:mm) NReq <input type="text"/> : NReq <input type="text"/> 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.		

Study Object Descriptions: PAIN BLOCK REMOVAL		
Type	RefName	Description
Form	BLCK	
Section	BLCK_S1	
Item	BLOCK_DAT	
Item	BLOCK_TM	

RDE Analytics: RD_BLCK		
Data Variable RefName	RD Column Name	Column Data Type
BLOCK_DAT	BLOCK_DAT	DATE
	BLOCK_DAT_DTS	VARCHAR2
	BLOCK_DAT_ND	VARCHAR2
BLOCK_TM	BLOCK_TM	DATE
	BLOCK_TM_TMS	VARCHAR2
	BLOCK_TM_TMR	VARCHAR2
	BLOCK_TM_ND	VARCHAR2

VX18-150-104: ELIGIBILITY VRS and NPRS SCORE (VRS) [VRS]		
1.* ✓	Date of VRS [Date of VRS]	[VRSELIGR] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Actual Time of VRS Score [Actual Time of VRS Score]	[VRSTM] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	VRS Score [VRS Score]	[VRSSCORE] [A:NONE] <input type="radio"/> None [A:MILD] <input type="radio"/> Mild [A:MODERATE] <input type="radio"/> Moderate [A:SEVERE] <input type="radio"/> Severe
4. ✓	Date of NPRS Score [Date of NPRS Score]	[NPRSDT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
5. ✓	Actual Time of NPRS Score [Date of NPRS Score]	[NPRSTM] (hh:mm) Req <input type="text"/> : Req <input type="text"/> 24-hour clock
6. ✓	NPRS Score [NPRS Score]	[NPRSC] <input type="text" value="N2"/>
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: ELIGIBILITY VRS and NPRS SCORE

Type	RefName	Description
Form	VRS	
Section	VRS_s1	
Item	VRSELIGR	
Item	VRSTM	
Item	VRSSCORE	
Item	NPRSDT	
Item	NPRSTM	
Item	NPRSC	

Codelist Values Tables: ELIGIBILITY VRS and NPRS SCORE

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clSCORE	String	None	NONE	cliNONE	VRSSCORE
		Mild	MILD	cliMILD	
		Moderate	MODERATE	cliMODERATE	
		Severe	SEVERE	cliSEVERE	

RDE Analytics: RD_VRS		
Data Variable RefName	RD Column Name	Column Data Type
VRSELIGR	VRSELIGR	DATE
	VRSELIGR_DTS	VARCHAR2
	VRSELIGR_ND	VARCHAR2
VRSTM	VRSTM	DATE
	VRSTM_TMS	VARCHAR2
	VRSTM_ND	VARCHAR2
VRSSCORE	VRSSCORE_C	VARCHAR2
	VRSSCORE	VARCHAR2
	VRSSCORE_ND	VARCHAR2
NPRSDT	NPRSDT	DATE
	NPRSDT_DTS	VARCHAR2
	NPRSDT_ND	VARCHAR2
NPRSTM	NPRSTM	DATE
	NPRSTM_TMS	VARCHAR2
	NPRSTM_ND	VARCHAR2
NPRSC	NPRSC	NUMBER
	NPRSC_ND	VARCHAR2

VX18-150-104: DOSE 1 and DOSE 2 (DOSEF) [DOSEF]		
1.* ✓	Date of First Dose of VX-150 or VX-150 placebo dose [Date of First Dose of VX-150 or VX-150 placebo dose]	[EXFDAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Time of First Dose of VX-150 or VX-150 placebo dose [Time of First Dose of VX-150 or VX-150 placebo dose]	[EXFTIM] (hh:mm) NReq <input type="text"/> : NReq <input type="text"/> 24-hour clock
3.* ✓	Number of capsules TAKEN [Number of capsules TAKEN]	[EXFDOS] N1 <input type="text"/>
4.* ✓	Date of Second Dose of VX-150 or VX-150 placebo dose [Date of Second Dose of VX-150 or VX-150 placebo dose]	[EXFDAT2] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
5.* ✓	Time of Second Dose of VX-150 or VX-150 placebo dose [Time of Second Dose of VX-150 or VX-150 placebo dose]	[EXFTIM2] (hh:mm) NReq <input type="text"/> : NReq <input type="text"/> 24-hour clock
6.* ✓	Number of capsules TAKEN [Number of capsules TAKEN]	[EXFDOS2] N1 <input type="text"/>
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: DOSE 1 and DOSE 2		
Type	RefName	Description
Form	DOSEF	
Section	DOSEF_S1	
Item	EXFDAT	
Item	EXFTIM	
Item	EXFDOS	
Item	EXFDAT2	
Item	EXFTIM2	
Item	EXFDOS2	

RDE Analytics: RD_DOSEF		
Data Variable RefName	RD Column Name	Column Data Type
EXFDAT	EXFDAT	DATE
	EXFDAT_DTS	VARCHAR2
	EXFDAT_ND	VARCHAR2
EXFTIM	EXFTIM	DATE
	EXFTIM_TMS	VARCHAR2
	EXFTIM_TMR	VARCHAR2
	EXFTIM_ND	VARCHAR2
EXFDOS	EXFDOS	NUMBER

	EXFDOS_ND	VARCHAR2
EXFDAT2	EXFDAT2	DATE
	EXFDAT2_DTS	VARCHAR2
	EXFDAT2_ND	VARCHAR2
EXFTIM2	EXFTIM2	DATE
	EXFTIM2_TMS	VARCHAR2
	EXFTIM2_TMR	VARCHAR2
	EXFTIM2_ND	VARCHAR2
EXFDOS2	EXFDOS2	NUMBER
	EXFDOS2_ND	VARCHAR2

VX18-150-104: DOUBLE STOPWATCH (DBWATCH) [DBWATCH]

1.* ✓	Actual Elapsed Time to PERCEPTIBLE Pain Relief [Date/time of PERCEPTIBLE pain relief]	<p>[PERPNDTCMP] [PERPNDT] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)</p> <p>[PRPAINHH] Hour <input type="text"/></p> <p>[PRPAINSS] Seconds <input type="text"/></p> <p>[PRPAINMM] Minute <input type="text"/></p> <p>[PERPNR] <i>[A:Did not reach perceptible pain relief]</i> <input type="checkbox"/> Did not reach perceptible pain relief</p>
2.* ✓	Actual Elapsed Time to MEANINGFUL pain relief: [Date/time of MEANINGFUL pain relief:]	<p>[MEANINGFUL_DATE] [MEANPNDT] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)</p> <p>[MNPAINHH] Hour <input type="text"/></p> <p>[MNPAINMM] Minute <input type="text"/></p> <p>[MNPAINSS] Seconds <input type="text"/></p> <p>[MEANNR] <i>[A:Did not reach meaningful pain relief]</i> <input type="checkbox"/> Did not reach meaningful pain relief</p>

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: DOUBLE STOPWATCH

Type	RefName	Description
Form	DBWATCH	
Section	DBWATCH_S1	
Item	PERPNDTCMP	
Item	PERPNDT	
Item	PRPAINHH	
Item	PRPAINSS	

Item	PRPAINMM	
Item	PERPNR	
Item	MEANINGFUL_DATE	
Item	MEANPNDT	
Item	MNPAINHH	
Item	MNPAINMM	
Item	MNPAINSS	
Item	MEANNR	

Codelist Values Tables: DOUBLE STOPWATCH					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clHour	String	01	01	cliHR01	PRPAINHH, MNPAINHH
		02	02	cliHR02	
		03	03	cliHR03	
		04	04	cliHR04	
		05	05	cliHR05	
		06	06	cliHR06	
		07	07	cliHR07	
		08	08	cliHR08	
		09	09	cliHR09	
		10	10	cliHR10	
		11	11	cliHR11	
		12	12	cliHR12	
clSECONDS	String	01	01	cliSEC1	PRPAINSS, MNPAINSS
		02	02	cliSEC2	
		03	03	cliSEC3	
		04	04	cliSEC4	
		05	05	cliSEC5	
		06	06	cliSEC6	
		07	07	cliSEC7	
		08	08	cliSEC8	
		09	09	cliSEC9	
		10	10	cliSEC10	
		11	11	cliSEC11	
		12	12	cliSEC12	
		13	13	cliSEC13	

14	14	cliSEC14
15	15	cliSEC15
16	16	cliSEC16
17	17	cliSEC17
18	18	cliSEC18
19	19	cliSEC19
20	20	cliSEC20
21	21	cliSEC21
22	22	cliSEC22
23	23	cliSEC23
24	24	cliSEC24
25	25	cliSEC25
26	26	cliSEC26
27	27	cliSEC27
28	28	cliSEC28
29	29	cliSEC29
30	30	cliSEC30
31	31	cliSEC31
32	32	cliSEC32
33	33	cliSEC33
34	34	cliSEC34
35	35	cliSEC35
36	36	cliSEC36
37	37	cliSEC37
38	38	cliSEC38
39	39	cliSEC39
40	40	cliSEC40
41	41	cliSEC41
42	42	cliSEC42
43	43	cliSEC43
44	44	cliSEC44
45	45	cliSEC45
46	46	cliSEC46
47	47	cliSEC47
48	48	cliSEC48
49	49	cliSEC49
50	50	cliSEC50

		51	cliSEC51	
		52	cliSEC52	
		53	cliSEC53	
		54	cliSEC54	
		55	cliSEC55	
		56	cliSEC56	
		57	cliSEC57	
		58	cliSEC58	
		59	cliSEC59	
cIMIN	String	01	cliMIN1	PRPAINMM, MNPAINMM
		02	cliMIN2	
		03	cliMIN3	
		04	cliMIN4	
		05	cliMIN5	
		06	cliMIN6	
		07	cliMIN7	
		08	cliMIN8	
		09	cliMIN9	
		10	cliMIN10	
		11	cliMIN11	
		12	cliMIN12	
		13	cliMIN13	
		14	cliMIN14	
		15	cliMIN15	
		16	cliMIN16	
		17	cliMIN17	
		18	cliMIN18	
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		22	cliMIN22	
		23	cliMIN23	
		24	cliMIN24	
		25	cliMIN25	
		26	cliMIN26	
		27	cliMIN27	
		28	cliMIN28	

		29	29	cliMIN29	
		30	30	cliMIN30	
		31	31	cliMIN31	
		32	32	cliMIN32	
		33	33	cliMIN33	
		34	34	cliMIN34	
		35	35	cliMIN35	
		36	36	cliMIN36	
		37	37	cliMIN37	
		38	38	cliMIN38	
		39	39	cliMIN39	
		40	40	cliMIN40	
		41	41	cliMIN41	
		42	42	cliMIN42	
		43	43	cliMIN43	
		44	44	cliMIN44	
		45	45	cliMIN45	
		46	46	cliMIN46	
		47	47	cliMIN47	
		48	48	cliMIN48	
		49	49	cliMIN49	
		50	50	cliMIN50	
		51	51	cliMIN51	
		52	52	cliMIN52	
		53	53	cliMIN53	
		54	54	cliMIN54	
		55	55	cliMIN55	
		56	56	cliMIN56	
		57	57	cliMIN57	
		58	58	cliMIN58	
		59	59	cliMIN59	
cIPERPNR	String	Did not reach perceptible pain relief	Did not reach perceptible pain relief	cliPERPNR	PERPNR
cIMEANNR	String	Did not reach meaningful pain relief	Did not reach meaningful pain relief	cliMEANNR1	MEANNR

RDE Analytics: RD_DBWATCH

Data Variable RefName	RD Column Name	Column Data Type

PERPNDTCMP	PERPNDTCMP_ND	VARCHAR2
PERPNDTCMP - PERPNDT	PERPNDT	DATE
	PERPNDT_DTS	VARCHAR2
PERPNDTCMP - PRPAINHH	PRPAINHH_C	VARCHAR2
	PRPAINHH	VARCHAR2
PERPNDTCMP - PRPAINSS	PRPAINSS_C	VARCHAR2
	PRPAINSS	VARCHAR2
PERPNDTCMP - PRPAINMM	PRPAINMM_C	VARCHAR2
	PRPAINMM	VARCHAR2
PERPNDTCMP - Did not reach perceptible pain relief	PERPNR_CLIPERNR_C	VARCHAR2
	PERPNR_CLIPERNR	VARCHAR2
MEANINGFUL_DATE	MEANINGFUL_DATE_ND	VARCHAR2
MEANINGFUL_DATE - MEANPNDT	MEANPNDT	DATE
	MEANPNDT_DTS	VARCHAR2
MEANINGFUL_DATE - MNPAINHH	MNPAINHH_C	VARCHAR2
	MNPAINHH	VARCHAR2
MEANINGFUL_DATE - MNPAINMM	MNPAINMM_C	VARCHAR2
	MNPAINMM	VARCHAR2
MEANINGFUL_DATE - MNPAINSS	MNPAINSS_C	VARCHAR2
	MNPAINSS	VARCHAR2
MEANINGFUL_DATE - Did not reach meaningful pain relief	MEANNR_CLIMEANNR1_C	VARCHAR2
	MEANNR_CLIMEANNR1	VARCHAR2

VX18-150-104: PK SAMPLE COLLECTION (PK) [PK]		
1.* ✓	Pre first Day 1 VX-150 or VX-150 placebo dose [Pre first Day 1 VX-150 or VX-150 placebo dose]	[PKPRECMP] [PRE_DAT] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [PRE_TM] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock
2.* ✓	1 hour post first Day 1 VX-150 or VX-150 placebo dose [1 hour post first Day 1 VX-150 or VX-150 placebo dose]	[PKPOST1CMP] [POST_DAT1] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST_TIM1] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock
3.* ✓	2 hour post first Day 1 VX-150 or VX-150 placebo dose [2 hour post first Day 1 VX-150 or VX-150 placebo dose]	[PKPOST2CMP] [POST_DAT2] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST_TIM2] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock
4.* ✓	4 hour post first Day 1 VX-150 or VX-150 placebo dose [4 hour post first Day 1 VX-150 or VX-150 placebo dose]	[PKPOST4CMP] [POST_DAT4] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST_TIM4] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock
5.* ✓	6 hour post first Day 1 VX-150 or VX-150 placebo dose [6 hour post first Day 1 VX-150 or VX-150 placebo dose]	[PKPOST6CMP] [POST_DAT6] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST_TIM6] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock
6.* ✓	8 hour post first Day 1 VX-150 or VX-150 placebo dose [8 hour post first Day 1 VX-150 or VX-150 placebo dose]	[PKPOST8CMP] [POST_DAT8] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST_TIM8] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock
7.*	12 hour post first Day 1 VX-150 or VX-150 placebo dose	[PKPOST12CMP]

✓	[12 hour post first Day 1 VX-150 or VX-150 placebo dose]	<div><div>[POST_DAT12] (DD/MM/YYYY)</div><div>Collection Date</div><div>Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2018-2020)</div><div>[POST_TIM12] (hh:mm)</div><div>Actual Time</div><div>Req <input type="button" value="v"/> : Req <input type="button" value="v"/> 24-hour clock</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>		

Study Object Descriptions: PK SAMPLE COLLECTION		
Type	RefName	Description
Form	PK	
Section	PK_S1	
Item	PKPRECMP	
Item	PRE_DAT	
Item	PRE_TM	
Item	PKPOST1CMP	
Item	POST_DAT1	
Item	POST_TIM1	
Item	PKPOST2CMP	
Item	POST_DAT2	
Item	POST_TIM2	
Item	PKPOST4CMP	
Item	POST_DAT4	
Item	POST_TIM4	
Item	PKPOST6CMP	
Item	POST_DAT6	
Item	POST_TIM6	
Item	PKPOST8CMP	
Item	POST_DAT8	
Item	POST_TIM8	
Item	PKPOST12CMP	
Item	POST_DAT12	
Item	POST_TIM12	

RDE Analytics: RD_PK		
Data Variable RefName	RD Column Name	Column Data Type
PKPRECMP	PKPRECMP_ND	VARCHAR2

PKPRECMP - PRE_DAT	PRE_DAT	DATE
	PRE_DAT_DTS	VARCHAR2
PKPRECMP - PRE_TM	PRE_TM	DATE
	PRE_TM_TMS	VARCHAR2
PKPOST1CMP	PKPOST1CMP_ND	VARCHAR2
PKPOST1CMP - POST_DAT1	POST_DAT1	DATE
	POST_DAT1_DTS	VARCHAR2
PKPOST1CMP - POST_TIM1	POST_TIM1	DATE
	POST_TIM1_TMS	VARCHAR2
PKPOST2CMP	PKPOST2CMP_ND	VARCHAR2
PKPOST2CMP - POST_DAT2	POST_DAT2	DATE
	POST_DAT2_DTS	VARCHAR2
PKPOST2CMP - POST_TIM2	POST_TIM2	DATE
	POST_TIM2_TMS	VARCHAR2
PKPOST4CMP	PKPOST4CMP_ND	VARCHAR2
PKPOST4CMP - POST_DAT4	POST_DAT4	DATE
	POST_DAT4_DTS	VARCHAR2
PKPOST4CMP - POST_TIM4	POST_TIM4	DATE
	POST_TIM4_TMS	VARCHAR2
PKPOST6CMP	PKPOST6CMP_ND	VARCHAR2
PKPOST6CMP - POST_DAT6	POST_DAT6	DATE
	POST_DAT6_DTS	VARCHAR2
PKPOST6CMP - POST_TIM6	POST_TIM6	DATE
	POST_TIM6_TMS	VARCHAR2
PKPOST8CMP	PKPOST8CMP_ND	VARCHAR2
PKPOST8CMP - POST_DAT8	POST_DAT8	DATE
	POST_DAT8_DTS	VARCHAR2
PKPOST8CMP - POST_TIM8	POST_TIM8	DATE
	POST_TIM8_TMS	VARCHAR2
PKPOST12CMP	PKPOST12CMP_ND	VARCHAR2
PKPOST12CMP - POST_DAT12	POST_DAT12	DATE
	POST_DAT12_DTS	VARCHAR2
PKPOST12CMP - POST_TIM12	POST_TIM12	DATE
	POST_TIM12_TMS	VARCHAR2

VX18-150-104: DOSE 3 and DOSE 4 (DOSEL) [DOSEL]		
1.* ✓	Date of Third Dose of VX-150 or VX-150 placebo dose [Date of Third Dose of VX-150 or VX-150 placebo dose]	[EXFDAT3] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Time of Third Dose of VX-150 or VX-150 placebo dose [Time of Third Dose of VX-150 or VX-150 placebo dose]	[EXFTIM3] (hh:mm) NReq <input type="text"/> : NReq <input type="text"/> 24-hour clock
3.* ✓	Number of capsules TAKEN [Number of capsules TAKEN]	[EXFDOS3] <input type="text"/> N1
4.* ✓	Date of Fourth Dose of VX-150 or VX-150 placebo dose [Date of Fourth Dose of VX-150 or VX-150 placebo dose]	[EXFDAT4] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
5.* ✓	Time of Fourth Dose of VX-150 or VX-150 placebo dose [Time of Fourth Dose of VX-150 or VX-150 placebo dose]	[EXFTIM4] (hh:mm) NReq <input type="text"/> : NReq <input type="text"/> 24-hour clock
6.* ✓	Number of capsules TAKEN [Number of capsules TAKEN]	[EXFDOS4] <input type="text"/> N1
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: DOSE 3 and DOSE 4		
Type	RefName	Description
Form	DOSEL	F
Section	DOSEL_S1	
Item	EXFDAT3	
Item	EXFTIM3	
Item	EXFDOS3	
Item	EXFDAT4	
Item	EXFTIM4	
Item	EXFDOS4	

RDE Analytics: RD_DOSEL		
Data Variable RefName	RD Column Name	Column Data Type
EXFDAT3	EXFDAT3	DATE
	EXFDAT3_DTS	VARCHAR2
	EXFDAT3_ND	VARCHAR2
EXFTIM3	EXFTIM3	DATE
	EXFTIM3_TMS	VARCHAR2
	EXFTIM3_TMR	VARCHAR2
	EXFTIM3_ND	VARCHAR2
EXFDOS3	EXFDOS3	NUMBER

	EXFDOS3_ND	VARCHAR2
EXFDAT4	EXFDAT4	DATE
	EXFDAT4_DTS	VARCHAR2
	EXFDAT4_ND	VARCHAR2
EXFTIM4	EXFTIM4	DATE
	EXFTIM4_TMS	VARCHAR2
	EXFTIM4_TMR	VARCHAR2
	EXFTIM4_ND	VARCHAR2
EXFDOS4	EXFDOS4	NUMBER
	EXFDOS4_ND	VARCHAR2

VX18-150-104: PK SAMPLE COLLECTION (PK2) [PK2]							
	Pre dose first Day 2 VX-150 or VX-150 placebo dose	1 hour post dose first Day 2 VX-150 or VX- 150 placebo dose	2 hour post dose first Day 2 VX-150 or VX- 150 placebo dose	4 hour post dose first Day 2 VX-150 or VX- 150 placebo dose	6 hour post dose first Day 2 VX-150 or VX- 150 placebo dose	8 hour post dose first Day 2 VX-150 or VX- 150 placebo dose	12 hour post dose first Day 2 VX-150 or VX-150 placebo dose
1. ✓							
1.1* ✓	Pre first Day 2 VX-150 or VX-150 placebo dose [Pre dose first Day 2 VX-150 or VX-150 placebo dose]			[PKPRE2CMP] [PRE2_DAT] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [PRE2_TIM] (hh:mm) Actual Time Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock			
1.2* ✓	1 hour post first Day 2 VX-150 or VX-150 placebo dose [1 hour post dose first Day 2 VX-150 or VX-150 placebo dose]			[PK2POST1CMP] [POST2_DAT1] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST2_TIM1] (hh:mm) Actual Time Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock			
1.3* ✓	2 hour post first Day 2 VX-150 or VX-150 placebo dose [2 hour post dose first Day 2 VX-150 or VX-150 placebo dose]			[PK2POST2CMP] [POST2_DAT2] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST2_TIM2] (hh:mm) Actual Time Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock			
1.4* ✓	4 hour post first Day 2 VX-150 or VX-150 placebo dose [4 hour post dose first Day 2 VX-150 or VX-150 placebo dose]			[PK2POST4CMP] [POST2_DAT4] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST2_TIM4] (hh:mm) Actual Time Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock			
1.5* ✓	6 hour post first Day 2 VX-150 or VX-150 placebo dose [6 hour post dose first Day 2 VX-150 or VX-150 placebo dose]			[PK2POST6CMP] [POST2_DAT6] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [POST2_TIM6] (hh:mm) Actual Time Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock			
1.6* ✓	8 hour post first Day 2 VX-150 or VX-150 placebo dose [8 hour post dose first Day 2 VX-150 or VX-150 placebo dose]			[PK2POST8CMP] [POST2_DAT8] (DD/MM/YYYY) Collection Date Req / Req / Req (2018-2020)			

		<div> <div>▼</div> <div>▼</div> <div>▼</div> </div> [POST2_TIM8] (hh:mm) Actual Time Req/Unk ▼ : Req/Unk ▼ 24-hour clock
1.7* ✓	12 hour post first Day 2 VX-150 or VX-150 placebo dose [12 hour post dose first Day 2 VX-150 or VX-150 placebo dose]	[PK2POST12CMP] [POST2_DAT12] (DD/MM/YYYY) Collection Date Req ▼ / Req ▼ / Req ▼ (2018-2020) [POST2_TIM12] (hh:mm) Actual Time Req/Unk ▼ : Req/Unk ▼ 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.		

Study Object Descriptions: PK SAMPLE COLLECTION

Type	RefName	Description
Form	PK2	
Section	PK2_S1	
Item	PKPRE2CMP	
Item	PRE2_DAT	
Item	PRE2_TIM	
Item	PK2POST1CMP	
Item	POST2_DAT1	
Item	POST2_TIM1	
Item	PK2POST2CMP	
Item	POST2_DAT2	
Item	POST2_TIM2	
Item	PK2POST4CMP	
Item	POST2_DAT4	
Item	POST2_TIM4	
Item	PK2POST6CMP	
Item	POST2_DAT6	
Item	POST2_TIM6	
Item	PK2POST8CMP	
Item	POST2_DAT8	
Item	POST2_TIM8	
Item	PK2POST12CMP	
Item	POST2_DAT12	

Item	POST2_TIM12	
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RDE Analytics: RD_PK2		
Data Variable RefName	RD Column Name	Column Data Type
RD_PK2_PK2_S1		
PKPRE2CMP	PKPRE2CMP_ND	VARCHAR2
PKPRE2CMP - PRE2_DAT	PRE2_DAT	DATE
	PRE2_DAT_DTS	VARCHAR2
PKPRE2CMP - PRE2_TIM	PRE2_TIM	DATE
	PRE2_TIM_TMS	VARCHAR2
	PRE2_TIM_TMR	VARCHAR2
PK2POST1CMP	PK2POST1CMP_ND	VARCHAR2
PK2POST1CMP - POST2_DAT1	POST2_DAT1	DATE
	POST2_DAT1_DTS	VARCHAR2
PK2POST1CMP - POST2_TIM1	POST2_TIM1	DATE
	POST2_TIM1_TMS	VARCHAR2
	POST2_TIM1_TMR	VARCHAR2
PK2POST2CMP	PK2POST2CMP_ND	VARCHAR2
PK2POST2CMP - POST2_DAT2	POST2_DAT2	DATE
	POST2_DAT2_DTS	VARCHAR2
PK2POST2CMP - POST2_TIM2	POST2_TIM2	DATE
	POST2_TIM2_TMS	VARCHAR2
	POST2_TIM2_TMR	VARCHAR2
PK2POST4CMP	PK2POST4CMP_ND	VARCHAR2
PK2POST4CMP - POST2_DAT4	POST2_DAT4	DATE
	POST2_DAT4_DTS	VARCHAR2
PK2POST4CMP - POST2_TIM4	POST2_TIM4	DATE
	POST2_TIM4_TMS	VARCHAR2
	POST2_TIM4_TMR	VARCHAR2
PK2POST6CMP	PK2POST6CMP_ND	VARCHAR2
PK2POST6CMP - POST2_DAT6	POST2_DAT6	DATE
	POST2_DAT6_DTS	VARCHAR2
PK2POST6CMP - POST2_TIM6	POST2_TIM6	DATE
	POST2_TIM6_TMS	VARCHAR2
	POST2_TIM6_TMR	VARCHAR2
PK2POST8CMP	PK2POST8CMP_ND	VARCHAR2

PK2POST8CMP - POST2_DAT8	POST2_DAT8	DATE
	POST2_DAT8_DTS	VARCHAR2
PK2POST8CMP - POST2_TIM8	POST2_TIM8	DATE
	POST2_TIM8_TMS	VARCHAR2
	POST2_TIM8_TMR	VARCHAR2
PK2POST12CMP	PK2POST12CMP_ND	VARCHAR2
PK2POST12CMP - POST2_DAT12	POST2_DAT12	DATE
	POST2_DAT12_DTS	VARCHAR2
PK2POST12CMP - POST2_TIM12	POST2_TIM12	DATE
	POST2_TIM12_TMS	VARCHAR2
	POST2_TIM12_TMR	VARCHAR2

1.*	12 hour post last Day 2 VX-150 or VX-150 placebo dose [12 hour post last Day 2 VX-150 or VX-150 placebo dose]	[PK3POST12CMP] [PK3POST_DT] (DD/MM/YYYY) Collection Date Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020) [PK3POST_TM] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> <i>24-hour clock</i>
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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.

Type	RefName	Description
Form	PK3	
Section	PK3_S1	
Item	PK3POST12CMP	
Item	PK3POST_DT	
Item	PK3POST_TM	

Data Variable RefName	RD Column Name	Column Data Type
PK3POST12CMP	PK3POST12CMP_ND	VARCHAR2
PK3POST12CMP - PK3POST_DT	PK3POST_DT	DATE
	PK3POST_DT_DTS	VARCHAR2
PK3POST12CMP - PK3POST_TM	PK3POST_TM	DATE
	PK3POST_TM_TMS	VARCHAR2

VX18-150-104: PHONE CALL (PH) [PH]	
Please record any new AEs, CMs and NTs on the appropriate form(s).	
Phone Call [PHON_S1]	
1.* ✓	<div>Was phone contact made with subject? [Was phone contact made with subject?]</div> <div>[PHYN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No</div>
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: PHONE CALL		
Type	RefName	Description
Form	PH	PHONE CALL
Section	PHON_S1	
Item	PHYN	

Codelist Values Tables: PHONE CALL					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	PHYN
		No	N	cliNO	

RDE Analytics: RD_PH		
Data Variable RefName	RD Column Name	Column Data Type
PHYN	PHYN_C	VARCHAR2
	PHYN	VARCHAR2
	PHYN_ND	VARCHAR2

VX18-150-104: END OF DOSING (ENDDOSE) [ENDDOSE]

Complete this page when the subject has stopped **dosing**. OR Complete this page when the subject takes the last dose of study drug.

Enter the reason the subject stopped DOSING with VX-150/Placebo.

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

<p>1.* ✓</p> <p>Select the PRIMARY reason DOSING ended. [Select the PRIMARY reason DOSING ended.]</p>	<p>[DSEND] [A:COMPLETED] <input type="radio"/> Completed [A:DISCONTINUED] <input type="radio"/> [DSDISCcmp] Discontinued [DSDISC] Discontinued, select the one MOST SIGNIFICANT reason: [A:ADVERSE EVENT] <input type="radio"/> [DSAE_Spcmp] Adverse Event [DSAE_SP] Record the adverse event(s) that led to discontinuation of dosing: <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div></p> <p>[A:LACK OF EFFICACY] <input type="radio"/> Subject Refused Further Dosing (due to Lack of Efficacy) [A:SUBJECT REFUSED FURTHER DOSING (NOT DUE TO AE)] <input type="radio"/> [DSRD_Spcmp] Subject Refused Further Dosing (for other reason) [DSRD_SP] Specify the reason subject refused further dosing (for other reason): <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div></p> <p>[A:LOST TO FOLLOW-UP] <input type="radio"/> Lost to Follow-Up [A:DEATH] <input type="radio"/> Death [A:DID NOT MEET ELIGIBILITY CRITERIA] <input type="radio"/> Did Not Meet Eligibility Criteria [A:NON-COMPLIANCE WITH STUDY DRUG] <input type="radio"/> Non-Compliance with Study Drug [A:OTHER NON-COMPLIANCE] <input type="radio"/> [DSOnc_Spcmp] Other Non-Compliance [DSOnc_SP] Specify the nature of non-compliance: <div style="border: 1px solid black; height: 60px; margin-top: 5px;"></div></p> <p>[A:PHYSICIAN DECISION] <input type="radio"/> [DSPD_Spcmp] Physician Decision [DSPD_SP] Specify the reason for the decision: <div style="border: 1px solid black; height: 40px; margin-top: 5px;"></div></p>
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Study Object Descriptions: END OF DOSING		
Type	RefName	Description
Form	ENDDOSE	END OF DOSING
Section	ENDDOSETI_S1	
Item	DSEND	
Item	DSDISCcmp	
Item	DSDISC	
Item	DSAE_SPcmp	
Item	DSAE_SP	
Item	DSRD_SPcmp	
Item	DSRD_SP	
Item	DSOnc_SPcmp	
Item	DSOnc_SP	

Item	DSPD_SPcmp	
Item	DSPD_SP	
Item	DSOTH_SPcmp	
Item	DSOTH_SP	
Item	DSND_SPcmp	
Item	DSND_SP	

Codelist Values Tables: END OF DOSING					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
DSENRDC	String	Completed	COMPLETED	DSENDCOM	DSEND
		Discontinued	DISCONTINUED	DSENDDIS	
		Never dosed	NEVER DOSED	DSENDNEV	
DSDISCRDC	String	Adverse Event	ADVERSE EVENT	cliDSAE	DSDISC
		Subject Refused Further Dosing (due to Lack of Efficacy)	LACK OF EFFICACY	cliLACKEFF	
		Subject Refused Further Dosing (for other reason), Specify the reason subject refused further dosing	SUBJECT REFUSED FURTHER DOSING (NOT DUE TO AE)	DSREF	
		Lost to Follow-Up	LOST TO FOLLOW-UP	cliDSLOSTFU	
		Death	DEATH	cliDSDEATH	
		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	cliDSOTHNONCOMP	
		Physician Decision	PHYSICIAN DECISION	cliDSMDDECISION	
		Pregnancy (Self or Partner)	PREGNANCY (SELF OR PARTNER)	DSPREG	
		Requires Prohibited Medication	REQUIRES PROHIBITED MEDICATION	DSPROHIBMED	
		Sponsor Decision	SPONSOR DECISION	cliDSSPONDEC	
		Study Terminated by Sponsor	STUDY TERMINATED BY SPONSOR	cliDSSPONTERM	
		Other	OTHER	cliDSOTHER	

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

VX18-150-104: END OF STUDY (ENDSTUDY) [ENDSTUDY]

Complete this page when the subject has completed the final visit required by protocol, or is no longer able or willing to participate in follow-up.

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

- 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.]

[DSEENDS]

[A:COMPLETED] ☐ Completed

[A:NOT COMPLETED] ☐ **[DSDISCScmp]**
 Not Completed

[DSDISCS]

Select the one MOST SIGNIFICANT reason:

[A:ADVERSE EVENT] ☐ **[DSAEScmp]**

Adverse Event

[DSAES_SP]

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

A200

[A:LACK OF EFFICACY] ☐ **[DSWC_SPcmp]**

Withdrawal of Consent (due to Lack of Efficacy)

[A:WITHDRAWAL OF CONSENT (NOT DUE TO AE)] ☐ **[DSWC_SP]**

Withdrawal of Consent (for other reason)

[DSWC_SP]

Specify the **reason** subject withdrew consent:

A200

[A:LOST TO FOLLOW-UP] ☐ **[DTHDATcmp]**

Lost to Follow-Up

[DTHDATcmp]

Death

[DTHDAT] (DD/MM/YYYY)

Specify the date of death:

Req / Req / Req (2018-2020)

[A:OTHER NON-COMPLIANCE] ☐ **[DSOnc_SPcmp]**

Other Non-Compliance

[DSOnc_SP]

Specify the **nature** of non-compliance:

A200

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

Physician Decision

[DSPD_SP]

Specify the **reason** for the decision:

A200

		<div><div><div>[A:SPONSOR DECISION]</div><div>[A:STUDY TERMINATED BY SPONSOR]</div><div>[A:OTHER]</div></div><div><div><input type="radio"/> Sponsor Decision</div><div><input type="radio"/> Study Terminated by Sponsor</div><div><input type="radio"/> [DSOTH_SPcmp] Other [DSOTH_SP] Specify: A200</div></div></div>
		<div><div>[A:NEVER DOSED]</div><div><input type="radio"/> [DSND_SPcmp] Never dosed [DSND_SP] Specify reason: A200</div></div>
2.* ✓	Date of Completion or Termination of STUDY [Date of Completion or Termination of STUDY]	[DSDAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
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 STUDY		
Type	RefName	Description
Form	ENDSTUDY	
Section	ENDSTUDY_S1	
Item	DSENDS	
Item	DSDISCScmp	
Item	DSDISCS	
Item	DSAEScmp	
Item	DSAES_SP	
Item	DSWC_SPcmp	
Item	DSWC_SP	
Item	DTHDATcmp	
Item	DTHDAT	
Item	DSONC_SPcmp	
Item	DSONC_SP	
Item	DSPD_SPcmp	
Item	DSPD_SP	

Item	DSOTH_SPcmp	
Item	DSOTH_SP	
Item	DSND_SPcmp	
Item	DSND_SP	
Item	DSDAT	

Data Series Summary: END OF STUDY					
Item No.	Data Variable RefName	Mapping RefName	Data Set Alias/RefName	Data Series Alias/RefName	Data Series Type
2.	DSDAT	IsTERM_DAT	dsTERM_DAT	dSrTERM_DAT	DateTime

Codelist Values Tables: END OF STUDY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clDSENDERDC_ES	String	Completed	COMPLETED	cliDSENDCOM_1	DSENDS
		Not Completed	NOT COMPLETED	cliDSENDS2	
		Never dosed	NEVER DOSED	cliDSENDNEV_1	
clDSDISC2RDC	String	Adverse Event	ADVERSE EVENT	cliDSAE	DSDISCS
		Withdrawal of Consent (due to Lack of Efficacy)	LACK OF EFFICACY	cliLACKOFEFF	
		Withdrawal of Consent (not due to AE)	WITHDRAWAL OF CONSENT (NOT DUE TO AE)	cliDSWDRAW	
		Lost to Follow-Up	LOST TO FOLLOW-UP	cliDSLOSTFU	
		Death	DEATH	cliDSDEATH	
		Other Non-Compliance	OTHER NON-COMPLIANCE	cliDSOTHNONCOMP	
		Physician Decision	PHYSICIAN DECISION	cliDSMDDECISION	
		Sponsor Decision	SPONSOR DECISION	cliDSSPONDEC	
		Study Terminated by Sponsor	STUDY TERMINATED BY SPONSOR	cliDSSPONTERM	
		Other	OTHER	cliDSOTHER	

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 - DTHDAT	DTHDAT	DATE
	DTHDAT_DTS	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

VX18-150-104: STATUS (STATUS) [STATUS]		
ADVERSE EVENTS [STATUS_S1]		
1. ✓	Has the subject had any adverse events during the protocol-specified collection period? [Has the subject had any adverse events during the protocol-specified 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? [Has the subject taken medication during the protocol-specified 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? [Has the subject had any non-pharmacological treatments or therapeutic procedures during the protocol-specified collection period?]	[NT_YN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
RESCUE MEDICATIONS [STATUS_S4]		
4. ✓	Has the subject had any rescue medications during the protocol-specified collection period? [Has the subject had any rescue medications during the protocol-specified collection period?]	[RESC_YN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No
SUPPLEMENTAL ANALGESIC MEDICATION [STATUS_S5]		
5.* ✓	Has the subject had any supplemental analgesic medications after surgery and before removal of popliteal block? [Has the subject had any supplemental analgesic medications after surgery and before removal of popliteal block?]	[SA_YN] [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.		

Study Object Descriptions: STATUS		
Type	RefName	Description
Form	STATUS	
Section	STATUS_S1	
Item	AEYN	
Section	STATUS_S2	
Item	CMYN	
Section	STATUS_S3	
Item	NT_YN	
Section	STATUS_S4	
Item	RESC_YN	
Section	STATUS_S5	
Item	SA_YN	

--

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, RESC_YN, SA_YN
		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
RESC_YN	RESC_YN_C	VARCHAR2
	RESC_YN	VARCHAR2
	RESC_YN_ND	VARCHAR2
SA_YN	SA_YN_C	VARCHAR2
	SA_YN	VARCHAR2
	SA_YN_ND	VARCHAR2

VX18-150-104: RESCUE MEDICATION (RSCMED) - Repeating Form [RSCMED]				
#	Line #	Enter date/time rescue medication was taken by the subject	Ibuprofen 400 mg	NPRS Score
1				
1.	Line # <i>[read-only]</i> [Line #]	[RMEDSPID] <input type="text" value="N3"/>		
2.* ✓	Enter date/time rescue medication was taken by the subject [Enter date/time rescue medication was taken by the subject]	[RSCMEDCMP] [RSCMED_D] (DD/MM/YYYY) Medication Date Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (2018-2020) [RSCMED_T] (hh:mm) Actual Time Req <input type="text"/> : Req <input type="text"/> 24-hour clock		
3.* ✓	Ibuprofen 400 mg [Ibuprofen 400 mg]	[TABLETS] <input type="text" value="N2"/> Tablets		
4. ✓	NPRS Score [NPRS Score]	[NPRSC] <input type="text" value="N2"/>		
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: RESCUE MEDICATION		
Type	RefName	Description
Form	RSCMED	
Section	RESCMED_S1	
Item	RMEDSPID	Line # will be calculated as a sequential number upon submission of the form.
Item	RSCMEDCMP	
Item	RSCMED_D	
Item	RSCMED_T	
Item	TABLETS	
Item	NPRSC	

RDE Analytics: RD_RSCMED		
Data Variable RefName	RD Column Name	Column Data Type
RMEDSPID	RMEDSPID	NUMBER
	RMEDSPID_ND	VARCHAR2
RSCMEDCMP	RSCMEDCMP_ND	VARCHAR2
RSCMEDCMP - RSCMED_D	RSCMED_D	DATE
	RSCMED_D_DTS	VARCHAR2
	RSCMED_D_DTR	VARCHAR2

RSCMEDCMP - RSCMED_T	RSCMED_T	DATE
	RSCMED_T_TMS	VARCHAR2
TABLETS	TABLETS	NUMBER
	TABLETS_ND	VARCHAR2
NPRSC	NPRSC	NUMBER
	NPRSC_ND	VARCHAR2

VX18-150-104: RECONSENT (RICA) [RICA]

Indicate whether the subject or his/her legal representative signed a revised consent/assent due to a protocol amendment **after** signing the original consent.

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

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

1.* ✓	Was reconsent obtained at any time? [Was reconsent obtained at any time?]	[RIC_YN] [A:Y] <input type="radio"/> Yes [A:N] <input type="radio"/> No		
	Line #	Reconsent given for:	Date of written informed consent	Corresponding Protocol Version
2. ✓				
If yes, click Add Entry to create a row for EACH reconsent/re-assent.				
2.1	Line # <i>[read-only]</i> [Line #]	[RICSPID] <input type="text" value="N3"/>		
2.2	Reconsent given for: <i>[read-only]</i> [Reconsent given for:]	[RICSTUDY_1] [A:MAIN STUDY] <input type="radio"/> Main Study		
2.3* ✓	Date of written informed consent [Date of written informed consent]	[RIC_DAT] (DD/MM/YYYY) Req <input type="text" value=""/> / Req <input type="text" value=""/> / Req <input type="text" value=""/> (2018-2020)		
2.4* ✓	Corresponding Protocol Version [Corresponding Protocol Version]	[RICPROTV] <input type="text" value="xx.x"/>		
2.5	Yes <i>[hidden]</i> [Yes]	[RIAS_DAT_CMP] [RIAS_DAT] (DD/MM/YYYY) Date of ASSENT Req <input type="text" value=""/> / Req <input type="text" value=""/> / Req <input type="text" value=""/> (2018-2020)		
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: RECONSENT

Type	RefName	Description
Form	RICA	
Section	RICA_S1	
Item	RIC_YN	
Section	RICA_R1	
Item	RICSPID	
Item	RICSTUDY_1	
Item	RIC_DAT	
Item	RICPROTV	
Item	RIAS_DAT_CMP	
Item	RIAS_DAT	

Codelist Values Tables: RECONSENT					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliYESNO	String	Yes	Y	cliYES	RIC_YN
		No	N	cliNO	
clIRICSTUDY_1	String	Main Study	MAIN STUDY	cliIRICSTUDY1	RICSTUDY_1

RDE Analytics: RD_RICA		
Data Variable RefName	RD Column Name	Column Data Type
RIC_YN	RIC_YN_C	VARCHAR2
	RIC_YN	VARCHAR2
	RIC_YN_ND	VARCHAR2
RD_RICA_RICA_R1		
RICSPID	RICSPID	NUMBER
	RICSPID_ND	VARCHAR2
RICSTUDY_1	RICSTUDY_1_C	VARCHAR2
	RICSTUDY_1	VARCHAR2
	RICSTUDY_1_ND	VARCHAR2
RIC_DAT	RIC_DAT	DATE
	RIC_DAT_DTS	VARCHAR2
	RIC_DAT_ND	VARCHAR2
RICPROTV	RICPROTV	FLOAT
	RICPROTV_ND	VARCHAR2
RIAS_DAT_CMP	RIAS_DAT_CMP_ND	VARCHAR2
RIAS_DAT_CMP - RIAS_DAT	RIAS_DAT	DATE
	RIAS_DAT_DTS	VARCHAR2

		1.5 HOURS POSTDOSE	1.5 HOURS POSTDOSE	cli15Post	
		2 HOURS POSTDOSE	2 HOURS POSTDOSE	cli2POST	
		3 HOURS POSTDOSE	3 HOURS POSTDOSE	cli3POST	
		4 HOURS POSTDOSE	4 HOURS POSTDOS	cli4POST	
		5 HOURS POSTDOSE	5 HOURS POSTDOSE	cli5POST	
		6 HOURS POSTDOSE	6 HOURS POSTDOSE	cli6POST	
		8 HOURS POSTDOSE	8 HOURS POSTDOSE	cli8POST	
		12 HOURS POSTDOSE	12 HOURS POSTDOSE	cli12POST	
		16 HOURS POSTDOSE	16 HOURS POSTDOSE	cli16POST	
		20 HOURS POSTDOSE	20 HOURS POSTDOSE	cli20POST	
		24 HOUR POSTDOSE	24 HOUR POSTDOSE	cli24POST	
		28 HOURS POSTDOSE	28 HOURS POSTDOSE	cli28POST	
		32 HOURS POSTDOSE	32 HOURS POSTDOSE	cli32POST	
		36 HOUR POSTDOSE	36 HOUR POSTDOSE	cli36POST	
		40 HOURS POSTDOSE	40 HOURS POSTDOSE	cli40POST	
		44 HOURS POSTDOSE	44 HOURS POSTDOSE	cli44POST	
		48 HOURS POSTDOSE	48 HOURS POSTDOSE	cli48POST	
cINPRSND	String	Not Done	NOT DONE	cliND	NPRSND

RDE Analytics: RD_NPRS

Data Variable RefName	RD Column Name	Column Data Type
NPRSPT	NPRSPT_C	VARCHAR2
	NPRSPT	VARCHAR2
	NPRSPT_ND	VARCHAR2
NPRSND	NPRSND_ND	VARCHAR2
NPRSND - Not Done	NPRSND_CLIND_C	VARCHAR2
	NPRSND_CLIND	VARCHAR2
NPRSDT	NPRSDT	DATE
	NPRSDT_DTS	VARCHAR2
	NPRSDT_ND	VARCHAR2
NPRSTM	NPRSTM	DATE
	NPRSTM_TMS	VARCHAR2
	NPRSTM_ND	VARCHAR2
NPRSC	NPRSC	NUMBER
	NPRSC_ND	VARCHAR2

file:///C:/Users/mcronin/AppData/Local/Apps/2.0/EORXC2ZA.PKP/1Q62PTEY.CJY/orac...264_040cb68c7390ff6f_0002.0001_fb44b57de71794cb/HtmlResources/Ann... 1/31/2019

8.	<div>Lowest Level Term Name <i>[hidden]</i></div> <div>[Lowest Level Term Name]</div>	<div>[LLT_NAME]</div> <div>A1500</div>
9.	<div>Lowest Level Term Code <i>[hidden]</i></div> <div>[Lowest Level Term Code]</div>	<div>[LLT_CODE]</div> <div>A1500</div>

10.	<div>Preferred Term Name <i>[hidden]</i> [Preferred Term Name]</div>	<div><div>[NTDECOD]</div><div>A1500</div></div>
11.	<div>Preferred Term Code <i>[hidden]</i> [Preferred Term Code]</div>	<div><div>[PT_CODE]</div><div>A1500</div></div>

12.	<div>High Level Term Name <i>[hidden]</i> [High Level Term Name]</div>	<div><div>[HLT_NAME]</div><div>A1500</div></div>
13.	<div>High Level Term Code <i>[hidden]</i> [High Level Term Code]</div>	<div><div>[HLT_CODE]</div><div>A1500</div></div>

14.	<div>High Level Group Term Name <i>[hidden]</i> [High Level Group Term Name]</div>	<div>[HLGTNAME] A1500</div>
15.	<div>High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]</div>	<div>[HLGTCODE] A1500</div>

16.	System Organ Class Name <i>[hidden]</i> [System Organ Class Name]	[NTBODSYS] A1500
17.	System Organ Class Code <i>[hidden]</i> [System Organ Class Code]	[SOC_CODE] A1500

Key: [*] = Item is required [✓] = 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
Section	NT_S1	
Item	NTSPID	Line # will be calculated as a sequential number upon submission of the form.
Item	NTNAME	
Item	NTSTDAT	
Item	NTONGO	
Item	NTENDAT	
Item	NTINDC	
Item	NTVERBATIM	
Item	VMEDDRA	
Item	LLT_NAME	
Item	LLT_CODE	
Item	NTDECOD	
Item	PT_CODE	
Item	HLT_NAME	
Item	HLT_CODE	
Item	HLGTNAME	
Item	HLGTCODE	
Item	NTBODSYS	
Item	SOC_CODE	

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
cINTEN_DTRDC	String	Stop Date	Stop Date	cliStopDate	NTONGO
		Continuing at end of study participation	Continuing	cliCTContinuing	

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

VX18-150-104: Supplemental Analgesic Medication (SAM) - Repeating Form [SAM]			
#	Analgesic Medication	NPRS Score	Date/Time of Drug Administration
1			
1.* ✓	Analgesic Medication [Analgesic Medication]		[SUPANALG] [A:IV ketorolac] <input type="radio"/> IV ketorolac [A:Morphine sulfate] <input type="radio"/> Morphine sulfate [A:Bolus of ropivacaine] <input type="radio"/> Bolus of ropivacaine
2. ✓	NPRS Score required for ketorolac and morphine [NPRS Score]		[NPRSUP] <input type="text" value="N2"/>
3.* ✓	Date/Time of Drug Administration [Date/Time of Drug Administration]		[SUPANALG_CMP] [SUPANALG_D] (DD/MM/YYYY) Date Drug Administration Req <input type="text" value=""/> / Req <input type="text" value=""/> / Req <input type="text" value=""/> (2018-2020) [SUPANALG_T] (hh:mm) Time of Drug Administration Req <input type="text" value=""/> : Req <input type="text" value=""/> 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.			

Study Object Descriptions: Supplemental Analgesic Medication

Type	RefName	Description
Form	SAM	
Section	SAM_s1	
Item	SUPANALG	
Item	NPRSUP	
Item	SUPANALG_CMP	
Item	SUPANALG_D	
Item	SUPANALG_T	



Codelist Values Tables: Supplemental Analgesic Medication

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliSUPANALG	String	IV ketorolac	IV ketorolac	cliSUPANALG1	SUPANALG
		Morphine sulfate	Morphine sulfate	cliSUPANALG2	
		Bolus of ropivacaine	Bolus of ropivacaine	cliSUPANALG3	

RDE Analytics: RD_SAM

Data Variable RefName	RD Column Name	Column Data Type
SUPANALG	SUPANALG_C	VARCHAR2

	SUPANALG	VARCHAR2
	SUPANALG_ND	VARCHAR2
NPRSUP	NPRSUP	NUMBER
	NPRSUP_ND	VARCHAR2
SUPANALG_CMP	SUPANALG_CMP_ND	VARCHAR2
SUPANALG_CMP - SUPANALG_D	SUPANALG_D	DATE
	SUPANALG_D_DTS	VARCHAR2
SUPANALG_CMP - SUPANALG_T	SUPANALG_T	DATE
	SUPANALG_T_TMS	VARCHAR2

VX18-150-104: ADVERSE EVENTS (AE) - Repeating Form [AE]										
#	Line #	Adverse Event	Is AE Serious?	Start Date	Stop Date	Relationship to study drug regimen	VX-150 Action Taken	Severity	Outcome	Treatment Required?
1										
1.	Line # [read-only] [Line #]	[AESPID] <input type="text" value="N3"/>								
2.* ✓ 	Adverse Event [Adverse Event]	[AETERM] <input type="text" value="A200"/>								
3.* ✓	Is AE Serious? [Is AE Serious?]	[AESER] [A:Y] <input type="radio"/> [AESER_CMP] Yes [AESERCR] Serious criteria (check all that apply): <div style="display: flex; justify-content: space-between;"> <div> [A:REQUIRES OR PROLONGS HOSPITALIZATION] [A:OTHER MEDICALLY IMPORTANT SERIOUS EVENT] [A:IS LIFE THREATENING] [A:PERSIST OR SIGNIF DISABILITY/INCAPACITY] [A:CONGENITAL ANOMALY OR BIRTH DEFECT] [A:RESULTS IN DEATH] </div> <div> <input type="checkbox"/> Requires or Prolongs Hospitalization <input type="checkbox"/> Other Medically Important Serious Event <input type="checkbox"/> Is Life Threatening <input type="checkbox"/> Persistent or Significant Disability/Incapacity <input type="checkbox"/> Congenital Anomaly or Birth Defect <input type="checkbox"/> Results in Death </div> </div> [A:N] <input type="radio"/> No								
4.* ✓ 	Start Date [Start Date]	[AESTDAT] (DD/MM/YYYY hh:mm) Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> / Req <input type="text" value=""/> (2018-2020) Req <input type="text" value=""/> : Req <input type="text" value=""/> 24-hour clock								
5. ✓	Stop Date [Stop Date]	[AEENDAT] (DD/MM/YYYY hh:mm) Req/Unk <input type="text" value=""/> / Req/Unk <input type="text" value=""/> / Req <input type="text" value=""/> (2018-2020) Req <input type="text" value=""/> : Req <input type="text" value=""/> 24-hour clock								
6.* ✓	Relationship to study drug regimen [Relationship to study drug regimen]	[AEREL] [A:NOT RELATED] <input type="radio"/> Not Related [A:UNLIKELY RELATED] <input type="radio"/> Unlikely Related [A:POSSIBLY RELATED] <input type="radio"/> Possibly Related [A:RELATED] <input type="radio"/> Related								
7.* ✓	VX-150 Action Taken [VX-150 Action Taken]	[AEACNVX150] [A:DOSE NOT CHANGED] <input type="radio"/> Dose Not Changed [A:DOSE REDUCED] <input type="radio"/> Dose Reduced [A:DRUG INTERRUPTED] <input type="radio"/> Drug Interrupted [A:DRUG WITHDRAWN] <input type="radio"/> Drug Withdrawn [A:NOT APPLICABLE] <input type="radio"/> Not Applicable								
8.* ✓	Severity [Severity]	[AESEV] [A:MILD] <input type="radio"/> Mild [A:MODERATE] <input type="radio"/> Moderate [A:SEVERE] <input type="radio"/> Severe								

		<i>[A:LIFE THREATENING]</i> <input type="radio"/> Life threatening
9. ✓	Outcome [Outcome]	[AEOUT] <i>[A:RECOVERED/RESOLVED]</i> <input type="radio"/> Recovered/Resolved <i>[A:NOT RECOVERED/NOT RESOLVED]</i> <input type="radio"/> Not Recovered/Not Resolved <i>[A:RECOVERED/RESOLVED WITH SEQUELAE]</i> <input type="radio"/> Recovered/Resolved with Sequelae <i>[A:FATAL]</i> <input type="radio"/> Fata <i>[A:UNKNOWN]</i> <input type="radio"/> Unknown
10.* ✓	Treatment Required? [Treatment Required?]	[AECONTRT] <i>[A:Y]</i> <input type="radio"/> Yes <i>[A:N]</i> <input type="radio"/> No
11.	Mapped Adverse Event <i>[hidden]</i> [Mapped Adverse Event]	[AEVERBATIM] A200
12.	Dictionary Name and Version <i>[hidden]</i> [Dictionary Name and Version]	[VMEDDRA] A1500
13.	Lowest Level Term Name <i>[hidden]</i> [Lowest Level Term Name]	[LLT_NAME] A1500

14.	Lowest Level Term Code <i>[hidden]</i> [Lowest Level Term Code]	<div>[LLT_CODE] A1500</div>
15.	Preferred Term Name <i>[hidden]</i> [Preferred Term Name]	<div>[AEDECOD] A1500</div>

16.	Preferred Term Code <i>[hidden]</i> [Preferred Term Code]	<div><div>[PT_CODE] A1500</div></div>
17.	High Level Term Name <i>[hidden]</i> [High Level Term Name]	<div><div>[HLT_NAME] A1500</div></div>

18.	High Level Term Code <i>[hidden]</i> [High Level Term Code]	<div>[HLT_CODE] A1500</div>
19.	High Level Group Term Name <i>[hidden]</i> [High Level Group Term Name]	<div>[HLGTNAME] A1500</div>

20.	High Level Group Term Code <i>[hidden]</i> [High Level Group Term Code]	<div>[HLGTCODE] A1500</div>
21.	System Organ Class Name <i>[hidden]</i> [System Organ Class Name]	<div>[AEBODSYS] A1500</div>

22.	System Organ Class Code <i>[hidden]</i> [System Organ Class Code]	<div><div>[SOC_CODE]</div><div>A1500</div></div>
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Key: [*] = Item is required [✓] = 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
Section	AE_S1	
Item	AESPID	Line # will be calculated as a sequential number upon submission of the form.
Item	AETERM	
Item	AESER	
Item	AESER_CMP	
Item	AESERCR	
Item	AESTDAT	
Item	AEENDAT	
Item	AEREL	

Item	AEACNVX150	
Item	AESEV	
Item	AEOUT	
Item	AECONTRT	
Item	AEVERBATIM	
Item	VMEDDRA	
Item	LLT_NAME	
Item	LLT_CODE	
Item	AEDECOD	
Item	PT_CODE	
Item	HLT_NAME	
Item	HLT_CODE	
Item	HLGTNAME	
Item	HLGTCODE	
Item	AEBODSYS	
Item	SOC_CODE	

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
clYESNO	String	Yes	Y	clYES	AESER, AECONTRT
		No	N	clINO	
clAESERCR	String	Requires or Prolongs Hospitalization	REQUIRES OR PROLONGS HOSPITALIZATION	clAESHOSP	AESERCR
		Other Medically Important Serious Event	OTHER MEDICALLY IMPORTANT SERIOUS EVENT	clAESMIE	
		Is Life Threatening	IS LIFE THREATENING	clAESLIFE	
		Persistent or Significant Disability/Incapacity	PERSIST OR SIGNIF DISABILITY/INCAPACITY	clAESDISAB	
		Congenital Anomaly or Birth Defect	CONGENITAL ANOMALY OR BIRTH DEFECT	clAESCONG	
		Results in Death	RESULTS IN DEATH	clAESDTH	
AERELTRDC	String	Not Related	NOT RELATED	NOTRELATED	AEREL

		Unlikely Related	UNLIKELY RELATED	UNLIKELYRELATED	
		Possibly Related	POSSIBLY RELATED	POSSIBLYRELATED	
		Related	RELATED	RELATED	
cIAEACNRDC	String	Dose Not Changed	DOSE NOT CHANGED	cliDOSENOTCHANGED	AEACNVX150
		Dose Reduced	DOSE REDUCED	cliDOSEREDUCED	
		Drug Interrupted	DRUG INTERRUPTED	cliDRUGINTERRUPTED	
		Drug Withdrawn	DRUG WITHDRAWN	cliDRUGWITHDRAWN	
		Not Applicable	NOT APPLICABLE	cliNOTAPPLICABLE	
AESEVRDC	String	Mild	MILD	cliMILD	AESEV
		Moderate	MODERATE	cliMODERATE	
		Severe	SEVERE	cliSEVERE	
		Life threatening	LIFE THREATENING	cliLIFETHREATENING	
cIAEOUTRDC	String	Recovered/Resolved	RECOVERED/RESOLVED	cliRECOVEREDRESOLVED	AEOUT
		Not Recovered/Not Resolved	NOT RECOVERED/NOT RESOLVED	cliNOTRECOVNOTRESOL	
		Recovered/Resolved with Sequelae	RECOVERED/RESOLVED WITH SEQUELAE	cliRECOVEREDWSEQ	
		Fatal	FATAL	cliFATAL	
		Unknown	UNKNOWN	cliUNKNOWN	

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
AESER - Requires or Prolongs Hospitalization	AESERCR_CLIAESHOSP_C	VARCHAR2
	AESERCR_CLIAESHOSP	VARCHAR2
AESER - Other Medically Important Serious Event	AESERCR_CLIAESMIE_C	VARCHAR2
	AESERCR_CLIAESMIE	VARCHAR2
AESER - Is Life Threatening	AESERCR_CLIAESLIFE_C	VARCHAR2
	AESERCR_CLIAESLIFE	VARCHAR2
AESER - Persistent or Significant Disability/Incapacity	AESERCR_CLIAESDISAB_C	VARCHAR2
	AESERCR_CLIAESDISAB	VARCHAR2
AESER - Congenital Anomaly or Birth Defect	AESERCR_CLIAESCONG_C	VARCHAR2
	AESERCR_CLIAESCONG	VARCHAR2
AESER - Results in Death	AESERCR_CLIAESDTH_C	VARCHAR2
	AESERCR_CLIAESDTH	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
AEACNVX150	AEACNVX150_C	VARCHAR2
	AEACNVX150	VARCHAR2
	AEACNVX150_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

VX18-150-104: PRIOR AND CONCOMITANT MEDICATIONS (CM) - Repeating Form [CM]								
#	Line #	Medication Name	Start date	Stop date or Continuing	Dose	Route	Frequency	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.								
Include transfusions of blood or blood products.								
1.	Line # [read-only] [Line #]	[CMSPID] <input type="text" value="N3"/>						
2.* ✓ 	Medication Name [Medication Name]	[CMTRT] <input type="text" value="A200"/>						
3.* ✓ 	Start date [Start date]	[CMSTDAT] (DD/MM/YYYY hh:mm) Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req <input type="text"/> (1900-2020) Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock						
4. ✓	Stop date [Stop date or Continuing]	[CMONGO] [A:Stop date] <input type="radio"/> [CMENDAT] (DD/MM/YYYY) Req/Unk <input type="text"/> / Req/Unk <input type="text"/> / Req/Unk <input type="text"/> (2018-2020) [A:CONTINUING] <input type="radio"/> Continuing at end of study participation						
5.* ✓	Dose [Dose]	[CMDOSE] <input type="text" value="A20"/>						
6.* ✓	Route [Route]	[CMROUTE] [A:ORAL] <input type="radio"/> Oral [A:INHALED] <input type="radio"/> [CMDOSFRM] Inhaled Dose Form [A:NEBULIZED] <input type="radio"/> Nebulized [A:MDI (METERED DOSE INHALATION)] <input type="radio"/> MDI (Metered Dose Inhalation) [A:DPI (DRY POWDER INHALATION)] <input type="radio"/> DPI (Dry Powder Inhalation) [A:INTRAMUSCULAR] <input type="radio"/> Intramuscular [A:INTRAUTERINE] <input type="radio"/> Intrauterine [A:INTRAVAGINAL] <input type="radio"/> Intravaginal [A:INTRAVENOUS] <input type="radio"/> Intravenous [A:INTRAVENOUS BOLUS] <input type="radio"/> Intravenous Bolus [A:NASAL] <input type="radio"/> Nasal [A:SUBCUTANEOUS] <input type="radio"/> Subcutaneous [A:SUBLINGUAL] <input type="radio"/> Sublingual [A:TOPICAL] <input type="radio"/> Topical [A:OTHER, SPECIFY] <input type="radio"/> [CMROUTSP] Other, specify: <input type="text" value="A80"/>						

7.* ✓	Frequency [Frequency]	[CMFREQ] [A:QD] <input type="radio"/> QD [A:BID] <input type="radio"/> BID [A:TID] <input type="radio"/> TID [A:QID] <input type="radio"/> QID [A:QOD] <input type="radio"/> QOD [A:PRN] <input type="radio"/> PRN [A:CONTINUOUS] <input type="radio"/> Continuous [A:OTHER] <input type="radio"/> [CMFREQSP] Other, Specify <input type="text" value="A128"/>
8.* ✓	Indication(s) [Indication(s)]	[CMINDC] <input type="text" value="A120"/>
9.	Mapped Route <i>[hidden]</i> [Mapped Route]	[TXTRROUTE] <input type="text" value="A80"/>
10.	Mapped Medication Name <i>[hidden]</i> [Mapped Medication Name]	[CMVERBATIM] <input type="text" value="A200"/>
11.	Mapped Route Text <i>[hidden]</i> [Mapped Route Text]	[MAPTXTRROUTE] <input type="text" value="A80"/>
12.	Mapped Indication(s) <i>[hidden]</i> [Mapped Indication(s)]	[MAPCMINDC] <input type="text" value="A120"/>
13.	Dictionary Name and Version <i>[hidden]</i> [Dictionary Name and Version]	[VWHODRUG] <input type="text" value="A1500"/>

14.	Drug name <i>[hidden]</i> [Drug name]	<div data-bbox="760 121 890 146">[DRUGNAME]</div> <div data-bbox="760 152 831 177">A1500</div>
15.	Drug code <i>[hidden]</i> [Drug code]	<div data-bbox="760 930 890 954">[DRUGCODE]</div> <div data-bbox="760 961 831 985">A1500</div>

16.	Preferred Name <i>[hidden]</i> [Preferred Name]	[CMDECODE] A1500
17.	Preferred Code <i>[hidden]</i> [Preferred Code]	[PREFCODE] A1500

18.	Ingredient List <i>[hidden]</i> [Ingredient List]	<div><div>[ING_LIST]</div><div>A1500</div></div>
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Key: [*] = Item is required [✓] = Source verification required [🔑] = Key item
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
Form	CM	
Section	CM_S1	
Item	CMSPID	Line # will be calculated as a sequential number upon submission of the form.
Item	CMTRT	
Item	CMSTDAT	
Item	CMONGO	
Item	CMENDAT	
Item	CMDOSE	
Item	CMROUTE	
Item	CMDOSFRM	

Item	CMROUTSP	
Item	CMFREQ	
Item	CMFREQSP	
Item	CMINDC	
Item	TXTRROUTE	
Item	CMVERBATIM	
Item	MAPTXTRROUTE	
Item	MAPCMINDC	
Item	VWHODRUG	
Item	DRUGNAME	
Item	DRUGCODE	
Item	CMDECOD	
Item	PREFCODE	
Item	ING_LIST	

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

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CMEN_DTRDC	String	Stop date	Stop date	CMstop	CMONGO
		Continuing at end of study participation	CONTINUING	Continuing	
CMROUTERDC	String	Oral	ORAL	ORAL	CMROUTE
		Inhaled	INHALED	INHALED	
		Intramuscular	INTRAMUSCULAR	INTRAMUSCULAR	
		Intrauterine	INTRAUTERINE	INTRAUTERINE	
		Intravaginal	INTRAVAGINAL	INTRAVAGINAL	
		Intravenous	INTRAVENOUS	INTRAVENOUS	
		Intravenous Bolus	INTRAVENOUS BOLUS	INTRAVENOUSBOLUS	
		Nasal	NASAL	NASAL	
		Subcutaneous	SUBCUTANEOUS	SUBCUTANEOUS	
		Sublingual	SUBLINGUAL	SUBLINGUAL	

		Topical	TOPICAL	TOPICAL	
		Other, specify:	OTHER, SPECIFY	cliOtherSP	
CMDOSFRM_RDC	String	Nebulized	NEBULIZED	NEBULIZED	CMDOSFRM
		MDI (Metered Dose Inhalation)	MDI (METERED DOSE INHALATION)	MDI	
		DPI (Dry Powder Inhalation)	DPI (DRY POWDER INHALATION)	DPI	
clCMFREQ	String	QD	QD	cliQD	CMFREQ
		BID	BID	cliBID	
		TID	TID	cliTID	
		QID	QID	cliQID	
		QOD	QOD	cliQOD	
		PRN	PRN	cliPRN	
		Continuous	CONTINUOUS	cliCONTINUOUS	
		Other	OTHER	cliOTHER	

Coding Summary: PRIOR AND CONCOMITANT MEDICATIONS

Verbatim RefName: CMTRT

Dictionary: WHODD Verbatim Type: MEDPROD

Coding Item RefName	Level	Level Type
CMDECODE	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	
TXTRROUTE	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
CMDOSE	CMDOSE	VARCHAR2
	CMDOSE_ND	VARCHAR2
CMROUTE	CMROUTE_C	VARCHAR2
	CMROUTE	VARCHAR2
	CMROUTE_ND	VARCHAR2
CMROUTE - CMDOSFRM	CMDOSFRM_C	VARCHAR2
	CMDOSFRM	VARCHAR2
CMROUTE - CMROUTSP	CMROUTSP	VARCHAR2
CMFREQ	CMFREQ_C	VARCHAR2
	CMFREQ	VARCHAR2
	CMFREQ_ND	VARCHAR2
CMFREQ - CMFREQSP	CMFREQSP	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

VX18-150-104: UNSCHEDULED (UNSCHED) [UNSCHED]

1.	Select the procedure(s) performed: [Select the procedure(s) performed:]	[UNSCRFS] <i>[A:UNSCHCLAB]</i> <input type="checkbox"/> Central Laboratory Sample <i>[A:UNSCHPK]</i> <input type="checkbox"/> PK Sample Collection <i>[A:UNSCHUPREG]</i> <input type="checkbox"/> Urine Pregnancy Test <i>[A:UNSCHVS]</i> <input type="checkbox"/> Vital Signs <i>[A:UNSCHSPREG]</i> <input type="checkbox"/> Serum Pregnancy
2.	Was an ECG Performed? [Was an ECG performed?]	[UNSCRFSTC1] <i>[A:Y]</i> <input type="radio"/> Yes <i>[A:N]</i> <input type="radio"/> No

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

Study Object Descriptions: UNSCHEDULED

Type	RefName	Description
Form	UNSCHED	
Section	UNSCHED_S1	
Item	UNSCRFS	
Item	UNSCRFSTC1	

Codelist Values Tables: UNSCHEDULED

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cliUNSCRFS	String	Central Laboratory Sample	UNSCHCLAB	cliUNSCHCLAB	UNSCRFS
		PK Sample Collection	UNSCHPK	cliUNSCHPK	
		Urine Pregnancy Test	UNSCHUPREG	cliUNSCHUPREG	
		Vital Signs	UNSCHVS	cliUNSCHVS	
		Serum Pregnancy	UNSCHSPREG	cliUNSCHSPREG	
cliYESNO	String	Yes	Y	cliYES	UNSCRFSTC1
		No	N	cliNO	

RDE Analytics: RD_UNSCHEd

Data Variable RefName	RD Column Name	Column Data Type
UNSCRFS	UNSCRFS_ND	VARCHAR2
UNSCRFS - Central Laboratory Sample	UNSCRFS_CLIUNSCHCLAB_C	VARCHAR2
	UNSCRFS_CLIUNSCHCLAB	VARCHAR2
UNSCRFS - PK Sample Collection	UNSCRFS_CLIUNSCHPK_C	VARCHAR2
	UNSCRFS_CLIUNSCHPK	VARCHAR2
UNSCRFS - Urine Pregnancy Test	UNSCRFS_CLIUNSCHUPREG_C	VARCHAR2

	UNSCRFS_CLIUNSCHUPREG	VARCHAR2
UNSCRFS - Vital Signs	UNSCRFS_CLIUNSCHVS_C	VARCHAR2
	UNSCRFS_CLIUNSCHVS	VARCHAR2
UNSCRFS - Serum Pregnancy	UNSCRFS_CLIUNSCHSPREG_C	VARCHAR2
	UNSCRFS_CLIUNSCHSPREG	VARCHAR2
UNSCRFSTC1	UNSCRFSTC1_C	VARCHAR2
	UNSCRFSTC1	VARCHAR2
	UNSCRFSTC1_ND	VARCHAR2

VX18-150-104: VITAL SIGNS (VS3) - Repeating Form [VS3]								
#	Line #	Date of Assessment	Height	Weight	Blood Pressure	Temperature	Pulse	Respiration Rate
1								
1.	Line # [read-only] [Line #]				[VS3PID] N3			
2.* ✓	Date of Assessment [Date of Assessment]				[VSDAT] (DD/MM/YYYY) Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2018-2020)			
3.* ✓	Height [Height]				[HEIGHT] xxx.x <input type="radio"/> cm [b] <input type="radio"/> in			
4.* ✓	Weight [Weight]				[WEIGHT] xxx.x <input type="radio"/> kg [b] <input type="radio"/> LB			
5.* ✓	Blood Pressure [Blood Pressure]				[PRESSURE] [SYSBP] N3 mmHg[b] / [DIABP] N3 mmHg[b]			
6.* ✓	Temperature [Temperature]				[TEMP] xxx.x <input type="radio"/> C [b] <input type="radio"/> F			
7.* ✓	Pulse Rate [Pulse]				[PULSE] N3 beats/min[b]			
8.* ✓	Respiration Rate [Respiration Rate]				[RESP] N2 breaths/min[b]			
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.								

Study Object Descriptions: VITAL SIGNS		
Type	RefName	Description
Form	VS3	
Section	VS3_S1	
Item	VS3PID	Line # will be calculated as a sequential number upon submission of the form.
Item	VSDAT	
Item	HEIGHT	
Item	WEIGHT	
Item	PRESSURE	
Item	SYSBP	
Item	DIABP	
Item	TEMP	
Item	PULSE	
Item	RESP	

RDE Analytics: RD_VS3		
Data Variable RefName	RD Column Name	Column Data Type
VS3PID	VS3PID	NUMBER
	VS3PID_ND	VARCHAR2
VSDAT	VSDAT	DATE
	VSDAT_DTS	VARCHAR2
	VSDAT_ND	VARCHAR2
HEIGHT	HEIGHT	FLOAT
	HEIGHT_N	FLOAT
	HEIGHT_U	VARCHAR2
	HEIGHT_NU	VARCHAR2
	HEIGHT_ND	VARCHAR2
WEIGHT	WEIGHT	FLOAT
	WEIGHT_N	FLOAT
	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
	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

VX18-150-104: PK SAMPLE COLLECTION (PK4) - Repeating Form [PK4]		
#	PK Draw	
1		
1.* ✓	PK Draw [PK Draw]	<div><div>[PKDRAWCMP]</div><div>[PK4DAT] (DD/MM/YYYY)</div><div>Collection Date</div><div>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)</div><div>[PK4TIM] (hh:mm)</div><div>Actual Time</div><div>Req <input type="text"/> : Req <input type="text"/> 24-hour clock</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.		

Study Object Descriptions: PK SAMPLE COLLECTION		
Type	RefName	Description
Form	PK4	
Section	PK4_S1	
Item	PKDRAWCMP	
Item	PK4DAT	
Item	PK4TIM	

RDE Analytics: RD_PK4		
Data Variable RefName	RD Column Name	Column Data Type
PKDRAWCMP	PKDRAWCMP_ND	VARCHAR2
PKDRAWCMP - PK4DAT	PK4DAT	DATE
	PK4DAT_DTS	VARCHAR2
PKDRAWCMP - PK4TIM	PK4TIM	DATE
	PK4TIM_TMS	VARCHAR2

VX18-150-104: LOCAL SERUM PREGNANCY TEST (SPREG) [SPREG]

1.* ✓	Date of local serum pregnancy test [Date of local serum pregnancy test]	[SLBDAT] (DD/MM/YYYY) Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2020)
2.* ✓	Result [Result]	[SLBORRES] [A:1] <input type="radio"/> Negative [A:2] <input type="radio"/> Positive

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: LOCAL SERUM PREGNANCY TEST

Type	RefName	Description
Form	SPREG	SERUM PREGNANCY TEST
Section	SRPREG_S1	SRPREG_S1
Item	SLBDAT	
Item	SLBORRES	

Codelist Values Tables: LOCAL SERUM PREGNANCY TEST

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clLB2ORRES	String	Negative	1	clitmLB2ORRES_1	SLBORRES
		Positive	2	clitmLB2ORRES_2	

RDE Analytics: RD_SPREG

Data Variable RefName	RD Column Name	Column Data Type
SLBDAT	SLBDAT	DATE
	SLBDAT_DTS	VARCHAR2
	SLBDAT_ND	VARCHAR2
SLBORRES	SLBORRES_C	VARCHAR2
	SLBORRES	VARCHAR2
	SLBORRES_ND	VARCHAR2

InForm Special Properties For Study Design: VX18-150-104			
InForm Special Property	Property Type	Data Object RefName	Data Object Path RefName
Screening	Visit	SYSSCR	SYSSCR
Enrollment	Visit	SYSENR	SYSENR
Screening	Form	INFSCR	SYSSCR.INFSCR
Enrollment	Form	INFENR	SYSENR.INFENR
Patient Identification	Form	RAND	vsRAND.RAND
Study Completion	Form	Unassigned	Unassigned
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Initials (Screening)	Item	SUBJINIT	SYSSCR.INFSCR.INFSCR_S1.SUBJINIT
DOB (Screening)	Item	BRTH_DAT	SYSSCR.INFSCR.INFSCR_S1.BRTH_DAT
Screening date (Screening)	Item	Unassigned	Unassigned
Patient No. (Enrollment)	Item	SUBJID	vsRAND.RAND.RAND_S1.SUBJID SYSENR.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	vsDMINUS1.DOV.DOV_S1.VISDAT vsD1.DOV.DOV_S1.VISDAT vsD2.DOV.DOV_S1.VISDAT vsSCREENING.DOV.DOV_S1.VISDAT vsUNS.DOV.DOV_S1.VISDAT vsD3.DOV.DOV_S1.VISDAT vsFUP.DOV.DOV_S1.VISDAT
Randomization field (Randomization)	Item	Unassigned	Unassigned

Unit Conversions For Study Design: VX18-150-104			
Conversion Type	From	To	Conversion
Length	cm	in	{value}/2.54
Temp	C	F	(({value}*9/5)+32)
Weight	kg	LB	{value}*2.205

Review States for Study: VX18-150-104
No Review States have been defined.

In-place Revisions Summary Table: VX18-150-104					
Deployment Instance: LIVE					
Data Object RefName	Type	Actual Change Path	Description	Study Version	Path
UNSCHED_S1	Section	UNSCHED.UNSCHED_S1	In accordance with TCC 190108-000288 added item two (ECG item)	VX18_150_104 2.2.4	UNSCHED.UNSCHED_S1.*
UNSCRFS	Item	UNSCHED.UNSCHED_S1.UNSCRFS	UAT 1 finding TCC 190108-000288 - update to Not required and SDV Nreq	VX18_150_104 2.2.4	UNSCHED.UNSCHED_S1.UNSCRFS