NIDA

Annotated Design For Trial: ctn0027

Protocol: CTN-0027

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August 30, 2010 12:53PM

Time and Events Schedule For Study: ctn0027

	Assessment	CRF	Baseline / Screening (SCR) [S]	WEEK 0 (WK0) [S]	Week 1 (WK1) [S]	Week 2 (WK2) [S]	Week 3 (WK3) [S]	Week 4 (WK4) [S]	Week 5 (WK5) [S]	Week 6 (WK6) [S]	Week 7 (WK7) [S]	Week 8 (WK8) [S]	Week 9 (WK9) [S]	Week 10 (WK10) [S]	Week 11 (WK11) [S]	Week 12 (WK12) [S]	Week 13 (WK13) [S]	Week 14 (WK14) [S]	Week 15 (WK15) [S]	Week 16 (WK16) [S]	Week 17 (WK17) [S]	Week 18 (WK18) [S]	Week 19 (WK19) [S]	Week 20 (WK20) [S]	Week 21 (WK21) [S]	Week 22 (WK22) [S]	Week 23 (WK23) [S]	Week 24 (WK24) [S]	Week 28 (WK28) [S]	Week 32 (WK32) [S]	Cross Active Study (CAS) [S]	Conflict (Conflict) [U/R/D]
1	Research Session Attendance	RSA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
2	Informed Consent	INF	2																													
3	Demographics	DEM	3																													
4	Alcohol Breathalyzer / Urine Drug Screen	UDSAB	4		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		2		
5	DSM-IV Checklist Summary	DSM-IV	5																													
6	Exclusion Criteria	EXC	6																													
7	Inclusion Criteria	IXC	7																													
8	Labs and Urinalysis	LAB	8-RF		3-RF	3-RF		3-RF				3-RF				3-RF				3-RF				3-RF				3-RF		3-RF		
9	Medical and Psychiatric History	MDH	9																													
10	Physical Exam	PEX	10																									4				
11	Pregnancy and Birth Control Assessment	PBC	11-DF																													
12	Risk Behavior Survey	RBS	12													5												6				
13	RISK BEHAVIORS SURVEY (2 of 2)	RBSMale	13-DF													6-DF												7-DF				
14	Risk Behaviors Surveys (2 of 2)	RBSFemale	14-DF													7-DF												8-DF				
15	Risk Behavior Surveys (2 of 2)	RBSAll	15-DF													8-DF												9-DF				
16	Substance Use	TFB-Lead	16					6				6				10				6				6				11		5		
17	Time Line Follow Back--Active Study	TFB	17-RF-DF					7-RF-DF				7-RF-DF				11-RF-DF				7-RF-DF				7-RF-DF				12-RF-DF		6-RF-DF		
18	Vital Signs	VSF	18		5	5		8				8				12				8				8				13		7		
19	Alcohol Breathalyzer	ABZ		2																												
20	Randomization	RAN		3																												
21	Study Drug Dose Log	DOS		4-RF	4-RF	4-RF	3-RF	5-RF	3-RF	3-RF	3-RF	5-RF	3-RF	3-RF	3-RF	9-RF	3-RF	3-RF	3-RF	5-RF	3-RF	3-RF	3-RF	5-RF	3-RF	3-RF	3-RF	10-RF				
22	Clinical Opiate Withdrawal Scale - Predose	COWS1		5																												
23	Clinical Opiate Withdrawal Scale - Postdose	COWS2		6																												
24	Pregnancy and Birth Control Assessment	PBC		7-DF				4-DF				4-DF				4-DF				4-DF				4-DF				5-DF	2-DF	4-DF		
25	Prior and Concomitant Medications	PCM																													1	
26	Adverse Events	AE																													2-RF	
27	Genetics	GEN																													3	
28	Serious Adverse Event	SAE																													4-RF	
29	Serious Adverse Event, 12, 13	SAE2a																													5-RF	
30	Serious Adverse Event (continued)	SAE2b																													6-RF	
31	Serious Adverse Event (continued), page 22.____	SAE3																													7-RF	
32	Pregnancy and Outcome	POC																													8	
33	Pregnancy and Outcome Contd	POC NB																													9	
34	Protocol Violation	PVL																													10-RF	
35	Study Medication Change Form	MED																													11	
36	Study Termination	TERM																													12	

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

ctn0027 : SYSTEM SCREENING (SCR)		
Protocol Number - NIDA-CTN-0027		
1.	NODE	A2 (CTN0027CDD:t_frmScr.txtScrPatInit)
2.	Participant ID **Please enter 4 numeric ID**	A4 (CTN0027CDD:t_frmScr.tcPATNUM)
3.	Date of Birth:	Req / Req / Req (1900-1992) (CTN0027CDD:t_frmScr.SCR003)
4.	Sex:	(CTN0027CDD:t_frmScr.SCR004) *[1]* 1 Male *[2]* 2 Female

Item Design Notes:	
Item No.	**Design Note**
1.	mapped from Screening form to INF form

CDD: CTN0027CDD Table: t_frmScr Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
tcPATNUM	STRING(4) - A4	
SCR003	DATE - DDMONYYYY	
SCR004	NUMERIC	
txtScrPatInit	STRING(2) - A2	

ctn0027 : SYSTEM ENROLLMENT (Enr)			
Study Enrollment			
1. Participant ID *[editable]*	A25	**Please do not enter or modify data on this field** NOTE: *If this box does not have a value, please ensure that the Participant Id on the Screening Form has 4 numbers.*	(CTN0027CDD:t_frmEnr.txtPInumber)

Item Design Notes:	
Item No.	**Design Note**
1.	mapped from Enrollment form to PI form

CDD: CTN0027CDD Table: t_frmEnr Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
txtPInumber	STRING(25) - A25	

ctn0027 : Research Session Attendance (RSA)

1.	**1. Did participant attend visit?**	(CTN0027CDD:t_frRSA.RSA001) *[0]* ◯ 0 No **[1]** ◯ 1 Yes **2. Date of Visit:** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frRSA.RSA002)
2.*	**3. Comments** (include reason for session if it is an unscheduled visit)	A200 (CTN0027CDD:t_frRSA.RSA003)

* Item is not required

CDD: CTN0027CDD Table: t_frRSA Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RSA001	NUMERIC	
RSA002	DATE - DDMONYYYY	
RSA003	STRING(200) - A200	

ctn0027 : Informed Consent (INF)			
Patient Information			
***WARNING: ANY CHANGES MADE TO THESE FIELDS BELOW WILL CHANGE THE IDENTIFICATION OF THIS SUBJECT - Changes that make these fields empty will not be acted upon and the prior values will remain for the purpose of identification. ***			
1.	**Patient Number**	A15 (CTN0027CDD:t_frINF.txtPInumber) siteno-NODE-Participant ID	
2.	**Node**	A3 (CTN0027CDD:t_frINF.txtScrPtInitials)	
Informed Consent			
3.	**Date informed consent signed:**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frINF.INF001)	

Item Design Notes:	
Item No.	**Design Note**
1.	mapped from Enrollment form to PI form
2.	mapped from Screening form to PI form

CDD: CTN0027CDD Table: t_frINF Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
txtPInumber	STRING(15) - A15	
txtScrPtInitials	STRING(3) - A3	
INF001	DATE - DDMONYYYY	

ctn0027 : Demographics (DEM)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frDEM.VISITDT)
Demographics		
2.	**1. Date of Birth:**	Req / Req / Req (1900-1992) (CTN0027CDD:t_frDEM.DEM001)
3.	**2. Sex:**	(CTN0027CDD:t_frDEM.DEM002) *[1]* ○ 1 Male *[2]* ○ 2 Female
4.	**3. Ethnicity:**	(CTN0027CDD:t_frDEM.DEM003a) **[1]** ○ 1 Spanish origin, Hispanic or Latino **Check all that apply:** (CTN0027CDD:t_frDEM.DEM003b1) *[1]* ☐ Mexican, Mexican-American, or Chicano (CTN0027CDD:t_frDEM.DEM003b2) *[2]* ☐ Puerto Rican (CTN0027CDD:t_frDEM.DEM003b3) *[3]* ☐ Cuban (CTN0027CDD:t_frDEM.DEM003b4) **[4]** ☐ Hispanic or Latino, other (specify): A50 (CTN0027CDD:t_frDEM.DEM003b5) *[2]* ○ 2 Not of Spanish origin, Hispanic or Latino
5.	**4. Race** (check all that apply):	(CTN0027CDD:t_frDEM.DEM004a) *[1]* ☐ American Indian or Alaska Native (CTN0027CDD:t_frDEM.DEM004b) **[2]** ☐ Asian; **Check all that apply:** (CTN0027CDD:t_frDEM.DEM004b1) *[21]* ☐ Asian-Indian (CTN0027CDD:t_frDEM.DEM004b2) *[22]* ☐ Chinese (CTN0027CDD:t_frDEM.DEM004b3) *[23]* ☐ Filipino (CTN0027CDD:t_frDEM.DEM004b4) *[24]* ☐ Japanese (CTN0027CDD:t_frDEM.DEM004b5) *[25]* ☐ Korean (CTN0027CDD:t_frDEM.DEM004b6) *[26]* ☐ Vietnamese (CTN0027CDD:t_frDEM.DEM004b7) **[27]** ☐ Asian, other (specify): A50 (CTN0027CDD:t_frDEM.DEM004b8) (CTN0027CDD:t_frDEM.DEM004c) *[3]* ☐ Black or African American (CTN0027CDD:t_frDEM.DEM004d) **[4]** ☐ Native Hawaiian or Pacific Islander **Check all that apply:** (CTN0027CDD:t_frDEM.DEM004d1) *[41]* ☐ Native Hawaiian (CTN0027CDD:t_frDEM.DEM004d2) *[42]* ☐ Guamanian or Chamarro (CTN0027CDD:t_frDEM.DEM004d3) *[43]* ☐ Samoan (CTN0027CDD:t_frDEM.DEM004d4) **[44]** ☐ Native Hawaiian or Pacific Islander, other (specify): A50 (CTN0027CDD:t_frDEM.DEM004d5) (CTN0027CDD:t_frDEM.DEM004e) *[5]* ☐ White (CTN0027CDD:t_frDEM.DEM004f) **[6]** ☐ Other (specify): A50 (CTN0027CDD:t_frDEM.DEM004fs) (CTN0027CDD:t_frDEM.DEM004g) *[7]* ☐ Participant chooses not to answer (CTN0027CDD:t_frDEM.DEM004h) *[8]* ☐ Unknown

CDD: CTN0027CDD Table: t_frDEM Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DEM004b5	STRING(255)	
DEM004b6	STRING(255)	
DEM001	DATE - DDMONYYYY	
DEM002	NUMERIC	
DEM003a	NUMERIC	
DEM004g	STRING(255)	
DEM004h	STRING(255)	
DEM004b7	STRING(255)	
DEM004d1	STRING(255)	
DEM004d2	STRING(255)	
DEM004d3	STRING(255)	
DEM004d4	STRING(255)	
DEM004d5	STRING(50) - A50	
DEM004e	STRING(255)	
DEM004f	STRING(255)	
DEM004fs	STRING(50) - A50	
DEM004b8	STRING(50) - A50	
DEM004c	STRING(255)	
DEM004d	STRING(255)	
VISITDT	DATE - DDMONYYYY	
DEM003b2	STRING(255)	
DEM003b3	STRING(255)	
DEM003b4	STRING(255)	
DEM003b5	STRING(50) - A50	
DEM004a	STRING(255)	
DEM004b	STRING(255)	

DEM004b1	STRING(255)	
DEM004b2	STRING(255)	
DEM004b3	STRING(255)	
DEM004b4	STRING(255)	
DEM003b1	STRING(255)	

ctn0027 : Alcohol Breathalyzer / Urine Drug Screen (UDSAB)

Alcohol Breathalyzer

1.	**1. Was an Alcohol Breathalyzer performed successfully?**	(CTN0027CDD:t_frUDSAB.AB001) *[0]* ○ 0 No **[1]** ○ 1 Yes Date alcohol breathalyzer test performed: Req / Req / Req (2006-2010) (CTN0027CDD:t_frUDSAB.AB001A) Alcohol Breathalyzer result: x.xxx (n < 0.000000) mg / mL (CTN0027CDD:t_frUDSAB.AB001B)
2.*	**2. Comments:**	A200 (CTN0027CDD:t_frUDSAB.AB002)

Urine Drug Screen

3.	**1. Was a Urine Drug Screen Performed?** **(Only answer questions 2, 3, and 4 if answer to this question is Yes or Lost Sample)**	(CTN0027CDD:t_frUDSAB.UDS001) **[0]** ○ 0 No (CTN0027CDD:t_frUDSAB.UDS001A) Specify reason *(check only one)* *[1]* ○ 1 Participant was unable to provide sample *[2]* ○ 2 Participant refused *[3]* ○ 3 Staff member could not collect **[98]** ○ 98 Other *(specify)*: A50 (CTN0027CDD:t_frUDSAB.UDS001B) *[1]* ○ 1 Yes *[2]* ○ 2 Lost sample
4.*	**2. Date urine collected:**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frUDSAB.UDS002)
5.*	**3. Was urine temperature within expected range** *(temperature 92°F ≤ X ≤ 96°F* **OR** *33.3°C ≤ X ≤ 35.5°C)* **?**	(CTN0027CDD:t_frUDSAB.UDS003) *[0]* ○ 0 No *[1]* ○ 1 Yes *[99]* ○ 99 Unknown
6.*	**4. Was the urine collection supervised?**	(CTN0027CDD:t_frUDSAB.UDS004) *[0]* ○ 0 No *[1]* ○ 1 Yes *[99]* ○ 99 Unknown

Select the result of the screen for each substance below.

7.	**5. Amphetamines** *(AMP)*:	(CTN0027CDD:t_frUDSAB.UDS005) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS005A) A50
8.	**6. Benzodiazapines** *(BZO)*:	(CTN0027CDD:t_frUDSAB.UDS006) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS006A) A50
9.	**7. Methadone** *(MTD)*:	(CTN0027CDD:t_frUDSAB.UDS007) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS007A) A50
10.	**8. Oxycodone**:	(CTN0027CDD:t_frUDSAB.UDS008) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS008A) A50
11.	**9. Cocaine metabolites** *(COC)*:	(CTN0027CDD:t_frUDSAB.UDS009) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS009A) A50
12.	**10. Methamphetamine** *(M-AMP)*:	(CTN0027CDD:t_frUDSAB.UDS010) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS010A) A50
13.	**11. Opiate 300**:	(CTN0027CDD:t_frUDSAB.UDS011) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS011A) A50
14.	**12. Cannabinoids** *(THC)*:	(CTN0027CDD:t_frUDSAB.UDS012) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS012A) A50
15.	**13. Propoxyphene**:	(CTN0027CDD:t_frUDSAB.UDS013) *[-5]* ○ -5 Not Assessed *[0]* ○ 0 Negative *[1]* ○ 1 Positive *[2]* ○ 2 Unclear Specify (CTN0027CDD:t_frUDSAB.UDS013A) A50

* Item is not required

CDD: CTN0027CDD Table: t_frUDSAB Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
UDS005	NUMERIC	
UDS005A	STRING(50) - A50	
AB001	NUMERIC	
AB001A	DATE - DDMONYYYY	
AB001B	FLOAT - F5.3	
AB002	STRING(200) - A200	
UDS001	NUMERIC	
UDS001A	NUMERIC	

UDS001B	STRING(50) - A50	
UDS002	DATE - DDMONYYYY	
UDS003	NUMERIC	
UDS004	NUMERIC	
UDS011A	STRING(50) - A50	
UDS012	NUMERIC	
UDS012A	STRING(50) - A50	
UDS013	NUMERIC	
UDS006	NUMERIC	
UDS006A	STRING(50) - A50	
UDS007	NUMERIC	
UDS007A	STRING(50) - A50	
UDS008	NUMERIC	
UDS008A	STRING(50) - A50	
UDS009	NUMERIC	
UDS009A	STRING(50) - A50	
UDS010	NUMERIC	
UDS010A	STRING(50) - A50	
UDS011	NUMERIC	
UDS013A	STRING(50) - A50	

ctn0027 : DSM-IV Checklist Summary (DSM-IV)		
1.	Assessment Date	Req / Req / Req (2006-2010) (CTN0027CDD:t_frDSM.DSMADT)
DSM-IV Checklist Summary		
2.	Opiates:	(CTN0027CDD:t_frDSM.DSMOPI) *[1]* Dependence *[2]* Abuse *[3]* No diagnosis
3.	Alcohol:	(CTN0027CDD:t_frDSM.DSMAL) *[1]* Dependence *[2]* Abuse *[3]* No diagnosis
4.	Amphetamines:	(CTN0027CDD:t_frDSM.DSMAM) *[1]* Dependence *[2]* Abuse *[3]* No diagnosis
5.	Cannabis:	(CTN0027CDD:t_frDSM.DSMCA) *[1]* Dependence *[2]* Abuse *[3]* No diagnosis
6.	Cocaine:	(CTN0027CDD:t_frDSM.DSMCO) *[1]* Dependence *[2]* Abuse *[3]* No diagnosis
7.	Sedatives:	(CTN0027CDD:t_frDSM.DSMSE) *[1]* Dependence *[2]* Abuse *[3]* No diagnosis

CDD: CTN0027CDD Table: t_frDSM Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DSMADT	DATE - DDMONYYYY	
DSMOPI	NUMERIC	
DSMAL	NUMERIC	
DSMAM	NUMERIC	
DSMCA	NUMERIC	
DSMCO	NUMERIC	
DSMSE	NUMERIC	

ctn0027 : Exclusion Criteria (EXC)

1.	**Assessment Date**	Req / Req / Req (2006- 2010) (CTN0027CDD:t_frEXC.VISITDT)
	Exclusion Criteria * For a list of abnormalities, please refer to the Operations Manual. ** See Appendix D of the Protocol.	
2.	**1. Does the participant have AST or ALT values > 5 times the upper limit of normal as per the criteria of the laboratory?**	(CTN0027CDD:t_frEXC.EXC001) *[0]* 0 No *[1]* 1 Yes
3.	**2. Does the participant have ALP > 3 times the upper limit of normal as per the criteria of the laboratory?**	(CTN0027CDD:t_frEXC.EXC002) *[0]* 0 No *[1]* 1 Yes
4.	**3. Does the participant have any documented past or present history of ascites, presence of esophageal or gastric varices, hepatic encephalopathy or other signs of significant liver disease as indicated by a Model for Endstage Liver Disease score** *(Kamath et al., 2001)* **of > = 11?**	(CTN0027CDD:t_frEXC.EXC003) *[0]* 0 No *[1]* 1 Yes
5.	**4. Does the participant have a total bilirubin > 2.0 mg/dL** *(patients with documented Gilbert's syndrome will be included)***?**	(CTN0027CDD:t_frEXC.EXC004) *[0]* 0 No *[1]* 1 Yes
6.	**5. Does the participant have a prothrombin time more than 3 seconds prolonged?**	(CTN0027CDD:t_frEXC.EXC005) *[0]* 0 No *[1]* 1 Yes
7.	**6. Does the participant have an albumin level less than 2.5 g/dL?**	(CTN0027CDD:t_frEXC.EXC006) *[0]* 0 No *[1]* 1 Yes
8.	**7. Does the participant have any cardiopathy or risk factor listed below without evdence of a normal ECG* with report performed within 6 months prior to first study medication dose?** **a Congestive heart failure** **b Left ventricular hypertrophy** **c Bradycardia** **d Hereditary QT prolongation** **e Uncorrected electrolyte imbalance** **f Concomitant medications which are know to result in QT interval prolongation****	(CTN0027CDD:t_frEXC.EXC007) *[0]* 0 No *[1]* 1 Yes
9.	**8. Does the participant have an acute medical condition that would make participation, in the opinion of the study physican, medically hazardous** *(e.g., unstable pancreatic, cardiovascular, or renal disease; significant anemia)***?**	(CTN0027CDD:t_frEXC.EXC008) *[0]* 0 No *[1]* 1 Yes
10.	**9. Does the participant have known allergy or sensitivity to BUP, naloxone, or MET, or to any of the inactive ingredients in the study medications** *(including lactose, mannitol, cornstarch, povidone K30, citric acid, sodium citrate, FD&C Yellow No 6 color, magnesium stearate, Acesulfame K sweetener)***?**	(CTN0027CDD:t_frEXC.EXC009) *[0]* 0 No *[1]* 1 Yes
11.	**10. Does the participant have a known diagnosis of acute psychosis, severe depression or imminent suicide risk as determined via clinical interview by study physician or surrogates?**	(CTN0027CDD:t_frEXC.EXC010) *[0]* 0 No *[1]* 1 Yes
12.	**11. Does the participant have a DSM-IV diagnosis of dependence on benzodiazapines or alcohol requiring immediate medical attention?**	(CTN0027CDD:t_frEXC.EXC011) *[0]* 0 No *[1]* 1 Yes
13.	**12. Does the participant have a DSM-IV diagnosis of dependence on other depressants, or stimulants requiring immediate medical attention?**	(CTN0027CDD:t_frEXC.EXC012) *[0]* 0 No *[1]* 1 Yes
14.	**13. Has the participant participated in an investigational drug study within the past 30 days?**	(CTN0027CDD:t_frEXC.EXC013) *[0]* 0 No *[1]* 1 Yes
15.	**14. Has the participant had a treatment with MET, BUP/ NX, or BUP for more than 15 of the past 30 days** *(illicit use of these medications is allowed)***?**	(CTN0027CDD:t_frEXC.EXC014) *[0]* 0 No *[1]* 1 Yes
16.	**15. Does the participant have pending legal action that could prohibit study participation?**	(CTN0027CDD:t_frEXC.EXC015) *[0]* 0 No *[1]* 1 Yes
17.	**16. Is the participant unable or unwilling to comply with study requirements?**	(CTN0027CDD:t_frEXC.EXC016) *[0]* 0 No *[1]* 1 Yes
18.	**17. Is the participant unable or unwilling to remain in the local area for duration of treatment?**	(CTN0027CDD:t_frEXC.EXC017) *[0]* 0 No *[1]* 1 Yes
19.	**18. Does the participant have poor venous access such that venipuncture could not be accomplished from a vein in an extremity during eligibility?**	(CTN0027CDD:t_frEXC.EXC018) *[0]* 0 No *[1]* 1 Yes
20.	**19. If female, is she pregnant or lactating?**	(CTN0027CDD:t_frEXC.EXC019) *[0]* 0 No *[1]* 1 Yes *[96]* NA

CDD: CTN0027CDD Table: t_frEXC Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
EXC012	NUMERIC	
EXC013	NUMERIC	
EXC014	NUMERIC	
EXC015	NUMERIC	
EXC016	NUMERIC	
EXC017	NUMERIC	
EXC018	NUMERIC	
EXC019	NUMERIC	
EXC008	NUMERIC	
EXC009	NUMERIC	
EXC010	NUMERIC	
EXC011	NUMERIC	
VISITDT	DATE - DDMONYYYY	
EXC001	NUMERIC	
EXC002	NUMERIC	
EXC003	NUMERIC	
EXC004	NUMERIC	
EXC005	NUMERIC	
EXC006	NUMERIC	
EXC007	NUMERIC	

ctn0027 : Inclusion Criteria (IXC)		
1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frIXC.VISITDT)
Inclusion Criteria		
2.	**1. Is the participant 18 years of age or older?**	(CTN0027CDD:t_frIXC.IXC001) *[0]* 0 No *[1]* 1 Yes
3.	**2. Does the participant meet DSM-IV criteria for opioid dependence?**	(CTN0027CDD:t_frIXC.IXC002) *[0]* 0 No *[1]* 1 Yes
4.	**3. Is the participant in good general health or, in case of a medical/ psychiatric condition requiring ongoing treatment, is the participant under the care of a physician willing to continue participant's medical management and to cooperate with study physicians?**	(CTN0027CDD:t_frIXC.IXC003) *[0]* 0 No *[1]* 1 Yes
5.	**4. If female of childbearing potential, does the participant agree to use one of the following acceptable methods of birth control throughout the study:** **a oral contraceptives** **b barrier** *(diaphragm, cervical cap)* **with spermicide, or condom** **c intrauterine device** *(IUD)* **d intrauterine progesterone contraceptive system** *(IUD)* **e levonorgestrel implant** **f medroxyprogesterone acetate contraceptive injection** **g contraceptive transdermal patch** **h hormonal vaginal contraceptive ring** **i surgical sterilization** **j complete abstinence from sexual intercourse?**	(CTN0027CDD:t_frIXC.IXC004) *[0]* 0 No *[1]* 1 Yes *[96]* 96 NA
6.	**5. Is the participant able to read and verbalize understanding and voluntarily sign the approved Informed Consent form prior to performance of any study-specific procedures?**	(CTN0027CDD:t_frIXC.IXC005) *[0]* 0 No *[1]* 1 Yes

CDD: CTN0027CDD Table: t_frIXC Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
IXC001	NUMERIC	
IXC002	NUMERIC	
IXC003	NUMERIC	
VISITDT	DATE - DDMONYYYY	
IXC004	NUMERIC	
IXC005	NUMERIC	

ctn0027 : Labs and Urinalysis (LAB) - Repeating Form

#		Assessment Date	Blood Chemistry	Hematology	Liver	Urine	Hepatitis	ITEM1_I	ITEM1_I	HIV test	
1	⊠										

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frLAB.VISITDT)
2. *	**1. Blood Chemistry:**	(CTN0027CDD:t_frLAB.LAB001a) *[97]* Not Done **[1] Date Drawn** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frLAB.LAB001b1) **Time Drawn** NReq : NReq *24-hour clock* (CTN0027CDD:t_frLAB.LAB001b2) **Repeat Test?** (CTN0027CDD:t_frLAB.LAB001b3) *[0]* No *[1]* Yes **Accession Number** (CTN0027CDD:t_frLAB.LAB001b4) A10
3. *	**2. Hematology:**	(CTN0027CDD:t_frLAB.LAB002a) *[97]* Not Done **[1] Date Drawn** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frLAB.LAB002b1) **Time Drawn** NReq : NReq *24-hour clock* (CTN0027CDD:t_frLAB.LAB002b2) **Repeat Test?** (CTN0027CDD:t_frLAB.LAB002b3) *[0]* No *[1]* Yes **Accession Number** (CTN0027CDD:t_frLAB.LAB002b4) A10
4. *	**3. Liver tests:**	(CTN0027CDD:t_frLAB.LAB003a) *[97]* Not Done **[1] Date Drawn** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frLAB.LAB003b1) **Time Drawn** NReq : NReq *24-hour clock* (CTN0027CDD:t_frLAB.LAB003b2) **Repeat Test?** (CTN0027CDD:t_frLAB.LAB003b3) *[0]* No *[1]* Yes **Accession Number** (CTN0027CDD:t_frLAB.LAB003b4) A10
5. *	**4. Urinalysis:**	(CTN0027CDD:t_frLAB.LAB004a) *[97]* Not Done **[1] Date Drawn** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frLAB.LAB004b1) **Time Drawn** NReq : NReq *24-hour clock* (CTN0027CDD:t_frLAB.LAB004b2) **Repeat Test?** (CTN0027CDD:t_frLAB.LAB004b3) *[0]* No *[1]* Yes **Accession Number** (CTN0027CDD:t_frLAB.LAB004b4) A10
6. *	**5. Hepatitis serologies:**	(CTN0027CDD:t_frLAB.LAB005a) *[97]* Not Done **[1] Date Drawn** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frLAB.LAB005b1) **Time Drawn** NReq : NReq *24-hour clock* (CTN0027CDD:t_frLAB.LAB005b2) **Repeat Test?** (CTN0027CDD:t_frLAB.LAB005b3) *[0]* No *[1]* Yes **Accession Number** (CTN0027CDD:t_frLAB.LAB005b4) A10
7.	**5a. Since the last visit, has the participant had a Hepatitis A Vaccine?** **(If this is the baseline visit, has the participant *ever* had a Hepatitis A vaccine?**	(CTN0027CDD:t_frLAB.LAB005aa) *[1]* Yes *[0]* No *[96]* NA
8.	**5b. Since the last visit, has the participant had a Hepatitis B Vaccine?** **(If this is the baseline visit, has the participant *ever* had a Hepatitis B vaccine?**	(CTN0027CDD:t_frLAB.LAB005bb) *[1]* Yes *[0]* No *[96]* NA
9. *	**6. HIV test:**	(CTN0027CDD:t_frLAB.LAB006a) *[97]* Not Done **[1] Date Drawn** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frLAB.LAB006b1) **Time Drawn** NReq : NReq *24-hour clock* (CTN0027CDD:t_frLAB.LAB006b2) **Repeat Test?** (CTN0027CDD:t_frLAB.LAB006b3) *[0]* No *[1]* Yes **Accession Number** (CTN0027CDD:t_frLAB.LAB006b4) A10

* Item is not required

CDD: CTN0027CDD Table: t_frLAB Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
LAB003b1	DATE - DDMONYYYY	
LAB003b2	DATE - HHMM	
LAB003b3	NUMERIC	
LAB003b4	STRING(10) - A10	
LAB004a	NUMERIC	
LAB004b1	DATE - DDMONYYYY	
LAB004b2	DATE - HHMM	
LAB004b3	NUMERIC	
LAB004b4	STRING(10) - A10	
LAB005a	NUMERIC	
LAB005bb	NUMERIC	
LAB006a	NUMERIC	
LAB006b1	DATE - DDMONYYYY	
LAB006b2	DATE - HHMM	
LAB006b3	NUMERIC	
LAB006b4	STRING(10) - A10	
LAB005aa	NUMERIC	
LAB002b1	DATE - DDMONYYYY	
LAB002b2	DATE - HHMM	
LAB002b3	NUMERIC	
VISITDT	DATE - DDMONYYYY	
LAB001a	NUMERIC	
LAB001b1	DATE - DDMONYYYY	
LAB001b2	DATE - HHMM	
LAB001b3	NUMERIC	

LAB001b4	STRING(10) - A10	
LAB002a	NUMERIC	
LAB003a	NUMERIC	
LAB005b3	NUMERIC	
LAB005b4	STRING(10) - A10	
LAB005b1	DATE - DDMONYYYY	
LAB005b2	DATE - HHMM	
LAB002b4	STRING(10) - A10	

ctn0027 : Medical and Psychiatric History (MDH)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frMDH.VISITDT)

Medical and Psychiatric History

*** NOTE: Evidence for hypertension: If participant provides a blood pressure that is higher than 140 mm HG (systolic) over 90 mm HG (diastolic) then they will be evaluated by the study physician to determine if they have clinically significant hypertension that is not controlled.**

Have you ever been treated for or have a history of:

2.	**1. Head Injury**	(CTN0027CDD:t_frMDH.MDH001) **History** *[0]* 0 No history **[1]** 1 Yes, history **If Yes: Specify** A200 (CTN0027CDD:t_frMDH.MDH001s) *[9]* 9 Not evaluated
3.	**2. Allergies**	(CTN0027CDD:t_frMDH.MDH002) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH002s) *[9]* 9 Not evaluated
4.	**3. Liver problems**	(CTN0027CDD:t_frMDH.MDH003) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH003s) *[9]* 9 Not evaluated
5.	**4. Kidney problems**	(CTN0027CDD:t_frMDH.MDH004) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH004s) *[9]* 9 Not evaluated
6.	**5. GI problems**	(CTN0027CDD:t_frMDH.MDH005) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH005s) *[9]* 9 Not evaluated
7.	**6. Thyroid condition**	(CTN0027CDD:t_frMDH.MDH006) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH006s) *[9]* 9 Not evaluated
8.	**7. Heart condition**	(CTN0027CDD:t_frMDH.MDH007) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH007s) *[9]* 9 Not evaluated
9.	**8. Asthma**	(CTN0027CDD:t_frMDH.MDH008) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH008s) *[9]* 9 Not evaluated
10.	**9. High blood pressure hypertension***	(CTN0027CDD:t_frMDH.MDH009) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH009s) *[9]* 9 Not evaluated
11.	**10. Any skin disease or problems with skin rashes**	(CTN0027CDD:t_frMDH.MDH010) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH010s) *[9]* 9 Not evaluated
12.	**11a. Routine drug or methadone withdrawal symptoms**	(CTN0027CDD:t_frMDH.MDH011A) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH011As) *[9]* 9 Not evaluated
13.	**11b. Routine alcohol withdrawal symptoms**	(CTN0027CDD:t_frMDH.MDH011B) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH011Bs) *[9]* 9 Not evaluated
14.	**12. Schizophrenia**	(CTN0027CDD:t_frMDH.MDH012) *[0]* 0 No history **[1]** 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH012s) 9 Not evaluated

		[9] ○
15.	**13. Major Depressive Disorder**	(CTN0027CDD:t_frMDH.MDH013) *[0]* ○ 0 No history **[1]** ○ 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH013s) *[9]* ○ 9 Not evaluated
16.	**14. Bipolar Disorder**	(CTN0027CDD:t_frMDH.MDH014) *[0]* ○ 0 No history **[1]** ○ 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH014s) *[9]* ○ 9 Not evaluated
17.	**15. Anxiety or Panic Disorder**	(CTN0027CDD:t_frMDH.MDH015) *[0]* ○ 0 No history **[1]** ○ 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH015s) *[9]* ○ 9 Not evaluated
18.	**16. Clinically significant neurological damage**	(CTN0027CDD:t_frMDH.MDH016) *[0]* ○ 0 No history **[1]** ○ 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH016s) *[9]* ○ 9 Not evaluated
19.	**17. Epilepsy or Seizure Disorder**	(CTN0027CDD:t_frMDH.MDH017) *[0]* ○ 0 No history **[1]** ○ 1 Yes, history A200 (CTN0027CDD:t_frMDH.MDH017s) *[9]* ○ 9 Not evaluated

Medical and Psychiatric History (continued)

If there are other medical conditions or psychiatric/neurological history not previously mentioned, then specify below.

20.*	**19. Other 1**	**Other 1** (specify) A200	(CTN0027CDD:t_frMDH.MDH018)	**History... specify** A200	(CTN0027CDD:t_frMDH.MDH018s)
21.*	**20. Other 2**	**Other 2** (specify) A200	(CTN0027CDD:t_frMDH.MDH019)	**History... specify** A200	(CTN0027CDD:t_frMDH.MDH019s)
22.*	**21. Other 3**	**Other 3** (specify) A200	(CTN0027CDD:t_frMDH.MDH020)	**History... specify** A200	(CTN0027CDD:t_frMDH.MDH020s)
23.*	**22. Other 4**	**Other 4** (specify) A200	(CTN0027CDD:t_frMDH.MDH021)	**History... specify** A200	(CTN0027CDD:t_frMDH.MDH021s)
24.*	**Comments**	A200	(CTN0027CDD:t_frMDH.MDH022)		

* Item is not required

CDD: CTN0027CDD Table: t_frMDH Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
MDH001	NUMERIC	
MDH001s	STRING(200) - A200	
VISITDT	DATE - DDMONYYYY	
MDH006	NUMERIC	
MDH006s	STRING(200) - A200	
MDH007	NUMERIC	
MDH007s	STRING(200) - A200	
MDH008	NUMERIC	
MDH009	NUMERIC	
MDH009s	STRING(200) - A200	
MDH010	NUMERIC	
MDH008s	STRING(200) - A200	
MDH012	NUMERIC	
MDH012s	STRING(200) - A200	
MDH013	NUMERIC	
MDH013s	STRING(200) - A200	
MDH014	NUMERIC	
MDH014s	STRING(200) - A200	
MDH015	NUMERIC	
MDH015s	STRING(200) - A200	
MDH016	NUMERIC	
MDH002	NUMERIC	
MDH002s	STRING(200) - A200	

MDH004	NUMERIC	
MDH004s	STRING(200) - A200	
MDH005	NUMERIC	
MDH005s	STRING(200) - A200	
MDH003	NUMERIC	
MDH003s	STRING(200) - A200	
MDH011As	STRING(200) - A200	
MDH011B	NUMERIC	
MDH011Bs	STRING(200) - A200	
MDH010s	STRING(200) - A200	
MDH022	STRING(200) - A200	
MDH016s	STRING(200) - A200	
MDH017	NUMERIC	
MDH017s	STRING(200) - A200	
MDH018	STRING(200) - A200	
MDH018s	STRING(200) - A200	
MDH019	STRING(200) - A200	
MDH019s	STRING(200) - A200	
MDH020	STRING(200) - A200	
MDH020s	STRING(200) - A200	
MDH021	STRING(200) - A200	
MDH021s	STRING(200) - A200	
MDH011A	NUMERIC	

ctn0027 : Physical Exam (PEX)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPEX.VISITDT)		
2.	**1. General Appearance**	Pulldown List 1 (CTN0027CDD:t_frPEX.PEX001a)	**Evaluation** A200 **Comments for Abnormal Results**	(CTN0027CDD:t_frPEX.PEX001b)
3.	**2. Head / Neck**	Pulldown List 2 (CTN0027CDD:t_frPEX.PEX002a)	A200	(CTN0027CDD:t_frPEX.PEX002b)
4.	**3. Ears, Eyes, Nose and Throat**	Pulldown List 3 (CTN0027CDD:t_frPEX.PEX003a)	A200	(CTN0027CDD:t_frPEX.PEX003b)
5.	**4. Cardiovascular**	Pulldown List 4 (CTN0027CDD:t_frPEX.PEX004a)	A200	(CTN0027CDD:t_frPEX.PEX004b)
6.	**5. Lymph Nodes**	Pulldown List 5 (CTN0027CDD:t_frPEX.PEX005a)	A200	(CTN0027CDD:t_frPEX.PEX005b)
7.	**6. Respiratory**	Pulldown List 6 (CTN0027CDD:t_frPEX.PEX006a)	A200	(CTN0027CDD:t_frPEX.PEX006b)
8.	**7. Musculoskeletal**	Pulldown List 7 (CTN0027CDD:t_frPEX.PEX007a)	A200	(CTN0027CDD:t_frPEX.PEX007b)
9.	**8. Gastrointestinal and Abdomen**	Pulldown List 8 (CTN0027CDD:t_frPEX.PEX008a)	A200	(CTN0027CDD:t_frPEX.PEX008b)
10.	**9. Extremities**	Pulldown List 9 (CTN0027CDD:t_frPEX.PEX009a)	A200	(CTN0027CDD:t_frPEX.PEX009b)
11.	**10. Neurological**	Pulldown List 10 (CTN0027CDD:t_frPEX.PEX010a)	A200	(CTN0027CDD:t_frPEX.PEX010b)
12.	**11. Skin**	Pulldown List 11 (CTN0027CDD:t_frPEX.PEX011a)	A200	(CTN0027CDD:t_frPEX.PEX011b)
13.*	**12. Other**	Pulldown List 12 (CTN0027CDD:t_frPEX.PEX012a) **Specify:** A200 (CTN0027CDD:t_frPEX.PEX012b) **Comments:** A200 (CTN0027CDD:t_frPEX.PEX012c)		

* Item is not required

Pulldown List 1:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 4:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 5:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 6:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 7:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	

ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 8:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 9:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 10:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 11:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

Pulldown List 12:

RefName	Display Text	Value	Design Note
ie1Norma	1 Normal	1	
ie2Abnor	2 Abnormal	2	
ie9NtDon	9 Not Done	9	

CDD: CTN0027CDD Table: t_frPEX Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PEX011a	STRING(255) - 1, 2, 9	
PEX011b	STRING(200) - A200	
PEX003b	STRING(200) - A200	
PEX004a	STRING(255) - 1, 2, 9	
PEX004b	STRING(200) - A200	
PEX010b	STRING(200) - A200	
PEX002a	STRING(255) - 1, 2, 9	
VISITDT	DATE - DDMONYYYY	
PEX001a	STRING(255) - 1, 2, 9	
PEX002b	STRING(200) - A200	
PEX003a	STRING(255) - 1, 2, 9	
PEX001b	STRING(200) - A200	
PEX006a	STRING(255) - 1, 2, 9	
PEX007b	STRING(200) - A200	
PEX008a	STRING(255) - 1, 2, 9	
PEX008b	STRING(200) - A200	
PEX009a	STRING(255) - 1, 2, 9	
PEX009b	STRING(200) - A200	
PEX010a	STRING(255) - 1, 2, 9	
PEX012b	STRING(200) - A200	
PEX012c	STRING(200) - A200	
PEX005b	STRING(200) - A200	
PEX006b	STRING(200) - A200	
PEX007a	STRING(255) - 1, 2, 9	
PEX005a	STRING(255) - 1, 2, 9	
PEX012a	STRING(255) - 1, 2, 9	

ctn0027 : Pregnancy and Birth Control Assessment (PBC)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPBC_BL.VISITDT)
Complete this form only for females.		
2.	**Is participant of childbearing potential?**	(CTN0027CDD:t_frPBC_BL.PBC5L) *[0]* ○ No *[1]* ○ Yes
3.	**Indicate all forms of birth control the participant uses:**	(CTN0027CDD:t_frPBC_BL.PBC005A) **a** Oral Contraceptives: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005B) **b** Barrier *(diaphragm, cervical cap)* with Spermicide, or Condom: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005C) **c** Intrauterine Device *(IUD)*: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005D) **d** Intrauterine Progesterone Contraceptive System *(IUD)*: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005E) **e** Levonorgestrel Implant: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005F) **f** Medroxyprogesterone Acetate Contraceptive Injection: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005G) **g** Contraceptive Transdermal Patch: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005H) **h** Hormonal Vaginal Contraceptive Ring: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005I) **i** Surgical Sterilization: *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frPBC_BL.PBC005J) **j** Complete Abstinence from Sexual Intercourse: *[0]* ○ 0 No *[1]* ○ 1 Yes
4.	**Was a pregnancy test performed?**	(CTN0027CDD:t_frPBC_BL.PBC001) *[0]* ○ 0 No *[1]* ○ 1 Yes
5.*	**Date of pregnancy test:**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPBC_BL.PBC002)
6.*	**Pregnancy test result:**	(CTN0027CDD:t_frPBC_BL.PBC003) *[1]* ○ 1 Negative **[2]** ○ 2 Positive (CTN0027CDD:t_frPBC_BL.PBC003a) **If positive AND on BUP/NX, specify outcome:** *[1]* ○ 1 Switched to Subutex (BUP/NX only) *[2]* ○ 2 Switched to Methadone (BUP/NX only) *[3]* ○ 3 Terminated from study (BUP/NX only) *[4]* ○ 4 NA (MET group only)
7.*	**Comments:**	A200 (CTN0027CDD:t_frPBC_BL.PBC006)

* Item is not required

CDD: CTN0027CDD	Table: t_frPBC_BL	Key Type: PATIENTVISIT
Column Name	**Column Data Type**	**Design Note**
PBC005A	NUMERIC	
PBC005B	NUMERIC	
PBC005C	NUMERIC	
PBC005D	NUMERIC	
PBC005E	NUMERIC	
PBC005F	NUMERIC	
PBC005G	NUMERIC	
PBC005H	NUMERIC	
VISITDT	DATE - DDMONYYYY	
PBC5L	NUMERIC	
PBC005I	NUMERIC	
PBC005J	NUMERIC	
PBC001	NUMERIC	
PBC002	DATE - DDMONYYYY	
PBC003	NUMERIC	
PBC003a	NUMERIC	
PBC006	STRING(200) - A200	

ctn0027 : Risk Behavior Survey (RBS)

A. Drug Use

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frRBS0A.VISITDT)

Risk Behaviors Survey

A. DRUG USE

a. Have you ever used?

2. **A 1a. Cocaine by itself (injected or snorted)?** (If no use, skip to next drug)

For text boxes enter:
-1 for 'Refused'
-2 for 'Don't Know'

(CTN0027CDD:t_frRBS0A.RBS0A1a)
[0] 0 No **[1]** 1 Yes *[9]* 9 Unknown *[7]* 7 Refused

b. How many days did you use __ in the last 30 days? (CTN0027CDD:t_frRBS0A.RBS0A1b)
(If 00, -1, -2, do not ask part C-F, and skip to next drug)
xx (-2 =< n <= 30)

c. How many days did you inject __ in the last 30 days? (CTN0027CDD:t_frRBS0A.RBS0A1c)
(If 00, -1, -2, skip to part e)
xx (-2 =< n <= 30)

d. How many times a day did you inject __? (CTN0027CDD:t_frRBS0A.RBS0A1d)
(Average # of injections/day)
xx (-2 =< n <= 99)

e. How many days did you use __ without injecting (smoking, snorting, swallowing) in the last 30 days? (CTN0027CDD:t_frRBS0A.RBS0A1e)
(If 00, -1, -2, then skip to next drug class)
xx (-2 =< n <= 30)

f. How many times a day did you use __ without injecting? (CTN0027CDD:t_frRBS0A.RBS0A1f)
xx (-2 =< n <= 99)

3. **A 2a. Heroin by itself?** (If no use, skip to next drug)

For text boxes enter:
-1 for 'Refused'
-2 for 'Don't Know'

(CTN0027CDD:t_frRBS0A.RBS0A2a)
[0] 0 No **[1]** 1 Yes *[9]* 9 Unknown *[7]* 7 Refused

b. How many days did you use __ in the last 30 days? ***(if 00, -1, -2, do not ask parts c-f, and skip to next drug)*** (CTN0027CDD:t_frRBS0A.RBS0A2b)
xx (-2 =< n <= 30)

c. How many days did you inject __ in the last 30 days? (CTN0027CDD:t_frRBS0A.RBS0A2c)
(If 00, -1, -2, skip to part e)
xx (-2 =< n <= 30)

d. How many times a day did you inject __? (CTN0027CDD:t_frRBS0A.RBS0A2d)
(Average # of injections/day)
xx (-2 =< n <= 99)

e. How many days did you use __ without injecting (smoking, snorting, swallowing) in the last 30 days? (CTN0027CDD:t_frRBS0A.RBS0A2e)
(If 00, -1, -2, then skip to next drug class)
xx (-2 =< n <= 30)

f. How many times a day did you use __ without injecting? (CTN0027CDD:t_frRBS0A.RBS0A2f)
xx (-2 =< n <= 99)

4. **A 3a. Heroin and cocaine mixed together (Speedball)** (If no use, skip to next drug)

For text boxes enter:
-1 for 'Refused'
-2 for 'Don't Know'

(CTN0027CDD:t_frRBS0A.RBS0A3a)
[0] 0 No **[1]** 1 Yes *[9]* 9 Unknown *[7]* 7 Refused

b. How many days did you use __ in the last 30 days? ***(if 00, -1, -2, do not ask parts c-f, and skip to next drug)*** (CTN0027CDD:t_frRBS0A.RBS0A3b)
xx (-2 =< n <= 30)

c. How many days did you inject __ in the last 30 days? ***(If 00, -1, -2, skip to part e)*** (CTN0027CDD:t_frRBS0A.RBS0A3c)
xx (-2 =< n <= 30)

d. How many times a day did you inject __? (CTN0027CDD:t_frRBS0A.RBS0A3d)
(Average # of injections/day)
xx (-2 =< n <= 99)

e. How many days did you use __ without injecting (smoking, snorting, swallowing) in the last 30 days? (CTN0027CDD:t_frRBS0A.RBS0A3e)
(If 00, -1, -2, then skip to next drug class)
xx (-2 =< n <= 30)

f. How many times a day did you use __ without injecting? (CTN0027CDD:t_frRBS0A.RBS0A3f)
xx (-2 =< n <= 99)

5. **A 4a. Have you ever used Other Opiates (Demerol, Codeine, Dilaudid)?** (If no use, skip to next drug)

For text boxes enter:
-1 for 'Refused'
-2 for 'Don't Know'

(CTN0027CDD:t_frRBS0A.RBS0A4a)
[0] 0 No **[1]** 1 Yes *[9]* 9 Unknown *[7]* 7 Refused

b. How many days did you use __ in the last 30 days? ***(if 00, -1, -2, do not ask parts c-f, and skip to next drug)*** (CTN0027CDD:t_frRBS0A.RBS0A4b)
xx (-2 =< n <= 30)

c. How many days did you inject __ in the last 30 days? ***(If 00, -1, -2, skip to part e)*** (CTN0027CDD:t_frRBS0A.RBS0A4c)
xx (-2 =< n <= 30)

d. How many times a day did you inject __? (CTN0027CDD:t_frRBS0A.RBS0A4d)
(Average # of injections/day)
xx (-2 =< n <= 99)

e. How many days did you use __ without injecting (smoking, snorting, swallowing) in the last 30 days? (CTN0027CDD:t_frRBS0A.RBS0A4e)
(If 00, -1, -2, then skip to next drug class)
xx (-2 =< n <= 30)

f. How many times a day did you use __ without injecting? (CTN0027CDD:t_frRBS0A.RBS0A4f)
xx (-2 =< n <= 99)

6. **A 5a. Have you ever used Amphetamines (Speed, Methamphetamine, Crank)?** (If no use, skip to next drug)

For text boxes enter:
-1 for 'Refused'
-2 for 'Don't Know'

(CTN0027CDD:t_frRBS0A.RBS0A5a)
[0] 0 No **[1]** 1 Yes *[9]* 9 Unknown *[7]* 7 Refused

b. How many days did you use __ in the last 30 days? ***(if 00, -1, -2, do not ask parts c-f, and skip to next drug)*** (CTN0027CDD:t_frRBS0A.RBS0A5b)
xx (-2 =< n <= 30)

c. How many days did you inject __ in the last 30 days? ***(If 00, -1, -2, skip to part e)*** (CTN0027CDD:t_frRBS0A.RBS0A5c)
xx (-2 =< n <= 30)

d. How many times a day did you inject __? ***(Average # of injections/day)*** (CTN0027CDD:t_frRBS0A.RBS0A5d)
xx (-2 =< n <= 99)

e. How many days did you use __ without injecting (smoking, snorting, swallowing) in the last 30 days? ***(If 00, -1, -2, then skip to next drug class)*** (CTN0027CDD:t_frRBS0A.RBS0A5e)
xx (-2 =< n <= 30)

f. How many times a day did you use __ without injecting? (CTN0027CDD:t_frRBS0A.RBS0A5f)
xx (-2 =< n <= 99)

B. Drug Injection (if no injection use in past 30 days, skip to section C.)

For text boxes enter -1 for 'Refused', -2 for 'Don't Know'

7.	**B1. In the last 30 days, how many times (# of injections) did you inject using works**	(CTN0027CDD:t_frRBS0A.rgRBS0B1)

	(needle/syringes) that you know had been used by somebody else? ***(If 0, -1, -2, or NA, then select NA for B2)***	**[1]** ○ | xxx (-2 =< n <= 999) | (CTN0027CDD:t_frRBS0A.RBS0B1) *[96]* ○NA
8.	**B2. Of the times you injected after someone, how many times did you clean the works with full-strength bleach?**	(CTN0027CDD:t_frRBS0A.rgRBS0B2) **[1]** ○ | xxx (-2 =< n <= 999) | (CTN0027CDD:t_frRBS0A.RBS0B2) *[96]* ○NA
9.	**B3. How many times in the last 30 days did you use a cooker/cotton /rinse water that had been used by another injector?**	(CTN0027CDD:t_frRBS0A.rgRBS0B3) **[1]** ○ | xxx (-2 =< n <= 999) | (CTN0027CDD:t_frRBS0A.RBS0B3) *[96]* ○NA
10.	**B4. How many times in the last 30 days did you fix drugs with another person, then split the drug solution (through use of the same cooker/spoon or through front or back loading)?**	(CTN0027CDD:t_frRBS0A.rgRBS0B4) **[1]** ○ | xxx (-2 =< n <= 999) | (CTN0027CDD:t_frRBS0A.RBS0B4) *[96]* ○NA
C. Sexual Activity **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**		
11.	**C1. During the last 30 days, with how many people did you have vaginal, oral or anal sex?(IF NONE, ENTER 000, AND THE QUESTIONNAIRE IS COMPLETED)**	(CTN0027CDD:t_frRBS0A.rgRBS0C1) **[1]** ○ | xxx (-2 =< n <= 999) | (CTN0027CDD:t_frRBS0A.RBS0C1) *[96]* ○NA
12.*	**C2. How many of your partners were female?**	(CTN0027CDD:t_frRBS0A.rgRBS0C2) **[1]** ○ | xxx (-2 =< n <= 999) | (CTN0027CDD:t_frRBS0A.RBS0C2) *[96]* ○NA
13.*	**C3. How many of your partners were male? (Number cannot exceed total number of people (qC1))**	(CTN0027CDD:t_frRBS0A.rgRBS0C3) **[1]** ○ | xxx (-2 =< n <= 999) | (CTN0027CDD:t_frRBS0A.RBS0C3) *[96]* ○NA
14.*	**C4.Interviewer: Code gender of respondent. After submission of this form, please complete relevant form (either RBSMale, RBSFemale, or RBSAll).**	(CTN0027CDD:t_frRBS0A.RBS0C4) *[1]* ○1 Male *[2]* ○2 Female *[9]* ○9 Don't know *[96]* ○NA

* Item is not required

Item Design Notes:	
Item No.	**Design Note**
14.	If Male and item 10 is >0, then dynamically create RBSMale, if female and item 10 is >0, then dynamically create RBS2Female, if Don't Know and item 10 is >0, then dynamically create RBS2All

CDD: CTN0027CDD Table: t_frRBS0A Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
RBS0A2f	NUMERIC - N2	
RBS0A3a	NUMERIC	
rgRBS0C2	NUMERIC	
RBS0C2	NUMERIC - N3	
rgRBS0C3	NUMERIC	
RBS0C3	NUMERIC - N3	
RBS0C4	NUMERIC	
RBS0A3b	NUMERIC - N2	
RBS0A3c	NUMERIC - N2	
RBS0A3d	NUMERIC - N2	
RBS0A3e	NUMERIC - N2	
RBS0A3f	NUMERIC - N2	
RBS0A4a	NUMERIC	
RBS0A4b	NUMERIC - N2	
RBS0A4c	NUMERIC - N2	
RBS0A4d	NUMERIC - N2	
RBS0A4e	NUMERIC - N2	
RBS0A4f	NUMERIC - N2	
RBS0A5a	NUMERIC	
RBS0A5d	NUMERIC - N2	
RBS0A5e	NUMERIC - N2	
RBS0A5f	NUMERIC - N2	
rgRBS0B1	NUMERIC	
RBS0B1	NUMERIC - N3	
rgRBS0B2	NUMERIC	
RBS0B2	NUMERIC - N3	
rgRBS0B3	NUMERIC	
RBS0B3	NUMERIC - N3	
rgRBS0B4	NUMERIC	
RBS0B4	NUMERIC - N3	
rgRBS0C1	NUMERIC	
RBS0C1	NUMERIC - N3	
RBS0A5b	NUMERIC - N2	
RBS0A5c	NUMERIC - N2	
RBS0A2e	NUMERIC - N2	
RBS0A2b	NUMERIC - N2	
RBS0A2c	NUMERIC - N2	
RBS0A2d	NUMERIC - N2	
VISITDT	DATE - DDMONYYYY	
RBS0A1a	NUMERIC	
RBS0A1b	NUMERIC - N2	
RBS0A1c	NUMERIC - N2	

RBS0A1d	NUMERIC - N2	
RBS0A1e	NUMERIC - N2	
RBS0A1f	NUMERIC - N2	
RBS0A2a	NUMERIC	

ctn0027 : RISK BEHAVIORS SURVEY (2 of 2) (RBSMale)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frRBSM.VISITDT)
	D. Ask Male/Female Clients who had Female Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
2.	**D 1a. How many women performed oral sex ("went down") on you? (If 0, then enter NA for 1b and 1c . Number cannot exceed total number of female partners (qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0D1a) b. How often did your partner(s) perform oral sex ('go down') on you? Pulldown List 1 (CTN0027CDD:t_frRBSM.RBS0D1b) c. How often did you use condoms/dental dams when your partner(s) perform oral sex ('went down') on you? Pulldown List 2 (CTN0027CDD:t_frRBSM.RBS0D1c)
3.	**D 2a. How many women did you perform oral sex ("go down") on? (If 0, then enter NA for 2b and 2c . Number cannot exceed total number of female partners (qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0D2a) b. How often did you perform oral sex ('go down') on your partner(s)? Pulldown List 3 (CTN0027CDD:t_frRBSM.RBS0D2b) c. How often did you use condoms/dental dams when you performed oral sex ('went down') on your partner(s)? Pulldown List 4 (CTN0027CDD:t_frRBSM.RBS0D2c)
	E. Ask Male Clients who had Female Partners: **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
4.	**E 1a. How many women did you have vaginal sex with? (If 0, then enter NA for 1b and 1c . Number cannot exceed total number of female partners (qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0E1a) b. How often did you have vaginal sex? Pulldown List 5 (CTN0027CDD:t_frRBSM.RBS0E1b) c. How often did you use a condom? Pulldown List 6 (CTN0027CDD:t_frRBSM.RBS0E1c)
5.	**E 2a. How many women did you have (insertive) anal with? (If 0, then enter NA for 2b and 2c. Number cannot exceed total number of female partners (q2C)).**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0E2a) b. How often did you have (insertive) anal sex? Pulldown List 7 (CTN0027CDD:t_frRBSM.RBS0E2b) c. How often did you use a condom? Pulldown List 8 (CTN0027CDD:t_frRBSM.RBS0E2c)
	F. Ask Male Clients who had Male Partners: **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
6.	**F 1a. How many men did you have (insertive) anal sex with? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners (qC3)).**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0F1a) b. How often did you have (insertive) anal sex? Pulldown List 9 (CTN0027CDD:t_frRBSM.RBS0F1b) c. How often did you use condom? Pulldown List 10 (CTN0027CDD:t_frRBSM.RBS0F1c)
	G. Ask Male/Female Clients who had Male Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
7.	**G 1a. How many men performed oral sex ("went down") on you? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners)**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0G1a) b. How often did your partner(s) perform oral sex ('go down') on you? Pulldown List 11 (CTN0027CDD:t_frRBSM.RBS0G1b) c. How often did you use condoms/dental dams when your partner(s) performed oral sex ('went down') on you? Pulldown List 12 (CTN0027CDD:t_frRBSM.RBS0G1c)
8.	**G 2a. How many men did you perform oral sex ("go down") on? (If 0, then enter NA for 2b and 2c. Number cannot exceed total number of male partners (qC3))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0G2a) b. How often did you perform oral sex ('go down') on your partner(s)? Pulldown List 13 (CTN0027CDD:t_frRBSM.RBS0G2b) c. How often did you use condoms/dental dams when you performed oral sex ('went down') on your partner(s)? Pulldown List 14 (CTN0027CDD:t_frRBSM.RBS0G2c)
	I. Ask Male/Female Clients who had Male Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
9.	**I 1a. How many men did you have (receptive) anal sex with? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners(qC3)**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSM.RBS0I1a) b. How often did you have (receptive) anal sex? Pulldown List 15 (CTN0027CDD:t_frRBSM.RBS0I1b) c. How often did you use a condom? Pulldown List 16 (CTN0027CDD:t_frRBSM.RBS0I1c)

Form Design Note:

created by 'Male' on RBS1

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	

ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 4:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 5:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 6:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 7:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 8:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	

ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 9:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 10:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 11:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 12:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 13:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 14:

RefName	Display Text	Value	Design Note

ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 15:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 16:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

CDD: CTN0027CDD Table: t_frRBSM Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RBS0D1a	NUMERIC - N3	
RBS0D1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0D1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0D2a	NUMERIC - N3	
VISITDT	DATE - DDMONYYYY	
RBS0G1a	NUMERIC - N3	
RBS0G1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0G1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0D2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0D2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0E1a	NUMERIC - N3	
RBS0E1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0E1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0E2a	NUMERIC - N3	
RBS0E2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0E2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0F1a	NUMERIC - N3	
RBS0F1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0F1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0I1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0G2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0I1a	NUMERIC - N3	
RBS0I1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0G2a	NUMERIC - N3	
RBS0G2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	

ctn0027 : Risk Behaviors Surveys (2 of 2) (RBSFemale)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frRBSF.VISITDT)
	D. Ask Male/Female Clients who had Female Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
2.	**D 1a. How many women performed oral sex ("went down") on you? (If 0, then enter NA for 1b and 1c . Number cannot exceed total number of female partners (qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSF.RBS0D1a) b. How often did your partner(s) perform oral sex ('go down') on you? Pulldown List 1 (CTN0027CDD:t_frRBSF.RBS0D1b) c. How often did you use condoms/dental dams when your partner(s) perform oral sex ('went down') on you? Pulldown List 2 (CTN0027CDD:t_frRBSF.RBS0D1c)
3.	**D 2a. How many women did you perform oral sex ("go down") on? (If 0, then enter NA for 2b and 2c . Number cannot exceed total number of female partners (qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSF.RBS0D2a) b. How often did you perform oral sex ('go down') on your partner(s)? Pulldown List 3 (CTN0027CDD:t_frRBSF.RBS0D2b) c. How often did you use condoms/dental dams when you performed oral sex ('went down') on your partner(s)? Pulldown List 4 (CTN0027CDD:t_frRBSF.RBS0D2c)
	G. Ask Male/Female Clients who had Male Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
4.	**G 1a. How many men performed oral sex ("went down") on you? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners)**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSF.RBS0G1a) b. How often did your partner(s) perform oral sex ('go down') on you? Pulldown List 5 (CTN0027CDD:t_frRBSF.RBS0G1b) c. How often did you use condoms/dental dams when your partner(s) performed oral sex ('went down') on you? Pulldown List 6 (CTN0027CDD:t_frRBSF.RBS0G1c)
5.	**G 2a. How many men did you perform oral sex ("go down") on? (If 0, then enter NA for 2b and 2c. Number cannot exceed total number of male partners (qC3))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSF.RBS0G2a) b. How often did you perform oral sex ('go down') on your partner(s)? Pulldown List 7 (CTN0027CDD:t_frRBSF.RBS0G2b) c. How often did you use condoms/dental dams when you performed oral sex ('went down') on your partner(s)? Pulldown List 8 (CTN0027CDD:t_frRBSF.RBS0G2c)
	H. Ask Female Clients who had Male Partners: **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
6.	**H 1a. How many men did you have vaginal sex with? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners (qC3)).**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSF.RBS0H1a) b. How often did you have vaginal sex? Pulldown List 9 (CTN0027CDD:t_frRBSF.RBS0H1b) c. How often did you use a condom? Pulldown List 10 (CTN0027CDD:t_frRBSF.RBS0H1c)
	I. Ask Male/Female Clients who had Male Partners	
7.	**I 1a. How many men did you have (receptive) anal sex with? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners(qC3)**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBSF.RBS0I1a) b. How often did you have (receptive) anal sex? Pulldown List 11 (CTN0027CDD:t_frRBSF.RBS0I1b) c. How often did you use a condom? Pulldown List 12 (CTN0027CDD:t_frRBSF.RBS0I1c)

Form Design Note:

created by 'Female' on RBS1

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	

ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 4:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 5:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 6:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 7:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 8:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 9:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	

ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 10:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 11:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 12:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

CDD: CTN0027CDD Table: t_frRBSF Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
RBS0G2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0G2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0H1a	NUMERIC - N3	
RBS0H1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0H1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0I1a	NUMERIC - N3	
RBS0I1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0I1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0G1a	NUMERIC - N3	
RBS0G1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0G1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
VISITDT	DATE - DDMONYYYY	
RBS0D1a	NUMERIC - N3	
RBS0D1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0D1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0D2a	NUMERIC - N3	
RBS0D2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0D2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0G2a	NUMERIC - N3	

ctn0027 : Risk Behavior Surveys (2 of 2) (RBSAll)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frRBS2All.VISITDT)
	D. Ask Male/Female Clients who had Female Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
2.	**D 1a. How many women performed oral sex ("went down") on you? (If 0, then enter NA for 1b and 1c . Number cannot exceed total number of female partners (qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0D1a) b. How often did your partner(s) perform oral sex ('go down') on you? Pulldown List 1 (CTN0027CDD:t_frRBS2All.RBS0D1b) c. How often did you use condoms/dental dams when your partner(s) perform oral sex ('went down') on you? Pulldown List 2 (CTN0027CDD:t_frRBS2All.RBS0D1c)
3.	**D 2a. How many women did you perform oral sex ("go down") on? (If 0, then enter NA for 2b and 2c . Number cannot exceed total number of female partners(qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0D2a) b. How often did you perform oral sex ('go down') on your partner(s)? Pulldown List 3 (CTN0027CDD:t_frRBS2All.RBS0D2b) c. How often did you use condoms/dental dams when you performed oral sex ('went down') on your partner(s)? Pulldown List 4 (CTN0027CDD:t_frRBS2All.RBS0D2c)
	E. Ask Male Clients who had Female Partners: **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
4.	**E 1a. How many women did you have vaginal sex with? (If 0, then enter NA for 1b and 1c . Number cannot exceed total number of female partners (qC2))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0E1a) b. How often did you have vaginal sex? Pulldown List 5 (CTN0027CDD:t_frRBS2All.RBS0E1b) c. How often did you use a condom? Pulldown List 6 (CTN0027CDD:t_frRBS2All.RBS0E1c)
5.	**E 2a. How many women did you have (insertive) anal with? (If 0, then enter NA for 2b and 2c. Number cannot exceed total number of female partners (q2C)).**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0E2a) b. How often did you have (insertive) anal sex? Pulldown List 7 (CTN0027CDD:t_frRBS2All.RBS0E2b) c. How often did you use a condom? Pulldown List 8 (CTN0027CDD:t_frRBS2All.RBS0E2c)
	F. Ask Male Clients who had Male Partners: **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
6.	**F 1a. How many men did you have (insertive) anal sex with? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners (qC3)).**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0F1a) b. How often did you have (insertive) anal sex? Pulldown List 9 (CTN0027CDD:t_frRBS2All.RBS0F1b) c. How often did you use condom? Pulldown List 10 (CTN0027CDD:t_frRBS2All.RBS0F1c)
	G. Ask Male/Female Clients who had Male Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
7.	**G 1a. How many men performed oral sex ("went down") on you? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners)**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0G1a) b. How often did your partner(s) perform oral sex ('go down') on you? Pulldown List 11 (CTN0027CDD:t_frRBS2All.RBS0G1b) c. How often did you use condoms/dental dams when your partner(s) performed oral sex ('went down') on you? Pulldown List 12 (CTN0027CDD:t_frRBS2All.RBS0G1c)
8.	**G 2a. How many men did you perform oral sex ("go down") on? (If 0, then enter NA for 2b and 2c. Number cannot exceed total number of male partners (qC3))**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0G2a) b. How often did you perform oral sex ('go down') on your partner(s)? Pulldown List 13 (CTN0027CDD:t_frRBS2All.RBS0G2b) c. How often did you use condoms/dental dams when you performed oral sex ('went down') on your partner(s)? Pulldown List 14 (CTN0027CDD:t_frRBS2All.RBS0G2c)
	H. Ask Female Clients who had Male Partners: **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
9.	**H 1a. How many men did you have vaginal sex with? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners (qC3)).**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0H1a) b. How often did you have vaginal sex? Pulldown List 15 (CTN0027CDD:t_frRBS2All.RBS0H1b) c. How often did you use a condom? Pulldown List 16 (CTN0027CDD:t_frRBS2All.RBS0H1c)
	I. Ask Male/Female Clients who had Male Partners **For text boxes enter -1 for 'Refused', -2 for 'Don't Know'**	
10.	**I 1a. How many men did you have (receptive) anal sex with? (If 0, then enter NA for 1b and 1c. Number cannot exceed total number of male partners(qC3)**	xxx (-2 =< n <= 999) (CTN0027CDD:t_frRBS2All.RBS0I1a) b. How often did you have (receptive) anal sex? Pulldown List 17 (CTN0027CDD:t_frRBS2All.RBS0I1b) c. How often did you use a condom? Pulldown List 18 (CTN0027CDD:t_frRBS2All.RBS0I1c)

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 4:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 5:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 6:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 7:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 8:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 9:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 10:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 11:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 12:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 13:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 14:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 15:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 16:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 17:

RefName	Display Text	Value	Design Note
ieSexFr1	1 Once or irregularly	1	
ieSexFr2	2 Less than once a week	2	
ieSexFr3	3 About once a week	3	
ieSexFr4	4 2-6 times a week	4	
ieSexFr5	5 About once a day	5	
ieSexFr6	6 2-3 times a day	6	
ieSexFr7	7 4 or more times a day	7	
ieSexFr8	99 Don't know/unsure	99	
ieSexFr9	77 Refused	77	
ieRBS_NA	96 NA	96	

Pulldown List 18:

RefName	Display Text	Value	Design Note
ieSexCo1	0 Never	0	
ieSexCo2	1 Less than half the time	1	
ieSexCo3	2 About half the time	2	
ieSexCo4	3 More than half the time	3	
ieSexCo5	4 Always	4	
ieSexCo6	99 Don't know/unsure	99	
ieSexCo7	77 Refused	77	
ieRBS_NA	96 NA	96	

CDD: CTN0027CDD Table: t_frRBS2All Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
VISITDT	DATE - DDMONYYYY	
RBS0D2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0D2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0E1a	NUMERIC - N3	
RBS0D1a	NUMERIC - N3	
RBS0D1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0D1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0D2a	NUMERIC - N3	
RBS0H1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	

RBS0H1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0I1a	NUMERIC - N3	
RBS0I1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0I1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0H1a	NUMERIC - N3	
RBS0F1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0F1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0G1a	NUMERIC - N3	
RBS0G1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0G1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0G2a	NUMERIC - N3	
RBS0G2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0E1b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0E1c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0E2a	NUMERIC - N3	
RBS0E2b	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 99, 77, 96	
RBS0E2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	
RBS0F1a	NUMERIC - N3	
RBS0G2c	STRING(255) - 0, 1, 2, 3, 4, 99, 77, 96	

ctn0027 : Substance Use (TFB-Lead)		
1.	**Assessment Date** [*editable*]	Req / Req / Req (2006-2010) (CTN0027CDD:t_frDRG.VISITDT / Assessment Date)
2.	**Have any illicit substances or alcohol been taken within the date range specified below?** **If Yes, please complete TFB form for this visit.**	(CTN0027CDD:t_frDRG.DRG) *[0]* No *[1]* Yes
3.	**Start Date:**	NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frDRG.DRGSTART / TFB Start Date)
4.	**Stop Date:** Please confirm that each day of the assessment period has been reviewed with the participant.	NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frDRG.DRGSTOP / TFB Stop Date)

CDD: CTN0027CDD Table: t_frDRG Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
DRG	NUMERIC	
VISITDT	DATE - DDMONYYYY	
DRGSTART	DATE - DDMONYYYY	
DRGSTOP	DATE - DDMONYYYY	

ctn0027 : Time Line Follow Back--Active Study (TFB) - Repeating Form

#		Substance Use Date	Alcohol taken?	Alcohol Quantity	Alcohol Route	Cannaboids taken?	Cannaboids Route	Cocaine taken?	Cocaine Route	Amphetamine taken?	Amphetamine Route	Methamphetamine taken?	Methamphetamine Route	Opiates taken?	Opiates Route	Benzodiazepines taken?	Benzodiazepines Route	Propoxyphene taken?	Propoxyphene Route	Methadone taken?	Methadone Route	Oxycodone taken?	Oxycodone Route	Other taken?	Other	Other Route
1																										

Time Line Follow Back--Active Study

1.	**Substance Use Date:**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frTFB.TFB001)
2.	**1. Alcohol:**	(CTN0027CDD:t_frTFB.TFB001A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
3.*	Alcohol Quantity	A50 (CTN0027CDD:t_frTFB.TFB001B)
4.*	Route	Pulldown List 1 (CTN0027CDD:t_frTFB.TFB001C)
5.	**2. Cannaboids:**	(CTN0027CDD:t_frTFB.TFB002A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
6.*	Route	Pulldown List 2 (CTN0027CDD:t_frTFB.TFB002B)
7.	**3. Cocaine:**	(CTN0027CDD:t_frTFB.TFB003A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
8.*	Route	Pulldown List 3 (CTN0027CDD:t_frTFB.TFB003B)
9.	**4. Amphetamine:**	(CTN0027CDD:t_frTFB.TFB004A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
10.*	Route	Pulldown List 4 (CTN0027CDD:t_frTFB.TFB004B)
11.	**5. Methamphetamine:**	(CTN0027CDD:t_frTFB.TFB005A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
12.*	Route	Pulldown List 5 (CTN0027CDD:t_frTFB.TFB005B)
13.	**6. Opiates:**	(CTN0027CDD:t_frTFB.TFB006A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
14.*	Route	Pulldown List 6 (CTN0027CDD:t_frTFB.TFB006B)
15.	**7. Benzodiazepines:**	(CTN0027CDD:t_frTFB.TFB007A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
16.*	Route	Pulldown List 7 (CTN0027CDD:t_frTFB.TFB007B)
17.	**8. Propoxyphene:**	(CTN0027CDD:t_frTFB.TFB008A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
18.*	Route	Pulldown List 8 (CTN0027CDD:t_frTFB.TFB008B)
19.	**9. Methadone:**	(CTN0027CDD:t_frTFB.TFB009A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
20.*	Route	Pulldown List 9 (CTN0027CDD:t_frTFB.TFB009B)
21.	**10. Oxycodone:**	(CTN0027CDD:t_frTFB.TFB010A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
22.*	Route	Pulldown List 10 (CTN0027CDD:t_frTFB.TFB010B)
23.	**11. Other:**	(CTN0027CDD:t_frTFB.TFB011A) Was substance taken? *[0]* 0 No *[1]* 1 Yes
24.*	Other (specify):	A255 (CTN0027CDD:t_frTFB.TFB011B)
25.*	Route	Pulldown List 11 (CTN0027CDD:t_frTFB.TFB011C)

* Item is not required

Pulldown List 1:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 4:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 5:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 6:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 7:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	

ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 8:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 9:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 10:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

Pulldown List 11:

RefName	Display Text	Value	Design Note
ie01Oral	01 Oral	1	
ie02Nasal	02 Nasal	2	
ie03Inhaled	03 Inhaled	3	
ie04Vein	04 Shot up - vein	4	
ie05Muscle	05 Shot up - muscle	5	
ie06Skin	06 Shot up - skin	6	
ie07Tongue	07 Dissolved under tongue	7	
ie08Topical	08 Topical	8	
ie09Rectal	09 Rectal	9	
ie10Vaginal	10 Vaginal	10	

CDD: CTN0027CDD Table: t_frTFB Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
TFB011A	NUMERIC	
TFB011B	STRING(255) - A255	
TFB011C	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB010A	NUMERIC	
TFB010B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB009A	NUMERIC	
TFB009B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB001A	NUMERIC	
TFB004A	NUMERIC	
TFB004B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB005A	NUMERIC	

TFB005B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB006A	NUMERIC	
TFB006B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB007A	NUMERIC	
TFB007B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB008A	NUMERIC	
TFB008B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB003A	NUMERIC	
TFB003B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
TFB002A	NUMERIC	
TFB002B	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	
VISITDT	DATE	
TFB001	DATE - DDMONYYYY	
TFB001B	STRING(50) - A50	
TFB001C	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10	

ctn0027 : Vital Signs (VSF)		
1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frVSF.VISITDT)
Vital Signs		
2.	**1. Time**	Req : Req *24-hour clock* *(00:00 to 23:59)* (CTN0027CDD:t_frVSF.VSF001)
3.	**2. Temperature:**	xxxx. (CTN0027CDD:t_frVSF.VSF002) (CTN0027CDD:t_frVSF.VSF002A) *[1]* ○ 1 °F *[2]* ○ 2 °C
4.	**3. Blood pressure:**	xxx (45 =< n <= 180) / (CTN0027CDD:t_frVSF.VSF003A) xxx (35 =< n <= 120) mmHg *(systolic / diastolic)* (CTN0027CDD:t_frVSF.VSF003B)
5.	**4. Pulse:**	xxx (35 =< n <= 150) bpm (CTN0027CDD:t_frVSF.VSF004)
6.	**5. Respirations:**	xx (6 =< n <= 30) *(1 minute)* (CTN0027CDD:t_frVSF.VSF005)
7.	**6. Weight**	xxxxx (CTN0027CDD:t_frVSF.VSF006) (CTN0027CDD:t_frVSF.VSF006A) *[1]* ○ 1 lb *[2]* ○ 2 kg

CDD: CTN0027CDD Table: t_frVSF Key Type: PATIENTVISIT		
Column Name	**Column Data Type**	**Design Note**
VSF006	NUMERIC - N5	
VSF006A	NUMERIC	
VISITDT	DATE - DDMONYYYY	
VSF001	DATE - HHMM	
VSF002	FLOAT - F5.0	
VSF002A	NUMERIC	
VSF003A	NUMERIC - N3	
VSF003B	NUMERIC - N3	
VSF004	NUMERIC - N3	
VSF005	NUMERIC - N2	

ctn0027 : Alcohol Breathalyzer (ABZ)

Alcohol Breathalyzer

1.	**1. Was an Alcohol Breathalyzer performed successfully?**	(CTN0027CDD:t_frABZ.AB001) *[0]* ○ 0 No **[1]** ○ 1 Yes Date alcohol breathalyzer test performed: Req / Req / Req (2006-2010) (CTN0027CDD:t_frABZ.AB001A) Alcohol Breathalyzer result: x.xxx (n < 0.000000) mg / mL (CTN0027CDD:t_frABZ.AB001B)
2.*	**2. Comments:**	A200 (CTN0027CDD:t_frABZ.AB002)

* Item is not required

CDD: CTN0027CDD Table: t_frABZ Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
AB001	NUMERIC	
AB001A	DATE - DDMONYYYY	
AB001B	FLOAT - F5.3	
AB002	STRING(200) - A200	

ctn0027 : Randomization (RAN)

Randomization

1.*	**Date of randomization:** [*read-only*]	Req / Req / Req (2006-2010) (CTN0027CDD:t_frRAN.INF002)
2.*	**Randomization number:** [*read-only*]	xxxx (CTN0027CDD:t_frRAN.INF003)
3.*	**Treatment Group** [*read-only*]	(CTN0027CDD:t_frRAN.INF004) *[1]* Buprenorphine/Naloxone *[2]* Methadone
4.*	**Liver Test Result** [*read-only*]	(CTN0027CDD:t_frRAN.INF005) *[1]* Normal *[2]* Abnormal
5.	**Are Date of randomization, Randomization number, Treatment Group, and Liver Test Result items complete and accurate?**	(CTN0027CDD:t_frRAN.INF006) *[1]* Yes *[0]* No

* Item is not required

CDD: CTN0027CDD Table: t_frRAN Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
INF005	NUMERIC	
INF006	NUMERIC	
INF002	DATE - DDMONYYYY	
INF003	NUMERIC - N4	
INF004	NUMERIC	

ctn0027 : Study Drug Dose Log (DOS) - Repeating Form

#		Assessment Date	Date:	Location	Total dose received	Location	
1							

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frDOS.VISITDT)
Please record daily dose of study drug that was dispensed to participant.		
2.	**Date:**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frDOS.DOS001)
3.	**Drug** (check only one):	(CTN0027CDD:t_frDOS.DOS002) *[1]* Methadone *[2]* Buprenorphine
4.	**Total dose received:**	xxx mg (CTN0027CDD:t_frDOS.DOS005)
5.	**Drug administration location:**	(CTN0027CDD:t_frDOS.DOS006) *[1]* Clinic *[2]* Home

CDD: CTN0027CDD Table: t_frDOS Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DOS005	NUMERIC - N3	
DOS006	NUMERIC	
DOS002	NUMERIC	
VISITDT	DATE - DDMONYYYY	
DOS001	DATE - DDMONYYYY	

ctn0027 : Clinical Opiate Withdrawal Scale - Predose (COWS1)		
1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frCOWS.VISITDT)
For each item, mark the choice that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.		
2.	**1. Resting pulse rate:** *measured after patient is sitting or lying for one minute*:	Pulldown List 1 (CTN0027CDD:t_frCOWS.COWS001) Actual pulse rate: xxx (n >= 0) (CTN0027CDD:t_frCOWS.COWS001a)
3.	**2. GI upset:** *over the last 1/2 hour*:	Pulldown List 2 (CTN0027CDD:t_frCOWS.COWS002)
4.	**3. Sweating:** *over the past 1/2 hour not accounted for by room temperature or patient activity*:	Pulldown List 3 (CTN0027CDD:t_frCOWS.COWS003)
5.	**4. Tremor:** *observation of outstretched hands*:	Pulldown List 4 (CTN0027CDD:t_frCOWS.COWS004)
6.	**5. Restlessness:** *observation during assessment*:	Pulldown List 5 (CTN0027CDD:t_frCOWS.COWS005)
7.	**6. Yawning:** *observation during assessment*:	Pulldown List 6 (CTN0027CDD:t_frCOWS.COWS006)
8.	**7. Pupil size:**	Pulldown List 7 (CTN0027CDD:t_frCOWS.COWS007)
9.	**8. Anxiety or irritability:**	Pulldown List 8 (CTN0027CDD:t_frCOWS.COWS008)
10.	**9. Bone or joint aches:** *If participant was having pain previously, only the additional component attributed to opiate withdrawal is scored*:	Pulldown List 9 (CTN0027CDD:t_frCOWS.COWS009)
11.	**10. Gooseflesh skin:**	Pulldown List 10 (CTN0027CDD:t_frCOWS.COWS010)
12.	**11. Runny nose or tearing:** *not accounted for by cold symptoms or allergies*:	Pulldown List 11 (CTN0027CDD:t_frCOWS.COWS011)
	12. Total score *(the total score is the sum of all 11 itmes)*: [*read-only*]	(CTN0027CDD:t_frCOWS.COWS012)
13.	**Initials of Evaluator:**	A3 (CTN0027CDD:t_frCOWS.COWS012a)

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieRPR0	0 Pulse rate 80 or below	0	
ieRPR1	1 Pulse rate 81 - 100	1	
ieRPR2	2 Pulse rate 101 - 120	2	
ieRPR4	4 Pulse rate greater than 120	4	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ieGIUP0	0 No GI symptoms	0	
ieGIUP1	1 Stomach cramps	1	
ieGIUP2	2 Nausea or loose stool	2	
ieGIUP3	3 Vomiting or diarrhea	3	
ieGIUP5	5 Multiple episodes of diarrhea or vomiting	5	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ieSWET0	0 No report of chills or flushing	0	
ieSWET1	1 Subjective report of chills or flushing	1	
ieSWET2	2 Flushed or observable moisture on face	2	
ieSWET3	3 Beads of sweat on brow or face	3	
ieSWET4	4 Sweat streaming off face	4	

Pulldown List 4:

RefName	Display Text	Value	Design Note
ieTREM0	0 No tremor	0	
ieTREM1	1 Tremor can be felt, but not observed	1	
ieTREM2	2 Slight tremor observable	2	
ieTREM4	4 Gross tremor or muscle twitching	4	

Pulldown List 5:

RefName	Display Text	Value	Design Note
ieRSTL0	0 Able to sit still	0	
ieRSTL1	1 Reports difficulty sitting still, but is able to do so	1	
ieRSTL2	2 Frequently shifting or extraneous movements of legs/arms	2	
ieRSTL3	3 Unable to sit still for more than a few seconds	3	

Pulldown List 6:

RefName	Display Text	Value	Design Note
ieYAWN0	0 No yawning	0	
ieYAWN1	1 Yawning once or twice during assessment	1	
ieYAWN2	2 Yawning three or more times during assessment	2	
ieYAWN4	4 Yawning several times/minute	4	

Pulldown List 7:

RefName	Display Text	Value	Design Note
iePUPL0	0 Pupils pinned abnormal size for room light	0	
iePUPL1	1 Pupils possibly larger than normal for room light	1	
iePUPL2	2 Pupils moderately dilated	2	
iePUPL5	5 Pupils so dilated that only the rim of the iris is visible	5	

Pulldown List 8:

RefName	Display Text	Value	Design Note
ieANX0	0 None	0	
ieANX1	1 Participant reports increasing irritability or anxiousness	1	
ieANX2	2 Participant obviously irritable or anxious	2	
ieANX4	4 Participant is rubbing joints and muscles and is unable to sit still because of discomfort	4	

Pulldown List 9:

RefName	Display Text	Value	Design Note
ieBONA0	0 Not present	0	
ieBONA1	1 Mild diffuse discomfort	1	
ieBONA02	2 Participant reports severe diffuse aching of joints/muscle	2	

Pulldown List 10:

RefName	Display Text	Value	Design Note
ieGOOS0	0 Skin is smooth	0	
ieGOOS3	3 Piloerection of skin can be felt or hairs standing up on arms	3	
ieGOOS5	5 Prominent piloerection	5	

Pulldown List 11:

RefName	Display Text	Value	Design Note
ieRUNY0	0 Not present	0	
ieRUNY1	1 Nasal stuffiness or unusually moist eyes	1	
ieRUNY4	4 Nose constantly running or tears streaming down cheeks	4	

CDD: CTN0027CDD Table: t_frCOWS Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
COWS002	STRING(255) - 0, 1, 2, 3, 5	
COWS003	STRING(255) - 0, 1, 2, 3, 4	
VISITDT	DATE - DDMONYYYY	
COWS001	STRING(255) - 0, 1, 2, 4	
COWS001a	NUMERIC - N3	
COWS004	STRING(255) - 0, 1, 2, 4	
COWS005	STRING(255) - 0, 1, 2, 3	
COWS006	STRING(255) - 0, 1, 2, 4	
COWS007	STRING(255) - 0, 1, 2, 5	
COWS008	STRING(255) - 0, 1, 2, 4	
COWS009	STRING(255) - 0, 1, 2	
COWS010	STRING(255) - 0, 3, 5	
COWS011	STRING(255) - 0, 1, 4	
COWS012	STRING(255)	
COWS012a	STRING(3) - A3	

ctn0027 : Clinical Opiate Withdrawal Scale - Postdose (COWS2)		
1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frCOWS2.VISITDT)
For each item, mark the choice that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.		
2.	**1. Resting pulse rate:** *measured after patient is sitting or lying for one minute*:	Pulldown List 1 (CTN0027CDD:t_frCOWS2.COWS001) Actual pulse rate: xxx (n >= 0) (CTN0027CDD:t_frCOWS2.COWS2001a)
3.	**2. GI upset:** *over the last 1/2 hour*:	Pulldown List 2 (CTN0027CDD:t_frCOWS2.COWS002)
4.	**3. Sweating:** *over the past 1/2 hour not accounted for by room temperature or patient activity*:	Pulldown List 3 (CTN0027CDD:t_frCOWS2.COWS003)
5.	**4. Tremor:** *observation of outstretched hands*:	Pulldown List 4 (CTN0027CDD:t_frCOWS2.COWS004)
6.	**5. Restlessness:** *observation during assessment*:	Pulldown List 5 (CTN0027CDD:t_frCOWS2.COWS005)
7.	**6. Yawning:** *observation during assessment*:	Pulldown List 6 (CTN0027CDD:t_frCOWS2.COWS006)
8.	**7. Pupil size:**	Pulldown List 7 (CTN0027CDD:t_frCOWS2.COWS007)
9.	**8. Anxiety or irritability:**	Pulldown List 8 (CTN0027CDD:t_frCOWS2.COWS008)
10.	**9. Bone or joint aches:** *If participant was having pain previously, only the additional component attributed to opiate withdrawal is scored*:	Pulldown List 9 (CTN0027CDD:t_frCOWS2.COWS009)
11.	**10. Gooseflesh skin:**	Pulldown List 10 (CTN0027CDD:t_frCOWS2.COWS010)
12.	**11. Runny nose or tearing:** *not accounted for by cold symptoms or allergies*:	Pulldown List 11 (CTN0027CDD:t_frCOWS2.COWS011)
	12. Total score *(the total score is the sum of all 11 itmes)*: [*read-only*]	(CTN0027CDD:t_frCOWS2.COWS012)
13.	**Initials of Evaluator:**	A3 (CTN0027CDD:t_frCOWS2.COWS012a)

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieRPR0	0 Pulse rate 80 or below	0	
ieRPR1	1 Pulse rate 81 - 100	1	
ieRPR2	2 Pulse rate 101 - 120	2	
ieRPR4	4 Pulse rate greater than 120	4	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ieGIUP0	0 No GI symptoms	0	
ieGIUP1	1 Stomach cramps	1	
ieGIUP2	2 Nausea or loose stool	2	
ieGIUP3	3 Vomiting or diarrhea	3	
ieGIUP5	5 Multiple episodes of diarrhea or vomiting	5	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ieSWET0	0 No report of chills or flushing	0	
ieSWET1	1 Subjective report of chills or flushing	1	
ieSWET2	2 Flushed or observable moisture on face	2	
ieSWET3	3 Beads of sweat on brow or face	3	
ieSWET4	4 Sweat streaming off face	4	

Pulldown List 4:

RefName	Display Text	Value	Design Note
ieTREM0	0 No tremor	0	
ieTREM1	1 Tremor can be felt, but not observed	1	
ieTREM2	2 Slight tremor observable	2	
ieTREM4	4 Gross tremor or muscle twitching	4	

Pulldown List 5:

RefName	Display Text	Value	Design Note
ieRSTL0	0 Able to sit still	0	
ieRSTL1	1 Reports difficulty sitting still, but is able to do so	1	
ieRSTL2	2 Frequently shifting or extraneous movements of legs/arms	2	
ieRSTL3	3 Unable to sit still for more than a few seconds	3	

Pulldown List 6:

RefName	Display Text	Value	Design Note
ieYAWN0	0 No yawning	0	
ieYAWN1	1 Yawning once or twice during assessment	1	
ieYAWN2	2 Yawning three or more times during assessment	2	
ieYAWN4	4 Yawning several times/minute	4	

Pulldown List 7:

RefName	Display Text	Value	Design Note
iePUPL0	0 Pupils pinned abnormal size for room light	0	
iePUPL1	1 Pupils possibly larger than normal for room light	1	
iePUPL2	2 Pupils moderately dilated	2	
iePUPL5	5 Pupils so dilated that only the rim of the iris is visible	5	

Pulldown List 8:

RefName	Display Text	Value	Design Note
ieANX0	0 None	0	
ieANX1	1 Participant reports increasing irritability or anxiousness	1	
ieANX2	2 Participant obviously irritable or anxious	2	
ieANX4	4 Participant is rubbing joints and muscles and is unable to sit still because of discomfort	4	

Pulldown List 9:

RefName	Display Text	Value	Design Note
ieBONA0	0 Not present	0	
ieBONA1	1 Mild diffuse discomfort	1	
ieBONA02	2 Participant reports severe diffuse aching of joints/muscle	2	

Pulldown List 10:

RefName	Display Text	Value	Design Note
ieGOOS0	0 Skin is smooth	0	
ieGOOS3	3 Piloerection of skin can be felt or hairs standing up on arms	3	
ieGOOS5	5 Prominent piloerection	5	

Pulldown List 11:

RefName	Display Text	Value	Design Note
ieRUNY0	0 Not present	0	
ieRUNY1	1 Nasal stuffiness or unusually moist eyes	1	
ieRUNY4	4 Nose constantly running or tears streaming down cheeks	4	

CDD: CTN0027CDD Table: t_frCOWS2 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
COWS2001a	NUMERIC - N3	
COWS002	STRING(255) - 0, 1, 2, 3, 5	
COWS003	STRING(255) - 0, 1, 2, 3, 4	
COWS006	STRING(255) - 0, 1, 2, 4	
COWS007	STRING(255) - 0, 1, 2, 5	
COWS008	STRING(255) - 0, 1, 2, 4	
COWS009	STRING(255) - 0, 1, 2	
COWS010	STRING(255) - 0, 3, 5	
COWS011	STRING(255) - 0, 1, 4	
COWS012	STRING(255)	
COWS012a	STRING(3) - A3	
COWS004	STRING(255) - 0, 1, 2, 4	
COWS005	STRING(255) - 0, 1, 2, 3	
VISITDT	DATE - DDMONYYYY	
COWS001	STRING(255) - 0, 1, 2, 4	

ctn0027 : Pregnancy and Birth Control Assessment (PBC)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPBC.VISITDT)
Complete this form only for females.		
2.	**Was a pregnancy test performed?**	(CTN0027CDD:t_frPBC.PBC001) *[0]* 0 No *[1]* 1 Yes
3. *	**Date of pregnancy test:**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPBC.PBC002)
4. *	**Pregnancy test result:**	(CTN0027CDD:t_frPBC.PBC003) *[1]* 1 Negative **[2]** 2 Positive (CTN0027CDD:t_frPBC.PBC003a) **If positive AND on BUP/NX, specify outcome:** *[1]* 1 Switched to Subutex (BUP/NX only) *[2]* 2 Switched to Methadone (BUP/NX only) *[3]* 3 Terminated from study (BUP/NX only) *[4]* 4 NA (MET group only)
5. *	**Comments:**	A200 (CTN0027CDD:t_frPBC.PBC006)

* Item is not required

CDD: CTN0027CDD Table: t_frPBC Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PBC003a	NUMERIC	
PBC006	STRING(200) - A200	
PBC001	NUMERIC	
VISITDT	DATE - DDMONYYYY	
PBC002	DATE - DDMONYYYY	
PBC003	NUMERIC	

ctn0027 : Prior and Concomitant Medications (PCM)

Prior and Concomitant Medications

1.*	**Has the participant taken any medications during the assessment period?** **(SCR = last 2 weeks, other visits = since last PCM assessment)** [*hidden*]	(CTN0027CDD:t_frPCM.PCM001) *[0]* ○ 0 No *[1]* ○ 1 Yes, **Complete below.**

	Con Med No.	Medication Name	Indication	Amount	Units	Specify Other Units	Freq	Specify Other Freq	Route	Specify Other Route	Medication Start Date	Medication End Date	Continuing
2.													

2.a	**Con Med No.**	xxx (CTN0027CDD:t_frPCM.PCM002)
2.b	**A Generic Name of Medication** *(refer to QT Prolongation Drug List)*	A30 (CTN0027CDD:t_frPCM.PCM002A)
2.c	**B Indication**	A30 (CTN0027CDD:t_frPCM.PCM002B)
2.d	**C Amount**	xxxxxxx. (CTN0027CDD:t_frPCM.PCM002C)
2.e	**D Units**	Pulldown List 1 (CTN0027CDD:t_frPCM.PCM002E)
2.f*	Specify Other Units	A20 (CTN0027CDD:t_frPCM.PCM002ES)
2.g	**E Freq**	Pulldown List 2 (CTN0027CDD:t_frPCM.PCM002F)
2.h*	Specify Other Freq	A20 (CTN0027CDD:t_frPCM.PCM002FS)
2.i	**F Route**	Pulldown List 3 (CTN0027CDD:t_frPCM.PMC002G)
2.j*	Specify Other Route	A20 (CTN0027CDD:t_frPCM.PCM002FGS)
2.k	**G Medication Start Date**	NReq / NReq / Req (1950-2010) (CTN0027CDD:t_frPCM.PCM002H)
2.l*	**H Medication End Date**	Req / Req / Req (1950-2010) (CTN0027CDD:t_frPCM.PCM002I)
2.m*	**I Continuing**	(CTN0027CDD:t_frPCM.PCM002J) *[1]* ☐ 1 Continuing

* Item is not required

Pulldown List 1:

RefName	Display Text	Value	Design Note
ie01Capsule	A=capsule	1	
ie02Drop	B=drop	2	
ie03Grain	C=grain	3	
ie04gram	D=gram	4	
ie05Microgram	E=microgram	5	
ie06Microliter	F=microliter	6	
ie07Milligram	G=milligram	7	
ie08Milliliter	H=milliliter	8	
ie09Ounce	I=ounce	9	
ie10Patch	J=patch	10	
ie11Puff	K=puff	11	
ie12Spray	L=spray/ squirt	12	
ie13Suppository	M=suppository	13	
ie14Tablespoon	N=tablespoon	14	
ie15Other	O=other (specify)	15	

Pulldown List 2:

RefName	Display Text	Value	Design Note
ie01qd	01 qd	1	
ie02bid	02 bid	2	
ie03tid	03 tid	3	
ie04qid	04 qid	4	
ie05qod	05 qod	5	
ie06qhs	06 qhs	6	
ie07contIV	07 cont. IV	7	
ie08prn	08 prn	8	
ie09q4h	09 q4h	9	
ie10q6h	10 q6h	10	
ie11q8h	11 q8h	11	
ie12q12h	12 q12h	12	
ie13x1	13 x 1	13	
ie14Other	14 Other (specify	14	

Pulldown List 3:

RefName	Display Text	Value	Design Note
ie1PO	1 PO	1	
ie2IV	2 IV	2	
ie3SC	3 SC	3	
ie4IM	4 IM	4	
ie5IVbolus	5 IV bolus	5	
ie6Sublingual	6 Sublingual	6	

ie7Inhaled	7 Inhaled	7	
ie8Topical	8 Topical	8	
ie9Other	9 Other (specify)	9	

CDD: CTN0027CDD Table: t_frPCM Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PCM002ES	STRING(20) - A20	
PCM002F	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14	
PCM002FS	STRING(20) - A20	
PCM001	NUMERIC	
PMC002G	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9	
PCM002FGS	STRING(20) - A20	
PCM002H	DATE - DDMONYYYY	
PCM002I	DATE - DDMONYYYY	
PCM002J	STRING(255)	
PCM002B	STRING(30) - A30	
PCM002C	FLOAT - F8.0	
PCM002E	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15	
VISITDT	DATE	
PCM002	NUMERIC - N3	
PCM002A	STRING(30) - A30	

ctn0027 : Adverse Events (AE) - Repeating Form

#		Week #	Assessment Date	AE Number	Adverse Event	Onset Date	Severity	Action taken	Study Drug Related	Expected?	Serious AE?	Outcome	End Date or Ongoing
1													

1.	**Week #**	xx (-1 =< n <= 32) (CTN0027CDD:t_frAE.VSWKAE)
2.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frAE.VSDTAE)
3.	**AE Number**	A3 (CTN0027CDD:t_frAE.AE002)
4.	**Adverse Event**	A200 (CTN0027CDD:t_frAE.AE003)
5.	**Onset Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frAE.AE003A)
6.	**Severity**	Pulldown List 1 (CTN0027CDD:t_frAE.AE004)
7.	**Action taken** *(check all that apply)*	(CTN0027CDD:t_frAE.AE005a) *[1]* ☐ 1 None (CTN0027CDD:t_frAE.AE005b) *[2]* ☐ 2 Delayed study drug dose (< 24 hour delay) (CTN0027CDD:t_frAE.AE005c) *[3]* ☐ 3 Increased study drug dose (CTN0027CDD:t_frAE.AE005d) *[4]* ☐ 4 Reduced study drug dose (CTN0027CDD:t_frAE.AE005e) *[5]* ☐ 5 Discontinued study drug temporarily (>24 hour delay) (CTN0027CDD:t_frAE.AE005f) *[6]* ☐ 6 Discontinued study drug permanently (CTN0027CDD:t_frAE.AE005g) *[7]* ☐ 7 Discontinued methadone (CTN0027CDD:t_frAE.AE005h) *[8]* ☐ 8 Discontinued buprenorphine (CTN0027CDD:t_frAE.AE005i) *[9]* ☐ 9 Administration of another medication
8.	**Study Drug Related?** *(check only one)*	(CTN0027CDD:t_frAE.AE006) *[1]* ○ 1 Unrelated *[2]* ○ 2 Possibly *[3]* ○ 3 Probably *[4]* ○ 4 Definitely
9.	**Expected?**	(CTN0027CDD:t_frAE.AE007) *[0]* ○ 0 No *[1]* ○ 1 Yes
10.	**Serious Adverse Event?**	(CTN0027CDD:t_frAE.AE008) *[0]* ○ 0 No *[1]* ○ 1 Yes
11.	**Outcome**	(CTN0027CDD:t_frAE.AE009) *[1]* ○ 1 Resolved *[2]* ○ 2 Resolved with sequelae *[3]* ○ 3 Not resolved *[4]* ○ 4 Death
12.	**End Date or Ongoing**	(CTN0027CDD:t_frAE.AE011) **End date:** **[0]** ○ Req / Req / Req (2006-2010) (CTN0027CDD:t_frAE.AE010) *[1]* ○ 1 Ongoing

Pulldown List 1:

RefName	Display Text	Value	Design Note
ieSEVR1	1 Mild	1	
ieSEVR2	2 Moderate	2	
ieSEVR3	3 Severe	3	
ieSEVR4	4 Life-threatening	4	
ieSEVR5	5 Death	5	

CDD: CTN0027CDD Table: t_frAE Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
VSDTAE	DATE - DDMONYYYY	
VSWKAE	NUMERIC - N2	
AE002	STRING(3) - A3	
AE003	STRING(200) - A200	
AE004	STRING(255) - 1, 2, 3, 4, 5	
AE005a	STRING(255)	
AE005b	STRING(255)	
AE005c	STRING(255)	
AE005d	STRING(255)	
AE005e	STRING(255)	
AE005f	STRING(255)	
AE005g	STRING(255)	
AE005h	STRING(255)	
AE005i	STRING(255)	
AE006	NUMERIC	
AE007	NUMERIC	
AE008	NUMERIC	
AE009	NUMERIC	
AE011	NUMERIC	
AE003A	DATE - DDMONYYYY	
AE010	DATE - DDMONYYYY	

ctn0027 : Genetics (GEN)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frGEN.VISITDT)
2.	**Does the participant agree to participate in the Genetics Study?**	(CTN0027CDD:t_frGEN.GEN001) *[0]* No *[1]* Yes
3. *	**Date Informed Consent Signed:**	NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frGEN.GEN002)
4. *	**Genetics Study ID (Unique Identifier)**	A7 (CTN0027CDD:t_frGEN.GEN008)
Sample Obtained		
5. *	**Week 2 (blood) Taken:**	**Date:** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frGEN.GEN003a) **Time:** NReq : NReq *24-hour clock* (CTN0027CDD:t_frGEN.GEN003b)
6. *	**Was the sample shipped?**	(CTN0027CDD:t_frGEN.GEN004) *[0]* No *[1]* Yes
7. *	**Week 12 (blood and urine) Taken:**	**Date:** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frGEN.GEN005a) **Time:** NReq : NReq *24-hour clock* (CTN0027CDD:t_frGEN.GEN005b)
8. *	**Were the samples shipped?**	(CTN0027CDD:t_frGEN.GEN006) *[0]* No *[1]* Yes
9. *	**Participant withdrew consent:**	(CTN0027CDD:t_frGEN.GEN007) *[0]* No **[1]** Yes NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frGEN.GEN007d)

* Item is not required

CDD: CTN0027CDD Table: t_frGEN Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
GEN008	STRING(7) - A7	
GEN003a	DATE - DDMONYYYY	
VISITDT	DATE - DDMONYYYY	
GEN001	NUMERIC	
GEN002	DATE - DDMONYYYY	
GEN007d	DATE - DDMONYYYY	
GEN003b	DATE - HHMM	
GEN004	NUMERIC	
GEN005a	DATE - DDMONYYYY	
GEN005b	DATE - HHMM	
GEN006	NUMERIC	
GEN007	NUMERIC	

ctn0027 : Serious Adverse Event (SAE) - Repeating Form

#		Seq Num	Week #	Assessment Date	Adverse Event Number	ReportType	SAE Name (name of event)	SAE Description	SAE Onset Date	SAE Resolution Date	SAE Categorization	Severity of SAE	SAE actions taken	Relationship to Study Drug	Was event expected?	SAE Outcome
1																

1.*	Calculated Sequence Number (this should be hidden) [*hidden*]	(CTN0027CDD:t_frSAE.SEQNUMGEN)
2.*	**Seq Num** *(automatic)* [*read-only*]	xx (CTN0027CDD:t_frSAE.SEQNUM)
3.	**Week #**	xx (-1 =< n <= 32) (CTN0027CDD:t_frSAE.VISWKAE)
4.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE.VSDTAE)
Serious Adverse Event		
5.	**Adverse Event Number**	xxx (CTN0027CDD:t_frSAE.SAE00A)
6.	**1. Type of Report**	(CTN0027CDD:t_frSAE.SAE001) *[1]* ○ Initial **[2]** ○ Follow-Up **Follow up number** xxx (CTN0027CDD:t_frSAE.SAE001a)
7.	**2. SAE Name** *(name of event)*	A200 (CTN0027CDD:t_frSAE.SAE002)
8.	**3. SAE Description**	A500 (CTN0027CDD:t_frSAE.SAE003)
9.	**4. SAE Onset Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE.SAE004)
10.*	**5. SAE Resolution Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE.SAE005)
11.	**6. SAE Categorization**	(CTN0027CDD:t_frSAE.SAE006a) **a. Death**..... *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006b) **b. Life-threatening**..... *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006c) **c. Hospitalization (other than detox or rehab)**... *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006d) **d. Disability**..... *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006e) **e. Congenital anomaly**..... *[0]* ○ 0 No **[1]** ○ 1 Yes *If yes, answer 1 through 5* (CTN0027CDD:t_frSAE.SAE006e1) **1. Anomaly** *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006e2) **2. Miscarriage** *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006e3) **3. Aborted** *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006e4) **4. Stillbirth.** *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006e5) **5. Infant death within 1 month of life** *[0]* ○ 0 No *[1]* ○ 1 Yes (CTN0027CDD:t_frSAE.SAE006f) **f. Required intervention to prevent one of the above outcomes** *[0]* ○ 0 No *[1]* ○ 1 Yes
12.	**7. Severity of SAE** *(check only one)*	(CTN0027CDD:t_frSAE.SAE007) *[1]* ○ 1 Mild *[2]* ○ 2 Moderate *[3]* ○ 3 Severe *[4]* ○ 4 Life-threatening *[5]* ○ 5 Death
13.	**8. SAE actions taken** *(check all that apply)*	(CTN0027CDD:t_frSAE.SAE0081) *[1]* ☐ 1 None (CTN0027CDD:t_frSAE.SAE0082) *[2]* ☐ 2 Delayed study drug dose (> 24 hour delay) (CTN0027CDD:t_frSAE.SAE0083) *[3]* ☐ 3 Increased study drug dose (CTN0027CDD:t_frSAE.SAE0084) *[4]* ☐ 4 Reduced study drug dose (CTN0027CDD:t_frSAE.SAE0085) *[5]* ☐ 5 Discontinued study drug temporarily (> 24 hour delay) (CTN0027CDD:t_frSAE.SAE0086) *[6]* ☐ 6 Discontinued study drug permanently (CTN0027CDD:t_frSAE.SAE0087) *[7]* ☐ 7 Discontinued Meth (CTN0027CDD:t_frSAE.SAE0088) *[8]* ☐ 8 Discontinued Bup
14.	**9. Relationship to Study Drug** *(check only one)*:	(CTN0027CDD:t_frSAE.SAE009) *[1]* ○ 1 Unrelated *[2]* ○ 2 Possibly *[3]* ○ 3 Probably *[4]* ○ 4 Definitely
15.	**10. Was event expected?**	(CTN0027CDD:t_frSAE.SAE010) *[0]* ○ 0 No *[1]* ○ 1 Yes
16.	**11. SAE Outcome**	(CTN0027CDD:t_frSAE.SAE011) *[1]* ○ 1 Resolved *[2]* ○ 2 Resolved with sequelae *[3]* ○ 3 Not resolved **[4]** ○ 4 Death **Date of Death:** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frSAE.SAE011a)

* Item is not required

CDD: CTN0027CDD Table: t_frSAE Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
VSDTAE	DATE - DDMONYYYY	
SAE00A	NUMERIC - N3	
SAE001	NUMERIC	
SAE009	NUMERIC	
SAE010	NUMERIC	
SAE011	NUMERIC	
SAE006e2	NUMERIC	
SAE006e3	NUMERIC	
SAE006e4	NUMERIC	
SAE001a	NUMERIC - N3	

SAE002	STRING(200) - A200	
SAE003	STRING(255) - A500	
SAE004	DATE - DDMONYYYY	
SAE005	DATE - DDMONYYYY	
SAE006a	NUMERIC	
SAE006b	NUMERIC	
SAE006c	NUMERIC	
SAE006d	NUMERIC	
SAE007	NUMERIC	
SAE0087	STRING(255)	
SAE0088	STRING(255)	
SAE006e	NUMERIC	
SAE006e1	NUMERIC	
SAE006e5	NUMERIC	
SAE006f	NUMERIC	
SAE0081	STRING(255)	
SAE0082	STRING(255)	
SAE0083	STRING(255)	
SAE0084	STRING(255)	
SAE0085	STRING(255)	
SAE0086	STRING(255)	
SEQNUMGEN	STRING(255)	
SAE011a	DATE - DDMONYYYY	
SEQNUM	NUMERIC - N2	
VISWKAE	NUMERIC - N2	

ctn0027 : Serious Adverse Event, 12, 13 (SAE2a) - Repeating Form

#		Seq Num	Assessment Date	Drug Name	Lot Number	Expiration Date	Quantity Administered	Start Date	Date Last Taken	Tests/Data/Dates	
1											

1.	**Seq Num**	xx (CTN0027CDD:t_frSAE2a.SEQNUM)
2.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE2a.VSDTAE)
Serious Adverse Event (continued)		
3. *	**12. Study Drug Name**	(CTN0027CDD:t_frSAE2a.SAE012) *[1]* 1 Methadone *[2]* 2 Buprenorphine (BUP)
4. *	**Study Drug Lot Number**	A50 (CTN0027CDD:t_frSAE2a.SAE012a)
5. *	**Study Drug Expiration Date**	Req / Req (2006-2011) (CTN0027CDD:t_frSAE2a.SAE012b) month / year
6. *	**Quantity of Study Drug Administered**	xxx mg *(buprenorphine dosed by sublingual tablet once daily; methadone dose by ingestion)* (CTN0027CDD:t_frSAE2a.SAE012c)
7. *	**Study Drug Start Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE2a.SAE012d)
8. *	**Date Study Drug Last Taken**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE2a.SAE012e)
9. *	**13. Relevant tests/laboratory data, including dates**	A200 (CTN0027CDD:t_frSAE2a.SAE013)

* Item is not required

CDD: CTN0027CDD Table: t_frSAE2a Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SEQNUM	NUMERIC - N2	
VSDTAE	DATE - DDMONYYYY	
SAE012	NUMERIC	
SAE012a	STRING(50) - A50	
SAE012b	DATE - MONYYYY	
SAE012c	NUMERIC - N3	
SAE012d	DATE - DDMONYYYY	
SAE012e	DATE - DDMONYYYY	
SAE013	STRING(200) - A200	

ctn0027 : Serious Adverse Event (continued) (SAE2b) - Repeating Form

#		Seq Num	Assessment Date	Concomitant Drug Therapy	
1					

1.	**Seq Num**	xx (CTN0027CDD:t_frSAE2b.SEQNUM)	
2.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE2b.VSDTAE)	
	Drug	**Quantity**	**Route**
3.			

Concomitant Drug Therapy Entry

3.a*	**14a. Drug *(including generic name)***	A100	(CTN0027CDD:t_frSAE2b.SAE014a)
3.b*	**14b. Quantity per Administration**	A100	(CTN0027CDD:t_frSAE2b.SAE014b)
3.c*	**14c. Route of Administration**	A100	(CTN0027CDD:t_frSAE2b.SAE014c)

* Item is not required

CDD: CTN0027CDD Table: t_frSAE2b Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
VSDTAE	DATE - DDMONYYYY	
SAE014a	STRING(100) - A100	
SAE014b	STRING(100) - A100	
SAE014c	STRING(100) - A100	
SEQNUM	NUMERIC - N2	

ctn0027 : Serious Adverse Event (continued), page 22._____ (SAE3) - Repeating Form

#		Seq Num	Assessment Date	Relevant History	Comments	Site Clinician	Phone Number	Email	SAE reporter	Clinician signed	Safety Monitor	Safety Monitor signed	
1													

1.	**Seq Num**	xx (CTN0027CDD:t_frSAE3.SEQNUM)
2.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frSAE3.VSDTAE)
Serious Adverse Event (continued)		
3.	**15. Relevant history, including date of consent and pre-existing medical conditons *(e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*:**	A200 (CTN0027CDD:t_frSAE3.SAE015)
4.*	**16. Additional Comments:**	A200 (CTN0027CDD:t_frSAE3.SAE016)
5.	**17a. Site Medical Clinician's Name:**	A50 (CTN0027CDD:t_frSAE3.SAE017a)
6.	**17b. Phone Number:**	(xxx) (CTN0027CDD:t_frSAE3.SAE017b1) - xxx (CTN0027CDD:t_frSAE3.SAE017b2) xxxx (CTN0027CDD:t_frSAE3.SAE017b3)
7.	**17c. Email:**	A50 (CTN0027CDD:t_frSAE3.SAE017c)
8.	**17d. SAE reporter's Name**	A50 (CTN0027CDD:t_frSAE3.SAE017d)
9.	**17e. Site Medical Clinician's signature date:**	NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frSAE3.SAE017e2)
10.	**17f. Study Safety Monitor's name**	A50 (CTN0027CDD:t_frSAE3.SAE017f)
11.	**17g. Study Safety Monitor's signature date**	NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frSAE3.SAE017g2)

* Item is not required

CDD: CTN0027CDD Table: t_frSAE3 Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
SAE017f	STRING(50) - A50	
SAE017g2	DATE - DDMONYYYY	
SEQNUM	NUMERIC - N2	
VSDTAE	DATE - DDMONYYYY	
SAE015	STRING(200) - A200	
SAE016	STRING(200) - A200	
SAE017a	STRING(50) - A50	
SAE017b1	NUMERIC - N3	
SAE017b2	NUMERIC - N3	
SAE017b3	NUMERIC - N4	
SAE017c	STRING(50) - A50	
SAE017d	STRING(50) - A50	
SAE017e2	DATE - DDMONYYYY	

ctn0027 : Pregnancy and Outcome (POC)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPOC.VISITDT)
2.	**Week Number**	(CTN0027CDD:t_frPOC.rcVSFRNUM) **[99]** ○ xxx (n <= 32) (CTN0027CDD:t_frPOC.tcVSFRNUM) *[96]* ○ NA
Section I: Information about Pregnancy		
3.	**1. Who discovered the pregnancy?**	(CTN0027CDD:t_frPOC.POC001) *[1]* ○ 1 Study Participant *[2]* ○ 2 Study Staff *[96]* ○ NA
4.	**2. How was the pregnancy verified?**	(CTN0027CDD:t_frPOC.rgPOC002a) **[99]** ○ **(Select all that apply)** (CTN0027CDD:t_frPOC.POC002a) *[1]* ☐ 1 Urine Pregnancy Test (CTN0027CDD:t_frPOC.POC002b) *[2]* ☐ 2 Serum Pregnancy Test (CTN0027CDD:t_frPOC.POC002c) *[3]* ☐ 3 Ultrasound *[96]* ○ NA
5.	**3. Date on which the pregnancy was verified:**	(CTN0027CDD:t_frPOC.rgPOC003) **[99]** ○ Req / Req / Req (2006-2010) (CTN0027CDD:t_frPOC.POC003) *[96]* ○ NA
6.	**4. Date on which study staff was aware of pregnancy:**	(CTN0027CDD:t_frPOC.rgPOC004) **[99]** ○ Req / Req / Req (2006-2010) (CTN0027CDD:t_frPOC.POC004) *[96]* ○ NA
7.	**5. Date on which study medication was discontinued:**	(CTN0027CDD:t_frPOC.rgPOC005) **[99]** ○ Req / Req / Req (2006-2010) (CTN0027CDD:t_frPOC.POC005) *[96]* ○ NA
8.	**6. Approximate due date:**	(CTN0027CDD:t_frPOC.rgPOC006) **[99]** ○ Req / Req / Req (2006-2010) (CTN0027CDD:t_frPOC.POC006) *[96]* ○ NA
Section II: Outcome of Pregnancy		
9.	**7. Outcome of Pregnancy:**	(CTN0027CDD:t_frPOC.POC007) *[1]* ○ 1 Normal **[2]** ○ 2 Abnormal **7.a** If Abnormal Outcome, specify abnormality: (CTN0027CDD:t_frPOC.POC007a) A100 *[3]* ○ 3 Miscarriage *[4]* ○ 4 Terminated **[5]** ○ 5 Other **7.b** If Other, Outcome, specify other: (CTN0027CDD:t_frPOC.POC007b) A100 *[96]* ○ NA
10.	**8. Date of Delivery:**	(CTN0027CDD:t_frPOC.rgPOC008) **[99]** ○ NReq / Req / Req (2006-2010) (CTN0027CDD:t_frPOC.POC008) *[96]* ○ NA
11.	**9. Number of live births - *this pregnancy*?**	(CTN0027CDD:t_frPOC.POC009) **[0]** ○ 0 **9.a** If 0 live births, indicate reason: (CTN0027CDD:t_frPOC.POC009a) *[1]* ○ 1 *[2]* ○ 2 *[3]* ○ 3 *[96]* ○ NA A100
12.	**10. Type of Delivery**	(CTN0027CDD:t_frPOC.POC010) *[1]* ○ 1 Vaginal *[2]* ○ 2 Cesarean Section *[96]* ○ NA

CDD: CTN0027CDD Table: t_frPOC Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
rgPOC004	NUMERIC	
VISITDT	DATE - DDMONYYYY	
rcVSFRNUM	NUMERIC	
tcVSFRNUM	NUMERIC - N3	
POC001	NUMERIC	
rgPOC002a	NUMERIC	
POC002a	STRING(255)	
POC002b	STRING(255)	
POC002c	STRING(255)	
rgPOC003	NUMERIC	
POC008	DATE - DDMONYYYY	
POC009	NUMERIC	
POC009a	STRING(100) - A100	
POC004	DATE - DDMONYYYY	
rgPOC005	NUMERIC	
POC005	DATE - DDMONYYYY	
rgPOC006	NUMERIC	
POC006	DATE - DDMONYYYY	
POC007	NUMERIC	
POC007a	STRING(100) - A100	
POC007b	STRING(100) - A100	
rgPOC008	NUMERIC	
POC010	NUMERIC	
POC003	DATE - DDMONYYYY	

ctn0027 : Pregnancy and Outcome Contd (POC NB)

1.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPOC1A.VISITDT)
2.	**Week Number**	(CTN0027CDD:t_frPOC1A.rcVSFRNUM) **[99]** xxx (n <= 32) (CTN0027CDD:t_frPOC1A.tcVSFRNUM) *[96]* NA

	Gender	Weeks	Days	Lbs	Ozs	Length	Circumference	APGAR Score: 1 min	APGAR Score: 5 min	APGAR Score: 24 hrs	Normal	Specify	Contributing factors
3.													

Newborn Information Entry

3.a	**Gender**	(CTN0027CDD:t_frPOC1A.POC011a) *[1]* 1 Male *[2]* 2 Female *[96]* NA
3.b	**Gestational age at delivery: Weeks**	(CTN0027CDD:t_frPOC1A.rgPOC011b1) **[99]** xx Weeks (CTN0027CDD:t_frPOC1A.POC011b1) *[96]* NA
3.c	**Gestional age at delivery: Days**	(CTN0027CDD:t_frPOC1A.rgPOC011b2) **[99]** x Days (CTN0027CDD:t_frPOC1A.POC011b2) *[96]* NA
3.d	**Weight: lbs**	(CTN0027CDD:t_frPOC1A.rgPOC011c1) **[99]** xx lbs (CTN0027CDD:t_frPOC1A.POC011c1) *[96]* NA
3.e	**Weight: ozs**	(CTN0027CDD:t_frPOC1A.rgPOC011c2) **[99]** xx ozs (CTN0027CDD:t_frPOC1A.POC011c2) *[96]* NA
3.f	**Length**	(CTN0027CDD:t_frPOC1A.rgPOC011d) **[99]** xx cm (CTN0027CDD:t_frPOC1A.POC011d) *[96]* NA
3.g	**Head circumference**	(CTN0027CDD:t_frPOC1A.rgPOC011e) **[99]** xx cm (CTN0027CDD:t_frPOC1A.POC011e) *[96]* NA
3.h	**APGAR Score: 1 min**	(CTN0027CDD:t_frPOC1A.rgPOC011f1) **[99]** xx 1 min (CTN0027CDD:t_frPOC1A.POC011f1) *[96]* NA
3.i	**APGAR Score: 5 min**	(CTN0027CDD:t_frPOC1A.rgPOC011f2) **[99]** xx 5 min (CTN0027CDD:t_frPOC1A.POC011f2) *[96]* NA
3.j	**APGAR Score: 24 hrs**	(CTN0027CDD:t_frPOC1A.rgPOC011f3) **[99]** xx 24 hrs (CTN0027CDD:t_frPOC1A.POC011f3) *[96]* NA
3.k	**Normal infant?**	(CTN0027CDD:t_frPOC1A.POC011g) *[0]* No *[1]* Yes *[96]* NA
3.l	**If No, specify abnormality:**	(CTN0027CDD:t_frPOC1A.rgPOC011g1) **[99]** A200 (CTN0027CDD:t_frPOC1A.POC011g1) *[96]* NA
3.m	**Contributing factors to abnormality**	(CTN0027CDD:t_frPOC1A.rgPOC011g2) **[99]** A200 (CTN0027CDD:t_frPOC1A.POC011g2) *[96]* NA

If more than 3 babies, record physical characteristics and any abnormality and contributing factors in comments.

4.*	**14. Comments:**	(CTN0027CDD:t_frPOC1A.rgPOC012) **[99]** A200 (CTN0027CDD:t_frPOC1A.POC012) *[96]* NA

* Item is not required

CDD: CTN0027CDD Table: t_frPOC1A Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
POC011d	NUMERIC - N2	
rgPOC011e	NUMERIC	
POC011e	NUMERIC - N2	
rcVSFRNUM	NUMERIC	
tcVSFRNUM	NUMERIC - N3	
POC011a	NUMERIC	
rgPOC011b1	NUMERIC	
POC011b1	NUMERIC - N2	
rgPOC011b2	NUMERIC	
POC011b2	NUMERIC - N1	
rgPOC011c1	NUMERIC	
POC011c2	NUMERIC - N2	
rgPOC011f1	NUMERIC	
POC011f1	NUMERIC - N2	
rgPOC011f2	NUMERIC	
POC011f2	NUMERIC - N2	
rgPOC011f3	NUMERIC	
rgPOC011g2	NUMERIC	
POC011g2	STRING(200) - A200	
POC011f3	NUMERIC - N2	
POC011g	NUMERIC	
rgPOC011g1	NUMERIC	
POC011g1	STRING(200) - A200	
rgPOC012	NUMERIC	
POC012	STRING(200) - A200	

VISITDT	DATE - DDMONYYYY	
POC011c1	NUMERIC - N2	
rgPOC011c2	NUMERIC	
rgPOC011d	NUMERIC	

ctn0027 : Protocol Violation (PVL) - Repeating Form

#		Week #	Assessment Date	PV Date	4 Violation Type	Description of PV	PV Resolved?	Comments	
1									

1.	**Week #**	xx (-1 =< n <= 32) (CTN0027CDD:t_frPVL.VISWEEK)
2.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPVL.VISITDT)
To be filled in by person(s) reporting this protocol violation:		
3.	**Date of violation:**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frPVL.PVL001)
4.	**Violation Type:**	Pulldown List 1 (CTN0027CDD:t_frPVL.PVL002) If Other is indicated, please provide the specification: (CTN0027CDD:t_frPVL.PVL002A) A50
5.	**Description of violation:**	A200 (CTN0027CDD:t_frPVL.PVL003)
6.	**Has this Protocol Violation been resolved?**	(CTN0027CDD:t_frPVL.PVL004) *[0]* ○ No **[1]** ○ 1 Yes - If Yes: Indicate resolution below. (CTN0027CDD:t_frPVL.PVL005) **Protocol violation resolution:** A255
7. *	**Comments:**	A255 (CTN0027CDD:t_frPVL.PVL006)

* Item is not required

Pulldown List 1:

RefName	Display Text	Value	Design Note
iePV_01	01A-No consent/assent obtained	1	
iePV_02	01B-Invalid/incomplete informed consent	2	
iePV_03	01C-Unauthorized assessments and/or procedures conducted prior to obtaining informed consent	3	
iePV_04	01D-Informed Consent Other (specify)	4	
iePV_05	02-Inclusion/Exclusion Criteria	5	
iePV_06	03-Concomitant Medication/Therapy	6	
iePV_07	04A-Required testing not obtained	7	
iePV_08	04B-Testing completed outside window	8	
iePV_09	04C-Unauthorized test/procedure obtained	9	
iePV_10	04D-Laboratory Assessments/ Procedures Other (specify)	10	
iePV_11	05A-Protocol required procedures not obtained	11	
iePV_12	05B-Procedure/ assessment obtained outside visit window/ timeframe	12	
iePV_13	05C-Study Procedures Other (specify)	13	
iePV_14	06A-SAE not reported	14	
iePV_15	06B-SAE reported out of time window	15	
iePV_16	06C-Serious Adverse Event Other (specify)	16	
iePV_17	07A-Randomization procedures not followed	17	
iePV_18	07B-Ineligible participant randomized	18	
iePV_19	07C-Improper un-blinding procedures	19	
iePV_20	07D-Randomization Procedures Other (specify)	20	
iePV_21	08A-Ineligible participant dispensed (given) medication	21	
iePV_22	08B-Incorrect medication dispensed (given to participant)	22	
iePV_23	08C-Incorrect medication dosage or amount of medication dispensed (given to participant)	23	
iePV_24	08D-Study Drug Dosing Other (specify)	24	
iePV_25	09A-Intervention not provided per protocol schedule or outside visit window/ timeframe	25	
iePV_26	09B-Incorrect Intervention Assignment	26	
iePV_27	09C-Behavioral Intervention Other (specify)	27	
iePV_28	10A-Visit conducted outside of window	28	
iePV_29	99A-Destroying study materials prior to obtaining authorization from Lead Node and/or other appropriate parties	29	
iePV_30	99B-Participating site starting the study prior to obtaining appropriate IRB(s) and/or CT approvals and any other approvals that would affect the ability to use the data for final analysis	30	
iePV_31	99C-Using advertising materials or brochures without prior IRB approval;	31	
iePV_99	99D-Other (specify)	99	

CDD: CTN0027CDD Table: t_frPVL Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
PVL005	STRING(255) - A255	
PVL006	STRING(255) - A255	
VISWEEK	NUMERIC - N2	
VISITDT	DATE - DDMONYYYY	
PVL001	DATE - DDMONYYYY	
PVL002	STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 99	
PVL002A	STRING(50) - A50	
PVL003	STRING(200) - A200	

PVL004	NUMERIC	

ctn0027 : Study Medication Change Form (MED)

1.	**Week #**	xx (-1 =< n <= 32) (CTN0027CDD:t_frDIS.VISWEEK)
2.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frDIS.VISITDT)
Inactive Status:		
3.	**1. Participant changed to:**	(CTN0027CDD:t_frDIS.DIS003) *[1]* ◯ 1-Methadone *[2]* ◯ 2-Buprenorphine\Naloxone Date: Req / Req / Req (2006-2010) (CTN0027CDD:t_frDIS.dcDIS003)
4.	**2. Reason for medication change***(check all that apply)*:	(CTN0027CDD:t_frDIS.DIS004b) *[1]* ☐ Pregnancy (Only if on BUP/NX) (CTN0027CDD:t_frDIS.DIS004c) **[1]** ☐ Elevated liver enzymes - **Check all that apply:** (CTN0027CDD:t_frDIS.DIS004c1) *[1]* ☐ ALT > 10x UNL (CTN0027CDD:t_frDIS.DIS004c2) *[1]* ☐ AST > 10x UNL (CTN0027CDD:t_frDIS.DIS004c3) *[1]* ☐ Total/Direct Bilirubin > 2x UNL (CTN0027CDD:t_frDIS.DIS004c4) *[1]* ☐ INR > 1.5 x UNL
5. *	**3. Comments:**	A200 (CTN0027CDD:t_frDIS.DIS005)

* Item is not required

CDD: CTN0027CDD Table: t_frDIS Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
DIS004b	STRING(255)	
DIS004c	STRING(255)	
DIS004c1	STRING(255)	
DIS004c2	STRING(255)	
DIS004c3	STRING(255)	
DIS004c4	STRING(255)	
DIS005	STRING(200) - A200	
VISWEEK	NUMERIC - N2	
VISITDT	DATE - DDMONYYYY	
DIS003	NUMERIC	
dcDIS003	DATE - DDMONYYYY	

ctn0027 : Study Termination (TERM)

1.	**Week #**	xx (-1 =< n <= 32) (CTN0027CDD:t_frTERM.VISWEEK)
2.	**Assessment Date**	Req / Req / Req (2006-2010) (CTN0027CDD:t_frTERM.VISITDT)
3.	**Did participant complete the study?**	(CTN0027CDD:t_frTERM.TER001) *[0]* No **[1] Yes, specify date:** Req / Req / Req (2006-2010) (CTN0027CDD:t_frTERM.dcTER001)
4.	**Whose decision was it to withdraw / terminate?**	(CTN0027CDD:t_frTERM.TER002) *[1]* Investigator's decision *[2]* Participant's Decision *[96]* NA
5.	**Reason for withdrawal / termination (Check only one Reason):**	(CTN0027CDD:t_frTERM.TER003a) **[1]** Screen failure (Check all that apply) (CTN0027CDD:t_frTERM.TER003aa) *[11]* Did not meet inclusion/exclusion criteria (CTN0027CDD:t_frTERM.TER003ab) *[12]* Did not complete screening within 30 days of consent (CTN0027CDD:t_frTERM.TER003ac) *[13]* Participant changed mind regarding participation (CTN0027CDD:t_frTERM.TER003b) *[2]* Missed 14 or more consecutive days of study medication (CTN0027CDD:t_frTERM.TER003c) *[3]* No longer wishes to participate (CTN0027CDD:t_frTERM.TER003d) *[4]* Administrative discharge (behavioral problems etc.) (CTN0027CDD:t_frTERM.TER003e) *[5]* Withdrew consent (CTN0027CDD:t_frTERM.TER003f) **[6]** No longer medically appropriate for study (check all that apply) (CTN0027CDD:t_frTERM.TER003fa) *[61]* Adverse event - record on AE CRF; if serious, complete questions and SAE CRF (CTN0027CDD:t_frTERM.TER003fb) *[62]* Pregnancy (CTN0027CDD:t_frTERM.TER03fc1) *[71]* Elevated liver enzyme: ALT>10x UNL (CTN0027CDD:t_frTERM.TER03fc2) *[72]* Elevated liver enzyme: AST>10x UNL (CTN0027CDD:t_frTERM.TER03fc3) *[73]* Elevated liver enzyme: Total/direct bilirubin>2x UNL (CTN0027CDD:t_frTERM.TER03fc4) *[74]* Elevated liver enzyme: INR>1.5x UNL (CTN0027CDD:t_frTERM.TER003fd) *[64]* Taking opioid medication (CTN0027CDD:t_frTERM.TER003fe) *[65]* Physical illness (disabling condition that precludes them from taking study medication) (CTN0027CDD:t_frTERM.TER003ff) *[66]* Requires more than 1 medical detoxification (sign they need more intensive treatment) (CTN0027CDD:t_frTERM.TER003fg) *[67]* Taking medication on the disallowed list (CTN0027CDD:t_frTERM.TER003fh) *[68]* Emergence of another substance abuse problem which necessitates inpatient admission or far more aggressive treatment than provided by the protocol (CTN0027CDD:t_frTERM.TER003fi) **[1]** Other (specify:) A30 (CTN0027CDD:t_frTERM.TER003fs) (CTN0027CDD:t_frTERM.TER003g) **[1]** Other (specify:) A30 (CTN0027CDD:t_frTERM.TER003gs) (CTN0027CDD:t_frTERM.TER003na) *[96]* NA
6.	**Last Study Drug Dose Date:**	(CTN0027CDD:t_frTERM.TER004) **[2]** NReq / NReq / NReq (2006-2010) (CTN0027CDD:t_frTERM.dcTER004) *[96]* NA
7.	**Did participant complete termination visit?**	(CTN0027CDD:t_frTERM.TER005) *[1]* Yes *[0]* No *[96]* NA

CDD: CTN0027CDD Table: t_frTERM Key Type: PATIENTVISIT

Column Name	Column Data Type	Design Note
VISWEEK	NUMERIC - N2	
TER003fs	STRING(30) - A30	
TER003g	STRING(255)	
TER003c	STRING(255)	
TER003fa	STRING(255)	
TER003fb	STRING(255)	
TER03fc1	STRING(255)	
TER03fc2	STRING(255)	
TER03fc3	STRING(255)	
TER03fc4	STRING(255)	
TER003fd	STRING(255)	
TER003fe	STRING(255)	
TER003ff	STRING(255)	
TER003fg	STRING(255)	
TER003fh	STRING(255)	
TER003fi	STRING(255)	
TER003e	STRING(255)	
TER003f	STRING(255)	
TER003gs	STRING(30) - A30	
TER003na	STRING(255)	
TER004	NUMERIC	
dcTER004	DATE - DDMONYYYY	
TER005	NUMERIC	
TER001	NUMERIC	

dcTER001	DATE - DDMONYYYY	
TER002	NUMERIC	
TER003a	STRING(255)	
TER003aa	STRING(255)	
TER003ab	STRING(255)	
TER003ac	STRING(255)	
TER003b	STRING(255)	
TER003d	STRING(255)	
VISITDT	DATE - DDMONYYYY	