CTN-0046 S-CAST

SDTM 1.1/IG 3.1.1 ANNOTATION FOR CTN0046

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NOTE: Boxed annotations indicate supplemental qualifier variables. Result found in QVAL field.

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F	orm completion (if fo	rm not complete, check one):	DOMAIN: AE
	1 Participant unavai	lable 🔲 2 Data collection	error 🔲 3 Pa	ficipant unable/unwilling to answer
USUBJID	Node #:	CTP Site ID #:		Participant ID #:
	Assessment	Date:/AE	DTC /	Week #:

DOMAIN: AE

	Assessment Date:/ Week #:
40	501 Adverse Events Source Document
_	AF symptom or diagnosis (and AF and form). AFTERM
1	At symptom or diagnosis jone At per form):
	1a If AE was a seizure, check here: □₁ ← QNAM=AESEIZ QLABEL=AE WAS A SEIZURE
2	Onset date (month in 3 letters, DD, YYYY):/AESTDTC IDVAR=AESEQ
3	Severity (check only one):, Mild
	Severe AESEV
	Life-threatening
	s Death
4	Was the event associated with any of the following (if more than one answer applies, please choose the most serious)?
	None of the following:
	Death? QLABEL=AE INPATIENT ADMISSION
	A life-threatening event? No Yes AESLIFE IDVAR=AESEQ
	Inpatient admission to hospital?
	A persistent or significant disability or incapacity? No, YesAESDISAB_ONAM=AFHSOP2
	OLAREL AF PROLONG HOCKITALIZATIO
	Required significant intervention to prevent permanent
	impairment/damage?
5	Bupropion XL related (check only one)?
6	Nicotine inhaler related (check only one)? Unrelated Probably related QNAM=AEREL1 QLABEL=NICOTINE INHALER RELATED IDVAR=AESEQ
	6a Action(s) taken for nicotine inhaler (check all that apply): □₀ None □₃ Temporarily stopped therapy
	QNAM=AEACN1 QLABEL=NICOTINE INHALER ACTION TAKEN QLABEL=NICOTINE INHALER ACTION TAKEN
	IDVAR=AESEQ Lacreased therapy Ls Participant terminated from study
7	Behavioral intervention related (check only one)?
	7a Action(s) taken (check all that apply): One State of the same o
QN	IAM=AEACN2 Decreased therapy
	ABEL=BEHAVIORAL INT ACTION TAKEN VAR=AESEQ Increased therapy Sparticipant terminated from study
8	Outcome (check only one): Ongoing
	Resolved AEOUT
	Resolved with sequelae
	4 Resolved by convention
	□ ₅ Death AEENDTC
9	Resolution Date (month in 3 letters, DD, YYYY):/
	monft day y≠ar

CTN-0046 S-CAST	ו	Form completion (if form not complete, check one):			
J-CAJ I	N	ode #: CTP S	ite ID #:	Participant ID #:	
		Assessment Date	month day	/ Visit #:	
4602 CTN-ASI Lite v.1					
Medical: Dro	vg:	Legal:	0.00000-000 0	Psychiatric:	
Employment: Alc	ohol:	Family:			
Introducing the CTN-A	SI Lite v. 1	<u> </u>		7.00 m	
All clients receive this same standa There are two time periods we w Participant Rating Scale: Particip	ill discuss: 1. The past 2. Lifetime	30 days Data		Key: Participant Rating Scale	
scale to let me know how bothered you how important treatment is for	you have been by an	y problems in each :			
Please refer to the Participant Rating	g Scale in the adjacen	t key.		2 = Moderately	
If you are uncomfortable giving an	answer, then don't an	iswer.		3 = Considerably	
The State of the S	do not give inaccur			4 = Extremely	
	351			Ñ	
Interviewer Instruction	15				
 Leave no blanks Make plenty of comments (if and his/her problems). Throughout the ASI, please note Terminate interview if client miss 	if not answered or n	ot applicable in the c		picture of the client's perceptions o	
5. When noting comments, please					
HALF TIME RULE: If a question as Round up 6 mo	ks the number of mor nths or more to 1 yea	[1] [THE SECTION SECT	ls of 14 days or m	ore to 1 month.	

- 2. Make his/her
- 3. Through
- 4. Termin
- 5. When

CONFIDENCE RATINGS: → Last two items in each section.

- → Do not over interpret.
- → Denial does not warrant misrepresentation.
- → Misrepresentation = overt contradiction in information.

Probe and make plenty of comments!

There were a number of variables that had a high level variable that was 1 for answering, 97 for NOT ANSWERED and 96 or 98 for NOT APPLICABLE. These were combined with the under variable in a variable with a name base.c. The following variables have been combined:

AsI0d14, asI0d17, asI0d19, asI0d20, asI0d21, asI0d22, asI0d23, asI0d24, asI0d25, asI0d26, asI0d27, asI0e11, asI0e12, asi0e13, asi0e14, asi0e15, asi0e16, asi0e17, asi0e18, asi0e19, asi0e1a, asi0e1b, asi0e2a, asi0e2b, asi0e6a, asi0e6b, asI0F23S, asI0F30, asI0F31, asI0g20, asI0l10, asI0l11, asI0l12, asI0l13, asI0l14, asI0l15, asI0l16, asI0l17, asI0l18, asI0l19, asI0120, asI0121, asI0125, asI0126, asI0127, asI014, asI015, asI016, asI017, asI018, asI019, asI0m1, asI0m6, asI0p12, asI0p1, Asl0p2, asl0l3



Form completion (if f	orm not complete, check one):	DOWAIN. Q3
1 Participant unav	ailable 🔲 2 Data collection error	3 Participant unable/unwilling to answer
Fields affected: □0	Entire CRF 1 Questions (specify):	
Node #:	CTP Site ID #:	Participant ID #:
Assessme	ent Date:/	/ Visit #:

4602 CTN-ASI Lite v. 1: Hollingshead Categories

- 1 = Higher Executive, Major Professionals, Owner of Large Business
- Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher) 2 =
- Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)
- 4 = Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)
- 5 = Skilled Manual—usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)
- Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)
- 7 = Unskilled (attendant, janitor, construction help, unspecified labor, porter). Include Unemployed.
- Homemaker
- Student/No Occupation/Disabled

List of Commonly Used Drugs

Alcohol: Beer, wine, liquor Methadone: Dolophine, LAAM

Opiates: Pain killers = Morphine, Diluaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4

Syrups = Robitussin, Fentanyl

Barbiturates: Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol

Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown, Sed/Hyp/Trang:

Other = Chloral Hydrate (Noctex), Quaaludes

Cocaine: Cocaine Crystal, Free-Base Cocaine or "Crack, and "Rock Cocaine"

Amphetamines: Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin

Methamphetamine: Speed, Ice, Crystal Cannabis: Marijuana, Hashish

Hallucinogens: LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy

Inhalants: Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, etc.

Just note if these are used: Antidepressants,

Ulcer Meds = Zantac, Tagamet

Asthma Meds = Ventoline Inhaler, Theodur Other meds = Antipsychotics, Lithium

Alcohol/Drug Section Instructions

The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However, if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol/drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

- → 30 day questions only require the number of days used.
- → Lifetime use is asked to determine extended periods of use.
- → Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.
- → Alcohol to intoxication does not necessarily mean "drunk;" use the words "felt the effects," "got a buzz," "high," etc., instead of intoxication. As a rule of thumb, 3+ drinks in one setting, or within a brief period of time, or 5+ drinks in one day defines "intoxication."
- → How to ask these questions: → "How many days in the past 30 have you used....?
 - → "How many years in your life have you regularly used....?"

CTN-0046 S-CAST

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected rm completion (if form not complete, check one):

 \square_1 Participant unavailable \square_2 Data collection error \square_3 Participant unable/unwilling to answer

•	S-CAST	Fields affected: □ ₀ Entire CRF	Questions (specify):	
•	J-CAJI	Node #: CTP S	ite ID #: SITEID	Participant ID #:USUBJIC
STCD		EPOCH ? Assessment Date: QSSCAT=GENERAL INFORMATION	QSDTC /	Visit #: VISITN
460	2 CTN-ASI Lite v	. 1: General Information	V2.	- E-1
G14	How long have you SORF lived at your current address?	RESU=YEARS/	Comments:	OT STORED
G18	Do you have a religious preference?	QSORRES/QSSTRESCC Catholic Jaylewish	DATANC	JI STORED
	=G18s	Sother (specify): None one		
G19	Have you been in a controlled environment in the past 30 days? (A place, theoretically, without access to drugs/alcohol)	In No In I		
G20	How many days? (Refers to total number of days detained in the past 30 days)	days OR Not answered Not applicable Not applicable if question G19 is "No." QSORRESU=DAYS		

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

S-CAST	☐ Participant unavailable ☐ Data collection Fields affected: ☐ Entire CRF ☐ Question Node #: CTP Site ID #:	
D		Participant ID #:
4602 CTN-ASI LITE V	. 1: Medical Status	
M1 How many times in your life have you been hospitalized for medical problems? QSTEST	times OR	Comments: DATA NOT STORED
M3 Do you have any chronic medical problems which continue to interfere with your life? M3SP	ONO	
M4 Are you taking any prescribed medication on a regular basis for a physical problem?	On No One of the second of th	
M4SP	or not the participant is currently taking them. The intent is to verify chronic medical problems.	
M 5 Do you receive c pension for a physical disability?	On No	F-32
M6 How many days have you experienced medical problems in the past 30 days?	days OR	
For questions M7 & M8, please	ask participant to use the Participant Rating Scale.	
M7 How troubled or bothered have you been by these medical problems in the past 30 days?	ONOT at all Slightly Extremely Moderately O7 Not answered Restrict response to problem days of question M6.	
M8 How important to you now is treatment for these medical problems?	ONOT at all Gonsiderably Slightly Gonsiderably Moderately Gonsiderably Refers to the need for new or additional medical treatment by the participant.	
	ve information significantly distorted by:	1
M10 Participant's misrepresentation?	□₀ No □₁ Yes	
M11 Participant's inability to understand?	□₀ No □₁ Yes	(

QSCAT=ADDIC	TION SEVERITY INDEX I	LITE (ASL)
Data not collected	rm completion (if form not	complete, check one):
Data Hot collected	Participant unavailable	□ - Data collection e

S-CAST	Fields affected: ☐0 Entire CRF ☐1 Que	
D Q	Assessment Date: SSCAT=EMPLOYMENT/ SUPPORT STATUS	day year
4602 CTN-ASI LITE V.	1: Employment/Support Status	
E1 Education completed:	/ OR	Comments:
QSORRESU	a. years b. months =YEARS QSORRESU=MONTHS • GED = 12 years	
QSTEST	GED = 12 years Include formal education only.	DATA NOT STORED
EA T-11	QSORRES/QSSTRESC	
E2 Training or technical education completed:	a. years / b. months OR	£ 7.00.000.000.000.000.000.000.000.000.00
QSORR	SU=YEARS QSORRESU=MONTHS * Formal/organized training only. For military training, only include	
	training that can be used in civilian life, i.e., electronics or computer	
E4 Do you have a valid	□₀ No	
driver's license?	Yes	
	₉₇ Not answered	
2000	Valid license; not suspended/revoked.	
E5 Do you have an automobile available?	∐₀ No	13124-1-1717-1814-1815-1814-1815-1814-1814-1814-1814
dololloble dvalable.	Yes Or Not answered	# 200 20 A CONTROL OF THE CONTROL OF
	• (If answer to E4 is "No", then E5 must be "No".) Does not require	
	awnership, only requires availability on a regular basis.	-
E6 How long was your	/ OR	
longest full time ob?	SU=YEARS QSORRESU=MONTHS	12222
	 Full time = 35+ hours weekly; does not necessarily mean most recent job. 	
E7 Usual (or (ast) occupation?	OR	
Specify:	• Use Hollingshead Categories Reference Sheet.	
E9 Does someone contribute	□ _o No	
the majority of your	1 Yes	
support?	□ ₉₇ Not answered	Reserved to see these telephones and
	□ ₉₆ Not applicable	
	 Is participant receiving any regular support (i.e., cash, food, housing) from family/friend? Include spouse's contribution; exclude support 	
	port by an institution.	
E10 Usual employment	Tull time (35+ hrs/week)	
pattern, past three years?		
 Answer should represent the majority of the last 3 years, 	3 Part time (irreg., day work)	
not just the most recent selec-	Student	
tion. If there are equal times for more than one category, select	□ ₅ Military service □ ₆ Retired/disability	
that which best represents the		
more current situation	B In controlled environment	
	97 Not answered	
E11 How many days were QSG	DRRESU=DAYS OR 0,7 Not answered	* <u>#22*******************************</u>
	TOTAL NAME Law INCH OHNWEIGH	

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

CTN-0046		ta collection error 🔲 3 Participant unable/unwilling to answer
S-CAST	Fields affected: □₀ Entire CRF □₁ · Node #: CTP Site ID :	
D C	SSCAT=EMPLOYMENT/SUPPORT STATUS Assessment Date:	
	1: Employment/Support Status	
	uch money did you receive from the following in the past 30 days? Max. = \$99999	Comments:
E12 Employment (net income): QSTEST	\$ QSORRESU=DOLLARS OR	DATA NOT STORED
E13 Unemployment compensation:	\$ QSORRESU=DOLLARS OR	
E14 Welfare:	\$ QSORRESU=DOLLARS OR	*
E15 Pensions, benefits, or Social Security:	\$ QSORRESU=DOLLARS OR	å
E16 Mate, family or friends:	S QSORRESU=DOLLARS OR Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments or include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.	
E 17 Illegal:	\$ QSORRESU=DOLLARS OR	
E18 How many people depend on you for the majority of their food, shelter, etc.?	max = 99 OR Not answered *Must be regularly depending on participant; do include alimony/child support; do not include the participant or self-supporting spouse, etc.	·
E19 How many days have you experienced employment problems in the past 30 days?	QSORRESU=DAYS days OR Not enswered • Include inability to find work, if they are actively looking for work problems with present job in which that job is jeopardized.	
	isk participant to use the Participant Rating Scale and E21 refer to question E19. Stress help in fi and them a job.	
E20 How troubled or bothered have you been by these employment problems in the past 30 days?	Onsiderably Slightly Slightly Moderately OSEVLINT=-P30 If the participant has been incarcerated or detained during the past 30 days, they cannot have employment problems.	e
E21 How important to you now is counseling for these employment problems?	Onsiderably Slightly Moderately Moderately Somewhat Considerably Extremely Not answered Not applicable	
	e information significantly distorted by:	
E23 Participant's misrepresentation?	□₀ No □₁ Yes	
E24 Participant's inability to understand?	□₀ No □₁ Yes	

CTN-0046 S-CAST

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collecte		vailable 🔲 2 Data co	ollection error	3 Participant unable/unwillin	-
	Node #:	CTP Site ID #:_	SITEID	Participant ID #:	USUBJID
	Assassm	ent Date:	QSDTC	/ Visit	# VISITNU

to ute of Administration: - Oral 2 - Nasal 3 - Note the usual or most recent the routes are listed from least sevent ould be "Not answered." QSTEST	route. For more ere to most sever	than one route, c	hoose the most severe. and Lifetime Use are zero, route	DATA NOT STORED
Substance	A Past 30 (Days)	B Lifetime Use (Years)	C Route of Administration	57 28 55 55 55 55 56
1 Alcohol (any use of all):	QSORRESU =DAYS	QSORRESU =YEARS		
2 Alcohol (to intoxicution):				
3 Heroin:	2 7777- 1		☐ 1 Oral ☐ 4 Non IV injection ☐ 2 Nasal ☐ 5 IV injection ☐ 3 Smoking ☐ 96 Not applicable ☐ 97 Not answered	
Methadone/LAAM (prescribed):			Oral 4 Non IV injection No sal 5 IV injection Smoking 96 Not applicable	
94a Methadone/LA/AM (illicit):			Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable 97 Not answered	
Other Opiates/ Analgesics:	3 <u>55567-</u> 16		Oral 4 Non IV injection No Smoking 96 Not applicable	
06 Barbiturates:			Oral 4 Non IV injection No sal 5 IV injection Smoking 96 Not applicable	
Other Sedatives/ Hypnotics/Tranquilizers:			Oral 4 Non IV injection No sal 5 IV injection Smoking 6 Not applicable 7 Not answered	
08 Cocaine:		(1000 - 100 - 100 s	Oral 4 Non IV injection Nosal 5 IV injection Smoking 6 Not applicable	

CTN-0046 S-CAST

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

 \square_1 Participant unavailable $\qquad \square_2$ Data collection error $\qquad \square_3$ Participant unable/unwilling to answer

S-CAST 4602 CTN-ASI LITE Route of Administration: 1 - Oral 2 - Nasal 3 - Note the usual or most recent	E V. 1: Drug	RUG/ALCOHOL US g/Alcohol SORRES/QSSTRE	Use (continued)	Participant ID #: USUB
The routes are listed from least se should be "Not answered." QSTEST Substance	A Past 30 (Days)	e. If Past 30 Days	C Route of Administration	DATA NOT STORED
D9 Amphetamines:	QSORRESU =DAYS	QSORRESU =YEARS	Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable	
D9a Methamphetamine:			☐ 1 Oral ☐ 4 Non IV injection ☐ 2 Nasal ☐ 5 IV injection ☐ 3 Smoking ☐ 96 Not applicable ☐ 97 Not answered	
D10 Cannabis:			Oral 4 Non IV injection Solution Solution Solution	
D11 Hallucinogens:			☐ 1 Oral ☐ 4 Non IV injection ☐ 2 Nasal ☐ 5 IV injection ☐ 3 Smoking ☐ 96 Not applicable ☐ 97 Not answered	
D12 Inhalants:	<u> </u>	<u> </u>	□₂ Nasal □96 Not applicable □97 Not answered	
D13 More than 1 substance per day fincluding alcohol, excluding				

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

	S-CAST	Fiel	ds affected: □0 Entire CRF □1 Question	OITED
D		QSSCAT=DRUG/ALCOHOL USE	Assessment Date: S/QSSTRESC CTP Site ID #:	SITEID
460	2 CTN-ASI LITE	v. 1: Drug/Alcoh	ol Use (continued)	
D14A ir	according to the nterviewer, which ubstance(s) is/are the najor problem?	• Interviewer should determine (excluding Nicotine use). Coo questions 01 - 12 (code presc 00 - no problem, 15 - alcoh	Not answered he major drug or drugs of abuse e the number next to the drug in ibed or illicit methadone as 04). ol and one or more drugs; 16 – more Ask participant when not clear.	Comments: DATA NOT STORED
	low many times have ou had Alcohol DT's?	Delirium Tremens (DT's): Occusignificant decrease in alcohol	Not answered - 24-48 hours after last drink, or intake. Characterized by shaking, flucinations; they usually require	8
		fe have you been treate in/outpatient counseling and AA or	l for: NA (if 3+ meetings within one month	Rest over to the teach stemes
D19 A	lcohol abuse	OR	Not answered	(
D20	Drug abuse:	OR 🖂 97	Not answered	
How	many of these were	letox only:		
D21	Alcohol:	OR	Not answered Not applicable 2 is Not applicable.	
D22	Drugs:	OR	Not answered Not applicable 22 is Not applicable	3 TO THE RESERVE TO THE RESERVE THE RESERV
How	nuch money would y	ou say you spent during	the past 30 days on:	1-22-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-2-
D23	Akohol:	\$ QSORRESU=DOLLARS OR		
D24	Drugs:	\$ QSORRESU=DOLLARS OR	<u>, </u>	
D25	How many days have you been treated in a outpatient setting for alcohol or drugs in the past 30 days?	- mcrode AA/NA	Not answered	8 -4
D26	How many days in the past 30 have you experienced alcohol problems?	QSORRESU=DAYS OR days OR Include: Craving, withdrawal sy wanting to stop and being unab	₉₇ Not answered imptoms, disturbing effects of use, or ble to.	2 -2

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

For qu	QSTEST	QSSCAT=DRUG/ALCOHO	Node #: CTP	Site ID #:SITEID	Destricted to #4 US
For qu	AN OFFICE A PROPERTY.	Q	Assessment Date SORRES/QSSTRESC	e: QSDTC /_	Participant ID #: Visit #:
	THE R. P. LEWIS CO., LANSING, SPINSTER, SPINST	v. 1: Drug/Al	cohol Use (continue	d)	**
treatm	The participant is ratio		use the Participant Rating onal substance abuse	Comments:	ATA NOT STORED
D28	How troubled or bothered have you been within the past 30 days by alcohol problems?	ONOT at all Slightly Moderately QSEVLINT=-P30	Considerably Extremely Not answered		
D30	How important to you now is treatment for alcohol problems?	On Not at all The Slightly The Moderately	Considerably Extremely Not answered	E	
D27	How many days in the past 30 have you experienced drug problems?	QSORRESU=DAYSdays C Include: Craving, withdraw use, or wanting to stop and QSEVLINT=-P30	al symptoms, disturbing effects of	F1	
D29	How troubled or bothered have you been within the past 30 days by drug problems?	Not at all Slightly Moderately QSEVLINT=-P30	Considerably A Extremely Of Answered	P	
D31	How important to you now is reat- ment for drug problems?	□₀ Not at all □₁ Slightly □₂ Moderately	Considerably Extremely Not answered		
Confid	dence Ratings: Is th	e above information si	ignificantly distorted by:		
D34	Participant's misrepresentation?	□₀ No □₁ Yes			
D35	Participant's inability to understand?	O No Yes	↓		

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

	CIN-0046	Data not collected IIII Companion (in John Not Companion) 1 Participant unavailable 2 Data of Fields affected: 0 Entire CRF 1 Que	ollection error 3 Participant unable/unwilling to answer
	S-CAST	Node #: CTP Site ID #: _	SITEID Participant ID #: USUBJID
	QSSCA [*]	T=LEGAL STATUS Assessment Date: QSORRES/OSSTRESC	
QSTEST	MATERIAL PRODUCTION OF BUILDING TO THE	IN SAVENWEIGH	day ywar
↓ L1	4602 CTN-A SI LITE v. 1:	□ ₀ No □ ₁ Yes □ ₉₇ Not answered	Comments:
L2	the criminal justice system? L2 Are you on parole or probation?	• Judge, probation / parole officer, etc.	DATA NOT STORED
	1 1/2 1 1/2 1 1/2 1 1 1 1 1 1 1 1 1 1 1	been arrested and charged with the following: 15. Do not include juvenile [under age 18] crimes, unless they	
L3	L3 Shoplifting/vandalism:	OR Not answered	
L4	L4 Parole/probation violations:	OR Not answered	
L5	L5 Drug charges:	OR Not answered	
L6	L6 Forgery:	OR Not answered	1022-0-01100000000000000000000000000000
L7	L7 Weapons offense:	OR Not answered	
L8	L8 Burglary/larceny/B&E:	OR Not answered	
L9	L9 Robbery:	OR Not answered	
L10	L10 Assault:	OR ₉₇ Not answered	
L11	L11 Arson:	OR Not answered	
L12 L13	L12 Rape:	OR Not answered	_
	L13 Homicide/manslaughter:	OR Not answered	_
L14 L15	L14 Prostitution: L15 Contempt of court:	OR Not answered	
L16	L16 Other (specify): L16S	OR Not answered	
L17	L17 How many of these charges	OR Or Not answered	_
	resulted in convictions?		AND SUPPLIES OF THE SUPPLIES O
		 Do not include midemeanor offenses from questions 118-L20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas. If L3-L16 = 00, if en L17 = Not applicable 	
	How many times in your life have	you been charged with the following:	
L18	L18 Disorderly conduct, vagrancy, public intoxication:	OR Not answered	
L19	L19 Driving while ntoxicated (DWI):	OR Not answered	
L20	L20 Major driving violations:	OR OR Not answered	
		 Moving violations: speeding, reckless driving, no license, etc. 	

STUDYID = CTN0046 CTN-0046

Data not collected orm completion (if form not complete, check one):

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

0.0	C1M-0040		Participant unavailable \(\bigcup_2 \) Data collected: \(\bigcup_0 \) Entire CRF \(\bigcup_1 \) Question	ction error 3 Participant unable/unwilling to answer
	S-CAST	Nod	e #: CTP Site ID #:	SITEID Participant ID #: USUBJID
QSTES1	TCD QSTEST	QSORRES/0	Assessment Date:	QSDTC / Visit #: VISITNUM
	4602 CTN-ASI LITE V. 1:	1715 CONTRACTOR (11)		
L21	L21 How many months were you incarcerated in your life? QSOR	months C RESU=MONTHS • If incarcerated 2 wee month. List total numbe	R Or Not answered	Comments: DATA NOT STORED
L24	L24 Are you presently awaiting charges, trial or sentence?	□₀ No □₁ Yes	□ ₉₇ Not answered	
L25	L25 What for (refers to L24)?		O. If more than one, choose most I cases, unless a criminal offense is 12 - Rape	
L26	L26 How many days in the past 30 were you detained or incarcerated?	ORRESU=DAYS	Opp Not answered and released on the same day.	
L27	L27 How many days in the past 30 have you engaged in illegal activities for profit?	SORRESU=DAYS • Exclude simple drug po prostitution, selling s ol	Doy Not answered assession. Include drug dealing, en goods, etc. May be cross checked er Employment/Family Support section.	
	For questions L28–29: Please ask p	participant to use the P	articipant Rating Scale.	
L28	L28 How serious do you feel your present legal problems are?	Not at all Slightly Shoderately Exclude civil problems.	Considerably Extremely Open Not answered	
L29	L29 How important to you now is counseling or referral for these legal problems?		Considerably Lacktremely Lacktremely Not answered seed for additional referral to legal ainst criminal charges.	
	Confidence Ratings: Is the above	information significa	atly distorted by:	
L31	L31 Participant's misrepresentation?	□₀ No □₁ Yet		
L32	L32 Participant's inability to understand?	□₀ No □₁ Yes		

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

	A 11.	1-0	<u> </u>			icipant unavailable cted: □₀ Entire CR] ₃ Participant unable/unwilling to answer
	S	-CA		AMILY/SOCIAL RELATION	Node #:	СТР	Site ID #:	SITEID	Participant ID #: USUBJID
QSTES1	CD	QST	EST	QSC	ORRES/QSS	Assessment Dat	te:	QSDTC /_	Visit #: VISITNU
Ţ	NAMES OF TAXABLE PARTY.	The second second second	100101010	. 1: Family/S	19 17 18 18 18		hips	VII.	100
F1		ital status] _s Divorce] _e Neveri	d married swered		Commer D/	ATA NOT STORED
F3		you satisfi situation?	ed with	On No On Yes • Satisfied • Generally like	CHARLES MARKET	100 to	ot answered	0-11	
F4	F4 Usua	al living ingements	(past 3 yrs.):	With sexual part With sexual part With sexual part With children ake With parents With family With friends Alone Controlled environ No stable arrang Por Not answered Choose arrangements in there is an even split in the	ner alone one onment gements out represent ime between	ative of the past 3			
F6		you satisfi e arrangei		□ No □ Yes • Refers to response in qui	1 Indiffe	rent 🔲 ₉₇ No	t answered		
	Do you l	live with (inyone who	•				12.00	
F7		a current o blem?	alcohol	□₀ No □₁ Yes	□ ₉₇ Not d	answered			
F8	F8 Uses drug	s non-preso js?	ribed	□₀ No □₁ Yes	□ ₉₇ Not o	answered			
F9		h whom do nd most of ?		Family 3 Al 2 Friends 97 N If a girlfriend/boyfriend they must refer to them a friend. Family is not to be	ot answere is considered is family thros	as family by parti ghout this section,			
F10	sper	you satisfi nding your way?		No 2 Yes • A satisfied response mus situation. Refers to quest			ot answered	15.55	

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

QSSC QSTEST	AT=FAMILY/SOCIAL RELATIONSHIPS	Assessment Date:	SITEID Participant ID #: US US US US US US US US
The second secon	re v. 1: Family/Socio	The second secon	(continued)
serious problems gettin • "Serious problems" m	t periods in which you have g along with: ean those that endangered the relationst contact of some sort, either by telephone QSEVLINT=-P30 A Past 30 Days	nip.	DATA NOT STORED
F18 Mother:	□₀ No □₀٫ Not answered □₁ Yes □₀₀ Not applicable	d □₀ No □₀٫ Not answ	1
19 Father:	□₀ No □₀٫ Not answered □₁ Yes □₀₀ Not applicable		1
•20 Brother/sisters:	O No O Not answered		l l
•21 Sexual partner/spous	e: O No O To Not answered In Yes O Not applicable		
22 Children:	O No O Py Not answered O Yes O Py Not applicable		
• 23 Other significant fami (specify):			
24 Close friends:	O No O Not answered Types O Not applicable	4	1
25 Neighbors:	□₀ No □₀७७ Not answered □₁ Yes □₀₀ Not applicable	2 13 TO 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
:26 Co-workers:	□ ₀ No □ ₉₇ Not answered □ ₁ Yes □ ₉₆ Not applicable	A	1
Did anyone (F18-F26) sbuse you?	A Past 30 Days	B Lifetime	.
28 Physically (caused you physical harm)?	□₀ No □₀७ Not answered □₁ Yes	d □₀ No □₀⁄7 Not answ □₁ Yes	vered
29 Sexually (forced sexual	□₀ No □₀₂ Not answered	I □₀ No □₀₂ Not answ	

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

Data not collected orm completion (if form not complete, check one):

 \square_1 Participant unavailable \square_2 Data collection error \square_3 Participant unable/unwilling to answer

	S-CAS	T2			Entire CRF □ ₁ Que			
	J-GA	QSSCAT=FAMILY/SOC	NAL BELATIONSHIP	lode #:	CTP Site ID #:	SITEID	Participant ID #	USUBJID
		QSSCAT=FAMILT/SOC	JAL RELATIONSHIP		ment Date:	Q\$DTC /		Visit #: VISITNUM
QSTEST				S/QSSTRESC	month	-	yeor	
\downarrow	4602 CTN-A	SI LITE V. 1: FO	amily/Soci	al Relat	ionships (a	ontinued)		
F30	F30 How many day have you had s with your famil	erious conflicts ^{QSOI} y?	RRESU=DAYays	OR □ ₉₇ No	at answered	Comments:	TA NOT STORED	
	For questions F32 (Scale.	nd F34, please ask	participant to us	e the Partici	pant Rating			
F32	F32 How troubled of you been in the these family p	past 30 days by oblems?	Not at all 1 Slightly 2 Moderately	□₃ Con □₄ Extre □₀₂ Not		5.00 St. 100 S		
F34	family problem Participant is rating	unseling for these s? his/her need for problems, not whether	☐₀ Not at all ☐₁ Slightly ☐₂ Moderately	4 Extre	siderably mely answered			
F31	F31 How many day have you had s with other peo (excluding family)? For questions F33	perious conflicts QSOF ple QS	BEVLINT=-P30					
	Scale.	nu roo, pieuse usk	purncipum ro vs	e the Partici	punt kuting	-	<u> </u>	
F33	F33 How troubled a you been in the these social pro	past 30 days by blems?	Not at all Slightly Moderately SEVLINT=-P30		siderably emely answered		(0.11) - 11 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1	
F35	F35 How important treatment or co social problems	unseling for these		n 's need to seek is loneliness, inab in with friends. Po ssatisfaction, con clude problems t	mely answered treatment for such pility to socialize, pricipant rating flicts, or other seri- teat would be elimi-			
	Confidence Rating	s: Is the above info	rmation signific	antly distor	ted by:			
F37	F37 Participant's misrepresent	ation?	□₀ No □₁	Yes		<u> </u>		
F38	F38 Participant's understand?	inability to	□₀ No □₁	Yes				

STUDYID = CTN0046

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

	TN-00 S-CAST	70		ticipant unav	ailable 🗌	plete, check of 2 Data collecti 1 Questions	on error 3	Participant unable/	unwilling to answer
	3-CA3	QSSCAT=PSYCHIATRIC	Node #			e ID #:		Participant ID	#: USUBJID Visit #: VISITNUM
STESTCI	QSTEST 4602 CTN-A <mark>.SI I</mark>	0.000	QSORRES/QSS	TREGO	em baie.	month	day	year	Y (3)1 W.
	How many times have problems? • Do not include substance abus	you been treated for	any psychol	logical o	series of mo	ore or less	DA	ments:	
P1	P1 In a hospital or inpo	atient setting?	OF	R □ ₉₇ h	Not answe	ered			
P2	P2 As an outpatient/pr	ivate patient?	OF	R □ ₉₇ h	Not answe	ered			
P3	P3 Do you receive a pe disability?	ension for a psychiatric	□₀ No □	Yes [g ₇ Not (answered	2002		
	H ave you had a signif drug/akohol use) in wh				/QSSTRES		200		<u>0.10020-00200-0</u> 9
			A Past 30		BI	ifetime	1		
P4A/	P4 Experienced serious hopelessness, loss o with daily function?	s depression—sadness, of interest, difficulty	QSEVLINT= 0 No 1 Yes 0 Not answ	P30 vered	No 1 Yes Not	answered			
P5A/ P5B	P5 Experienced serious uptight, unreasonab feel relaxed?	anxiety/tension— oly worried, inability to	O No O Yes O Not answ	vered	No Yes 	answered	_	10.000-00-00-00-00-00-00-00-00-00-00-00-0	
P6A/	P6 Experienced hallucin heard voices that of hear or see?		ONO The Notes The Notes of the	ered	No Yes 	answered	_	40 a 5 a 4 a 4 a 4 a 4 a 4 a 4 a 4 a 4 a 4	
P7A/ P7B	P7 Experienced trouble concentrating, or re-	Di W (200 00)	ONO The Notes The Notes of the		No 1 Yes Not	answered	_		
	For questions P8-P10, par	rticipant could have been	under the infl	ence of	alcohol/c	rugs	7		
P8A/ I	P8 Experienced trouble behavior including e violence? • Participant can be under alcohol/drugs.	episodes of rage, or	o No to Yes to No ansv	rered	O No O Yes O Not	answered		10000 1000	
P9A/ P9B	P9 Experienced serious * Participant seriously con his/her life.	s thoughts of suicide? sidered a plan for taking	O No O Yes O Not ansv	ered	No Yes 	answered	-		
10A/ 210B	P10 Attempted suicide? • Include actual suicidal g	restures or attempts.	O No The Second of the Second	ered	No Yes Not	answered	2010		
11A/ 11B	P11 Been prescribed me psychological/emot *Prescribed for the particl Record "Yes" if a medica the participant is not take	ional problem? ipant by M.D. ation was prescribed even if	No 1 Yes 97 Not answ	vered	No Yes 	answered			

STUDYID = CTN0046

QSCAT=ADDICTION SEVERITY INDEX LITE (ASL)

CTN-0046 S-CAST		completion (if form not complete, of $_1$ Participant unavailable $\ \ \ \ \ \ \ \ \ \ \ \ \ $	collection error 3 Participant unable/unwilling to answe
	ELEGAL STATUS QSORRES/0	Assessment Date:	
4602 CTN-A SI LITE V. 1: F	THE RESERVE TO THE RESERVE	QOUTREOU	in the second se
P12 How many days in the past 30 have you experienced these psychological or emotional problems?	OR QSEVLINT=-P30	₉₇ Not answered	Comments: DATA NOT STORED
 This refers to problems noted in questions P4-P10. 	3		(
For questions P13-P14, please ask pa	articipant to use the	Participant Rating Scale.	.]
P13 How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?	Not at all Slightly Shoderately Participant should be question P12.	Considerably 4 Extremely 97 Not answered e rating the problem days from QSEVLINT=-P30	
P14 How important to you now is treatment for these psychological or emotional problems?	□ Not at all □ Slightly □ Moderately	☐3 Considerably ☐4 Extremely ☐97 Not answered	
Confidence Ratings: Is the above inf	ormation significa	ntly distorted by:	1,022-0-10000000000000000000000000000000
P22 Participant's misrepresentation?	□₀ No □₁ Ye	5 §	1-2
P23 Participant's inability to understand?	□₀ No □₁ Ye	5	* <u>-3</u>

CTN-0046 S-CAST

THE PROPERTY OF THE PARTY OF TH	orm not complete, check		DOMAIN: Q
	ailable □2 Data colle Entire CRF □1 Questio		Participant unable/unwilling to ans
Node #:	CTP Site ID #:		Participant ID #:
Assessme	ent Date:	//_	Visit #:
	month	day	year

4603 ASI-LITE Follow-up Medical: Drug: Alcohol: Employment: Family:

Introducing the ASI-LITE Follow-up

Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.

There are two time periods we will discuss: 1. The past 30 days

2. Since your last ASI

Participant Rating Scale: Participant input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.

Please refer to the Participant Rating Scale in the adjacent key.

If you are uncomfortable giving an answer, then don't answer.

Please do not give inaccurate information!

	Key: Participant Rating Scale
0 -	Not at all
1 -	Slightly
2 -	Moderately
3 -	Considerably
4 -	Extremely

Interviewer Instructions

- Leave no blanks
- 2. Make plenty of comments (if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems).
- Throughout the ASI, please note if not answered or not applicable in the appropriate box.
- 4. Terminate interview if client misrepresents two or more sections.
- When noting comments, please write the question number.

HALF TIME RULE: If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.

CONFIDENCE RATINGS: → Last two items in each section.

- → Do not over interpret.
- → Denial does not warrant misrepresentation.
- → Misrepresentation = overt contradiction in information.

Probe and make plenty of comments!

There were a number of variables that had a high level variable that was 1 for answering, 97 for NOT ANSWERED and 96 or 98 for NOT APPLICABLE. These were combined with the under variable in a variable with a name base.c. The following variables have been combined:

asf0d14, asf0d17, asf0d19, asf0d20, asf0d21, asf0d22, asf0d23, asf0d24, asf0d25, asf0d26, asf0d27, asf0e11, asf0e12, asf0e13, asf0e14, asf0e15, asf0e16, asf0e17, asf0e18, asf0e19, asf0e7, asf0e1a, asf0e1b, asf0e2a, asf0e2b, asf0F23S, asf0F30, asf0F31, asf0g20, asf0l10, asf0l11, asf0l12, asf0l13, asf0l14, asf0l15, asf0l16, asf0l17, asf0l18, asf0l19, asf0l20, asf0l21, asf0l25, asf0l26, asf0l27, asf0l3, asf0l4, asf0l5, asf0l6, asf0l7, asf0l8, asf0l9, asf0m1, asf0m6, asf0p12, asf0p1, asf0p2



Form completion (if fo	rm not complete, check one):	DOMAII 1. QO	
1 Participant unava	ilable 🔲 2 Data collection error	3 Participant unable/unwilling to answer	
Field's affected: □ ₀ E	ntire CRF		
Node #:	CTP Site ID #:	Participant ID #:	_
Assessme		/ Visit #:	_
	month day	year	

4603 ASI-LITE Follow-up (ASF): Hollingshead Categories

- 1 = Higher Executive, Major Professionals, Owner of Large Business
- 2 = Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher)
- Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)
- 4 = Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)
- 5 = Skilled Manual—usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)
- Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)
- 7 = Unskilled (attendant, janitor, construction help, unspecified labor, porter). Include Unemployed.
- Homemaker
- Student/No Occupation/Disabled

List of Commonly Used Drugs

Alcohol: Beer, wine, liquor Methadone: Dolophine, LAAM

Opiates: Pain killers = Morphine, Diluaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4

Syrups = Robitussin, Fentanyl

Barbiturates: Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol

Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown, Sed/Hyp/Trang:

Other = Chloral Hydrate (Noctex), Quaaludes

Cocaine: Cocaine Crystal, Free-Base Cocaine or "Crack, and "Rock Cocaine"

Amphetamines: Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin

Methamphetamine: Speed, Ice, Crystal Cannabis: Marijuana, Hashish

Hallucinogens: LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy

Inhalants: Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, etc.

Just note if these are used: Antidepressants,

Ulcer Meds = Zantac, Tagamet

Asthma Meds = Ventoline Inhaler, Theodur Other meds = Antipsychotics, Lithium

Alcohol/Drug Section Instructions

The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However, if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol/drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

- → 30 day questions only require the number of days used.
- → Lifetime use is asked to determine extended periods of use.
- → Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.
- → Alcohol to intoxication does not necessarily mean "drunk;" use the words "felt the effects," "got a buzz," "high," etc., instead of intoxication. As a rule of thumb, 3+ drinks in one setting, or within a brief period of time, or 5+ drinks in one day defines "intoxication."
- → How to ask these questions: → "How many days in the past 30 have you used....?
 - → "How many years in your life have you regularly used....?"

STUDYID = CTN0046 QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF) DOMAIN: QS IN-0046 Form completion (if form not complete, check one): \square_1 Participant unavailable \square_2 Data collection error \square_3 Participant unable/unwilling to answer Fields affected: □0 Entire CRF □1 Questions (specify): S-CAST CTP Site ID #: _ Participant ID #: Node #: QSSCAT=GENERAL INFORMATION Visit #: VISITNUM Assessment Date: QSTESTCD OSORRES/OSSTRESC 4603 ASI Lite Follow-up (ASF): General Information , No G19 Have you been in a Comments: controlled environment Jail in the past 30 days? (A place, theoretically, DATA NOT STORED 3 Alcohol or drug treatment Medical treatment without access to drugs/ alcohol) , Psychiatric treatment Other (specify): G19S Not answered G20 G20 How many days? days OR , Not answered (Refers to total number of 96 Not applicable

Not applicable if question G19 is "No."

days detained in the past

30 days)

CTN-0046
S-CAST

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF)

Form completion (if form not complete, check one):

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer

	S-CAST		ields attected: 🔲 Enlire CRF 🔠 Ques	
	J CALL	QSSCAT=MEDICAL STATUS	Node #: CTP Site ID #: _	SITEID Participant ID #: USUBJID
			Assessment Date:	Q\$DTC / Visit #: VISITNUM
QSTEST			NEO/QOOTNEOO	day ywar
- ↓	4603 ASI-LITE Fol	low-up (ASF): Medi	cal Status	
M1	M1 How many times since your last ASI have you been hospitalized for medical problems?		3 7 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	DATA NOT STORED
M4	M4 Are you taking any prescribed medication a regular basis for a physical problem? M4SP	Yes → If Yes: Spe • Medication prescribed by	a M.D. for medical conditions; not include medicines prescribed, whether urrently taking them.	
M5	M 5 Do you receive a pension for a physical disability? M5SP	☐, Yes → If Yes: Spe	cify:sation, exclude psychiatric disability.	
M6	M6 How many days have you experienced medi problems in the past 3 days?	 Include flu, colds, etc. Incl. 	rectly caused by drugs/alcohol. ude serious ailments related to drugs/ inue even if the participant were abstinent	1
	For questions M7 & M8, pl	ease ask participant to use	the Participant Rating Scale.	
M7	M7 How troubled or bother have you been by these medical problems in the past 30 days?	ered Not at all	Considerably Lacktremely Not answered	
M8	M8 How important to you now is treatment for these medical problem	Slightly Moderately	Considerably Lacktremely Dy Not answered or additional medical treatment by the	2
	Confidence Ratings: Is the above information sig	gnificantly distorted by:		
M10	M10 Participant's misrepresentation	□₀ No □₁ Yes	\	1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-
M11	M11 Participant's inabi	lity □₀ No □₁ Yes		

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOW	MID(ASE)

Form completion (if form not complete, check one):

	S-CAST			₀ Entire CRF □ ₁ Que		AND SHARE OF THE STREET, AND	LICI
		EMPLOYMENT/SUPPORT S		• • • • • • • • • • • • • • • • • • •			USU
D	QSTEST	QSC	Assess ORRES/QSSTRESC	ment Date:	QSDTC /	year	#: _V
46	03 ASI-Lite Folk	w-up (ASF): Emp	oloyment/	Support St	atus		
E1	090		OR ON Not all QSORRESU	swered	Comme	ITA NOT STORED	
E2	Training or technical QSC education completed since your last ASI:	A-Years B-Months • Formal/organized train training that can be used	ing only. For military t	raining, only include		-15000-00-00-00-00-00-00-00-00-00-00-00-00	
E4	Do you have a valid driver's license?	□ ₀ No □ ₁ Yes □ ₉₇ Not answered * Valid license; not suspe	nded frevoked.		\$		
E5	Do you have on automobile available?	No Yes Opp Not answered If answer to E4 is "No", ownership, only require			1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
E7	Usual (or last) occupation since your last ASI? Specify:E7SP	• Use Hollingshead Cate	OR □ ₉₇ N gories Reference Shee				
E9	Does someone contribut the majority of your support?	e					
E11	How many days were you paid for working in the past 30 days?	days OR • Include "under the table QSORRESU=DAYS	Opp Not answer				
					V	ASTROCAL STREET	

QSCAT=ADDICTION	I SEVERITY INF	YEX LITE E	O(1)O(M)

Form completion (if form not complete, check one):

CTN-0046		☐ ₁ Participant u		collection error	3 Participant unable/unwilling to answer
S-CAST		Node #:	CTP Site ID #:		
QSSCAT=EMI	PLOYMENT/SUPPORT STAT		sment Date:		
QSTEST		KLO/QUOTIKLUC		· · · · · · · · · · · · · · · · · · ·	en.
4603 ASI-Li <mark>re Follow</mark>	CONTRACTOR OF THE PARTY	- OFFICE AND PROPERTY.		TROUBLE	ntinued)
For questions E12-E17: How m the pa	uch money did you red st 30 days?	eive from the	e tollowing sourc	es in Co	mments:
E12 Employment (net income):	\$ QSORRESU=DOLLARS				DATA NOT STORED
E 13 Unemploymert	Net or "take home" pay, it \$ QSORRESU=DOLLARS		400.9		
compensation	A OCORDECIA DOLLAR		2200 F		
E14 Welfare:	QSORRESU=DOLLAR: Include food stamps, trans	1000		y to go	
E15 Pensions, benefits, or	to and from treatment. \$ QSORRESU=DOLLAR	S OR \square	Not answered	-	
Social Security:	•Include disability, pension			1	
E 16 Mate, family or friends:	workers' compensation. \$ QSORRESU=DOLLARS	OR	Not answered		
84.55	 Money for personal exper of income (e.g., gambling, (unexpected), money from inheritance, tax returns, et).Record cash pay loans, gambling,	yments only, include wi	NOT & C. ST. C.	
E17 Illegal:	\$ QSORRESU=DOLLAR	S OR	Not answered		
	 Cash obtained from drug bling, prostitution, etc. Do not attempt to conver 	1000	N 51 1650 1	gam	
E18 How many people depend on you for the majority of their food, she ter, etc.?	QSORRESU=PEOPLE max = 99 • Must be regularly depend support; do not include the	RNot o	answered at, do include alimony/o		
E19 How many days have you experienced employment problems in the past 30	QSORRESU=DAYS days OR	2011			20.713 H2F-170-14-7-000000000000000000
days?	problems with present job			-	
For questions E20-E21: Please of participant's ratings in questions or preparing for a job, not givin	E20 and E21 refer to	27.7	200-000		
E20 How troubled or bothered have you been by these employment problems in the past 30 days?	O Not at all Slightly Moderately QSEVLINT=-P30 If the participant has been days, they cannot have en	4 Extre	applicable answered detained during the po	- 	
E21 How important to you now is counseling for these employment problems?	ONOT at all Slightly Moderately	Extre	siderably mely applicable answered		
Confidence Ratings: Is the above	e information signific	antly distort	ed by:		
E23 Participant's misrepresentation?	□₀ No □₁ Yes				
E24 Participant's inability to understand?	□₀ No □₁ Yes			-	

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASI	בו

Form completion (if form not complete, check one):

CIN-UU		☐ 1 Participant unavailable ☐ 2 Data collection Fields affected: ☐ Entire CRF ☐ 1 Questions (i	n error 3 Participant unable/unwilling to answ specify):
S-CAST	QSSCAT=ALCOHOL/DRUGS	Assessment Date: QSE	
QSTEST 4603 ASI-LI <mark>te Fo</mark>	llow-up (ASF): Alc	A comment	usy yes.
Route of Administratio 1 - Oral 2 - Nasal Note the usual or most rea The routes are listed from leas	3 - Smoking 4 - Non-IV	Vinjection 5 - IV Injection e route, choose the most severe.	DATA NOT STORED
Substance	A Past 30 (Days)	Route of Administration	
D1 Alcohol (any use at all):	QSEVLINT=-P30		***************************************
D2 Alcohol (to intoxication):			
D3 Heroin:	.—-	Oral 4 Non IV injection Nasal 5 IV injection Smoking 96 Not applicable 97 Not answered	
D4 Methadone/LAAM (prescribed):		Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable 97 Not answered	
D4a Methadone/LAAM (illicit):		Oral 4 Non IV injection Nasal 5 IV injection Smoking 96 Not applicable	
D5 Other opiates/ analgesics:	,	Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable 97 Not answered	
D6 Barbiturates:		Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable 97 Not answered	
D7 Other sedatives/ hypnotics/tranquilize	ers:	Oral 4 Non IV injection Nosal 5 IV injection Smoking 6 Not applicable 97 Not answered	

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLO	$\Delta M = D(\Delta SE)$

Form completion (if form not complete, check one):

S CAST		Fields affected: □ Entire CRF □ Questions	n error 3 Participant unable/unwilling to an
S-CAST	QSSCAT=ALCOHOL/DRUGS	Node #: CTP Site ID #:S Assessment Date:Q\$ DRRES/OSSTRESC	
QSTEST		pres/Osstresc month	day ywar
Route of Administration:	ow-op (ASF). Aice	o Toty Drugs (confinued)	
1 - Oral 2 - Nasal 3 - Note the usual or most recent The routes are listed from least se	t route. For more than one	injection 5 = IV Injection route, choose the most severe.	DATA NOT STORED
Substance	A Past 30 (Days)	Route of Administration	
D8 Cocaine:	QSEVLINT=-P30	Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable	
D9 Amphetamines:		Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable 7 Not answered	
D9a Methamphetamine:		Oral 4 Non IV injection Nosal 5 IV injection Smoking 6 Not applicable Not answered	
D10 Cannabis:		Oral 4 Non IV injection 5 IV injection 96 Not applicable	
D11 Hallucinogens:		Oral 4 Non IV injection Nasal 5 IV injection Smoking 6 Not applicable 7 Not answered	
D 12 Inhalants:			
D13 More than 1 substance per day (including alcohol, excluding nicotine);	a		

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF)

Form completion (if form not complete, check one):

	N-00-	PO	☐ ₁ Participant una elds affected: ☐ ₀	vailable \square_2 Date Entire CRF \square_1 C	a collection error [] ₃ Participant unable/unwi	lling to answer
	S-CAST		Node #:	CTP Site ID #	SITEID	Participant ID #:	USUBJ
D	QSTEST		EO/ QUOTREUU		QSDTC /_	year	sii w.
460	3 ASI Li <mark>te Fol</mark>	low-up (ASF): Alcoh	ol/Drugs	(continued)			
	ccording to the sterviewer, which	OR,	Not answered		Comme	nts:	
s	ubstance(s) is/are the najor problem?	 Interviewer should determine (excluding Nicotine use). Co- questions 01 - 12 (code press 00 - no problem, 15 - alco than one drug but no alcoho 	de the number ne: cribed or illicit met nol and one or m	d to the drug in hadone as 04). ore drugs; 16 – m	12-02-02-02	ATA NOT STORED	
у	ow many times, since our last ASI, have you ad Alcohol DI's?		intake. Characte	fter last drink, or rized by shaking,	-		
	detoxification, ha fway house	our last ASI have you bee es, in/outpatient counseling and AA o					este dinar
D19 A	lcohol abuse:	OR	Not answered				-
	Drug abuse:	OR 🗀,	Not answered	i .			
How	many of the se were	detox only:					
D21	Akohol:	OR 🔲 ,	Not answered Not applicable		F		987
		• If D19 = 00, then question D	021 is Not applica	ble.			
D22	Drugs:	OR	, Not answered		33132		***************************************
		• If D20 = 00, then question D			30000		
How	much money would	you say you spent during Max. = \$99999	the past 30	days on:	100123-001		
D23	Alcohol:	\$ QSORRESU=DOLLARS			15025-0-0		
	QSEVLINT=-P30	OR, Not answere Only count actual money spe		ancial burden cau			
D24	Drugs:	\$ QSORRESU=DOLLARS			A TOTAL CONTROL OF		
	QSEVLINT=-P30	OR, Not answere • Only count actual money spe by drugs?		ancial burden cau	sed		
D25	How many days have		Opp Not answ	wered			
	you been treated in outpatient setting fo	* Include AA/INA			9-3-3-3-3		
	alcohol or drugs in t past 30 days?					-48 (18) - 18 (18) - 18 (18)	
D26	How many days in t	he days OR	Opp Not answ	wered	>		
	past 30 have you	Include: Craving, withdrawal s	ymptoms, disturbir				
	experienced alcohol problems?		ible to.		-		
	Problems:	QSEVLINT=-P30					

CTN-0046 S-CAST

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF)

Form completion (if form not complete, check one):

 \square_1 Participant unavailable \square_2 Data collection error \square_3 Participant unable/unwilling to answer

	S-CAST		Field's affected: □₀	Entire CRF □ ₁ Q	Duestions (specify):		
•		SCAT=GENERAL INFORMA	Node #:	CTP Site ID #	SITEID	Participant ID #: _	USUBJID
	QS	SCATEGENERAL INFORMA	Assessme	ent Date:	Q\$DTC /	Visi	#: VISITNU
CD	QSTEST	Q	SORRES/QSSTRESC	топ		year	
460	3 ASI-Lire Follo	ow-up (ASF): Ale	cohol/Drugs	(continued)			
	pestions D28–D31, plea The participent is ration				omments:	ATA NOT STORED	
							
D28	How troubled or bothered have you been within the past 30 days by alcohol problems?	Not at all Slightly Moderately QSEVLINT=-P30	Considerable 4 Extremely Not answer	- E			n — 8884-58
D30	How important to you now is treat- ment for alcohol problems?	On Not at all Slightly Moderately	Considerable 4 Extremely Q ₉₇ Not answer				
D27	How many days in Q the past 30 have you experienced drug problems?	SORRESU=DAYSdays QSEVLINT=-P30 • Include: Craving, withdrause, or wanting to stop ar	wal symptoms, disturbing e	E			
D29	How troubled or bothered have you been within the past 30 days by drug problems?	OsevLINT=-P30	Considerabl Extremely Or Not answer				
D31	How important to you now is treatment for drug problems?	□ ₀ Not at all □ ₁ Slightly □ ₂ Moderately	Considerabl A Extremely One of answer	53			
Confi	dence Ratings: Is the	above information si	gnificantly distorte	ed by:			
D34	Participant's misrepresentation?	□₀ No □₁ Yes					
D35	Participant's inability to understand?	□₀ No □₁ Yes	•			-1000000000	

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF)

Form completion (if form not complete, check one):

	CIN-0046	□ı Fields o	Participant unavailable affected: □0 Entire CRI	□2 Data collection error □ F □1 Questions (specify): □	3 Participant unable/unwilling to answer
	S-CAST QSSCAT=LEGA	Node	e #: CTP	Site ID #:SITEID	Participant ID #:USUBJID
00750			Assessment Date	e: QSDTC /_	Visit #: VISITNUM
QSTES*	CD QSTEST 4603 ASI-LITE Follow-up (AS	QSORRES/Q	1000	more say	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
₩ L2	L2 Are you on probation or parole?	On No, neither 1 Yes, parole of 1 Yes, probation 1 Not answere	r post release super n or pre-sentencing d	rvision	ATA NOT STORED
	Francis de la composición de	• Note duration and le		S 67-78-71	
	How many times since your last ASI hawith the following: Include total numbers of counts, not just convictions. Do a were charged as an adult. Include formal charges only			(Ti)	——————————————————————————————————————
L3	L3 Shoplifting/vandalism:	OR [₉₇ Not answered	V	
L4	L4 Parole/probation violations:	OR [₉₇ Not answered	120112-001	
L5	L5 Drug charges:	OR [₉₇ Not answered		
L6	L6 Forgery:	OR	₉₇ Not answered	100.150-0000	
L7	L7 Weapons offense:	OR [₉₇ Not answered	0.0000000	
L8	L8 Burglary/larceny/B&E:	OR [₉₇ Not answered	10000000	
L9	L9 Robbery:	OR [₉₇ Not answered	12 Table 2	Annual Comments and Comments
L10	L10 Assault:	OR [₉₇ Not answered		
L11	L11 Arson:	OR [₉₇ Not answered	· ·	
L12	L12 Rape:	OR [₉₇ Not answered	9 <u>20 90-000</u>	
L13	L13 Homicide/manslaughter:	OR [₉₇ Not answered		
L14	L14 Prostitution:	OR [₉₇ Not answered		
L15	L15 Contempt of court:	OR [₉₇ Not answered		,
L16	L16 Other (specify):	OR [₉₇ Not answered	2	- (500)-1103-1600-1500-1600-160 2
L17	L17 How many of these charges resulted in convictions?		₉₆ Not applicable ₉₇ Not answered	·	
	1	L18-L20 below. Conv	neanor offenses from q ictions include fines, pr ded sentences, and gui	obation,	0000-000-00000 0-00 0
	How many times since your last ASI ho	ive you been cl	arged with	8-8-9-	0.000 0.50 0.000 0.000 0.000
L18	L18 Disorderly conduct, vagrancy, public intoxication:	OR _	₉₇ Not answered	5	
L19	L19 Driving while intoxicated (DWI):	OR [₉₇ Not answered		
L20	L20 Major driving violations:	OR [₉₇ Not answered	S 1551 876-1550	
	ž.	 Moving violations: sp license, etc. 	peeding, reckless drivin	g, no	
- 5				- W	

OSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWS	ID/ACE	

Form completion (if form not complete, check one):

CIN-0046	\square_1 Participant unavailable \square_2 Fields affected: \square_0 Entire CRF \square	Data collection error 3 Participant unable/unwilling to answer 3. Questions (specify):
S-CAST		D #:SITEID Participant ID #:USUBJID
	Assessment Date:	
ASO2 ASILITE FOLLOWING	QSORRES/QSSTRESC	month day ywar
4603 ASI-Lire Follow-up (ASF): Legal Status (continued)	
incarcerated since your last ASI? QSORRESU=MONTHS	OR OR Not answered If incarcerated 2 weeks or more, round this up to month. List total number of months incarcerated (up If more than 99, code 99 and enter the number in Comments.	
L24 Are you presently awaiting charges, trial or sentence?	□ ₀ No □ ₁ Yes □ ₉₇ Not answered	·
L25 What for (refers to 124)?	Use code 03 - 16, 18 - 20. If more than one, chaose is severe. Dan't include civil cases, unless a criminal offer involved. 03 - Shoplifting 04 - Probation violation 05 - Drug 06 - Forgery 07 - Weapons 08 - Burglary 10 - Assaut 10 - Assaut 11 - Arson	most ense is
L26 How many days in the past 30 SOR were you detained or incarcerated?	• Include being arrested and released on the same d	lay.
have you engaged in illegal activities for profit?	*Exclude simple drug possession. Include drug dealir prostitution, selling stolen goods, etc. May be cross to with question E17 under Employment/Family Suppo	checked
For questions L28-29: Please ask part	icipant to use the Participant Rating Sca	le
L28 How serious do you feel your present legal problems are?	Onsiderable Street Considerable	
L29 How important to you now is counseling or referral for these legal problems?	Onsiderably Not at all Slightly Moderately Participant is rating a need for additional referral counsel for defense against criminal charges.	red
Confidence Ratings: Is the above info	rmation significantly distorted by:	
L31 Participant's misrepresentation?	□ ₀ No □₁ Yes	:
L32 Participant's ability to understand?	□₀ No □₁ Yes	

OSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(AS	
	=\

Form completion (if form not complete, check one):

	S-CAS	T		Fields affected:	□ ₀ Entire CRF □ ₁	Questions (specify):	3 Participant unable/unwil	
	-CAS		MILY/SOCIAL RELATION	Node #:	CTP Site ID 4	SITEID	Participant ID #:	USI
D	QSTES'	-	0.5	Ass SORRES/QSSTRES	essment Date:	QSDTC /_	Vi	sit #: _VI
	and the second second	111 0 000	-up (ASF): Fai					
	larital status		□1 Married □2 Remarried	□ ₅ Divorced □ ₆ Never marr □ ₉₇ Not answer	ied ed	Commen	ITA NOT STORED	
	re you satisfied is situation?		O No 1 Yes			red	-11000000000000000000000000000000000000	
ar	sual living rrangements (sii	nce last	With sexual pa With sexual pa With sexual pa With children of With parent With family With friends Alone Controlled envi	alone ironment	n			
	re you satisfied tese arrange me		□ No □ Yes	3 In different	Opp Not answe	red		
Do yo	u live with an	yone who						
F7 He	as a current alc roblem?	ohol	□₀ No □₁ Yes	□ ₉₂ Not answ	ere d	1 <u>1.01</u>		
	ses non-prescrib rugs?	bed	□₀ No □₁ Yes	□ _{g3} Not answ	ere d		-20 ans 10 m - 1000	
sp	ith whom do yo pend most of yo me?		In Family In Internal	Not answered d is considered as fo as family throughou	it this section, not as a	en		
sp	re you satisfied sending your fre is way?	ee time	O No 1 Yes A satisfied response m situation. Refers to que		M9	an I		

DSCAT=ADDICTION SE	VEBITY INDEX I	ITE FOLL	$O(M) ID(\Delta SE)$

Form completion (if form not complete, check one):

S-CAST QS QSTEST	SCAT=FAMILY/SOCIAL RELA	Node #: CTP TIONSHIPS Assessment Date QSORRES/QSSTRESC	Site ID #: SITEID SITEID OSDTC Month day	
The second secon		amily/Social Rela		
Have you had signific serious problems gett • Serious problems r	ant periods in which y	ou have experienced	Comments:	DATA NOT STORED
		Past 30 Days		·········
F18 Mother:	□₀ No □₁ Yes	□ ₉₇ Not answered □ ₉₆ Not applicable		
F19 Father:	□₀ No □₁ Yes	Opportunity of answered Opportunity of applicable	ALCONO DE LA CONTRACTOR	S. IF THE TRACE THE TABLE TO SEE
F20 Brothers/sisters:	□₀ No □₁ Yes	□ ₉₇ Not answered □ ₉₆ Not applicable		
F21 Sexual partner/spo	use:	Opt answered Opt applicable		
F22 Children:	□₀ No □₁ Yes	Opt answered Opt applicable	-	
F23 Other significant far	mily (specify): No	Opt answered Opt applicable		
F24 Close friends:	□₀ No □₁ Yes	☐ ₉₇ Not answered ☐ ₉₆ Not applicable		
F25 Neighbors:	□ ₀ No □ ₁ Yes	□ ₉₇ Not answered □ ₉₆ Not applicable		ris and house the second resistance is about
F26 Co-workers:	□₀ No □₁ Yes	□ ₉₇ Not answered □ ₉₆ Not applicable		
Did anyone abuse you	12	Past 30 Days		
F28 Physically (cause your	hysical harm]?	□ ₉₇ Not answered	-	
F29 Sexually (force sexual	advances/acts)?	07 Not answered		

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF)

Form completion (if form not complete, check one):

CIN-0046	□₁ Pa Fields affe	ticipant unavailable \square_2 Data coected: \square_0 Entire CRF \square_1 Que	ollection error 3 stions (specify):	Participant unable/unwillin	g to a
S-CAST	Node #	: CTP Site ID #: _		Participant ID #: _	US
QSSCAT=FAMILY/SOCIAI		Assessment Date:	Q\$DTC /	Visit	#:_V
AND THE PROPERTY OF THE PROPER	QSORRES/QSS	THE CO	100	- 10	
4603 ASI-Life Follow-up (ASF): Family/S	ocial Relationsh	IIPS (continue	ed)	
F30 How many days in the past 30		₉₇ Not answered	Comments:		
have you had serious conflicts QSORR	ESU=DAYS		DAT	A NOT STORED	
with your family? QSEVLINT	=-P30			ANOTOTOKED	
For questions F32 and F34, please ask partic	ipant to use the Pa	rticipant Rating Scale.	-		11 - 20
F32 How troubled or bothered have	Not at all	☐₃ Considerably			
you been in the past 30 days by 🔲,		4 Extremely			
these family problems?	Moderately	□ ₉₇ Not answered	g	<u> </u>	
QSEVLINT=	-P30				
F34 How important to you now is	Not at all				72
treatment or counseling for	Not at all Slightly	Considerably Extremely			
these family problems?	Moderately	□ ₉₇ Not answered	WENT SERVICE		51:00
		need for counseling for family amily would be willing to	200000000000000000000000000000000000000		
atte	Control of the contro	anny would be mining to			
F31 How many days in the past 30 SORRES	U=DAYS. OF	Not answered	2007		CE-10
have you had serious conflicts	uuy, U	97 1401 ulisweled			
with other people					
(Excreaing ransity)	NT=-P30				
For questions F33 and F35, please ask par Scale.	ticipant to use the	Participant Rating			
	Not at all	a Considerably	-		
have you been in the past 30	Slightly	Extremely	Against against an a		
	Moderately	97 Not answered			
QSEVLI	NT=-P30				-
F35 How important to you now is	Not at all	a Considerably			
treatment or counseling for	Not at all Slightly Moderately	☐3 Considerably ☐4 Extremely ☐97 Not answered	per construction		-
\$24.757		s seek treatment for such s, inability to socialize, and			
diss	atisfaction with friends. I	Participant rating should refer			
		r ather serious problems. d be eliminated if participant	1800 1800 1000 1		11 - 20
	no substance abuse	1 1			
Confidence Ratings: Is the above informa	ation significantl	y distorted by:		nesaa ahaa ahaa	(40-700
F37 Participant's	No 🔲 Yes	2002	Si Santa Paranta		
res runicipani)	INO □1 Tes		######################################		7
misrepreser tation?			20		
misrepreser tation?	No 🔲 Yes				

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF)

Form completion (if form not complete, check one):

C 114-00	740		□1 Participant unava ds affected: □0 E] ₃ Participant unable	/unwilling to answer
S-CAS	QSSCAT=PSYCHIATRIC S	TATUS	lode #:	CTP Site ID #: _	SITEID	Participant II	#: USUBJID
CD QSTES			Assessme S/QSSTRESC	nt Date:	Q\$DTC /	year	Visit #: VISITNU
NATIONAL PROPERTY OF THE PROPE	Follow-up (ASF): P		THE STATE STATE SAID	US	VII.	44.	
How many times sin	ice your last ASI have y	ou bee	treated for	any	20	nents:	
	nt days, not the number of visits or t					ATA NOT STORE	D
P1 In a hospital or in	npatient setting?	/ 	_ OR □ ₉₇ N	ot answered			
P2 As an outpatient/	private patient?		_ OR ₉₇ N	ot answered			
P3 Do you receive a disability?	pension for a psychiatric	□₀ No] ₉₇ Not answere	ed		
Have you had a sign drug/akohol use) in t	nificant period of time († which you have:	hat was	not a direct re	sult of	<u> </u>		
			Past 30	Days			
	ous depression—sadness, ss of interest, difficulty on?	O No	QSEVLII t answered	NT=-P30			
	ous anxiety/tension— nably worried, inability to	O No	t answered		_		
	ucinations—saw things or tother people did not	O No	t answered		_		
P7 Experienced trou concentrating, or	. NOTE TO SEE BY SEED OF THE S	O No	t answered		_		
For questions P8-P10,	participant could have been	under th	e influence of a	lcohol/drugs			
	ble controlling violenting episodes of rage, or under the influence of	O No	t answered		_		
100	ous thoughts of suicide? considered a plan for taking	O No	t answered		_		
P10 Attempted suicide	e? al gestures or attempts.	O No	t answered				
 Prescribed for the po 	notional problem? articipant by M.D. dication was prescribed even if	□₀ No □₁ Yes □₀₁ No		V	_		

STUDYID = CTN0046 CTN OOAK

QSCAT=ADDICTION SEVERITY INDEX LITE FOLLOWUP(ASF)	
Form completion (if form not complete, check one):	

OSTESTCD	QSTEST QSTEST 603 ASI-Lite Follow-up (ASF): P	Assessment Date:	SITEID Participant ID #: USUBJID QSDTC / Visit #: VISITNUM day year
	have you experienced these psychological problems? This refers to problems noted in questions P4-P10.	AYSOR	Comments: DATA NOT STORED
Fo	r questions P13-P14, please ask participant to	use the Participant Rating Scale.	
P13 P1	troubled or bothered by these, Slig	of at all	
P14 P1	treatment for these psychological, Slig	ot at all	
Co	onfidence Ratings: Is the above information	significantly distorted by:	
P22 P2	22 Participant's misrepresentation?	Yes	
P23 P2	23 Participant's inability to	Yes , Yes	

DOMAIN: LB Form completion (if form not complete, check one): □ Participant unavailable □ Data collection error □ Participant unable/unwilling to answer Fields affected: 🔲 Entire CRF 🔠 Questions (specify): ____ Visit #: VISITNUM

	LBCAT=CHEMISTRY		- Or Great Automotive Comment Special	month day ywar					
40	604 Blood Chemistry								
Sec	quence #: LBGRPID								
lab Exc	Complete blood level of analyte (value) and unit of measurement below. Indicate whether each measurement is Normal (within laboratory normal limits), Abnormal (outside of laboratory normal limits but, does not exclude participation), Abnormal Excludes (outside laboratory normal limits and excludes participation [4631 Study Eligibility, Q-14]), or Not Done. Provide comments for any abnormal or significantly abnormal values below.								
	LBTEST Analyte	LBORRES Value	LBORRESU Standard Unit	Normal/Abnormal/ Abnormal Excludes/ Not Done LBNRIND (check only one)					
1	Glucose	(सर्वेक्टर, संस्कृत संस्कृतको)	mg/dL	☐, Normal ☐, Abnormal/Excludes ☐, Abnormal ☐, Not Done					
2	Creatinine	57070 ³ 75770	mg/dL	☐, Normal ☐, Abnormal/Excludes ☐, Abnormal ☐, Not Done					
3	Alanine Aminotransferase (ALT/SGPT)	S ————————————————————————————————————	U/L	☐₁ Normal ☐₃ Abnormal/Excludes ☐₂ Abnormal ☐₀ Not Done					
4	Aspartate Aminotransferase (AST/SGOT)	\$ 	U/L	☐ Normal ☐ Abnormal/Excludes ☐ Abnormal ☐ Not Done					
5	Gamma Glutamyl-transpeptidase (GGT)		U/L	☐₁ Normal ☐₃ Abnormal/Excludes ☐₂ Abnormal ☐₀ Not Done					
6	Blood Urea Nitrogen (BUN)		mg/dL	☐, Normal ☐, Abnormal/Excludes ☐, Abnormal ☐, Not Done					
7	Provide comments for any abnormal	Q Q	NOT STORED NAM=ABNORMAL LABEL=TEST VALUE VAR=LBSEQ	IS ABNORMAL QNAM=EXCLUDES QLABEL=TEST VALUE IS ABNORMAL/EXCLUDES IDVAR=LBSEQ	======================================				
		ste annide sintense (1.576) e 1			9				

STUDYID = CTN0046 N-0046 S-CAST

☐ ₁ Participant	(if form not complete, ch	heck one): collection error] ₃ Participant unable/unwi	OMAIN: QS
			Participant ID #:	USUBJID
Asses	ssment Date:	Q\$DTC /		sit #: VISITNUM
No. 1997 Oct.	month	h day	yeor	
ing Scale				
oice (check only one):], Cocaine] ₂ Methamphetamin	ne		
egard to your craving	for your prima	ry drug (chec	k one per question):	
ow much I desi <mark>red this d</mark>	rug in the past 24	hours was:		
	QSEVLINT=-H2			
	N. 1902 (1912			
how often I de <mark>sired</mark> this	drug in the past 2	24 hours was:		
	22			
his drug during the past	24 hours was:			
you had craving for thi		past 24 hour	s:	
oast 24 hours was (check	only one).			

BSCS07

BSCS08

BSCS09

BSCS010

Ŋ	CTN-0046 S-CAST	QSCAT=BRIEF SUBSTANCE CRAVING SCALE (BSCS) Form completion (if form not complete, check one):
QSTEST	TCD QSTEST	Assessment Date: QSDTC / Visit #: VISITNUM QSORRES/QSSTRESC day year
	4605 Brief Substance	and the second of the second o
	Please answer the following que	stions with regard to a second craved drug (check one per question):
SCS07		at is, how much I desired this drug in the past 24 hours was:
	□ _o None at all □, Slight	
	Moderate	QSEVLINT=-H24
	□ ₃ Considerable □ ₄ Extreme	
SCS08		hat is, how often I desired this drug in the past 24 hours was:
	□, Almost Never	
	Several Times	
SCS09	The second secon	aving this drug during the past 24 hours was:
	□, None at all □, Very Short	
	Short	
	3 Somewhat Long	
	4 Very Long	j j

10 Write in the NUMBER of times you think you had craving for this drug during the past 24 hours:

LBCAT=CARBON MONOXIDE ASSESSMENT

Form completion (if form not complete, check one):	DOMAIN: LB
☐ Participant unavailable ☐ Data collection error Fields affected: ☐ Entire CRF ☐ Questions (specify):	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	Participant ID #:USUBJID
Assessment Date:/	/Visit #: VISITNUM

4	606 Carbon Monoxide (CO) Assessment
,	Carbon monoxide reading: LBTEST=CARBON MONOXIDE
	1a Current time:
ı	1b Trial #1 CO: LBORRES ppm LBORRESU=ppm LBSPID=TRIAL #1
	1c Trial #2 CO: LBORRES ppm LBORRESU=ppm LBSPID=TRIAL #2
2	Was the average of the two CO levels < 4 ppm? QNAM=LBAVGCO QLABEL=AVERAGE OF 2 CO2 LEVELS < 4 PPM IDVAR=LBSEQ
3	Was the CO level (Trial #1 or Trial #2) above 8 ppm? ONO QNAM=LBCOGT8 QLABEL=CO LEVEL > 8 PPM FOR EITHER TRIAL IDVAR=LBSEQ
ı	3a If Yes, does the participant report having smoked any tobacco in the past 7 days? □ №
	3b If No, please ask the following: QNAM=LBSMOKE QLABEL=SMOKED TOBACCO IN PAST 7 DAYS IDVAR=LBSEQ
ı	1 Have you smoked anything else besides tobacco products in the past 7 days (for example, herbal cigarettes,
	marijuana joints, etc.)? O QNAM=LBSMOKE2 QLABEL=SMOKED OTHER THAN TOBACCO IN PAST 7 DAYS IDVAR=LBSEQ
ı	2 Do you work, or have you been, in an area where there is quite a bit of car exhaust (for example, garage, etc.)?
	QNAM=LBEXHAUS QLABEL=NEAR QUITE A BIT OF EXHAUST IDVAR=LBSEQ
ı	3 Do you know if you have a defective furnace at home that could be giving out a higher-than-normal reading of CO?
	QNAM=LBFURNAC QLABEL=HAVE A DEFECTIVE FURNACE AT HOME IDVAR=LBSEQ
4	Comments (print; limit 200 characters):
	DATA NOT STORED
ı	S_01101111 _ 00001 00000 00001

Form completion (if	form not complete, check one):	DON	MAIN: MH
☐ ₁ Participant unav	vailable 🔲 2 Data collection en	ror α Participant unable/unwillin	
Node #:	CTP Site ID #:		USUBJID
Assessm	ent Date:/	/Visit	#: VISITNUM

МН

CAT=0	CIDI SUMMARY		Assessment Date:	mth/day	_/	Visit #	VISITNUM	
46	607 CIDI Summary							
A	Substance Dependence MHSCA	T=SUBS	TANCE DEPENDENCE	MHOCCUR=0		MHOCCUR=1		
МНТ	ERM Diag	nosis	QNAM=MHDUR_LF	Neg	Life	12 mo	30 days	
1	Nicotine Dependence [TBD]		QLABEL=HISTORICAL OCCURANCE LIFE IDVAR=MHSEQ					
2	Alcohol Dependence [ALD] (past 30 a	excludes	; 4631 Q-8)		D/			
3	Sedatives/Tranquilizers Dep [SEDD]	(past 30	excludes; 4631 Q-8)					
4	Stimulants Dep—Meth Only [STIMD]	(past 12	or 30 required; 4631 Q-3)	D/	9			
5	Analgesics Dependence [PAIND]		QNAM=MHDUR_YR QLABEL=HISTORICAL OCCURANCE 12	ло 🗆				
6	Marijuana/Hashish Dependence [M	ARD]	IDVAR=MHSEQ					
7	Cocaine Dependence [COCD] (past 1	2 or 30	required; 4631 Q-3)					
8	Club Drugs Dependence [CLUBD]		AM=MHDUR_MH ABEL=HISTORICAL OCCURANCE 30 DAYS					
9	Hallucinogens Dependence [HALD]	IDV	AR=MHSEQ					
10	Heroin/Opium Dependence [OPID]							
11	Inhalants/Solvents Dependence [INh	ID]						
12	Other Dependence—Other (non-met)	n) stimu	lants [OTHD]					
В	Substance Abuse MHSCAT=SUB	STANCE	ABUSE					
МНТ	Diag	nosis		Neg	Life	12 mo	30 days	
13	Alcohol Abuse [ALA]							
14	Sedatives/Tranquilizers Abuse [SEDA	A]						
15	Stimulants Abuse—Methamphetamin	e Only	[STIMA]					
16	Analgesics Abuse [PAINA]							
17	Marijuana/Hashish Abuse [MARA]							
18	Cocaine Abuse [COCA]							
19	9 Club Drugs Abuse [CLUBA]							
20	Hallucinogens Abuse [HALA]							
21	Heroin/Opium Abuse [OPIA]							
22	Inhalants/Solvents Abuse [INHA]							
23	Other Abuse—Other (non-meth) stim	ulants (OTHA]					

Form completion (if form not complete, check one):	DOMAIN: MH
\square_1 Participant unavailable \square_2 Data collection error	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	USUBJID
Assessment Date:/	/Visit #: VISITNUM

MHCAT=CIDI SUMMARY

10.000	MATERIAL DESCRIPTION OF THE PARTY OF THE PAR	2000	onth day	year		-		
40	4607 CIDI Summary (continued)							
c	Non-Substance Use Disorders MHSCAT=NON	I-SUBSTANCE USE DISORDERS	MHOCCUR=0		MHOCCUR=1			
	Diagnosis	¬ Neg	Life	12 mo	30 days			
Ψ.	ERM I	QNAM=MHDURAT QLABEL=HISTORICAL OCCURANCE	M. M		-			
24	Agoraphobia without Panic Disorder [AGP]	IDVAR=MHSEQ		Ш				
25	Anorexia [ANO] (Excludes; 4631 Q-10)							
26	Attention Deficit Disorder [ADD]							
27	Bipolar I Disorder [BIPOLARI] (12 or 30 exclude	s; 4631 Q-10)						
28	Bipolar II Disorder [BIPOLARII] (12 or 30 exclud	les; 4631 Q-10)						
29	Bulimia [BUL] (Excludes; 4631 Q-10)							
30	Dysthymia [DYS]							
31	Generalized Anxiety Disorder [GAD]							
32	Major Depressive Disorder [MDD]							
33	Obsessive Compulsive Disorder [OCD]							
34	Panic Disorder [PDS]	3						
35	Pathological Gambling [GAM]							
36	Posttraumatic Stress Disorder [PTS]							
37	Premenstrual Syndrome [PMS] females only; if	male 🗸 "Neg"						
38	Social Phobia [SO]							
39	Specific Phobia [SP]							
D	Psychosis Screen MHSCAT=PSYCHOSIS SCR	REEN						
	40 Indicate whether or not the participant screened positive for psychosis: MHTERM=PSYCHOSIS Participant DID screen positive for psychosis Participant DID NOT screen positive for psychosis MHOCCUR							

CTN-0046	Form completion (if form not complete, check one):				e/unwilling to answer	21	
S-CAST	USUBJID	Node #:	CTP Site ID #:		Participant	ID #:	
	Assessment [Date:/_	/	Visit #:	VISITNUM	Sequence #:	85.0

DOMAIN: DA, EX

4	4608 Compliance—Medication—Participant Report								
1 Study week being assessed:									
	Medication	A Date	Bupropion XL DA.DATEST EX.EXTRT		Nicotine Inhaler EX.EXTRT	F Comments			
	Day		B mg Prescribed	C mg Taken	D Carts. Used	(Print; 200 character limit)			
2	Day 1	DA.DADTC / EX.EXDTC	DA.DAORRES	EX.EXDOSE	EX.EXDOSE	DATA NOT STORED			
4	Day I	manth day ywar		EX.EXDOSU EX.EXDOSFRM	EX.EXDOSU				
3	Day 2				A				
4	Day 3								
5	Day 4								
6	Day 5								
7	Day 6								
8	Day 7	manth day year			A UT.				

K		Form completion (if 6	orm not complete, check one):		DOMAIN: DA, EX
0		1 Participant unav	ailable \square_2 Data collection er		le/unwilling to answer
	USUBJID	Node #:	CTP Site ID #:	Participant	ID #:
	Assessment	Date: /	/	Visit #: VISITNUM	Sequence #:

ACAT=	COMPLIANCE-MEDICATION-PARTICIPATION-PILL C	OUNT	month	day	year		
46	09 Compliance—Medicatio	n—Pill	Count		***		
1	Study week being assessed: VISITNUM						
Sec	tion I: Scheduled Bupropion XL DASC	CAT=SECTION	ON 1: SCHEDU	JLED BUPRO	OPION XL		
2	Date bottle dispensed:		DADTC				
•	DATEST=PILLS RETURNED-EXPECTED	month	_//_	year	7.0		
3	Number of pills returned—expected:	DAORRE	S				
4	DATEST=PILLS RETURNED-ACTUAL Number of pills returned—actual:	DAORRES	s				
5	DATEST=PILLS REPORTED LOST Number of pills reported lost:	DAORRES	s				
6	Date bottle returned:	month	DADTC	year	_ OR □ ₉₆ NA		
	Was replacement Bupropion XL dispensed? ATEST=REPLACEMENT BUPROPRION DISPENSED		27.10111		ection II below		
8	Are there any inconsistencies between pill of DAT				tration of pills (se PORTED PILL CNT	e CRF 4608)?	
Sec	tion II: Replacement Bupropion XL DA	SCAT=SEC	TION 2: REPL	ACEMENT B	UPROPION XL		
9	Date replacement bottle dispensed:	mon#s	DADTC _//_	year	_:		
10	Number of pills dispensed:	DAORRE	S				
5000000	TEST=NUMBER OF PILLS RETURNED-EXPECTED Number of pills returned—expected:	DAORRE	S				
	ATEST=NUMBER OF PILLS RETURNED-ACTUAL Number of pills returned—actual:	DAORRE	ss.				
13	DATEST=NUMBER OF PILLS REPORTED-LOST Number of pills reported lost:	DAORRE	es \				
14	Date replacement bottle returned:	month	_/DADTC	year	_ OR □ ₉₆ NA		



0046		Form completion (if fo	rm not complete, check one):		DOMAIN: DA
0046		☐ ₁ Participant unava	ilable \square_2 Data collection error ntire CRF \square_1 Questions (specif	Contract of the contract of th	e/unwilling to answer
AST	USUBJID	Node #:	CTP Site ID #:	Participant	ID #:
	Assessment	Date: /	_/	Visit #: VISITNUM	Sequence #:

	10 Compliance—Medicat	ion—Cartr	idae Count			
	no compilante mountain		age coom			
1	Study week being assessed: _VISITNUM					
	SCAT=SECTION 1: SCHEDULED NICOTINE CAR	TRIDGES				
	tion I: Scheduled Nicotine Cartridge					
			DTC			
2	Date cartridges dispensed:	/_	_/			
	DATEST=CARTRIDGES DISPENSED	manfi d	ау унат			
3	Number of cartridges dispensed:	DAORRES				
	DATEST=USED CARTRIDGES RETURNED					
4	Number of <u>used</u> cartridges returned:	DAORRES				
	DATEST=UNUSED CARTRIDGES RETURNED					
5	Number of unused cartridges returned:	DAORRES 🔪	\			
	DATEST=CARTRDGES REPORTED LOST					
6	Number of cartridges reported lost:	DAORRES				
	,		DADTC			
7	Date cartridges returned:	/_	/	OR ON NA		
D	ATEST=REPLACEMENT CARTRIDGES DISPENS	ED month d	ay year	— ∀ °		
8	Were replacement cartridges dispensed?	P O No DAC	RRES			
		25/7000	es: Complete Sec	tion II below		
9		artridae count a	nd self-renorted o	administration o	f cartridges (see C	RF 460832
	Are there any inconsistencies between of One One DAORRES 1 Yes		nd self-reported o	administration o	f cartridges (see C	RF 4608)?
DA	DAORRES Types ASCAT=SECTION 2: REPLACEMENT CARTRIDGE	ES	nd self-reported o	administration o	f cartridges (see C	RF 4608)?
DA	□ No DAORRES □ Yes	ES	nd self-reported o	administration o	f cartridges (see C	RF 4608)?
Sec	No DAORRES 1 Yes ASCAT=SECTION 2: REPLACEMENT CARTRIDGE Tion II: Replacement Nicotine Cartrid	ES	nd self-reported o	administration o	f cartridges (see C	RF 4608)?
Sec	DAORRES Types ASCAT=SECTION 2: REPLACEMENT CARTRIDGE	≣s Iges /		administration o	f cartridges (see C	RF 4608)?
Sec 10	Date replacement cartridges dispensed: DateSt=CARTRIDGES DISPENSED	ES Iges /	DADTC	administration o	f cartridges (see C	RF 4608)?
Sec 10	Date replacement cartridges dispensed: DATEST=CARTRIDGES DISPENSED Number of cartridges dispensed:	≣s Iges /	DADTC	administration o	f cartridges (see C	RF 4608)?
D/ Sec 10	Date replacement cartridges dispensed: DATEST=CARTRIDGES DISPENSED Number of cartridges dispensed: DATEST=USED CARTRIDGES RETURNED	es lges 	DADTC	administration o	f cartridges (see C	RF 4608)?
D/ Sec 10	Date replacement cartridges dispensed: DATEST=CARTRIDGES DISPENSED Number of cartridges dispensed:	ES Iges /	DADTC	administration o	f cartridges (see C	RF 4608)?
10 11 12	Date replacement cartridges dispensed: DATEST=CARTRIDGES DISPENSED Number of cartridges dispensed: DATEST=USED CARTRIDGES RETURNED	es lges 	DADTC	administration o	f cartridges (see C	RF 4608)?
D/N Secc 10 11 12 13	Date replacement cartridges dispensed: DATEST=USED CARTRIDGES DISPENSED Number of cartridges dispensed: DATEST=USED CARTRIDGES RETURNED Number of used cartridges returned: DATEST=UNUSED CARTRIDGES RETURNED	DAORRES	DADTC	administration o	f cartridges (see C	RF 4608)?



	S-CAS	Г		Entire CRF 1 Questions (specify):	Partici	•	
٩T	/EXCAT=COMPLIANCE-S	SMOKING-CESSATION (COUNSELING	Assessment D	ate:	DTC / DADTC	yec
-	BOTTO BUT SHE	70731 NOVEMBER	ng-Cessation Cour	10-21			
ì	of Compile	nce—smokin	ig-cessarion cool	seling			
i	Such week for wh	:-bliumen is by	eing assessed: VISITNUM				
	How many session	s were scheduled de	uring the study week?	NORRES DA.DATEST=SCHED	ULED SESSION	18	
	How many sessions	were attended dur	ring the study week? EX.EX	EX.EXDOSU=SE	SSION	UNSELING	
	How many schedu	ed sessions did the	participant miss?DA.DAO				
8				DA.DAORRESU=SESSION			
1	How many sessions	s did you cancel?DA.	.DAORRES DA.DATEST=SESSIO	NS CANCELLED			
	Based on the nartic	singul's sassion nar	DA.DAORRESU=SESSI ticipation and completion of		how compli	ant was the	
			icipation and completion of	nomework dangimona,	now compile	JII WUSTIN	
	participant (check or	100					
	Participant did no	of aftend					
	A-0.75 (#0.400)	SUPPEX					
		QNAM=EXCOMPLY					
	3 Moderately	¿LABEL=HOW COMPLIA	ANT WAS THE PARTICIPANT				
	4 Considerably	DVAR=EXSEQ					
	Extremely						
	Comments (print lin	nit 200 characters): _					
,	comments (prim, in	· 아니는 사이를 잃었다면서 아니는 아니는 사람이 없다.					

ì	TN-0046 S-CAST	Form completion (if form not complete, $a = b + b = 1$). Participant unavailable $a = b = 1$. Data Fields affected: $a = b = 1$	collection error	
	S-CASI	ISUBJID Node #: CTP Site ID #		1
٠٨٦	F/EXCAT=CONTINGENCY MANAGEMENT TRACKING F	Assessment Date:		Visit #:
- 22	Production and the second second	Secretary Charles Control	th day	ywor
ŀć	512 Contingency Manageme	ent Tracking Form		
	22. VICITALIA			
1	Study week being assessed: VISITNUM			
	st CM Visit for the Study Week EX.EXGRI	PID / DA.DAGRPID = FIRST CM VISIT		
		DA.DAORRES DA.DATEST=DRAWS	S EARNED	
		DA.DAOKKESU-DKAW		
3	If no draws earned, indicate the reason (che	19 800 MM (19 19 8 8 19 19 11)	SUPPDA	
		Unexcused absence	QNAM=DADF	RAWC1 ASON NO DRAWS EARNED
	EX.EXTRT		IDVAR=DASE	
4	If draws were earned, please indicate the no	umber of prizes won in each of the f	ollowing cat	egories:
ien I	a "Good Jobs": EX.EXDOSE	Territoria de la como transferio de la mandator des anad		
	b "Small" prizes:			
	W VIIIMII PLIEVA			
	"Medium" prizes:			
	d "Medium" prizes:	L-DD17E		
	d "Large" prizes: d "Jumbo" prizes: EX.EXDOSU			
Sec	d "Medium" prizes:		ΙΤ	
	d "Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU	EXGRPID / DA.DAGRPID = SECOND CM VIS		
5	d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU cond CM Visit for the Study Week: EX.EX Number of draws earned (If 0 then enter "00")	EXGRPID / DA.DAGRPID = SECOND CM VISI DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW	ARNED	
5	d "Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU	EXGRPID / DA.DAGRPID = SECOND CM VISION (I): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW Ock only one): Was not abstinent		AWC2
5	d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU cond CM Visit for the Study Week: EX.EX Number of draws earned (If 0 then enter "00")	EXGRPID / DA.DAGRPID = SECOND CM VISION (1): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW DA.DAORR	SUPPDA QNAM=DADRA	AWC2 SON NO DRAWS EARNED
5 6	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU cond CM Visit for the Study Week: Number of draws earned (If 0 then enter "00 If no draws earned, indicate the reason (che	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU sond CM Visit for the Study Week: Number of draws earned (If 0 then enter "00 If no draws earned, indicate the reason (che	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU cond CM Visit for the Study Week: Number of draws earned (If 0 then enter "00 If no draws earned, indicate the reason (che	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU sond CM Visit for the Study Week: Number of draws earned (If 0 then enter "00 If no draws earned, indicate the reason (che	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU and CM Visit for the Study Week: Number of draws earned (If 0 then enter "00 If no draws earned, indicate the reason (che EX.EXTRT If draws were earned, please indicate the ne a "Good Jobs": EX.EXDOSE	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU sond CM Visit for the Study Week: Number of draws earned (If 0 then enter *00 If no draws earned, indicate the reason (che EX.EXTRT If draws were earned, please indicate the ne a "Good Jobs": EX.EXDOSE b "Small" prizes:	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS E DA.DAORRESU=DRAW	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU cond CM Visit for the Study Week: Number of draws earned (If 0 then enter "00) If no draws earned, indicate the reason (che EX.EXTRT If draws were earned, please indicate the no a "Good Jobs": EX.EXDOSE b "Small" prizes: "Medium" prizes:	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS EDA.DAORRESU=DRAW eck only one): 1 Was not abstinent 1 Unexcused absence 1 Excused a	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6 7	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU cond CM Visit for the Study Week: Number of draws earned (If 0 then enter "00 If no draws earned, indicate the reason (che EX.EXTRT If draws were earned, please indicate the no a "Good Jobs": EX.EXDOSE b "Small" prizes: C "Medium" prizes: C "Large" prizes: C "Jumbo" prizes: C "Jumbo" prizes: C EX.EXDOSU=PR	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS EDA.DAORRESU=DRAW eck only one): 1 Was not abstinent 1 Unexcused absence 1 Excused a	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q
5 6 7	"Medium" prizes: d "Large" prizes: e "Jumbo" prizes: EX.EXDOSU cond CM Visit for the Study Week: Number of draws earned (If 0 then enter "00 If no draws earned, indicate the reason (che EX.EXTRT If draws were earned, please indicate the no a "Good Jobs": EX.EXDOSE b "Small" prizes: "Medium" prizes: d "Large" prizes:	EXGRPID / DA.DAGRPID = SECOND CM VISION (*): DA.DAORRES DA.DATEST=DRAWS EDA.DAORRESU=DRAW eck only one): 1 Was not abstinent 1 Unexcused absence 1 Excused a	SUPPDA QNAM=DADRA QLABEL=REA IDVAR=DASEG	SON NO DRAWS EARNED Q



USUBJID	Node #:	CTP Site ID	#:	Participant II) #:
	Assessmen	2000 100 10 10 - 10 1 1	DM.DMDTC / SC	SCDTC	Visit #:

4	613 Demographics
1	Date of birth: / / DM.BRTHDTC / / DM.SEX
2	Sex: 1 Male 2 Female 98 Participant chooses not to answer
3	Ethnicity: DM.ETHNIC 1 Hispanic or Latino 2 Not Hispanic or Latino 1 General Participant chooses not to answer
4	Race (check all that apply): DM.RACE (if multiple, then 'MULTIPLE') American Indian or Alaska Native Asian Black or African American Native Hawaiian or Pacific Islander White Other (specify): Participant chooses not to answer Unknown

Form completion (if form not complete, check on ☐1 Participant unavailable ☐2 Data collection Field's affected: ☐0 Entire CRF ☐1 Questions	in error	□3 Participant unable	
USUBJID Node #: CTP Site ID #:		Participant	ID #:
Assessment Date:/	day /	VISITNUM	Visit #:
))		62	

				Assessment Date:	/	/_	VISITNU	M_ Visit i	#:
46	14 Electrocardiogram	(ECG)			Month	day	year		
			6053						
1	ECG overall results: ☐ EGORRES Normal →							NORMAL I	
ı	∐₂ Abnormal •	→ If Abnorr		r questions 2–34: clude the participa					
ı				DES and does exc	*	0.70		10,000	
F	STEST	EGOR	Eligibili	ity, Q-14).		•	TEST	FGOR	
	Specific ECG Abnormality	Abnormal	Abnormal /Excludes	Cnaciti	c ECG Abr			Abnorma	Abnormal /Excludes
2	Increased QRS voltage	П,		18 Superventric	ular prem	ature beat		Π.	
3	QTc prolongation			19 Ventricular	premature	beat			
4	Left atrial hypertrophy	□,		20 Supraventria	cular tachy	cardia		<u> </u>	
5	Right atrial hypertrophy			21 Ventricular t	achycardio	1		Π,	
6	Left ventricular hypertrophy			22 Atrial fibrilla	ation			\Box ,	
7	Right ventricular hypertrophy			23 Atrial flutter					
8	Acute infarction			24 Other rhythi	m abnorm	alities			
9	Subacute infarction			25 Implanted p	acemaker				
10	Old infarction			26 First degree	A-V block				
11	Myocardial ischemia			27 Second deg	ree A-V bk	ock			
12	Digitalis effect			28 Third degree	A-V block	c			
13	Symmetrical T-wave inversions			29 LBB block				\Box_1	
14	Poor R-wave progression			30 RBB block					
15	Other nonspecific ST/T			31 Pre-excitatio	n syndrom	ie			
16	Sinus tachycardia			32 Other intrav	entricular (condition b	ock		
17	Sinus bradycardia								
33	Other abnormality (print; limit 200 c	haracters):	EGORF	RES					
"	The abilitinally (print, min 2000)	naraciers,.							
							<u> </u>		(2)
EC	STEST FOODERS				n	341 -4	- 1111111	1985-1885-	
	Ventricular rate: EGORRES bpm E	GORRESU							
35	QRS:EGORRESU								
36	PR:EGORRES _ ms EGORRESU								
37	EGORRESU ms EGORRESU								
	ırdiologist's Signature		ONIAA	A FOONAME					
38	Cardiologist name (please print):			M=EGCNAME BEL=EG CARDIOLOGI	ST NAME	4 5 3555-0 1055-0 200			
			IDVAF	R=VISITNUM					
1000404	Date signed://	204,072,000		M=EGSIGDTC	2475				
40	Cardiologist signature: DATA NOT ST	ORED		EL=EG SIGNATURE [R=VISITNUM	JAIE			- 1000000000000000000000000000000000000	



QSCAT=FAGERSTROM	TEST FOR	NICOTINE	DEPENDENCE	(FTND)
QUOATEL AULICUITOR	I LOI I OI	INICOTINE	DEI LINDLINGE	(1 1110)

Form completion (if fo	orm not complete, ch	eck one):	DOI	IVIAIN: QS
□ ₁ Participant unava	iilable □2 Data c		□3 Participant unable/unwilli	ng to answer
Node #:	CTP Site ID #:	SITEID	Participant ID #:	USUBJID
Assessme	nt Date:	QSDTC	/ Visi	##: VISITNUM

QSTEST How soon after you wake do you smoke your first ciga	rette (check only one)?
Within 5 minutes	ADDITIONAL QUESTION ADDED TO FORM:
Within 6 - 30 mir utes QSORRES/QSSTRES	QSTEST= DO YOU SMOKE AT ALL?
Within 31 - 60 m nutes	QSTESTCD = FTN007
After 60 minutes	
Do you find it difficult to refrain from smoking in places	where it is forbidden, e.g., in church, at the library,
at the movies, etc. check only one)?	251 PC 1770) Missing despitation (145 per ▼ Formation and Horizonavious surveys, is shown I for
□ No QSORRES/QSSTRES	
Yes	
Which cigarette would you hate most to give up (check	anh: anal?
The first one in the morning	only one;:
All others QSORRES/QSSTRES	
How many cigarettes per day do you smoke (check only	one/?
□ 11 20	
QSORRES/QSSTRES	
31 or more	
	fter waking than during the rest of the day (check only one)?
QSORRES/QSSTRES	
Yes QSORRES/QSSTRES	

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STUDYID = CTN0046 CTN-0046

QSCAT=HOSPITAL	ΔΝΧΙΕΤΎ ΔΝΟ	DEPRESSION	SCALE	(HADS)
QOUATEROSFITAL		DEFINESSION	SUALL	HADSI

Form completion (if form not complete, check one):

DOMAIN: QS

0.	CIN-0046		icipant unavailable □2 Data collection error □3 Participant unable/unwilling to answer cted: □6 Entire CRF □1 Questions (specify):
	S-CAST		: CTP Site ID #:SITEID Participant ID #:USUBJID
QSTESTC		QSTES	Assessment Date: QSDTC / Visit #: VISITNUM
USTESTO	4616 Hospital Anxiety and Dep	QUILU	700
	UNITED THE ME WE SEE THE TOTAL THE T	0.00	Read each item and place an "X" next to the reply which comes
	closest to how you have been feeling in the past we	ek. Don't t	ake too long in thinking about your replies; your immediate
\downarrow	reaction to each item will probably be more accurate QSTEST	e than a lo	ng thought-out response. QSTEST
HAD1	I feel tense or "wound up": Most of the time A lot of the time SORRES/QSSTRES From time to time, occasionally Not at all	HAD8	8 I feel as if I am slowed down: Nearly all the time Very aften QSORRES/QSSTRES Sometimes Not at all
HAD2	I still enjoy the hings I used to enjoy: Definitely as much Not quite so much Only a little Hardly at all	HAD9	9 I get a sort of frightened feeling like "butterflies" in the stomach: Not a all Occasionally QSORRES/QSSTRES Quite often Very often
HAD3	3 I get a sort of frightened feeling as if something about to happen: Very definite y and quite badly Yes, but not too badly QSORRES/QSSTRES A little, but it doesn't worry me	awful is HAD10	Definitely I don't take so much care as I should I may not take quite as much care I take just as much care as ever
HAD4	4 I can laugh and see the funny side of things: As much as I always could Not quite so much now Definitely not so much Not at all	HAD11	11 I feel restless, as if I have to be on the move: Very much indeed Quite a lot QSORRES/QSSTRES Not very much Not a all
HAD5	5 Worrying thoughts go through my mind: A great deal of the time A lot of the time QSORRES/QSSTRES From time to time but not too often Only occasionally	HAD12	12 I look forward with enjoyment to things: As much as I ever did Rather less than I used to QSORRES/QSSTRES Definitely less than I used to Hardly at all
HAD6	6 I feel cheerful: Not at all Not often QSORRES/QSSTRES Sometimes Most of the time	HAD13	13 I get sud den feelings of panic: Very often indeed Quite often QSORRES/QSSTRES Not very often Not a all
HAD7	7 I can sit at ease and feel relaxed: Definitely Usually QSORRES/QSSTRES Not often Not at all	HAD14	14 I can enjoy a good book or radio or TV program: Often QSORRES/QSSTRES Sometimes Not often Very seldom

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QSCAT=INITIAL QC Form completion (if for		DOMAIN: QS		
☐1 Participant unavail	able □2 Data co	ollection error stions (specify):	3 Participant unable	
Node #:	CTP Site ID #: _	SITEID	Participant ID	#: USUBJID
Assessmen	t Date:	QSDTC day	/	Visit #: VISITNUM

QSTESTCD=IQ4DT IQ4SDT
IQ5DT IQ5SDT
IQ6DT IQ6SDT smoke at all?
STESTCD=IQ4ABSDT IQ4SABSDT
smoke at all? QSTESTCD=IQ5ABSDT IQ5SABSDT
TLFB Time-Frames STESTCD=IQ6ABSDT IQ6SABSDT

N AAAA		Form completion (if form not complete, check one):	DOMAIN: M	Н
N-0046		☐ Participant unavailable ☐ Data collection error Fields affected: ☐ Entire CRF ☐ Questions (specify):	3 Participant unable/unwilling to answ	wer
S-CAST		Node #: CTP Site ID #:	Participant ID #:	JBJID
MEDICAL HISTORY	MHGRPID=1	Assessment Date: MHDTC	/ Visit #: VISI	TNUM

	3-CA3 I		Node #: CTP Site ID #:	Participa	nt ID #:
инс	AT=MEDICAL HISTORY	MHGRPID=1	Assessment Date:/	OTC /	Visit #: VISITNUM
20000	40 NOT THE THE RESIDENCE	-2	month	day ywar	
40	618 Medical Hi	story			
		S	te medical history for each condition		2572
			he response is Yes, specify the medica ion excludes the participant from the		ate if the
CO.	- 15	TERM MHOCCUR	on excludes the participant from the	sroay.	
	Condition	History of the Condition?	If Yes: Specify	Condition Present Currently?	Condition Excludes Participant?
1	Asthma	□ No □ Yes → □ Unknown	QNAM=MHSPEC QLABEL=MEDICAL HISTORY SPECIFIED	□₀ No □₁ Yes	□₀ No □₁ Yes
2	Cardiovascular	□ ₀ No □ ₁ Yes → □ ₉ Unknown	IDVAR=MHSEQ	No 🔲 Yes	□₀ No □₁ Yes
3	Dermatologic	□ ₀ No □ ₁ Yes → □ ₉ Unknown		□ No □ Yes	□₀ No □₁ Yes
4	Drug Allergies	□ ₀ No □ ₁ Yes → □ ₉ Unknown	QNAM=MHCURREN QLABEL=CONDITION PRESENT CURRENT	No 1 Yes	□₀ No □₁ Yes
5	Endocrine	□ No □ Yes → □ Unknown	IDVAR=MHSEQ	□₀ Nø □₁ Yes	□₀ No □₁ Yes
6	Gastrointestinal	□ ₀ No □ ₁ Yes → □ ₉ Unknown	QNAM=MHEXCLUD	□₀ No □₁ Yes	□₀ No □₁ Yes
7	Genitorurinary	□ ₀ No □ ₁ Yes → □ ₉ Unknown	QNAM=MHEXCLUD QLABEL=CONDITION EXCLUDES PATIENT IDVAR=MHSEQ	□₀ No □₁ Yes	□₀ No □₁ Yes
8	Head Injury	□ ₀ No □ ₁ Yes → □ ₀ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
9	HEENT	□ No □ Yes → □ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
10) Hematologic	□ ₀ No □ ₁ Yes → □ ₉ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
11	l Hepatic	□ ₀ No □ ₁ Yes → □ ₉ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
12	2 Infectious Disease	□ ₀ No □ ₁ Yes → □ ₉ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
13	3 Metabolic	□ No □ Yes → □ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
14	Musculoskeletal	□ ₀ No □ ₁ Yes → □ ₀ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
15	Other Allergies	□ ₀ No □ ₁ Yes → □ ₉ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
16	5 Pulmonary	□ ₀ No □ ₁ Yes → □ ₉ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
17	Renal	□ No □ Yes → □ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes
18	Reproductive System	□ No □ Yes → □ Unknown		□₀ No □₁ Yes	□₀ No □₁ Yes

orm completion (if Participant una ields affected:	**************************************		ant unable/unwillin	
Node #:			icipant ID #: _	USUBJID
Assessm	ent Date:/_	_/	Visit	#: VISITNUM

DOMAIN: MH

MHGRPID=1 MHCAT=MEDICAL HISTORY 4618 Medical History (continued) History of the Condition Present Condition Excludes Condition If Yes: Specify Condition? Currently? Participant? MHSCAT= PSYCHIATRIC/NEUROLOGICAL HISTORY

Psychiatric/Neurological History (Indicate history of disorders listed below) MHOCCUR MHTERM , Yes → No QNAM=MHSPEC 19 Anxiety or Panic Disorder , Yes ___, Yes QLABEL=MEDICAL HISTORY SPECIFIED Unknown IDVAR=MHSEQ 20 Attention Deficit No , Yes → No. , No , Yes , Yes Hyperactivity Disorder , Unknown _ No yes → 21 Bipolar Disorder D. No No. , Yes , Yes o Unknown 22 Clinically significant - No , Yes → Yes , No , Yes **Neurological Damage** Unknown QNAM=MHCURREN QLABEL=CONDITION PRESENT CURRENTLY 23 Epilepsy or Seizure IDVAR=MHSEQ o No , Yes → Disorder (4631 Study ___, Yes _o Unknown Eligibility, Q 12) 24 Major Depressive _ No , Yes → D, No No. , Yes ___, Yes Disorder QNAM=MHEXCLUD o Unknown QLABEL=CONDITION EXCLUDES PATIENT No , Yes → 25 Schizophrenia IDVAR=MHSEQ No _ No ___, Yes ___, Yes o Unknown _ No , Yes → 26 Tourette's Syndrome D. No O No , Yes , Yes . Unknown No $Yes \rightarrow$ 27 Suicidal Ideation , Yes No ___, Yes Unknown No , Yes → 28 Suicidal Behavior D. No , Yes , No , Yes Unknown No , Yes → 29 Homicidal Ideation No. , Yes _ No , Yes Unknown No ___, Yes → 30 Homicidal Behavior O No , Yes No. , Yes o Unknown No . Yes → 31 Violent Behavior No. , Yes No. , Yes o Unknown , Yes → . No 32 Psychotic Episodes No , Yes No , Yes . Unknown Indicate other relevant medical history below. Complete data for body system, provide specific details in the Specify section: (print; limit 200 characters) MHSCAT=OTHER RELEVANT MEDICAL HISTORY MHOCCUR=Y 33 _____, Yes _ No 34 No Yes , No , Yes 35 □₀ No □₁ Yes □₀ No □₁ Yes

form completion (if form not complete, check one):	DOMAIN: MH			
☐1 Participant unavailable ☐2 Data collection error	3 Participant unable/unwilling to answer			
Node #: CTP Site ID #:	Participant ID #: USUBJID			
Assessment Date:/	/ Visit #: VISITNUM			

MHCAT=MEDICAL HISTORY MHGRPID=1 4618 Medical History (continued) MHSCAT=SURGICAL HISTORY Surgical History 36 Has the subject had any major surgery? MHTERM=MAJOR SURGERY No MHOCCUR , Yes -> If Yes: Provide surgery data below, including date of surgery or check if date is unknown. Unknown

Ty	pe of Surgery (limit 50 charac	cters per line)	Surgery Date (partial dates allowable)	OR Date Unknown
MHTERM /	MHOCCUR=1		MHSTDTC	. □,
38			//	_ □,
39			//	,
40			/	,
41			//	
42 Clinician name ar	nd degree (please print):	QNAM=MHNAME QLABEL=MH CLINICIAN NAI IDVAR=MHGRPID	мЕ	
43 Date signed: —	onth / day / year	QNAM=MHSIGDTC QLABEL=MH SIGNATURE DATI	<u> </u>	
44 Clinician signatur	DATA NOT STORED	IDVAR=MHGRPID		

CTN-0046

Form completion (if form not complete, check one): Tarticipant unavailable 2 Data collection error Fields affected: Entire CRF 1 Questions (specify):	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	USUBJID
Assessment Date:/	/Visit #: VISITNUM

DOMAIN: MH

S-CAST MHGRPID=2 MHCAT=MEDICAL HISTORY 4619 Medical History Addendum I Cardiovascular History (4631 Study Eligibility, Q-14) MHSCAT=PERSONAL CARDIOVASCULAR HISTORY

A Personal History QNAM=MHAGE QLABEL=MH PARTICIPANT AGE IDVAR=VISITNUM 1 Participant age: MHOCCUR MHOCCUR
History of the
Condition? MHTERI Condition Present If Yes: Specify Condition Currently? , Yes → QNAM=MHSPEC Hypertension _ No Yes QLABEL=MEDICAL HISTORY SPECIFIED Unknown IDVAR=MHSEQ No , Yes → Coronary artery disease Yes , No Unknown , No Yes -Chest pain _ No _____, Yes Unknown , No , Yes → 5 Palpitations No Yes Unknown No , Yes → Shortness of breath Yes , No Unknown ___, Yes → 7 Dizziness _ No , Yes Unknown No , Yes → 8 Syncope ___, Yes , No Unknown o No Yes -History of CHF Yes No Unknown , No , Yes → 10 History of MI Yes , No Unknown **B** Family History MHSCAT=FAMILY CARDIOVASCULAR HISTORY History of the If Yes: Specify Condition? MHCCCUR MHTERM No , Yes → 11 History of early MI QNAM=MHSPEC o Unknown QLABEL=MEDICAL HISTORY SPECIFIED 12 History of sudden No IDVAR=MHSEQ , Yes → cardiac death o Unknown 13 History of significant - No ___, Yes → arrhythmias o Unknown 14 History of congenital No Yes → heart disease (particularly , Unknown cardiomyopathy) 15 Comments (print; limit 200 characters): DATA NOT STORED

	Form completion (if form not complete, check one):	DOMAIN: MH		
	☐ Participant unavailable ☐ Data collection error Fields affected: ☐ Entire CRF ☐ Questions (specify):	3 Participant unable/unwilling to answer		
	Node #: CTP Site ID #:	USUBJID		
MHGRPID=2	Assessment Date: MHDTC	/Visit #: VISITNUM		

DOMAIN: MH

				MHGRPID=2	Assessment Date:	MHDTC	Visit #: VISITNUM
MHCA	ΑI	Γ=MEDICAL HI	STORY	WINGRPID=2		month day	year
40	5	19 Med	dical H	istory Addendun	1 (continued)		
				'ELEGIBILITY CRITERIA	TO TO CONTRACT OF CONTRACTORS		
Ш				er Study Eligibility Criter	ia:		
		. 2					
10				en smoking for at least 3 n	nonths (4631 Study Eligibility,	Q 4)? MHTERM	
	-	No MHOO	l 				
	L	1 Yes					
17	1	Does the pa	rticipant h	nave a physiological depend	dence on alcohol or sedative	es requiring medic	al detoxification (4631 Study
	E	Eligibility, Q &	8)?			12.01	
		□₀ No					
18	1	Does the pa	rticipant h	nave a history of closed hea	d trauma with > 30 minutes	loss of conscious	ness (4631 Study Eligibility,
		Q 13)?					
	Γ	□ _o No					
	-	Yes					
10		S-39-3-30	rticinant h	nave AIDS according to the	current CDC criteria for AID:	S 14631 Study Fligib	vility O 1/12
.,		No	incipain i	dive AID3 according to the	correll CDC Chiefia for Alb.	J (403) Siddy Lligib	omiy, Q 14):
		, Yes					
							and the second
20			rticipant h	ave diabetes treated with I	nypoglycaemics or insulin (4	631 Study Eligibility,	, Q 14) ?
	-	_ No					
	L	1 Yes					
21	I	Does the pa	rticipant h	nave a known or suspected	hypersensitivity to bupropio	n, nicotine, or mer	nthol (4631 Study Eligibility,
	(Q 16)?					
		o No					
		, Yes				↓	
22	1	Comments (print; limit 2	200 characters):			
			•		T STORED		
	-				3		
	-						
Cl	i	nician S	ignatı	Jre .			
					QNAM=MHNAME		
23	1	Clinician nar	me and de	egree (please print):	◆ QLABEL=MH CLINICIAN	NAME	
				50 M W W. SHELL	IDVAR=MHGRPID		
24	1	Date signed	:	//_	QNAM=MHSIGDTC		
		1151	mon th	day year	QLABEL=MH SIGNATURE D	ATE	
25	1	Clinician sign	nature:	DATA NOT STORED	IDVAR=MHGRPID		
			5 27				
4							



QSCAT=NON-STUDY SMOKING TREATMENT Form completion (if form not complete, check one):			DOI	MAIN: QS
☐ ₁ Participant un	ovailable □₂ Data c a Entire CRF □₁ Que	ollection error	☐3 Participant unable/unwillin	ng to answer
Node #:	CTP Site ID #:	SITEID	Participant ID #:	USUBJID
Assessr	nent Date:	QSDTC	/Visi	#: VISITNUM

	4620 Non-Study Smoking Treatment
STESTCD NSST01	QSTEST QSORRES/QSSTRES Since the last research visit, have you used ANY <u>non-study</u> smoking cessation treatment (i.e., that would be any smoking
	cessation treatment if you are in the non-smoking treatment group or any smoking cessation treatment not provided by the study staff if
	you are in the smoking treatment group) such as medication, courseling, or self-help materials?
	$\square_{\circ} \bowtie \rightarrow \text{If No: S}^{\bullet} \text{OP. This form is complete.}$
NSST02	Have you used any medications, like the nicotine patch, Zyban® or Chantix®?
	V ☐, Yes → If Yes: Please check all medications used:
	NOCTOCALO
	NSST02A_0
	NISSTO2A 2 OTHER MEDICATION USED:
	NSST02A 3 UNicotine gum QSTESTCD=NSST02A_7
	☐ Nicotine patch
	NSST02A_4 OTHER MEDICATION USED SPECIFY:
	NSST02A_5 QSTESTCD = NSST02_OT
	NSST02A_6 Nicotine lozenge
NSST03	3 Have you attended an in-person smoking cessation program (e.g., classes, group/individual discussions, etc.)? No
NSST04	4 Have you used telephone smoking-cessation treatment (e.g., the smoking quitline, etc.)? \[\bigcup_0 \text{ No} \\ \bigcup_1 \text{ Yes} \]
NSST05	5 Have you used self-help material to stop smoking (e.g., American Lung Association material, materials from your doctor, tapes, books, etc.)? 0 No 1 Yes
NSST06	6 Have you received any other smoking cessation treatment not listed above?
	□ _o No
	☐, Yes → If Yes: Please describe briefly:
NSST06A	
	7 Comments (print; limit 200 characters):
	7 Comments (print, limit 200 characters):
	DATA NOT STORED

Dare last researc	h visit attended:/_	day year		
Please indicate ti Completer:	ne participant's status at the e	이 경기 내가 있었다. 이 사람들은 이 이 사람들이 되었다.	in the active st	udy phase (check only one):
Withdrawn:		pecify below)*		
Non-completer:	Withdrew consent Moving from area Practical problems (no child Medical problems (hospital) Incarceration Pressure or advice from out 12 Feels treatment no longer no l	ization, other) tsiders necessary, cured necessary, not working	DSTERM	1
	14 Failed to return to clinic an 15 Other (specify below)* 2a *Specify (for administrative		200 characters)	QNAM=DSPECIFY QLABEL=ADMIN DISCHARGE SPECIFIED IDVAR=DSSEQ

Form completion (if form not complete, check one):	DOMAIN: PE
☐ Participant unavailable ☐ Data collection error Fields affected: ☐ Entire CRF ☐ Questions (specify):	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	USUBJID
Assessment Date: PEDTC	/Visit #: VISITNUM

		Viieii	ment Date: _	month	day year	
4622 Physical Examinati	on					
	1	Eval	vation	If 'Not Done'	thon	
Body System PETEST	03-02/03/03/03	Abnormal PEORRES	Abnormal Excludes (4631 Study Eligibility, O 14g)	PESTAT=NO PEREASND=	T DONE and	
1 General Appearance:				□,	DATA NOT STORED	
2 Head/Neck:	□,		□₃	□•		
3 Ears, Eyes, Nose and Throat:						
4 Cardiovascular and Pulse:				□ _{\$}		
5 Lymph Nodes:	□,		□₃			
6 Respiratory:						
7 Musculoskeletal:			□₃	□ ₉		
8 Gastrointestinal and Abdomen:			□₃			
9 Extremities:						
10 Neurological:	□,		□₃	□,		
11 Skin: QNAM=OTHER			□₃			
QLABEL=OTHER BODY SY IDVAR=PESEQ	(STEM]		Пз	□ ₉		
Clinician's Signature						
13 Clinician name and degree (print): _	QNAM=PENA QLABEL=PE IDVAR=VISIT	CLINICIAN NA	ME			
15 Clinician signature:	QNAM=PE	E SIGNATUR	E DATE			



QSCAT=PITTSBURGH SLEEP QUALITY INDEX (PSQI) Form completion (if form not complete, check one):			DOM	MAIN: QS
☐ ₁ Participant	unavailable □2 Data collection □0 Entire CRF □1 Questions	n error 🔲 3 P	articipant unable/unwillin	
Node #:		ITEID	Participant ID #: _	USUBJID

Assessment Date: _____QSDTC /_____

Visit #: VISITNUM

				month day	lay year	
40	523 Pittsburgh	Sleep Quality Ind	ex (PSQI)			
Instructions: The following questions relate to your usual sleep habits during the past month <u>only</u> . Your answers should indicate the most accurate reply for the <u>majority</u> of days and nights in the past month. Please answer all questions.						
1	QSTEST During the past month, QSTEST=BEDTIME AM/PM	QSTESTCD=PSQI1 what time have you usually QST	gone to bed at n	ight? QSORRES/QSSTRES	Bed time: Q <u>SORRE</u> S S	S/ <u>QSSTR</u> ES
2	During the past month, night? QSTEST	how long (in minutes) has it QSTESTCD=PSQI2	6350 93	u to fall asleep each SU=MINUTES	E 2 000	RES/QSSTRES
3	QSTEST During the past month, QSTEST=WAKEUP AM/PM	QSTESTCD=PSQI3 what time have you usually QS	gotten up in the STESTCD=PSQI3A	morning? QSORRES/QSS	Getting up time:QS	ORRES/QSSTRES
4		how many hours of actual s of hours you spent in bed.) QSTESTCD=PSQI4	May 15 1550	at night? (This may be SU=HOURS	Hours of sleep	RES/QSSTRES
Fo	r each of the remainin	ng questions, check the or	ne best respons	e. Please answer <u>a</u>	<u>all</u> questions.	
5	During the past month,	how often have you had tro	uble sleeping be	cause you	u _a	
	a Cannot get to sleep v	within 30 minutes QSTESTCD=PSQI5A		QSORRES/QSSTRES	Not during the Less than once Once or twice Three or more	a week a week
	b Wake up in the midd	dle of the night or early morn	0 10 1 1 0 0	QSORRES/QSSTRES	Not during the Less than once Once or twice Three or more	a week a week
	c Have to get up to use QSTEST	e the bathroom QSTESTCD=PSQI5C		QSORRES/QSSTRES	Not during the Less than once Once or twice Three or more	a week a week
	d Cannot breathe com	fortably QSTESTCD=PSQI5D	,	QSORRES/QSSTRES	Not during the Less than once Once or twice Three or more	a week a week
	e Cough or snore loud	QSTESTCD=PSQI5E		QSORRES/QSSTRES	Not during the Less than once Once or twice Three or more	a week a week
	f Feel too cold QSTEST	QSTESTCD=PSQI5F	(QSORRES/QSSTRES	Not during the Less than once Once or twice	a week a week

Buysse, D.J., Reynolds, C.F., Monk, T.H., Berman, S.R., & Kupfer, D.J. (1989). The Pittsburgh Sleep Quality Index (PSQI): A new instrument for psychiatric research and practice. Psychiatry Research, 28(2), 193-213. The detailed scoring instructions are at the end of this journal article.

STUDYID = CTN0046 CTN-0046

QSCAT=PITTSBURGH SLEEF	QUALITY INDEX (PSQI)
------------------------	----------------------

Form completion (if form not complete, check one):

Fields affected: O Entire CRF Ouestions (specify): ___

 \square_1 Participant unavailable $\qquad \square_2$ Data collection error $\qquad \square_3$ Participant unable/unwilling to answer

DOMAIN: QS

	J-GAJI		Node #:	CTP Site ID #: _	SITEID	Participant	ID #:	USUBJID ————
			Assessme	ent Date:	QŞDTC /		Visit #:	VISITNUM
	QSTEST		-10 0-000 0.000	month	day	year		
4	623 Pittsburgh S	leep Qualtiy II	ndex (PSQI)	(continued)				
Tours	During the past month, ho	20 40 27 00	79530 CK SK 995		continued)			
(1)	g Feel too hot QSTEST	QSTESTCD=PSQI5G		QSORRES/QSST	TRES	Not during	nce a we	ek
					3	Once or tv	ore times	a week
	h Had bad dreams QSTEST	QSTESTCD=PSQI5H		QSORRES/QSST	TRES	Not during Less than of Once or tw	once a wee	ek ek
	i Have pain QSTEST	QSTESTCD=PSQI5I		QSORRES/QSST	TRES	Not during Less than c Once or tv Three or m	once a wee	ek ek
	i Other reason(s), please QSTEST QS	describe: STESTCD=PSQI5J	QSOI	RRES/QSSTRES		Not during		
	How often during the po QSTEST	ast month have you ha QSTESTCD=PSQI5J	d trouble sleeping	because of this QSORRES/QSST	RES	Once or tv		
6	During the past month, how QSTEST	v would you rate your QSTESTCD=PSQI6		SORRES/QSSTRE	s	Very good Fairly good Fairly bad Very bad		
7	During the past month, had or "overstime founter")?	ow often have you take		you sleep (pre		Not during Less than of Once or tv	once a wee	ek ek
8	eating meals, or engaging	in social activity?		vake while driv SORRES/QSSTRE	3	Not during	nce a we	ek
2	QSTEST	QSTESTCD=PSQI8				Three or m		
9	During the past month, ho	w much of a problem	has it been for you	to keep up en	ough	Not a prol	olem at all	

enthusiasm to get things done?

QSTESTCD=PSQI9

QSTEST

QSORRES/QSSTRES

Only a very slight problem

Somewhat of a problem

A very big problem



QSCAT=PREGNANCY A	ND OUTCOME	ck onel:	DC	DMAIN: QS
[2008/04 Ballin 2008]	available 🔲 2 Data co		☐3 Participant unable/unwill	
Node #:	CTP Site ID #:_	SITEID	Participant ID #:	USUBJID
Assess	ment Date:	QSDTC	/ Vis	if #: VISITNUM

		month day	ywar
40	524 Pregnancy and Outcome		
	Administration - Commission - C		
Inf	formation about Pregnancy OR GONDA	TO/OCCIDED	OSTESTOD
	QSURRE	ES/QSSTRES	QSTESTCD
1	Who discovered the pregnancy?	₉₇ Unknown	POA101
2	How was the pregnancy verified (select all that apply)?		
_	Urine pregnar cy test		POA12U
	Serum pregnancy test		POA12S
	3 Ultrasound		POA12T
	Unknown		POA12UNK
3	Date on which the pregnancy was verified:/	D _{o7} Unknown	POA103R/POA103DT
222	26 3/3 16 3950 DEAT		POA104P/POA104DT
4	Date on which study staff was aware of pregnancy:////		Unknown
ı	4a How was the pregnancy verified by study staff (check only one)?	, Urine pregnancy test	
		2 Participant clinic reco	POA14AR
		₉₇ Unknown	
	4b Date on which study staff verified pregnancy://_		nknown POA14BR/ POA14BDT
5	Date on which study medication was discontinued:/		nknown POA105R/ POA105DT
6	Approximate due date:/	1	POA106R/ POA106DT
٥.	thome of Pregnancy CSSCAT		
ľ	nome of Freguency		
7	Outcome of pregnancy:		POA107R
1	, Normal		
ı	Abnormal - If Abnormal: Specify abnormality:		POA17ASP
ı	☐3 Miscarriage → STOP. This form is complete.		
ı	Terminated - STOP. This form is complete.	ı	
ı	S Other (specify):		POA17BSP
ı	□ ₉₇ Unknown		TONTIBOL
	55000		
8	Date of delivery://		POA08R/ POA08DT
9	Number of live births (this pregnancy):		POA09R
7.01	○ → If O live births, indicate reason:		
			POA09SP
	_ 2		
	□ 3		
	□ ₉₇ Unknown		
10	Type of delivery:		
	, Vaginal		POA10
	Cesarean section		
	O ₉₇ Unknown		

Form completion (if form not complete, check one): \[\begin{align*} alig	DOMAIN: QS
Node #: CTP Site ID #:	USUBJID
Assessment Date: QSDTC	/ Visit #: <u>VISITNUM</u>

		month day year	
40	524 Pregnancy and Outcome (continued)		
2		ere n = birth number (in case of multipl	e births (e.g. twins))
Ne	wborn #1 Information QSORRE	S/QSSTRES	QSTESTCD
1	Gender:1 Male		POAN01
2	Gestational age at delivery: /	POAN02R/ POAN2WK	POAN02R/ POAN2DAY
3	Weight:/	POANO3R/ POAN3LBS	POAN3OZS
4	Length: cmg Unknown	POAN4LNG	
5	Head circumference: cmg, Unknown	POAN5CIR	
6	APGAR score at minute:1 min1 mknown	POAN61MN	
7	APGAR score at 5 minute: 5 min 5 min	POAN75MN	
8	APGAR score at 24 hours: 24 hrs Unknown	POAN824H	
9	Normal infant?	DOANOD	
	No → If No: Specify abnormality:	POAN9R POAN9B	SP
	Contributing factors to abnormality:	POAN9CSI	D
	Is this a congenital abnormality? on No , Yes	Unknown POAN9BR	
	Yes		
	Unknown		
_	TA: CONTACT (CONTACT)		
Ne	wborn #2 Information		
1	Gender: Male	THE ABOVE FIELDS A REPEATED ON SEPARA	
2	Gestational age at delivery: /	RECORD FOR EACH BI	RHT
3	Weight:/		
١,			
*	Length: cm		
5	——————————————————————————————————————		
6	APGAR score at 1 minute:1 min1 min		
7	APGAR score at 5 minute: 5 min 5 min 10 minute: 5 min 5 minute:		
8	APGAR score at 24 hours: 24 hrs 24 hrs		
9	Normal infant?		
	No → If No: Specify abnormality:		
	Contributing factors to abnormality:		
	Is this a congenital abnormality? 🔲 No 🔲 Yes	□ ₉₇ Unknown	
	, Yes		

☐ ₁ Participant u		3 Participant unable/unwilling to answer
Fields affected: [o Entire CRF of Questions (specify):	
Node #:	CTP Site ID #:	Participant ID #:
Asses	sment Date:/	/ Visit #:
	month day	Year

4624 Pregnancy and Outcome (continued)
Newborn #3 Information
1 Gender:, Male
2 Gestational age at delivery: /
3 Weight: /
4 Length: cm cm Unknown
5 Head circumference: cm cm g7 Unknown
6 APGAR score at 1 minute: 1 min 1 mknown
7 APGAR score at 5 minute: 5 min
8 APGAR score at 24 hours: 24 hrs 2 nknown
9 Normal infant?
No → If No: Specify abnormality:
Contributing factors to abnormality:
Is this a congenital abnormality? O No 1 Yes 0,7 Unknown
Yes
Unknown
Comments:

CTN-0046_CRF_V.004_18 SEP 2009

Data collection error			articipant ID #:
O, Participant unavailable O2 Data collection	 Participant unable/unwilling to answer 	□, Questions (specify):	
m completion: □₀ Complete	☐ ₃ Participant	saffected: 🗖 Entire CRF	# Classis and
Form		Fields	# oPoN CII MIN
			al al

				☐3 Participant unable/unwilling to an Fields affected: ☐ Entire CRF ☐1 Questions (paredy):	□, Participant unable/unwilling to answer b, Entire CRF □, Questions (speedy):	
N-CANI			D	USUBJID Node#: CTP Si		Participant ID #:
	CMCAT = PRIOR AND CONCOMITANT MEDICATIONS	OMITANT MEDICATIONS				
4625 Prior and Concomitant Medications	ncomitant Medic	ations				
Assessment Date	Medication Name (Generic preferred)	Purpose/Indication	Treating an AE?	Start Date	Stop Date	Comments
CMDTC month day / year	CMTRT	CMINDC	° 2 □□	monft day year	CMENDTC month day / year Active Tx phase ended	DATA NOT STORED
mon fin day / year			° ° ° °		month day /year	

Active Tx phase ended	month day / year	month day / herr		month day / year	month day /year.
	month day year	month day year	month day year	monft day year	monft day year
ž	Yes No	∑ Yes	∑ Yes	∑ ≺es	∑ Kes
		QNAM=CMACTIVE QLABE =ACTIVE TX PHASE ENDED IDVAR=CMSEQ			
year	/year	/y+cr	, year	/year	/y
day	-/	_/	_/doy_	/	/
€ 80 E		mon #	mon th	- SE	# 80

e we

Active Tx phase ended

year

şe 2 □□

ş°≥°

QNAM=TRTFORAE QLABEL=DRUG GIVEN AS TREATMENT FOR AE IDVAR=CMSEQ

year



DOMAIN: QS

Form completion (if i	form not complete, che	ck one):	Di	OWAIN. Q3
☐1 Participant unav	ailable 🔲 2 Data co	ollection error stions (specify):	☐3 Participant unable/unwi	
Node #:	CTP Site ID #: _	SITEID	Participant ID #:	USUBJID
Assessm	ent Date:	Q\$DTC day	/V	isit #: VISITNUM

4626 PRISM Suicidal and	Homicidal Intent (P	RISM)			
1 Recurrent Thoughts of Death					
Did you ever find yourself thinking about death or dying? QSTEST=.RATING QSTESTCD=PRISM1A Do you think you would be better off dead? QSTEST=.MOST RECENT QSTESTCD=PRISM1B Did you feel as though you wanted to die (did you wish you wouldn't wake up in the morning when you went to bed at night?) UNCLEAR: Can you describe these thoughts/feelings? How often were you thinking about these things? IF YES: Do you still have these thoughts/feelings at the present time? How often? For how long have you been having these thoughts/feelings?	Must have spent some time thinking about death at least three times in a week (not necessarily all day). Include recurrent thoughts that she would be better off dead. Include thoughts of death attributed to health problem or HIV status that occur without a change in health status. Exclude if preoccupied with death when someone close is ill or dying, as long as preoccupation is at expected level. Exclude normal fear of death.	Prior to	Sub Threshold QSQRRES/QS ent Occurrence:	Шз	Not Answered
2 Recurrent Sucicidal Ideation					
Did you ever think about suicide or killing yourself? (What did you think of? How often did you have that thought?)	Must have a thought about this at least three times in a week.	A Rating Sca	Sub Threshold	Present	Not Answered
IF YES: Do you still think about killing yourself at the present time? QSTEST=.RATING	Must think actively of killing oneself even if ambivalent.	□,	OSORRES/	QSSTRES	□4
How often? QSTESTCD=PRISM2A For how long have you been having these thoughts? QSTEST=.MOST RECENT QSTESTCD=PRISM2B	Can have suicidal ideation without having suicidal plan.	Prior to	ent Occurrence: the past 6 mon past 6 months		STRES



QSCAT=PRISM SUICIDAL AND HOMI Form completion (if fo	-	,	DOI	MAIN: QS
☐ Participant unava	ilable 🔲 2 Data col	lection error	3 Participant unable/unwillin	
Node #:	CTP Site ID #:	SITEID	Participant ID #:	USUBJID

Assessment Date: ____Q\$DTC / _____ Visit #: VISITNUM

very plante and a literature programmer of the second seco		month	day	year	
4626 PRISM Suicidal and	Homicidal Intent (P	RISM) (con	tin ved)		
3 Specific Suicide Plan			Galana Kathora		
Did you ever think of any specific plan	Must be thinking of actual	A Rating Sca	le:		977
for committing suicide? QSTEST=.RATING	method of suicide.		Sub		Not
QSTESTCD=PRISM3A What did you think of doing?	Intent to carry out the plan is	Absent	Threshold	Present	Answered
IF YES: When was that?	not required; formulation of a specific plan is enough.		QSORRES/	QSSTRES	\square_4
For how long did you think of this plan?					(1)
How often would you think about this plan? QSTEST=.MOST RECENTQSTESTCD=PRISM3B	Include even if fleeting plan.	Prior to	ent Occurrence: the past 6 mor past 6 months (4	ths QSORRES/QSST	RES ibility, Q-22)
IF YES: Do you think of any specific plan for committing suicide at the present time?	or feasible				
What do you think of doing?					
How often do you think about it?					
For how long have you been thinking about this plan?					
39-350-30 (4-20) (340-340) • • • • • • • • • • • • • • • • • • •					
4 Suicide Gesture					
Did you start to do something in order	Must be thinking about sui-	A Rating Sca	le:		
to kill yourself, even if you changed	cide at the time of act but	The second second	Sub		Not
your mind and stopped, or if someone	believe that the extent of	Absent	Threshold	Present	Answered
else stopped you? QSTEST=.RATINGQSTESTCD=PRISM4A	action taken would not		QSQRRES/	NSSTRES	
What did you do? QSTEST=.MOST RECENT	actually result in death.			331111	4
What happened then STESTCD=PRISM4B	include apparent suicide gesture even if subject eleims	B Most Rece	nt Occurrence	:	~
What were you thinking of when you did that?	intent was only attention- seeking.		o the past 6 mor past 6 months	QSORRES/QS	STRES
If Yes: When was that?	Exclude self-mutilation for				
How many times did this happen?	tension relief.				
	Exclude preparation for				
	attempt.				



QSCAT=PRISM SUICIDAL AND HOM Form completion (if I	•	,	DOI	MAIN: QS
1 Participant unav	ailable 🔲 2 Data col	lection error	3 Participant unable/unwillin	
Node #:	CTP Site ID #:	SITEID	Participant ID #:	USUBJID

	Assessment	Date:	QSD	OTC /	year	Visit #: VISITNUM
4626 PRISM Suicidal and	Homicidal Intent (P	RISM)	Icontinue	ad)		
5 Suicide Attempt			(COMMITTO	/	_	_
		A D II	c - l -			
Did you ever do anything to hurt or kill yourself? (4631 Study Eligibility, Q 22)	Need not have been planned or pre-meditated; include	A Rating	Scale:	T		
16 ASS 1 55	totally impulsive attempts.	_ Abs	ent	Pres	ent	Not
Did you do anything on purpose that	N. 15.7	7	51.5.51			Answered
you knew could have killed you? (What	Very impulsive suicidal behav-		-	QSORRES/Q	SSTRES	□₄
did you do? What happened then? Did you think you could die as a result?)	ior can occur even when other death/sucide items are		ור	1	13	4
TO Line A STORM AND THE STORM	regative.			occurrence:		
If Yes: When was that? QSTEST=.RATING QSTESTCD=PRISM5A		Pr	ior to the	past 6 mont	hs QSORRES/C	SSTRES Eligibility, Q 22)
How many times did you do anything to	Include if completed act was	☐ In	the past	6 months (4	631 Study	Eligibility, Q 22)
kill yourself?	believed to be lethal but					
30.4849 (0.00 +0.00 s.R.O.0	subject was discovered and					
QSTEST=.MOST RECENT	squed.					
QSTESTCD=PRISM5B	Must have believed that the					
	act was lethal, regardless of					
	objective reality.					
6 Recurrent Homicidal Ideation	20					
Did you ever think about harming or	Must think actively of harming	A Rating	Scale:			
killing someone? (What did you think	or killing someone, even if			Sub	9	Not
of? How often did you have that	ambivalent.	Absen	* T	hreshold	Present	
thought?) QSTEST=.RATINGQSTESTCD=PRISM6A	Can have homicidal ideation		1850	QSQRRES/(neetdee	
IF YES: Do you still think about harming	without having homicidal plan			USUKKES/	233TRES	□4
or killing someone at the present time?	A STATE OF THE STA			(800	- N
How often? QSTEST=.MOST RECENT		024-257		ccurrence:	- STO	D TL:- f :-
QSTESTCD=PRISM6B		→ L Pri		RES/QSSTRE		P. This form is plete.
For how long have you been having						o question 7.
these thoughts?		Ш	me pas	o moning		o quosiioii //
7 Specific Homicide Plan						
Have you taken any steps toward	Must be thinking of actual	A Rating	Scale:			
carrying out this plan (4631-Study Eligibility,	method of harming or killing				Т	Not
Q-22)? QSTEST=.RATING	someone. Intent to carry out	Abs	ent	Pre	sent	Answered
U-22/:		4,1				
QSTESTCD=PRISM7A	the plan is not required, for	***		OSOBBES	/OCCTREC	,
U-22/:	the plan is not required, for mulation of a specific plan is],	100	/QSSTRES	□4
QSTESTCD=PRISM7A	the plan is not required, for	Γ],	100	The state of the s	□ ₄
QSTESTCD=PRISM7A	the plan is not required, for mulation of a specific plan is],	100	The state of the s	□ ₄
QSTESTCD=PRISM7A	the plan is not required, for mulation of a specific plan is enough. Include even if fleeting plan. Need not have been recurrent],	100	The state of the s	□4
QSTESTCD=PRISM7A	the plan is not required, for mulation of a specific plan is enough. Include even if fleeting plan.],	100	The state of the s	□ ₄



Node #:	CTP Site	ID #:		Participan	nt ID #: _	USUBJID
Assessmen	t Date: _	DS.DSD	TC / SC.SCD	TC	Visit	#:VISITNUM

Se	ection 1: Must be completed prior to randomizing the study candidate.
1	SCCAT=RANDOMIZATION Has it been determined that the individual is eligible for the study, as defined by the inclusion/exclusion criteria (4631.5)
CT	TEST Eligibility Form)? O SCORRES
	. Yes
2	Did the participant have a stimulant-positive UDS result during baseline/screening? No SCORRES
	SCTEST Yes
_	
Se	ection 2: Complete Randomization procedure
2	Total Division
•	Treatment assignment (check only one):, TAU_DM.ARM
	□₂ TAU + SCT
4	Date of randomization://_DM.RFSTDTC
	DSCAT=DISPOSITION EVENT day year
5	If participant was eligible, but not randomized, please mark reason (check only one):
	1 No longer interested in participating in the study
	2 Left prior to randomization and failed to return
	3 Other (specify):



QSCAT=RISK ASSESSMENT BATTERY (RAB) Form completion (if form not complete, check one):	DOMAIN: QS
☐ Participant unavailable ☐ Data collection error Fields affected: ☐ Entire CRF ☐ Questions (specif	
Node # CTR SHOLD # SITEID	Participant ID # USUBJID

			Assessment Date: Q	SDTC / V	isit #: VISITNUM			
1	4(00 P' 4	. D (DAD)	month	day ywar				
	4628 Risk Assessment Battery (RAB)							
	Please read each of the following questions very carefully. As you will see, many of these questions are very personal. We understand this and have taken great care to protect the privacy of your answers.							
	It is very important that you answer EVERY question honestly. In fact, it's better not to answer a question at all than to tell us something that is not accurate or true. Some questions may not seem to have an answer that is true for you. When this happens, you should simply choose the answer that is most right. Don't spend too much time on any one question. Remember, always ask for help if you're unsure about what to do. Thank you for your time and cooperation.							
	QSTE	ST A Past Month	Drug and Alcohol Use	QSORRES/QSSTRES				
QSTEST	Please fill in the most corre	ct response QSEVI	LINT=-P30					
RAB1	In the past month, how cocaine and heroin tog	often have you <u>injected</u> ether (speedball)?	Not at all A few times	s A few times each week	Everyday			
RAB2	2 In the past month, how (not mixed)?	often have you <u>injected</u> heroin	□ Not at all □ A few times	s A few times each week	Everyday			
RAB3	3 In the past month, how (not mixed)?	often have you <u>snorted</u> heroin	□ Not at all □ A few times	s A few times each week	Everyday			
RAB4	4 In the past month, how	often have you <u>smoked</u> heroin?	Not at all A few times	s A few times each week	Everyday			
RAB5	5 In the past month, how cocaine (not mixed)?	often have you <u>injected</u>	□ Not at all □ A few times	s A few times each week	Everyday			
RAB6	6 In the past month, how (not mixed)?	often have you <u>snorted</u> cocaine	□ Not at all □ A few times	s 🗌 A few times each week	Everyday			
RAB7	7 In the past month, how rock, or freebase coca	often have you <u>smoked</u> crack, ne?	□ Not at all □ A few times	s A few times each week	Everyday			
RAB8		often have you <u>injected</u> speed, crank, or crystal?	□ Not at all □ A few times	s A few times each week	Everyday			
RAB9		often have you <u>snorted</u> speed, crank, or crystal?	□ Not at all □ A few times	s A few times each week	Everyday			
RAB10	10 In the past month, how amphetamines, meth,	often have you <u>smoked</u> speed, crank, or crystal?	□ Not at all □ A few times	s A few times each week	Everyday			
RAB11	11 In the past month, how benzodiazepines, (ben Valium, Klonopin, or A	zos, benzies) such as Xanax,	□ Not at all □ A few times	s A few times each week	Everyday			
RAB12		often have you taken s Percodan, Percocet, Vicodin, von, Darvocet, or syrup	□ Not at all □ A few times	s A few times each week	Everyday			
RAB12_3A	12a Which types of painle	killers did you use?						

STUDYID = CTN0046 CTN-0046

QSCAT=RISK ASSESSMENT BATTERY	(RAB)
	()

DOMAIN: QS

	CTN-0046	□ ₁ Parli	pletion (if form not complete, check one): icipant unavailable	
	S-CAST		cted: © Entire CRF 1 Questions (specify): CTP Site ID #: SITEID	
			Assessment Date: QSDTC	
QSTEST	GD QSTEST 4628 Risk Asses <mark>smen</mark>	QSEVEINT=-F3		QSORRES/QSSTRES
RAB13	13 In the past month, how often he	or an artist of the section of the s	Not at all A few times A	few times each week Everyday
DADAG	Dilaudid?	15% \$6		
RAB12	14 In the past month, how often he or other hallucinogens?	ave you used acid, LSD	Not at all A few times A	few times each week 🔲 Everyday
RAB15	15 In the past month, how often h	ave you used marijuana?	Not at all A few times A	few times each week Everyday
RAB16	16 In the past month, how often he or liquor?	•		few times each week 🔲 Everyday
		B Ne	edle Use	
RAB17	17 In the past month, have you inj	ected drugs?	□₀ No □₁ Yes	
RAB18	18 In the past month, have you sh	ared needles or works?	O No or I have not shot up in t	he pas month 🔲 1 Yes
RAB19	19 With how many different peop the past month?	le did you share needles in	Zero or I have not shot up or	shared in the past month
	rne pasi monin:		1 other person 2 or 3 different people	
			3 4 or more different people	
RAB20	20 In the past month, how often he	Th 1960 Th		or shared in the past month
	someone (with or without clear	iing)?	1 A few times (1 or 2 times) 2 About once a week (3 or 4 t	imas)
			3 More than once a week (5 c	
RAB21	21 In the past month, how often h	ave others used after you	□ ₀ Never or I have not shot up o	or shared in the past month
	(with or without cleaning)?	<u></u>	1 A few times (1 or 2 times)	or management past mount
			About once a week (3 or 4 t	500 to contract 500
			☐ ₃ More than once a week (5 o	or more times)
RAB22	22 During the past month, how off			or shared in the past month
	with someone you knew (or lat was positive for HIV, the AIDS		1 A few times (1 or 2 times) 2 About once a week (3 or 4 times)	imes)
			3 More than once a week (5 c	
RAB23	23 Where did you get your needle		- 17 - 17 - 17 - 17 - 17 - 17 - 17 - 17	month
	ALL that apply)?	RAB23_0 RAB2	23_1 From a diabetic	
	QSTEST			100
	RAB23_err has no data,	RAB2	23_4 Shooting gallery or other plac 23_5 Needle Exchange Program	ce where users go to shoot up
	not collected		23_6 Other (specify):	QSTESTCD=RAB23_6A
RAB24	24 In the past month, how often h	ave you been to a shooting	o Never	
TOTOL	gallery/house or other place w		1 A few times (1 or 2 times)	NO
	Anadis		About once a week (3 or 4 t	rimes)
RAB25	25 In the past month, how often h	ave you been to a crack	Never	*
	house or other place where pe		1 A few times (1 or 2 times)	
	sée		The second secon	

STUDYID = CTN0046

	\$10DYID = C1N0046 QSCATERISK ASSES			DOMAIN: QS
9			omplete, check one): □2 Data collection error	☐3 Participant unable/unwilling to answer
			Questions (specify)	
	S-CASI			
	Node #: _	CTP S	Site ID #:SITEID	Participant ID #: USUBJID
	A	Assessment Date	Q\$DTC	/Visit #:VISITNUM
QSTEST			~ 	RES/QSSTRES
	4628 Risk Assessment Battery (RAB) (con	ntinued)		
		- 20		
RAB26	26 Which statement best describes the way you cleaned your		ot shot up in the pa	st month
	needles during the past month (please choose ONE)?		use new needles	
		1 always	clean my needle ju	st <u>before</u> I shoot up
		3 After I sl	noot up, I <u>always</u> cl	ean my needle
				e, sometimes I don't
			lean my needle	
		□ 5 1 liever	lean my needle	
RAB27	27 If you cleaned your needles and works in the past month,	I have no	t shot up in the pas	month
	how did you clean thein (check ALL that apply)? RAB27_1	37 <u></u> 3	d water only	
	RAB27_0 RAB27_2	Alcohol	,	
	→RAB27_3	Bleach		
	QSTESTCD RAB27_4	Boiling w	ater	
	RAB23_err	Other		
	has no data,	l did not	clean my needles ir	the past month
	not collected RAB27_7	I ALWAY:	S used new needle:	s in the past month
RAB28	28 In the past month, how often have you shared rinse-water?			or shared in the past month
			mes (1 or 2 times)	
			nce a week (3 or 4	times)
		a More th	an once a week (5	or more times)
	2004 25 25 25 25 25 25 25 25 25 25 25 25 25	52_5;		1 000 APTS 1910 30 VA CR TV.
RAB29	29 In the past month, how often have you shared a cooker?	Never o	r I have not shot up	or shared in the past month
			mes (1 or 2 times)	
		About o	nce a week (3 or 4	limes)
			an once a week (5	38.
			an once a meet to	s. more times,
RAB30	30 In the past month, how often have you shared a cotton?	Never o	r I have not shot up	or shared in the past month
		, A few tir	mes (1 or 2 times)	· · · · · · · · · · · · · · · · · · ·
			nce a week (3 or 4	times)
			an once a week (5	40
		□3 Mole III	an once a week (5	or more rimes)
RAB31	31 In the past month, how often have you divided or shared	☐ Never		
	drugs with others by using one syringe (yours or somebody		mes (1 or 2 times)	
	else's) to squirt or load the drugs into the other syringe(s)		nce a week (3 or 4	l rimes)
	(backloading, for example)?		an once a week (5	5 P. S.
	• • • • • • • • • • • • • • • • • • • •	_,	**************************************	₩
	C Sexua	Practices		
	and the second s			
RAB32_0	32 How would you describe yourself? Straight or Heterosexue	al Gay o	r Homosexual	Bisexual
	, , , , , , , , , , , , , , , , , , ,			TO A TO THE PROPERTY OF THE PR
	PLEASE NOTE: For the following questions, sex means an oral sex (blowjobs, for example).	y vaginal in	tercourse, anal	intercourse (in the butt) or
RAB33	equality of the stand	П-		l
IVADOO	33 With how many men have you had sex with in the past	0 men	2 or 3 men	l
	month?	☐ 1 man	4 or more men	iii
	200			I
RAB34	34 With how many women have you had sex with in the past	0 women	2 or 3 wom	nen
	month?	1 woman	\equiv	2017
	NETHOLINES.	i woman		7 THE STATE OF THE

QSCAT=RISK ASSESSMENT BATTERY (RAB)

		(ASSESSMENT BATTERY (RAB)
		completion (if form not complete, check one):
	S-CASI	
	N	OSDTC:
QSTEST	CD QSTEST QS	Assessment Date: Visit #: VISITNUM EVLINT=-P30 QSORRES/QSSTRES
40.20	4628 Risk Assessment Battery (RAI	
RAB35	35 In the past month, how often have you had sex so yo	S 45-45
200	could get drugs?	
	coold get drogs.	1 A few times (1 or 2 times)
	Assessment of the talk of the talk of	
RAB36	36 In the past month, how often have you given drugs to	30 <u></u>
	someone so you could have sex with them?	, A few times (1 or 2 times)
RAB37	37 In the past month, how often were you paid money to	have never
	sex with someone?	A few times (1 or 2 times)
	SEC A REPORT OF THE REPORT OF THE PARTY OF T	☐₂ About once a week (3 or 4 tirtes)
		More than once a week (5 or more times)
RAB38	38 In the past month, how often did you give money to s	**************************************
	one so you could have sex with them?	, A few times (1 or 2 times)
RAB39	39 In the past month, how often had you had sex with so	ome Never
	one you knew (or later found out) had AIDS or was	, A few times (1 or 2 times)
	positive for HIV, the AIDS virus?	About once a week (3 or 4 times)
		3 More than once a week (5 or more times)
RAB40	40 In the past month, how often did you use condoms w	hen I have not had sex in the past month
	you had sex?	
		4 None of the time
RABH	D Concern	s about HIV and Testing
	If you know that you are HIV positive, skip to ques	tion 44.
RAB41	41 How worried are you about getting HIV or AIDS?	□₀ Not at all □₃ Considerably
	,	, Not at all
RAB42	42 How worried are you that you may have already bee	en □₀ Not at all □₃ Considerably
NAD42	exposed to the HIV or AIDs virus?	Slightly 4 Extremely
		, Moderately
RAB43	43 How many times have you had a blood test for the A	
	virus (HIV)?	678910 or more times
RAB44	AA Whan was and but a total for UNA Plantage of	month. /
.0.044	44 When were you last tested for HIV? Please write the and year of your most recent test.	month
	and your or your most recent rest.	85_43 489 W_S
RAB45	45 Were you ever told you had HIV, the AIDS virus?	□ No □ 1 Yes □ 2 I never got the results

Thank you. Please let the staff person know that you have finished.

Form completion	(if form not complete, check one)	DOMAIN: AE, CM, LB
☐₁ Participant u Fields affected: [mavailable 🔲 2 Data collection	
Node #:	CTP Site ID #:	Participant ID #: USUBJID
AED ate: /	TC	Week #: VISITNUM Sequence #:

	9 Serious	s Adverse	Events			
1 C	orresponding A	E symptom or d	liagnosis: AETER	RM		
2 N	arrative descrip	ition of serious	adverse event and any s	equelae (if associated	with hospitali	ization, include the dates of
	ospitalization):					
: -	QNAM=AESNAR QLABEL=SAE NARRATIVE DESCRIPTION					
25		IDVAR=AESEQ	ARRATIVE BEGORI. HOR			
3 Ki	medical h	istans including	are switting medical cou	-datang fallargies preg	emok	
	Known medical history including pre-existing medical conditions (allergies, pregnancy, smoking diabetes, epilepsy, depression, etc.): OR Unknown QNAM=AESMH					ing ana aiconoi use, nyperierisk
2.5886		The Transplant South	2071270 J. Stock Conversion V	QLABEL=SAE MEDICA	L HISTORY	
100				IDVAR=AESEQ		
72						
100	(**C1145(**C0**C54) (**C**)	-00-000-1000-1000			710-088-08	
4 W	AT = 'SAE CONCON hat concomitan	MITANT DRUGS US t medications w	SING' vas the participant using	at the time of this eve	nt? (Include	name of medication, indication
			n if known) OR Unkno			
	Medication	n Name	Indication	Do	sage	Date Last Taken
CMSEQ	CMTR	RT	CMINDC	CMD	OSE	CMSTDTC / day / yes
		-			· · · · · · · · · · · · · · · · · · ·	//
-				27		month day ye
						month day ye
						//
						month day ye
-					Ş	month day ye
5 CMC/	AT = 'SAE CONCOI	VIITANT DRUGS EN	(GAGED'	d in at the time of this	event? (Incl	/
			NGAGED's the participant engage	d in at the time of this	event? (Incl	//
	eatment, and date				event? (incl	/
	eatment, and date	e last treated if kn atment Name		None Indication	event? (Incl	Date Last Treated
tre	eatment, and date	e last treated if kn		None	event? (Incl	Jate Last Treated
tre	eatment, and date	e last treated if kn atment Name		None Indication	event? (incl	Date Last Treated
tre	eatment, and date	e last treated if kn atment Name		None Indication	event? (Incl	Date Last Treated CMSTDTC /
tre	eatment, and date	e last treated if kn atment Name		None Indication	event? (Incl	Date Last Treated CMSTDTC / / yes month day yes day yes
tre	eatment, and date	e last treated if kn atment Name		None Indication	event? (incl	Date Last Treated CMSTDTC / / yes manth day yes and day yes manth day yes manth day yes manth day yes
cMSEQ	eatment, and date	e last treated if kn stment Name CMTRT	nown) OR Unknown	Indication CMINDC		Date Last Treated CMSTDTC / / yes month day yes day yes
cMSEQ	eatment, and date	e last treated if kn stment Name CMTRT		Indication CMINDC		Date Last Treated CMSTDTC / / / yes month day yes
CMSEQ 6 W	eatment, and date	e last treated if kn stment Name CMTRT AB TESTS PERFORMER PERFORMER PERFORMER	nown) OR Unknown	Indication CMINDC		Date Last Treated CMSTDTC / / / yes month day yes
CMSEQ	Trea LBCAT = 'SAE L	e last treated if kn stment Name CMTRT AB TESTS PERFORMER PERFORMER PERFORMED	RMED' In conjunction with this	Indication CMINDC		Date Last Treated CMSTDTC / / yes month day / yes LBDTC / / / / yes
CMSEQ	LBCAT = SAE L /hat tests/labs v	e last treated if kn stment Name CMTRT AB TESTS PERFORMER PERFORMER PERFORMED	RMED' In conjunction with this	Indication CMINDC		Date Last Treated CMSTDTC / / yes month day / yes



QSCAT=SMOKING HISTORY SURVEY (DOMAIN: QS		
Form completion (if form not com			
☐ ₁ Participant unavailable ☐	2 Data collection error	3 Participant unable/unwi	lling to answer
Fields affected: □ ₀ Entire CRF	1 Questions (specify):		
Node #: CTP Site	ID #: SITEID	Participant ID #:	USUBJID
Assessment Date:	QSDTC	/V	isit #: VISITNUM
	month day	year	

- Dag			morn usy	yeor
	46	530 Smoking History Survey (SHS)		
	Thi	s assessment is to be administered by a Research Assistant.		
QSTESTCD		QSTEST	QSORRES	/QSSTRES
SHS01	1	How old were you when you first smoked a cigarette? years old ←	QSSTRES	SU=YEARS
SHS02	2	How old were you when you first started regular daily cigarette smoking?	years old	
SHS03	3	On average, how many cigarettes are you currently smoking per day [463]	Study Eligibility, G	4) ? cigarettes/day
SHS04	4	Over the past year how many cigarettes did you smoke per day?	_ cigarettes/day	QSSTRESU=CIGARETTES
SHS05	5	How many years have you been smoking?years		QSEVLINT=-P1Y
SHS06A	6а	What brand of ciga ettes or tobacco do you smoke most? Specify brand (prin	nt):	
SHS06B	6b	Length (check only or e):, Regular		
	228	Other (specify in 6c)		
SHS06C	2373	If 6b = other (3), then specify other length (print):		
SHS06D	6d	Pack style (check only one):, Hard pack, Soft pack		
SHS06E	0e	Mentholated (check only one):, Non-mentholated		
SHS07	7	Among your close friends and family, what percentage would you say smoke	e cigarettes (chec	k only one!?
	8	□ _o None		/
		Approximately 50% Approximately 75%		
		_ Approximately 100%		
SHS08A	8a	Are there any other cigarette smokers in your household/living arrangement	s?	
311300A		□ _o No		
SHS08B				
SHS09	9	How much do the people closest to you want you to stop smoking (check only	one)?	
		Not at all		
		Not much Neutral		
		Somewhat		
SHS010	10	If you were to stop, how helpful would the people closest to you be?		Y
		Not helpful		
		Not much help		
		Neutral Somewhat helpful		
		Very helpful		
SHSC	RIS	*CONT *CONT * A *CONT * CONT *		

	SCAT=SMOKING HISTORY SURVEY (SHS) Form completion (if form not complete, check one):			DOMAIN: QS		
☐ ₁ Participant unav	ailable 🔲 2 Data co	ollection error	3 Participant unable/unwillin			
Node #:	CTP Site ID #: _	SITEID	Participant ID #: _	USUBJID		
Assessm	ent Date:	QŞDTC	Visi	#: VISITNUM		

	463	30 Smoking	History Survey (continued)
STCD	253	QSTI	ST QSORRES/QSSTRES
1A	11a		d non-cigarette tobacco products?
		∐₀ No	QSSCAT=NON-CIGARET E TOBACCO PRODUCTS USED
		Yes → If Yes: 0	heck an answer for each of the following:
11B			1 b Cigars
11C		2	1c Pipes
11D			1d Bidis (tobacco wrapped in a temburni leaf)
11E			1e Smokeless tobacco (pan, chewing tobacco, snuff) □₀ No □₁ Yes
12	12	How many times	ave you attempted to quit smoking? → If zero times, enter 000 and then a swer questions 13 and 14; then
		stop.)	
13	13	Since you started	smoking regularly, what is the longest time that you have gone without smoking any cigarettes (check
			ver gone without smoking
			than a day
			east one day, but less than a week
			east one week, but less than a month
		E 100 CO LO	east one month, but less than a year
			e year or more
4A	14a	1.0	perienced uncomfortable symptoms when you stopped smoking (check only one)?
		o Does not apply	-I have never stopped smoking
		, I have stopped	smoking in the past but never experienced uncomfortable symptoms
		2 I have stopped	smoking in the past and have experienced uncomfortable symptoms → If answered: What symptoms (check an
		answer for eac	of the following)?
4B		14b Craving	No 1 Yes QSSCAT=UNCOMFORTABLE SYMPTOMS EXPERIENCED
4C		14c Decrea	ed heart rate 🔲 No 🔲 1 Yes
4D		14d Irritabil	y 🔲 No 🔲 1 Yes
4E		14e Anxiety	□₀ No □₁ Yes
14F		14f Increase	d eating 🔲 No 🔲 Yes
4G		14g Restless	ness 🔲 No 🔲 Yes
4H		14h Difficult	y concentrating 🔲 No 🔲 Yes
141		14i Other (pecify in 14j) 🔲 No 🔲 Yes
14J			pecify (print; limit 200 characters):
	15	Enter the number	of times you have tried the following methods to stop smoking (if zero, enter 000):
15A	15		p material (for example American Lung Association material, materials from your doctor, etc.): times
15B			tl cessation program (for example with classes, group discussions, etc.):
15C			te consultation with your doctor or mental health physician:
15D			is/acupuncture: QSSCAT=SMOKING CESSATION METHODS ATTEMPTED times
15E		1.55	e medicated gum:times
			일 등입니다. 그런 그런 그런 그런 보다 보고 있다면 보다 그리다. 그래요
15F		(U. D. C.)	(bupropion SR):times
15G			(varenicline):times
15H			inhaler, spray, or lozenge:times
15I I5J		20	r own (cold turkey):times
			f not 000, specify in 15k):times specify (print; limit 200 characters):
5JS		TEL OIL	



QSCAT=SMOKING HISTORY	SURVEY (SHS)	DOMAIN: QS		
Form completion (if	Form completion (if form not complete, check one):			WAIN. Q3
□₁ Participant una	and the second s	ollection error	Participant unable/unwill	ing to answer
Field's affected: □₀	Entire CRF 1 Que	shors (specify):		
Node #:	CTP Site ID #:	SITEID	Participant ID #:	USUBJID
Assessm	ent Date:	QŞDTC	/ Vis	it #: VISITNUM

	4630 Smoking History Survey (continued)				
QSTESTCD	QSTEST QSORRES/QSSTRES				
SHS16A	16a Have you ever used nicotine skin patches? QSSCAT=NICOTINE SKIN PATCHES				
	QSSCAT=NICOTINE SKIN PATCHES 1 Yes → If Yes: Answer 16b-16d below.				
SHS16B	16b If you have used nicotine skin patches, how many times?				
SHS16C	16c If you have used nicotine skin patches, did you have any problems with the patch?				
SHS16D	No No No No No No No No No No No No No No No No No No No No No No No No No No No No No No No No No				
SHS17A	17a When was your last attempt to stop/quit smoking?				
	QSSCAT=LAST ATTEMPT TO STOP SMOKING				
	Days ago				
	☐₃ Weeks ago ☐₄ Months ago				
	s Years ago				
SHS17BDT	17b When was the date of the last attempt to quit smoking (4631 Study Eligibility, Q 15)://				
	month day year				
SHS17C	17¢ Did you use a smoking cessation counseling program or medication to help you quit smoking (4631 Study Eligibility, Q 15):				
0110470	properties for the first the same of the s				
SHS17D	17d For how long did you go without smoking at that time?				
	, Hours				
	Days				
	☐₃ Weeks				
	Months				
	□ _s Years				
SHS17E	17e How did you stop? Please describe (print; limit 200 characters):				
0110475					
SHS17F	17f Why did you start again? Please describe (print; limit 2 00 characters):				
SHS18	18 What is the longest period of time you have gone without smoking?				
011010	, Hours				
	Days				
	☐ ₅ Years				

Form completion (if form not complete, check one):	DOMAIN: IE		
\square_1 Participant unavailable \square_2 Data collection error Fields affected: \square_0 Entire CRF \square_1 Questions (specify):	3 Participant unable/unwilling to answer		
Node #: CTP Site ID #:	Participant ID #: USUBJID		
Assessment Date:/	/Visit #: VISITNUM		

	month day ye	ar						
40	531 Study Eligibility							
Inc	Inclusion Criteria: Is the individual: (include if Yes) IECAT = INCLUSION CRITERIA							
1ET	An adult, age 18 or older (see 4613 Demographics, Q 1)?	No IEORRES Ves Not assessed						
2	Able to understand and provide written informed consent in English (see signed consent form)?	O No O Yes						
3	Diagnosed with a DSM-IV-TR diagnosis of current (within the last 12 months) dependence for cocaine or methamphetamine (see 4607 CIDI Summary, Q 4 and Q 7)?	□₀ No □₁ Yes □₀ Not assessed						
4	Confirmed as having smoked cigarettes for at least 3 months (see 4619 Medical History Addendum, Q 16), currently smoking at least 7 cigarettes/day (see 4630 Smoking History Survey, Q 3) and having a measured exhaled CO level ≥ 8 ppm (see 4606 Carbon Monoxide Assessment, Q 1)?	□₀ No □₁ Yes □₀ Not assessed						
5	Interested in quitting smoking (see 4636 Thoughts about Abstinence–Cigarettes, Q 1) and willing to comply with all study procedures and medication instructions (based on the judgment of the study investigator, inherent in Informed Consent Form)?	□₀ No □₁ Yes □₀ Not assessed						
6	Enrolled in outpatient/intensive outpatient treatment at a participating CTP and scheduled to attend at least one treatment session per week for at least 10 weeks after randomization (see 4633 Substance Abuse Treatment Status, Q 1 and Q 3a-3b)?	□ ₀ No □ ₁ Yes □ ₉ Not assessed						
7	Confirmed, if female and of childbearing potential, having agreed to use one of the specified methods of birth control during the study (see 4643 Urine Pregnancy Test, Q 5a)?	□ ₀ No □ ₁ Yes □ ₀ Not assessed						
Ex	clusion Criteria: Does the individual: (Exclude if Yes) IECAT = EXCLUSION CRITERIA							
8	Meet DSM-IV-TR diagnostic criteria for current (within the past month) dependence for alcohol or sedatives (see 4607 CIDI Summary Form, Q 2 and Q 3) or have a physiological dependence on alcohol or sedatives requiring medical detoxification (see 4619 Medical History Addendum, Q 17)?	□₀ No □₁ Yes □₀ Not assessed						
9	Have an Axis-I psychiatric condition that, in the judgment of the study medical clinician, would make study participation unsafe or which would make treatment compliance difficult (see 4607 CIDI Summary Form and judgement of study medical clinician)?	□₀ No □₁ Yes □₀ Not assessed						
10	Meet DSM-IV-TR criteria for current (within the past 12 months) bipolar disorder (see 4607 CIDI Summary, Q 27 and Q 28) <u>QR</u> current or lifetime anorexia nervosa or bulimia (see 4607 CIDI Summary, Q 25 and Q 29)?	□₀ No □₁ Yes □₀ Not assessed						
11	Report seeking/receiving treatment for opiate-agonist replacement therapy, naltrexone, or for detoxification only (see 4633 Substance Abuse Treatment Status, Q 5a and 5b)	□ ₀ No □ ₁ Yes □ ₀ Not assessed						
12	Have a history of seizure disorder (see 4618 Medical History, Q 23)?	□₀ No □₁ Yes □₀ Not assessed						
	Have a history of a closed head trauma with > 30 minutes loss of consciousness (see 4619 Medical History Addendum, Q 18)?	□₀ No □₁ Yes □₀ Not assessed						

Form completion (if	form not complete, check one):	DO	MAIN: IE
☐ Participant una Field's affected: ☐		3 Participant unable/unwilli	
Node #:	CTP Site ID #:		USUBJID
Assessm	ent Date:/	_/ Visi	#: VISITNUM

2007016	50000000 - 2000	. mo	nth day year	9				
40	531 S	tudy Eligibility (continued)						
Ex	Exclusion Criteria: Does the individual: (Exclude if Yes) IECAT = EXCLUSION CRITERIA IEORRES							
14	□₀ No □₁ Yes □₀ Not assessed							
	14.1	Uncontrolled hypertension (i.e., blood pressure readings ≥ 140/90 on two clinic visits) (see 4644 Vital Signs)	□₀ No □₁ Yes □₀ Not assessed					
	14.2	Known coronary artery disease including myocardial infarction or angina (see 4619 Medical History Addendum, Section 1), or an ECG with significant conduction abnormality (see 4614 ECG)	□₀ No □₁ Yes □₀ Not assessed					
	14.3	AIDS according to the current CDC criteria for AIDS (see 4619 Medical History Addendum, Q 19)	□₀ No □₁ Yes □₀ Not assessed					
	14.4	Liver function tests greater than 3X upper limit of normal (see 4604 Blood Chemistry)	□ ₀ No □ ₁ Yes □ ₉ Not assessed					
	14.5	Serum creatinine greater than 2 mg/dL (see 4604 Blood Chemistry)	□₀ No □₁ Yes □₀ Not assessed					
	14.6	Diabetes treated with hypoglycaemics or insulin (see 4619 Medical History Addendum, Q 20)	□₀ No □₁ Yes □₀ Not assessed					
	14.7	Other (see 4622 Physical Exam, etc.) If Yes, specify:	□₀ No □₁ Yes □₀ Not assessed					
15		using or having used other smoking-cessation programs or medication to the last 30 days (see 4630 Smoking History Survey, Q 17b–17c)?	reatments currently, or	□ ₀ No □ ₁ Yes □ _p Not assessed				
16		known or suspected hypersensitivity to bupropion, nicotine, or menthol um, Q 21)?	(see 4619 Medical History	□₀ No □₁ Yes □₀ Not assessed				
17	If femal	□₀ No □₁ Yes □₀ Not assessed						
18	(MAO) i investiga (e.g., iso	using any of the following medications within 14 days of randomizations inhibitors, antimalarials, tramadol, theophylline, systemic steroids, quint ational drug, or any drug with known potential for toxicity to a major of miazid, methotrexate) and/or have used sedating antihistamines within 7 of 15 Prior and Concomitant Medications)?	olones, bupropion, any rgan system	□ ₀ No □ ₁ Yes □ ₉ Not assessed				
19	interacti	aking any medications which, in the judgment of the study medical clinicons with bupropion XL that are sufficiently dangerous so as to exclude tating in the study (see 4625 Prior and Concomitant Medications)?		□₀ No □₁ Yes □₀ Not assessed				

Form completion (if form not complete, check one):	DOMAIN: IE
☐1 Participant unavailable ☐2 Data collection error	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	USUBJID
Assessment Date:/	/Visit #: VISITNUM

month day year	
4631 Study Eligibility (continued)	
Exclusion Criteria: Does the individual: (Exclude if Yes) EXECUSION CRITERIA IEO EXECUTION CRITERIA	RRES
20 In the judgement of the investigator, seems unlikely to complete the study protocol (see RA checklist for Visit 101)?	□₀ No □₁ Yes □₀ Not assessed
21 Report having used tobacco products, other than cigarettes, in the past week (see 4638 TLFB Pre-Study)?	□₀ No □₁ Yes □₀ Not assessed
22 Represent a significant suicidal/homicidal risk (see 4626 PRISM, Q 3b, Q 5b, Q 7a)	□₀ No □₁ Yes □₀ Not assessed
23 Have a desire and present a likelihood of entering residential/inpatient treatment within 10 weeks (see 4633 Substance Abuse Treatment Status, Q 7)?	□₀ No □₁ Yes □₀ Not assessed
24 Have all stimulant-positive UDS results during screening/baseline (see 4642 Urine Drug Screen)	□₀ No □₁ Yes □₀ Not assessed
25 Is the individual eligible for the study?	□ ₀ No □ ₁ Yes
26 Investigator name (print legibly): QNAM=IENAME QLABEL=IE CLINICIAN NAME IDVAR=VISITNUM	
27 Date signed:/	
QNAM=IESIGDTC QLABEL=IE SIGNATURE DATE IDVAR=VISITNUM	0



QSTESTCE

SQ01

SQ02

SQ03

SQ04

SQ05

SQ06

SQ07A-SQA7G

SQ07GSP

SQ08

This met l	STUDYID = CTN0046 TN - OO 46 S-CAST OSTEST 32 Study Questionnal questionnaire is designed to help us hamphetamine use. Please answer to tamine at least once a week.	Form com In Par Fields affe Node #	cted: O Entire CRF O Oue CTP Site ID #: Oue Assessment Date: One mont	SITEID Q\$DTC / QSORRES/QS igarette smoki	ng and crack/cocaine or
_	How often did you smoke cigarette:	to try to avoid using	rack/cocaine or metha	mphetamine?	
ō	□₀ Not at all		\square_2 A few times ea		☐₃ Everyday
2	How often did you use crack/cocair	ne or methamphetamin	ne to avoid smoking ciga		□₃ Everyday
3	How often did your use of crack/co	caine or methampheta	mine increase your desi	- 580	cigarettes?
4	How often did smok ng a cigarette i	. <u></u>	raving for crack/cocain	50 mg	netamine?
5	How often did your use of crack/co	caine or methampheta	mine increase your use		□₃ Everyday
6	How often did smok ng a cigarette i □₀ Not at all	increase your use of cr	ack/cocaine or metham		□₃ Everyday
	If you smoked cigarettes while also explain why you used cigarettes wit NA (did not use both together) Cigarette smoking helps the high fromethamphetamine or last longer Cigarette smoking is just a habit—no	using crack/cocaine or th crack/cocaine or me m crack/cocaine or particular reason for	thamphetamine: Cigarette smoking Smoking cigarettes use so that the crac	helps to feel mo slows down are ck/cocaine meth	of the responses that

8 If you have tried to quit both cigarette smoking and using crack/cocaine or methamphetamine at the same time, please select the response that best captures your experience:

NA (never tried to quit at the same time)

Trying to quit both made it easier to stay clean from crack/cocaine or methamphetamine

Trying to quit both made it harder to stay clean from crack/cocaine or methamphetamine

QSCAT=STUDY QUESTI		eck one):		DOMAI	N: QS
☐1 Participant unave Fields affected: ☐0 E	silable □2 Data co	ollection error stions (specify):	□ ₃ Participant unable/u		
Node #:	CTP Site ID #: _	SITEID	Participant ID	#:	USUBJID
Assessme	nt Date:	QSDTC		Visit #:	VISITNUM

- 04	QSTEST QSORRES/QSSTRES
	4633 Substance Abuse Treatment Status
TESTCD	
ATS01	1 Are you currently enrolled in outpatient or intensive outpatient substance abuse treatment (4631 Study Eligibility, Q 6)?
	U ₁ Outpatient
S02DT	2 When did you enroll in your present outpatient/IOP treatment:/
TS03A	3a Are you scheduled to attend at least one treatment session per week (4631 Study Eligibility, Q 6)?
	, Yes → If Yes: Answer question 3b.
TS03B	3b Will you be scheduled to attend at least one treatment session per week for at least 10 weeks as of
	[give estimated date of randomization] (4631 Study Eligibility, Q 6)?
	No → If NO: STOP. Participant is not eligible for CTN-0046.
TS03C	36 How many weeks will you be scheduled to attend treatment as of [give estimated date of randomization]?
	weeks Dingoing treatment (no end date set) SATS03c = 1 for # of weeks, =2 for ongoing SATS03cr = the number of weeks
ATS04	4 Did you complete residential treatment within two weeks of starting your present outpatient/IOP treatment?
	□₀ No
T0054	Yes
TS05A	5a Are you receiving methodone or buprenorphine (Subutex®), buprenorphine naloxone (Subokone®), or naltrexone (4631 Study Eligibility, Q 11)?
	□₀ No → If NO: Answer question 5b.
	☐, Yes → If Yes: STOP. Participant is not eligible for CTN-0046.
TS05B	5b Are you trying to get into treatment in which you would receive methadone, buprenorphine naloxone, or naltrexone (463)
	Study Eligibility, Q 11)*
	No → If NO: Answer question 6.
	, Yes → If Yes: STOP. Participant is not eligible for CTN-0046.
	6 Potential pressure to attend treatment: Answer questions 6a-6e below:
TS06A	6a Are you currently on probation?
TS06B	6b Are you cou <mark>rt ordered to substance abuse treatment?</mark>
TS06C	6c Have you been formally notified that you will go to jail if you fail to attend treatment?
TS06D	6d Have you been formally notified that a child will be removed from you if you fail to attend treatment?
TS06E	attend treatment?
	if you fail to attend treatment?
	7 Will you be trying to get into residential/inpatient treatment within the next 2 to 3 months (4631 Study Eligibility, Q 23)?
ATS07	No
	tial/inpatient treatment within 10 weeks of randomization—if entry into residential/inpatient treatment is
	likely then the participant is not eligible for CTN-0046.
	8 Comments (print; limit 200 characters):
	Data not collected

STUDYID = CTN0046 CTN-0046 S-CAST QSSCAT=CLINICIAN RATING

09	CAT=SUPERVISOR TAPE	PATING (STP)	OR SLIPERVISOR T	APE PATING (ITP)
QC	CAT-001 LIVIOUR TAIL	KATINO (STK)	OK OUI EKVIOUK I	ALL IVALINO (ITIV)
_	_			

	Form completion (if fo	orm not complete, che	ck one):	DOI	MAIN: QS
00	☐ 1 Participant unaver Fields affected: ☐ 0 E	리아 (1985년) (198 7년) 후 (1985년) (1987년)	llection error stions (specify):	☐3 Participant unable/unwillin	
GS	Node #:	CTP Site ID #: _	SITEID	Participant ID #: _	USUBJID
	Assessme	ent Date:	QSDTC	/ Visi	#: VISITNUM

NOTE: THERE ARE TWO FORMS STR AND ITR WITH ALMOST (SEE SUPPQUAL) IDENTICAL FIELDS

1	4634 Supervisor Tape Rating—Smoking Cesso	ation	ay year	
	SEE DETAIL BELOW	isor Node: SQ 3	(A)	SQ 4 SQ 7
QSTESTCD	Counseling Compliance Checklist QSTEST	Meets Expectations QSORRE	Needs Improvement ES/QSSTRES	Expectations Not Met: Additional Training Required
STR001/ ITR001	1 Familiarity with each of the intervention topics.	□,		
STR002/ ITR002	Ability to effectively guide study participant through key points in the 10 minute time a lowed.	□,		□₃
STR003/ ITR003	3 Ability to make and maintain eye contact.			□₃
STR004/ ITR004	4 Ability to listen.			
STR005/ ITR005	5 Ability to identify individual needs and provide the appropriate intervention.			٦
STR006/ ITR006	6 Ability to remain nor-judgmental and encouraging.			□₃
STR007/ ITR007	7 Ability to recognize the opportunity for teaching vs. the need to allow for more interaction and discussion remaining within the 10 minute time allowed.			□₃
S	JBSTITUTE 'STR' FOR 'ITR' WHEN USING STR FORM	'A		

IDVAR SQ1 - SQ9 = VISITNUM IDVAR SQ1 – SQ9 = VISITNUM
SQ1 QNAM=ITR001A QLABEL= CLINICIAN ID Also in STR
SQ2 QNAM=ITR001B QLABEL=SUPERVISOR ID Also in STR
SQ3 QNAM=ITR001B1 QLABEL=SUPERVISOR NODE Also in STR
SQ4 QNAM=ITR001B2 QLABEL=SUPERVISOR SITE Also in STR
SQ5 QNAM=ITR001E QLABEL=IR ID (ITR FORM ONLY)
SQ6 QNAM=ITR001E1 QLABEL=IR NODE (ITR FORM ONLY)
SQ7 QNAM=ITR001E2 QLABEL=IR SITE (ITR FORM ONLY)
SQ8 QNAM=ITR001C QLABEL=IR SITE (ITR FORM ONLY)
SQ8 QNAM=ITR001C QLABEL=SESSION NUMBER Also in STR
SQ9 QNAM=ITR001DT QLABEL=SESSION DATE Also in STR



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Form completion (i 1 Participant uni Fields affected:		eck one): ollection error stions (specify):	D Participant unable/unw	OMAIN: QS
Node #:		SITEID	Participant ID #:	USUBJID
Assessr	ment Date:	QSDTC	/ V	isit #: VISITNUM

number tha	II DEN I	81	550		-7-	$\overline{}$	0346									
	→ IF No	: STOP		5.5			QSEVLIN	√T=-D	90							
2 Using the	e scale d	at right,	how wou	ld you desc	ribe your desi i	re to guit	No desire to quit									Gı de
vsing a	konor	at this ri	ime in you	r lite?			0	1	2	3	4	5	6	7	8	_
3 Using the		11.1		ld you desc	ribe <u>how succe</u>	essful you	Very low chance of success									Ver cho
- Althorn		111	<u> </u>				0	1	2	3	4	5	6	7	8	
1900					ribe how diffic	liw ii vill	Very easy									d
		m usin	a alcoho	I at this time	in your life?		78-	100					7545	144		_
5 What is the Please remest to you	the <u>GO/</u> ead the	AL you l goals li pice. Plea	have chose sted below ase read o	en for yours v and choos all of them b	e in your life? self about using se which goal b pefore you pick	est represen		1 vn go	2 pal at	3 t this	4 s time	5 e by	6 chec	7 :king	8 the	bo
Section 2 5 What is the Please renext to your line of the Please renext t	the <u>GO/</u> ead the your cho	AL you l goals li pice. Plea pal – I re	have chose sted belov ase read o eally don't	en for yours v and choos all of them b have a clear	self about using se which goal b pefore you pick goal in mind.	est represen one.	his time? nts your ow	vn go	oal at	t this	s time	e by	chec	king	the	bo
Section 2 5 What is the Please renext to your line of the Please renext t	the <u>GO/</u> ead the your cho	AL you l goals li pice. Plea pal – I re	have chose sted belov ase read o eally don't	en for yours v and choos all of them b have a clear	self about using se which goal b pefore you pick	est represen one.	his time? nts your ow	vn go	oal at	t this	s time	e by	chec	king	the	: bo
Section 2 5 What is the Please remext to your land to yo	the GO/ead the your choclear go	AL you l goals li pice. Plea oal – I re use – I v	have chose sted below ase read of eally don't	en for yours w and choos all of them b have a clear in a controll	self about using se which goal b pefore you pick goal in mind.	one. a able to be in	his time? Ints your own In control of	n go	oal al	t this	s time	e by	chec	king	the	
5 What is the Please remext to your next to	the GO/ead the your choclear go	AL you I goals li pice. Plea oal – I re use – I v on – I w use agai	have chose sted below ase read of eally don't want to use rant to be to n in any wo	en for yours v and choos all of them b have a clear in a controll otally abstine ay.	self about using se which goal b before you pick goal in mind.	est represent one. e able to be in	his time? nts your ow n control of	how	often	l usa	s time	e by	chec	ch I u	the	ut w
Section 2 5 What is the Please remember to your model of the Please remember to your	the GO/ead the your chood clear go on trolled with a decision of I will a decision along the casional	AL you I goals li bice. Plea oal – I re use – I v use agai	have chose sted below ase read of eally don't want to use rant to be to n in any wo	en for yours v and choos all of them b have a clear in a controll otally abstine ay. using to be	self about using se which goal b before you pick goal in mind. ed manner—to be ent from all use fo	e able to be in	his time? In control of time, after v	how	often h I wil	t this	s time e and kke a	e by	chec	ch I u	the	ut w
Section 2 5 What is the Please remember to your new or not	the GO/ead the your choclear go at the will a saional ay slip -	AL you I goals li pice. Plea oal — I re use — I v use agai	have chose sted below ase read of eally don't want to use and to be to n in any wo don't want to quit using	en for yours v and choos all of them b have a clear in a controll otally abstine ay. using to be a	self about using se which goal before you pick goal in mind. ed manner—to be ent from all use for a habit for me, b	e able to be in or a period of ut I would like	time? n control of time, after to	how to or	often h I wil	t this	e and while a	e by	chec v muc decis	ch I u	the see.	ut w



QSCAT=THOUGHTS ABOUT ABSTINENCE-CIGARETTES

QUONT-11	Form completion (if form not complete, check one):	DOMAIN: QS
	☐ 1 Participant unavailable ☐ 2 Data collection error Field's affected: ☐ 6 Entire CRF ☐ 1 Questions (specify):	3 Participant unable/unwilling to answer
	Node #: CTP Site ID #:SITEID	Participant ID #:USUBJID
	Assessment Date: QSDTC month day	/Visit #: _VISITNUM
	161	

D			bout stopping all cigarette : w you feel about <u>stopping,</u> ho											
	The second second		you describe your <u>desire to qu</u> your life (4631 Study Eligibi ^l ity,	it de	No sire to quit									Greates desire to quit
	Q 5) ?		US 68 VT 88 MTD		0	1	2	3	4	5	6	7	8	9
		ale at right, how would be in quitting?	you describe how success [u] 3	_ cho	ry low ince of iccess									Very hig chance of success
	60 50 54 54	-,		10 .	0	1	2	3	4	5	6	7	8	9
	and the second		you describe how <u>difficult</u> it w ** <u>ttes</u> at this time in your life?		ery easy									Very difficult
	SC IV RVV	HOM SHOKING SIGGIS	di mismine in your inc.		0	1	2	3	4	5	6	7	8	9
	Section 2	,	↓											
	, No clea	u r goal – I really don't ha	ve a clear goal in mind.											
		led use – I want to use in	a controlled manner→o be able to	be in con	trol of	how	ofter	n I us	e an	d hov	v muk	ch I u	se.	
						which	ılw	ill ma	ıke a	new				
		ecision – I want to be tota will use again in any way.	lly abstinent from all use for a perio	d of time,	, after v	MIIICI					deci	sion (abou	t whether
		will use again in any way.						ional	ly use					
		will use again in any way. •nal use _ I don't want us		d like to b	e able	to o	ccasi			e whe				
	s I may s	will use again in any way. onal use – I don't want us lip – I want to quit using o	ing to be a habit for me, but I woul	d like to b	e able slip and	to o	ccasi onc	e in o	a whi	e whe	en Ire	eally	hav	the urge

CTN-0046_CRF_V.004_18 SEP 2009



QSCAT=THOUGHTS	ABOUT ABS	TINENCE-DRUGS

Form completion (if form not complete, check one):

Fields affected: □0 Entire CRF □1 Questions (specify): _____

 \square_1 Participant unavailable \square_2 Data collection error \square_3 Participant unable/unwilling to answer

DOMAIN: QS

4637 Thoughts About Abstinence—Drugs Section I QSTEST QSORRES/QSSTRES This section asks about how you feel about stopping all drug use at this time in your life. On the scales below, circle to number that best represents how you feel about stopping, how successful you will be, and how you will do after your desire to quit Using the scale at right, how would you describe your desire to quit using drugs at this time in your life? O 1 2 3 4 5 6 7 8	637 Thoughts About Abst		Jate:	_Q\$		/_		ywar			/isit i	VISIT
This section asks about how you feel about stopping all drug use at this time in your life. On the scales below, circle to number that best represents how you feel about stopping, how successful you will be, and how you will do after your stopping, how successful you will be, and how you will do after your single the scale at right, how would you describe your stopping. The scale at right, how would you describe how successful you chance of success in quitting? 2 Using the scale at right, how would you describe how successful you chance of success 3 Using the scale at right, how would you describe how difficult it will be to keep from using drugs at this time in your life? 4 What is the GOAL you have chosen for yourself about using drugs at this time? Please read the goals listed below and choose which goal best represents your own goal at this time by checking the next to your choice. Please read all of them before you pick one. 1, No clear goal — I really don't have a clear goal in mind. 2 Controlled use — I want to use in a controlled manner—to be able to be in control of how often I use and how much I use. 3, New decision — I want to use in a controlled manner—to be able to be in control of how often I use and how much I use. 3, New decision — I want to be totally abstinent from all use for a period of time, after which I will make a new decision about whether or not I will use again in any way.	637 Thoughts About Abst	inence—Drugs										
This section asks about how you feel about stopping all drug use at this time in your life. On the scales below, circle to number that best represents how you feel about stopping, how successful you will be, and how you will do after your desire to guit at this time in your life? 1 Using the scale at right, how would you describe your desire to guit at this time in your life? 2 Using the scale at right, how would you describe how successful you chance of success 2 Using the scale at right, how would you describe how difficult it will be to keep from using drugs at this time in your life? 3 Using the scale at right, how would you describe how difficult it will be to keep from using drugs at this time in your life? 4 What is the GOAL you have chosen for yourself about using drugs at this time? Please read the goals listed below and choose which goal best represents your own goal at this time by checking the next to your choice. Please read all of them before you pick one. 1 No clear goal — I really don't have a clear goal in mind. 2 Controlled use — I want to use in a controlled manner—to be able to be in control of how often I use and how much I use. 3 No desire to guit desire to		mente-biogs										
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2 Using the scale at right, how would you describe how success ful you chance of success Very low chance of success Very low chance of success	이번 경우 그 사람들이 가는 그 사람들이 가장 하는 것이 되었다.	escribe your <u>desire</u> to avit	desire to									Great desire qui
Using the scale at right, how would you describe how success ful you in quitting? Using the scale at right, how would you describe how difficulty it will be to keep from using drugs at this time in your life? Using the scale at right, how would you describe how difficulty it will be to keep from using drugs at this time in your life? Using the scale at right, how would you describe how difficulty it will be to keep from using drugs at this time? Using the scale at right, how would you describe how difficulty it will be to keep from using drugs at this time? Using the scale at right, how would you describe how difficulty it will be to be to an in a control of how often lost to your drugs at this time? Using the scale at right, how would you describe how difficulty it will be to be in control of how often lost to your drugs at this time by checking the lost to your choice. Please read all of them before you pick one.	sing aregs at this time in your me:		0	1	2	3	4	5	6	7	8	9
Using the scale at right, how would you describe how difficult it will be to keep from using drugs at this time in your life? O 1 2 3 4 5 6 7 8 estion 2 What is the GOAL you have chosen for yourself about using drugs at this time? Please read the goals listed below and choose which goal best represents your own goal at this time by checking the next to your choice. Please read all of them before you pick one. In No clear goal — I really don't have a clear goal in mind. Controlled use — I want to use in a controlled manner—to be able to be in control of how often I use and how much I use. In New decision — I want to be totally abstinent from all use for a period of time, after which I will make a new decision about whether or not I will use again in any way.		escribe how succes: ful you	chance of	•								Very l chanc succe
be to keep from using drugs at this time in your life? O 1 2 3 4 5 6 7 8	ny esta de les estates author		0	1	2	3	4	5	6	7	8	9
What is the GOAL you have chosen for yourself about using drugs at this time? Please read the goals listed below and choose which goal best represents your own goal at this time by checking the next to your choice. Please read all of them before you pick one.												Ver diffic
What is the GOAL you have chosen for yourself about using drugs at this time? Please read the goals listed below and choose which goal best represents your own goal at this time by checking the next to your choice. Please read all of them before you pick one.		me in vour lite?										
whether or not I will use again in any way.	estion 2 What is the GOAL you have chosen for y Please read the goals listed below and ch	ourself about using drugs at the	his time?	-								
Occasional use - I don't want using to be a habit for me but I would like to be able to occasionally use when I really have	estion 2 What is the <u>GOAL</u> you have chosen for y Please read the goals listed below and choext to your choice. Please read all of the No clear goal — I really don't have a c	ourself about using drugs at the cose which goal best represe m before you pick one.	his time? nts your ov	vn ge	oal a	t this	s time	e by	che	eckin	g the	e box
14 - 14 - 1 don't want assign be a habit for me, but I would like to be able to occasionally use when I featily have	what is the GOAL you have chosen for y Please read the goals listed below and che next to your choice. Please read all of the 'I No clear goal - I really don't have a coal controlled use - I want to use in a coal coal next to your choice.	purself about using drugs at the cose which goal best represe make before you pick one. The companies of th	his time? nts your ov	v n g e	oal a	t this	s time	e by	che	ecking	g the	e box
s I may slip — I want to quit using once and for all, even though I realize I may slip and use once in a while.	What is the GOAL you have chosen for your please read the goals listed below and choosen to your choice. Please read all of the	courself about using drugs at the cose which goal best represe make before you pick one. The companies of t	his time? nts your ov in control of f time, after	how	often	t this	s time e and	e by	che v m	uch I	g the	e box
Quit completely — I want to quit using once and for all, to be totally abstinent, and never use ever again for the rest of my li	what is the GOAL you have chosen for y Please read the goals listed below and choext to your choice. Please read all of the No clear goal - I really don't have a coal controlled use - I want to use in a coal whether or not I will use again in any works.	pourself about using drugs at the cose which goal best represe makefore you pick one. ear goal in mind. rolled manner—to be able to be timent from all use for a period one. be a habit for me, but I would like	his time? nts your ov in control of f time, after se to be able	how how	often h I wi	t this	s time e and kke a	d hove	che v m	uch I	g the	e box
	what is the GOAL you have chosen for your please read the goals listed below and choosen to your choice. Please read all of the	courself about using drugs at the coose which goal best represent before you pick one. The ear goal in mind. The interior of the cool of	his time? nts your ov in control of f time, after e to be able may slip an	how how i to o	often h I wi	t this	e and whi	d hove	che v m dec	uch I	g the	e box
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CTN-0046

3 Participant unable/unwilling to answer 2 Data collection error 1 Questions (specfy): Form completion (if form not complete, check one): \Box_1 Participant unavailable Fields affected: \Box_0 Entire CRF

Participant ID #:

USUBJID

CTP ID #

Node#:

Assessment Date: V is WISITNUM

SUDTC

SUCAT=TIMELINE FOLLOW-BACK PRE-STUDY

Pre-Study
e Follow-Back—
4638 Timelin

>	Visit number: VISITNUM	Visit number: VISITNUM						
	Бау	GIASNS I	8	n	4	ın	v	7
-	Date	SUSTDTC /20	month day	month / doy	month / day	month day	month day	month / day
64	SUTRT Alcohol	# Standard drinks: # Standard drinks: SUDOSE	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
က	SUTRT Marijuana	SUDOSU SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT SUI	SUDOSU # Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	#Cigarettes/day:	# Cigarettes/day:
ın	Other tobacco	SUOCCUR, Yes 1	L ves C on o	□ No □, Yes ↓	↑ Ses ↑ O O O	L Sey C	↑ sey ' □ °N ° □	□ No □ Yes ↓
δ.	other tobacco	Chew Cgar	Chew Cigar	Chew Cigar	Chew Cigar Dip Pipe	Chew Cigar	Chew Cgar	Chew Cigar Dip Pipe
۰	SUTRT SUOC	SUOCCUR ON No Nes	O No O Yes	□ ₀ No □, Yes	□₀No □, Yes	□, No □, Yes	□ _o No □, Yes	□, No □, Yes Route*:
^	SUTRT SUOR	SUOCCUR O TYPES Route*: SUROUTE	O No Tres	□ No □, Yes	□ _o No □ ₁ Yes	□, No □, Yess Route*:	□ No □, Yes	□ _o No □ ₁ Yes Route *:
00	mpheta	SUOGOUR ON Yes	O No O, Yes	□ _o No □, Yes Route*:	□ _o No □, Yes	□, No □, Yes	□ _o No □, Yes	□, No □, Yes
•	SUTRT Sedatives SUC	SUOCCUR ^O , No O, Yes	□, No □, Yes	□ No □, Yes	□ ₀ No □ ₁ Yes	□, No □, Yes	□ No □, Yes	□ _o No □ ₁ Yes
10		SUOCCUR ON ON Yes Route*: SUROUTE	O No O Yes	□ _o No □, Yes	□ _o No □ ₁ Yes Route*:	□, No □, Yes	□ _o No □, Yes	□ _o No □, Yes
Ξ		CCUR □ ₀ No □ ₁ Yes Route*: SUROUTE	O No O, Yes	□o No □, Yes	□ _o No □ ₁ Yes Route*:	□, No □, Yes	□ _o No □, Yes	□ _o No □, Yes Route*:
12	SUTRT	Route*: SUROUTE	□, No □, Yes	□, No □, Yes	□ _o No □, Yes	Route*:	□ ₀ No □, Yes	□ _o No □, Yes

* Bondo Codolist	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up through vein 05 = shot up th	05 = shot up through muscle
	06 = shot up through skin	07 = dissolved undertongue	08 = topical	09 = rectal	10 = vaginal

CTN-0046 S-CAST SUCAT=TIMELINE FOLLOW-BACK PRE-STUDY

CTN-0046_CRF_V.004_18 SEP 2009

Participant ID #:

Assessment Date: VISITNUM Visit #: CTP ID #: USUBJID

4	638 Timeline	4638 Timeline Follow-Back—Pre-Study	e-Study (continued)	(pen				
	Day	SUSPID 8	9	10	11	12	13	14
-	Date	SUSTDTC / day	month day	month day	yop / wom	month day	month day	month day
М	SUTRT Alcohol	# Standard drinks: SUDOSE SUDO	nks: # Standard drinks: SUDOSU	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks
ო	SUTRT Marijuana	SUDOSU # Joints: SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT Cigarelles	subosu # CigareHes/day: subose	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
ın	Other tobacco	SUOCCUR	↑ Ses ON	D No O	† sø, ' on ° o	, Yes \downarrow Oo O, Yes \downarrow Oo O, Yes \downarrow Oo O, Yes \downarrow Oo O	o No	□, No □, Yes =
D.	If Yes: Specify o tobacco (check all	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar
•	SUTRT SUOC	SUOCCUR O O Yes Route*SUROUTE	O No O, Yes	Route*:	Route*:	□, No □, Yes	O No Types	Route*:
_	SUTRT SUO	SUOCGUR No Yes	O No O, Yes	Route*:	Route*:	□, No □, Yes	O No Types	Route*:
00	SUTRT SUOC	SUOCCUR O Yes	O No O, Yes	O No Tyes	Route*:	Route*:	O No Types	Route*:
0	SUTRT Sedatives SUO	SUOCGUR□, No □, Yes	O, No O, Yes		□, No □, Yes	□, No □, Yes	□ _o No □, Yes	□, № □, Yes
2	SUTRT Opiates	SUOCCUR O Yes	O No O, Yes	O No O Yes	Route*:	□o No □, Yes	O No Types	□ _o No □, Yes
Ξ	Other 1 (specify) SUOCCUR O No SUTRT Route*:	CCUR ☐, No ☐, Yes Route*: SUROUTE	O No O, Yes	O No O, Yes	□o No □, Yes	□o No □, Yes	□ _o No □, Yes	O _o No O, Yes
12	SUTRI Route & Route *	CUR ONO TYPES Route * SUROUTE	Route*:	Route*:	□ No □ Yes	□, No □, Yes	O No Tres	Route*:

* Banto Cadolist	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up through vein 05 = shot up through m	05 = shot up through muscle
	06 = shot up through skin	gh skin 07 = dissolved under tongue	08 = topical	09 = rectal	10 = vaginal
30					

CTP ID #: USUBJID # epoN

Participant ID #: __

VISIT #:

SUDTC Assessment Date:

4	638 Timeline	4638 Timeline Follow-Back—Pre-Study		(continued)				
	Day	SUSPID 15	16	17	18	19	20	21
-	Date	SUSTDTC / doy	mom day	yob Anom		Acop /	month — doy	Yop / — doy
М	SUTRT Alcohol	# Standard drinks: # Standard	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks
ო	SUTRT Marijuana	SUDOSU SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT SUDO Cigarelles	SUDOSU # Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
ın	Other tobacco	SUOCCUR	↑ s ⇒ .	° N° □ Yes † □ ° N° □	D _o N _o D ₁ Y _{es} ↓	° N° □ Yes ↓	↑ Ses Company Yes	□ No □, Yes-
5 B	If Yes: Specify other tobacco (check all used)	Chew Cigar SUTRT Dip Pipe	Chew Cigar	Chew Cigar Dip	Chew Cigar Dip	Chew Cigar Dip Pipe	Chew Cigar	Chew Cigar
v	SUTRT SUOC	SUOCCUR O O Yes	O No O Yes	□ No □, Yes	□ No □, Yes	□ No □, Yes	□o No □, Yes	□ _o N _o □ ₁ Yes
^	SUTRT SUOC	SUOCGUR O Yes	O No O, Yes	□o No □, Yes	□₀ No □, Yes	□o No □, Yes	□o No □, Yes	□ _o No □, Yes
ω	SUTRT SUOCCUR Methamphetamine	dur 🖺 No 📋 Yes	□ _o No □ ₁ Yes	□o No □, Yes	□₀ No □₁ Yes Route*:	∏₀ No ☐₁ Yes	□o No □, Yes	□ _o No □ ₁ Yes
•	SUTRT Sedatives SUOC	SUOCGUR No T, Yes	O No Types	□ No □, Yes	□, No □, Yes	□, No □, Yes	□ No □ Yes	□, No □, Yes
10	SUTRT Opiates	SUOCCUR O O Yes	O No O, Yes	□o No □, Yess Route*:	□ No □, Yes	□o No □, Yes Route*:	□ _o No □, Yes	O _o No O _o Yes
=	Other 1 (pecify)SUOCCUR [SUR ONO ON Yes Route*: SUROUTE	O No Tyes	O No Yes	□₀ No □₁ Yes Route*:	□₀ No □₁ Yes Route*:	□₀No □,Yes Route*:	□, No □, Yes Route*:
12	2 Other 2 (speedly) SUOCCUR [Route * SUROUTE	O No Tyles	□, No □, Yes	□, No □, Yes Route*:	D _o N _o D _o Y _{es}	D, No D, Yes	D _o No D ₁ Yes

* Doute Codelist	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up through vein	05 = shot up through muscle
	06 = shot up through skin	07 = dissolved under tongue	08 = topical	09 = rectal	10 = vaginal

CTN-0046 S-CAST SUCAT=TIMELINE FOLLOW-BACK PRE-STUDY

CTP ID #: USUBJID Wode #

Participant ID #:

Assessment Date:

year

SUDTC

VISIT #: Visit

4	4638 Timeline F	Timeline Follow-Back—Pre-Study	125	(continued)				
	Day	SUSPID 22	23	24	25	26	27	28
-	Date	SUSTDTC / day	month day	month day	month / day	month day	month / day	month day
М	SUTRT Akohol	# Standard drinks: # Standard drinks: SUDOSE SUDOSU	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
ო	SUTRT Manjuana	SUDOSU SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT SUDOSU Cigarettes	u # Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
ın	Other tobacco	SUOCCUR	□, No □, Yes ↓	Yes + O, No O, Yes + O, No		□, Yes ↓ □, No □, Yes ↓	No O Ves t	O No O Yes
50	If Yes: Specify other tobacco (check all used)	Chew Cigar SUTRT Dip	Chew Cigar	Chew Cigar	Chew Cigar Dip Pipe	Chew Cigar	Chew Cigar	Chew Cigar
٥	SUTRT SUOCCUR Cocaine	JR □, No □, Yes Route*\$UROUTE	O No O, Yes	O No Types	□₀ No □₁ Yes	Route*:	O No Types	□, No □, Yes
7	SUTRT SUOCO Amphetamine	SUOCCUR O No Nes	□o No □, Yes	□o No □, Yes	□o No □₁ Yes	□o No □, Yes	□o No □, Yes	□o No □, Yes
00	SUDCCUR 0, No.	UR □, No □, Yes Route *, SUROUTE	□o No □, Yes	□ _o No □, Yes	□o No □, Yes	□, No □, Yes	□ _o No □, Yes	□, No □, Yes
0	SUTRT Sedatives SUOCO	SUOCCUR□, No □, Yes	□, No □, Yes	No Tyles	□, No □, Yes	□ No □ Yes	□ No □, Yes	□ No □
9	SUTRT Opiates	SUOCCUR O O Yes	□o No □, Yes	□ _o No □, Yes	□₀ No □, Yes	□o No □, Yes	□ _o No □, Yes	□, No □, Yes Route* :
=	Other 1 (pecify) SUOCCUR On No SUTRT Route*:	JR O Yes Route*: SUROUTE	□₀ No □, Yes	O No Types	□₀ No □₁ Yes	□o No □, Yes	□ _o No □, Yes	□o No □, Yes
12	SUTRT Route*	R □, No □, Yes Route *SUROUTE	□o No □, Yes	□ _o No □, Yes	□o No □, Yes	□, No □, Yes	□, No □, Yes	□, No □, Yes Route*:

*Route Codelist 01 = oral 02 = nasal 03 = inhaled/smoked 04 = shot up through vein 05 = shot up through skin 07 = dissolved undertongue 08 = topical 09 = rectal 10 = vaginal			Colonia de			
09 = rectal	* Bourto Codelist	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up through vein	05 = shot up through musc
	No ote sometist	06 = shot up through skin	07 = dissolved undertongue	08 = topical	09 = rectal	10 = vaginal

<u>v.</u>	Day
Follow	4639 Timeline
ACK ACTI	SUCAT=TIMELINE FOLLOW-BACK ACT
46	CTN-00

946		Form completion	(if form not complete, check one): □, Participant unav Fields affected: □, Er	idpant unavailable ad: □ ₀ Entire CRF	Data collection error	3 Participant unable/unvilling
		USUBJID		VISITNUM		SUDTC
BACK ACTIVE STUDY	Node#:TUDY	CTP ID #:	Participant ID #:	Visit #:	Assessment Date:	

	OSY LIMETIME	4024 Ilmeline rollow-back-Active Stody	clive sindy					
	Day	SUSPID	2	3	4	2	9	7
-	Date	SUSTDIC Month day year	menth day	moon day	month day	month day	month doy	month
11	SUTRT Alcohol	# Standard drinks: SUDOSE SUDOSU	# Standard drinks: U	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drink
m	SUTRT Marijuana	SUDOSU SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT SU Cigarettes	Subosu# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day
10	Other to bacco	SUOCCUR Yes 1	t sey (² □	Thes thes the last these	U No U Yes	U No U Yes	No D, Yes
, a	If Yes: Specify other tobacco (check all used)	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Dip
ø	SUTRT SUC	SUCCOURTONO TYPES Route*: SUROUTE	□, No □, Yes	Route*:	□, No □, Yes	Route*:	Route*:	Route.
^	SUTRT SUC Amphetamine	SUCCURI, No I, Yes Route*:	□, No □, Yes	□, No □, Yes Route*:	□ _o No □, Yes	□, No □, Yes	Route*:	Route, ∵
œ	SUTRT SUCCUR, No Methamphetamine Route*	SCCUR [™] ON O Nes Route*: SUROUTE	□ _o No □, Yes Route*: □	□, No □, Yes Route*:	□₀No □₁Yes	□ _o No □, Yes	□ _o No □ ₁ Yes	Route*:
٥	SUTRT Sedatives SUO0	SUOCCUR No T, Yes	□, No □, Yes	□, No □, Yes	□, No □, Yes	□ _o No □ ₁ Yes	□, No □, Yes	² □
2	SUTRT Opiates	SUOCCURTO, No Types Route*: SUROUTE	□, No □, Yes	□, No □, Yes	□, No □, Yes	Route*:	Route*:	Route*:
=	100000	¢cur∏ _o No ∏, Yes Route*: _ SURQUTE	□₀ No □, Yes	□o No □, Yes	□₀ No □₁ Yes	□, No □, Yes	□o No □, Yes	No No Route*:
72	Other 2 (specify) SUOCCUR O No SUTRT Route*:	¢cuR∏, No ☐, Yes	Boute*:	Route*:	Route*:	Boute *:	Route*:	°Z °

	01 - oral	02 = nasa	03 = inhaled/smoked	04 - shot up through vein	05 = shot up through musc
*Route Codelist	-			8	
	Short up rhrough skin	n O = dissolved under rongue	Oo - Popical	- rectal	Io = vaginal

 \square_3 Participant unable/unwilling to answer

CTN-00

46

10000		USUBJID		VISITNUM			SUDTC	
10A2-0	Node#	CTP ID #	Participant ID #:	Visit #:	Assessment Date:			
SUCAT=TIMELINE FOLLOW-BACK FOLLOW-UP						monfi	doy	year

# Standard drinks: # Standard dr	40	40 Ilmeline	4040 IImeline Follow-Back—Follow-Up	do-woll					
SUTRT # Standard drinks: # Joints: # Standard drinks: # Standard drinks: # Subosumers: # Joints: # Joints: # Subosumers: # Joints: # Joint		Day	SUSPID	7	ဗ	4	S.	9	7
SUTRT # Standard drinks: # Subose SUDOSU # Cigarettes/day: # Cigar	-	Oate	SUSTDIC ANY	1	dop wouth	month doy		month day	month / day
SUTRT # SUDOSU SUDOSE # Joints:		SUTRT Akohol	Standard drinl SUDOSE	Standard d	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
SUTRT # Cigarettes/day: # Cigarettes/day: # Cigarettes Cigarett		SUTRT Marijuana	i si	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
Other tobacco SUCCUR (chew other tobacco) SUTRT (chew other tobacco) Chew other tobacco Chew other other Chew other other Chew other Ch		SUTRT Gigarettes	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	#Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
SUTRT SUOCCUR O No 1 Yes Cigar Chew Cigar Coding Chew Cigar Chew Cigar Coding Check all used) SUTRT SUOCCUR O No 1 Yes Cocaine Route*: SUROUTE Route*: Route*: SUROUTE Route*: Route*: Route*: Route*: Route*: Cocaing		Other tobacco	J. J			° № ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° ° °	° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2° ° 1 ° 2°	↑ sey ON	† se, '
SUTRT SUCCUR ON O ON	_	If Yes: Specify other tobacco	Chew Cigar SUTRT Pipe		Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar
SUTRT Amphetamine Amphetamine Route*: Route*: SUROUTE Route*: Route*: No			Rode .:		O No O, Yes	Route*:	Route*:	Route*:	Route*:
SUTRT Methamphetamine Route*: SURDUTE SUTRT Sedatives SUCCUR O No O, Yes O, No O, Yes SUTRT SUCCUR O No O, Yes O, No O, Yes O Opiates Route*: SUROUTE Route*: O, No O, Yes Route*: SUROUTE Route*: SUROUT		SUTRT SUOC	J, № SUR		□, No □, Yes	Route*:	□ _o No □, Yes	□ _o No □, Yes	, N₀, Yes
SUTRT Suddives Surr Opiates SUTRT SuddouR Other 1 (specify) SUTRT SuddouR Other 2 (specify) SuddouR Other 2 (specify) SuddouR Other 2 (specify) SuddouR Other 3 Surr Route*: Surr		SUTRT SUOCE	Route *		O No O Yes	□₀ No □, Yes	□, No □, Yes	□ _o No □, Yes	□, No □, Yes Route* :
SUTRT SUDGCUR O, No O, Yes O, No O, Yes Other 1 (specify) SUOCCUR O, No O, Yes SUTRT Route*: SUROUTE Route*: Other 2 (specify) SUOCCUR O, No O, Yes Other 2 (specify) SUOCCUR O, No O, Yes					□, No □, Yes	□ No □, Yes	□ No □ Yes	□ No □, Yes	O No O Yes
Other 1 (specify) SUCCURIL, No I, Yes I, No I, Yes SUTRT SUTRT Route*: SUROUTE Route*:				$ \sqcup $	O No O Yes	Route*:	Route*:	□, No □, Yes	Route*:
Other 2 (speecity) SUOD CUR ON ON Yes OTHER		SUO	CCURT _O No Route*: _		□₀ No □, Yes	□₀ No □, Yes	□₀No □₁Yes Route*:	□₀ No □₁ Yes	□, No □, Yes Route* :
SUROUTE Route*:		Other 2 (specify)SUOC SUTRT		O No Yes	□ _o No □, Yes Route*:	□ _o No □, Yes Route*:	□₀No □₁Yes Route*:	□ _o No □, Yes Route*:	□, No □, Yes Route* :

* Banda Cadallat	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up through vein	05 = shot up through muscle
Note concilor	06 = shot up through skin	07 = dissolved undertongue	08 = topical	09 = rectal	10 = vaginal

CTN-0046 S-CAST SUCAT=TIMELINE FOLLOW-BACK FOLLOW-UP

CTP ID # USUBJID Node #

Participant ID #: _

Visit #:

Assessment Date:

SUDTC

4	640 Timelii	ne Fo	4640 Timeline Follow-Back—Follow-Up		(continued)				
	Day		SUSPID 8	6	10	11	12	13	14
-	Date		SUSTDTC /	month day	month day	month day	worth day	yop / wom	won / qoi
64	SUTRT		# Standard drinks: SUDOSE SUDOS	# Standard drinks: # Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
ო	SUTRT Marijuana	SOL	SUDOSU SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT Cigarettes	SUDC	SUDOSU# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
ın	Other tobacco	SUOC	SUOCCULR No I, Yes \$	U No U Yes	U, No U, Yes ↓	↑ sə, '	□, No □, Yes ↓	↓ No ☐, Yes ↓	U, No □, Yes ↓
, 0	If Yes: Specify other tobacco (deck all used)	ther used)	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar
vo	SUTRT	SUOCGL	SUOCGUR ON ON Yes	Route*:	□o No □, Yes	Route*:	□, No □, Yes	O No Types	O No O, Yes
•	SUTRT Amphetamine	SUOCOL	SUOCGUR No Yes	Route*:	□, No □, Yes	Route*:	O No O, Yes	O No O, Yes	O No O, Yes
œ	SUTRT SUCCOUR O No Methamphetamine Route*;	suoca	JR ∏ _o No ∏ ₁ Yes Route* S <u>UROUTE</u>	Route*:	□o No □, Yes	□ No □, Yes	□o No □, Yes	O No Types	O No Types
٥	SUTRT Sedatives	SUOCOL	SUOCGUR O O Yes	□, No □, Yes	□ _o No □ ₁ Yes	□ No □ Yes	□, No □, Yes	□ _s N _o □ ₁ Y _{es}	O No Types
2	SUTRT Opiates	SUOCCI	SUOCGUR No Yes	No No	O No Types	□ No □ Yes	□o No □, Yes	O No Types	O No O Yes
=	Other 1 (specify) SUOCCUR O No SUTRT Route*	SUOCG	JR∏ _o No ∏ı Yes Route* ; SUROUTE	□, No □, Yes	□ _o No □, Yes	□o No □₁ Yes	□, No □, Yes	□ _o No □, Yes	□, No □, Yes
12	Other 2 (specify) SUTRT	SUOCCI	SUOCCUR O O Yes Route*: SUROUTE	□, No □, Yes Route*:	□o No □, Yes	□ No □, Yes	□, No □, Yes Route*:	□, No □, Yes Route*:	□, No □, Yes Route*:

					Č.
*Boute Codelist	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up thigh vein	up thigh vein 05 = shot up thigh muss
voor exercise	06 = shot up thigh skin	07 = dissolved undertongue	08 = topical	09 = rectal	10 = vaginal

CTN-0046

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Node#: ____ CTP ID #: ____

USUBJID Participant II

Participant ID #: ______

Visit #:

it #: _____ Assessment Date: _____

SUDTC

4	640 Timeline I	4640 Timeline Follow-Back—Follow-Up		(continued)				
	Day	SUSPID 15	16	17	18	61	20	21
-	Date	SUSTDTC / day	month / day	month day	month day	month day	month day	month / day
М	SUTRT Alcohol	# Standard drinks: SUDOSE SUDOSU	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
m	SUTRT S Manjuana	SUDOSU SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT SUD	SUDOSU # Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
ın	SU Other tobacco	SUCCCUR	U No U Yes	↑ No □ Yes	t sək i on one	Loo No C	U No U Yes	L sey . C S
S _B	If Yes: Specify other tobacco (check all used)	Chew Cigar	Chew Cgar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar	Chew Cigar
٥	SUTRT SUOC	SUOCCUR No Yes Route*: SUROUTE	O No O, Yes	O No Tyes	Route*:	Route*:	Route*:	Route*:
_	SUTRT SUOC	SUOCCUR No TYGS Route*: SUROUTE	Route*:	Route*:	Route*:	Route*:	Route*:	O No Tyes
œ	SUTRT SUOO Methamphetamine	SUOCCUR O Yes	O No O, Yes	Route*:	No □, Yes	□, No □, Yes	□, No □, Yes	Route*:
0	SUTRT Sedatives SUOC	SUOCCUR □ No □ Yes	□ No □, Yes	□ No □, Yes	□ No □, Yes	□ _o No □ ₁ Yes	No □, ≺es	□ No □ Yes
2	SUTRT Opiates	SUOCGUR No Yes	Route*:	Route*:	Route*:	Route*:	Route*:	Route*:
=	Other 1 (specify) SUOCGUR O No SUTRT Route*:	duR∏ _o No ∏, Yes Route*:	O No Types	□o No □, Yes	□₀ No □₁ Yes	□o No □, Yes Route*:	□ _o No □ ₁ Yes	O No Types
72	Other 2 (specify) SUOCGUR	duR□, No □, Yes	Route*:	Route*:	□, No □, Yes	Route*:	Route*:	□, No □, Yes

*Route Codelist *Route Codelist 05 = shot up thigh skin 07 = dissolved under tongue 08 = topical 09 = redal 10 = vaginal						
07 = dissolved under tongue 08 = topical 09 = redal	* Boute Codelist	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up thigh vein	05 = shot up thigh muscle
		06 = shot up thigh skin	eq	08 = topical	09 = redal	10 = vaginal

Participant I

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SUDTC Assessment Date: VISITNUM

4	4640 Timeline Follow-Back—Follow-Up	ollow-Back—Fo		(continued)				
	Day	SUSPID 22	23	24	25	26	27	28
-	Date	SUSTDTC / dey	You day	Yop / wow	/ quou	month day	month / doy	month day
М	SUTRT Akohol	# Standard drinks: # Standard drinks: SUDOSE SUDOSE	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
ო	SUTRT SU Manijuana	SUDOSU SUDOSE # Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4	SUTRT Cigarettes SUD	SUDOSU# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
'n	Other tobacco	SUOCCUR No I, Yes	U, No U, Yes	Yes \$\bullet\$ \Boxed \Boxed \cdot \c	U No U Yes	□ No □ Yes ↓	No ☐, Yes ↓ ☐ No	U, No U, Yes
n B	If Yes: Specify other tobacco (check all used)	Chew Cigar	Chew Cigar Dip Pipe	Chew Cigar	Chew Cigar Dip Pipe	Chew Cigar	Chew Cgar	Chew Cigar
۰	SUTRT SUOCCUR Cocaine	OUR ON ON Yes	□, No □, Yes	□, No □, Yes	□o No □, Yes	O No O Yes	O No Types	□, No □, Yes
7	SUTRT SUOCC	SUOCCUR ONO ON Yes Route*: SUROUTE	□o No □, Yes	□o No □, Yes	□o No □, Yes	O No O, Yes	□₀ No □, Yes	□ _o No □, Yes
00	SUCCUR SUCCUR Methamphetamine	XUR □, No □, Yes Route*: SUROUTE	□, No □, Yes	□, No □, Yes	□, No □, Yes	O. No O. Yes	O No O, Yes	□, No □, Yes
•	SUTRT Sedatives SUOCC	SUOCCUR, No, Yes	□, No □, Yes	□, No □, Yes	□, No □, Yes	□ No □ Yes	□ No □, Yes	□ _s N _o □ ₁ Yes
2	SUTRT SUOCOUR	OUR ONO ON Yes Route*: SUROUTE	O No O, Yes	□ _o No □, Yes	□o No □, Yes	□ _o No □, Yes	O No Types	□ _o No □ ₁ Yes
=	Other 1 (pecify) SUOCCUR O No SUTRT Route*:	3UR ☐, No ☐, Yes Route*; SUROUTE	O No O, Yes	□ _o No □ ₁ Yes	□₀ No □₁ Yes	O No Tyes	O No O, Yes	□ _o No □, Yes
21	Other 2 (specify) SUTRT	SUOCCUR O O Yes	Route*:	□ No □, Yes	D _o N _o	Route*:	□, No □, Yes Route*:	No , ≺es

					500 m
* Bouto Codolict	01 = oral	02 = nasal	03 = inhaled/smoked	04 = shot up thigh vein	05 = shot up thigh muscle
	06 = shot up thigh skin	07 = dissolved under tongue	08 = topical	09 = rectal	10 = vaginal

CTN-0046

orm completion (if form not c	omplete, check one):			
□ ₁ Participant unavailable elds affected: □ ₀ Entire CRF			nt unable/unwilling	to answer
Node #:	CTP Site ID #:		Participant ID	USUBJID
	Assessment Da	te:	//_	yeor

DOMAIN: EX

S-CAST **EXCAT=TREATMENT TRACKING FORM** 4641 Treatment Tracking Form Study week number: VISITNUM Please record the number of hours that the participant was scheduled to attend treatment and the number of treatment hours actually attended during the study week: Actual Hours EXDOSU Scheduled Hours **EXDOSE EXTRT** EXDOSRGM Total outpatient/IOP treatment hours **EXDOSE** Individual outpatient/IOP treatment hours EXTRT EXDOSRGM 2 **EXDOSE** EXDOSRGM Group outpatient/IOP treatment hours 4 Did the participant attend other substance abuse treatment at the CTP? DATA NOT STORED. IF YES, THE BELOW VARIABLES WILL BE IN THE EX DATASET , Yes If Yes: Continue to question 5. 5 Please check each treatment utilized and provide the scheduled and actual hours attended: Treatment(s) Utilized Actual Hours EXDOSU **Scheduled Hours** (check all that apply) **EXDOSRGM EXDOSE** Outpatient detax EXTRT EXDOSE **EXDOSRGM** I law astrony alabasis

Inparient delox	EXDOSRGM	EXDOSE
Residential EXTRT Methadone EXTRT	EXDOSRGM	EXDOSE
5 Comments: DATA NOT STORED		OR HER CHIEF HERS ACCOMMENTED

Form completion (if form not complete, check one):	DOMAIN: LB
☐ Participant unavailable ☐ Data collection error rields affected: ☐ Entire CRF ☐ Questions (φ=cñy):	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	USUBJID
Assessment Date:/	/Visit #: VISITNUM

LBCAT=DRUG SCREEN

4	4642 Urine Drug Screen				
50	ction I: Urine Collection				
36					
1	Was a urine sample obtained?	33			
	No → If No: 1a Why was a urine sample not obtaine				
	LBSTAT/LBREASND		ile		
	Study staff error	е			
	Other (specify):		QNAM=I BT	FMP	
	, Yes		QLABEL= U		N EXPECTED RANGE
			. ▶		le was not within the
2	Urine temperature within expected range (between 90° and 99° F)? $\square_0 \text{ No}^* \rightarrow \square_1 \text{ Yes}$ If the urine sample was not within the expected range or was not valid on the adulterant test, please collect another				
L	Sample from the participant. Do not test				
3	ONAM=LBABNORM ONAM=LBABNORM ONAM=LBABNORM				
	QLABEL= URINE POTENTIALLY ABNORMAL L1 Tes range or are not valid.				
Se	ection II: Urine Drug Screen Results LBORRES				
	LBTEST	Negative	Positive	Unknown	Agree with TLFB?
4	Methamphetamine				↑ □₀ No □₁ Yes
5	THC (marijuana)				□₀ No □₁ Yes
6	Cocaine				□₀ No □₁ Yes
7	Opioids (2000)*				□₀ No □₁ Yes
8	Amphetamine				□₀ No □₁ Yes
9	Benzodiazapine				□₀ No □₁ Yes
٠,,	Comments: DATA NOT STORED	- 12		QNAM=LBAGREE	
١,	Comments:			QLABEL= LAB AGR DVAR=LBSEQ	EES WITH ILFB
		51121-711-12 -71 -			
					Side Calcula (Man Calculated)



Form completion (if form not complete, check one):	DOMAIN: LB, SC
☐ Participant unavailable ☐ Data collection error Fields affected: ☐ Entire CRF ☐ Questions (specify):	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	USUBJID
Assessment Date: SC.SCDTC	/ Visit #: VISITNUM

LBCAT=PRF	EGNANCY TEST	ONLY COMPLETE THIS FORM FOR FEMALES	
Pregnancy			
. 107	LB.LBTEST	C C IRIRSTAT	
		No Tyes LBLBSTAT	
2 Date of	pregnancy test:	day year	
3 Pregna	ncy test result (4631 Study E	ligibility, Q 17): 🔲 Negative 🔲 Positive LB.LBORRES	
B rea stfee	ding—Complete only dur	ing Baseline/Screening SC.SCCAT=BIRTH CONTROL ASSE	SSMENT
4 Is the p	articipant breastfeeding (46	531 Study Eligibility, Q 17)? 🔲 No SC SCORRES	
A. C. S.	SC.SCTEST	SC.SCORRES , Yes	
	50.001E01		
SC.S	SCTEST	nly during Baseline/Screening	
		an acceptable method of birth control (4631 Study Eligibility, Q 7)?	
□ _o No		SC.SCTEST birth control the participant agrees to use (answer all questions):	SC.SCORRES
SC.SCORRES		billi control the participant agrees to use (answer an questions).	
		ant	
		ne acetate injection	
	5g Oral contraceptives		🔲 No 🔲 Ye
	5h Patch		🔲 No 🔲 Ye
	5 j Other	•	🔲 No 🔲 1 Ye
	5k Specify:	Value is SC.SCORRES for question 5j	
5 Comme	nts (print; limit 200 characters	s):	9383 - 9835 - 98 - 88 - 98 -
		DATA NOT STORED	
<u> </u>			

Form completion (if form not complete, check one):	DOMAIN: VS
\square_1 Participant unavailable \square_2 Data collection error	☐3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	USUBJID
Assessment Date: VSDTC	/Visit #: VISITNUM

Reading	A Pulse VSTEST	Blood Press (4631 Study E VSTEST B Systolic	sure (sitting) ligibility, Q 14) VSTEST	VSTEST D Weight (Screening, Weeks 5, 10)	VSTEST E Height (Screening)
VSSPID	VSORRES	VSORRES	VSORRES	VSORRES Ibs	VSORRES IN VSORRESU
f the systol	ic blood pressure fo	r the first reading is ≥ 1 < 65 then wait for five	140 or < 90 OR the dia minutes and then rep	stolic blood pressure for the eat the assessment.	first reading is ≥ 90 o
			sure (sitting)		
		B Systolic	C Diastolic		
VSSPID 2		VSORRES	VSORRES		
	If two	o blood pressure readinge the diastolic readin	ngs were completed th ngs and record the ave	hen average the systolic read trages in the appropriate fiel	lings and ds below.
VSSPID	Average of 1 and 2	VSORRES	VSORRES		
Comment	s (print; limit, 200 cha				
		DATA NOT STORED			
				· · · · · · · · · · · · · · · · · · ·	



OSCAT-WITHDRAWAL SCALE-TO	7D V C C (

DOMAIN: QS

Form completion (i	f form not complete, ch	eck one):	DC	JIVIAIN. Q3
☐ ₁ Participant und Fields affected: ☐	available 🔲 Data c	ollection error	☐3 Participant unable/unwil	
Node #:	CTP Site ID #:		Participant ID #:	USUBJID
Assessr	nent Date:	QSDTC	/ Vi	sit #: VISITNUM

Siline	king the box by the number that b	est reflects how yo	QSORRES/QSSTRES		QSEVLI	NT=-P24
		None	Slight	Mild	Moderate	Sever
1	Desire to smoke	□ 0	1	□ 2	□ 3	□ 4
2	Anger, irritability, frustration	□ 0	[] 1	□ 2	□ 3	□ 4
3	Anxiety, nervousness	_ o	1	□ 2	☐ 3	_ 4
4	Difficulty concentrating	□ 0	1	□ 2	□ 3	□ 4
5	Impatience, restlessness	□ 0	<u> </u>	□ 2	□ 3	□ 4
6	Hunger	□ 0	[] 1	□ 2	□ 3	□ 4
7	Awakening at night	□ 0	<u> </u>	□ 2	□ 3	□ 4
8	Depression	По		□ 2	Пз	□ 4



QSCAT=PROTOCOL VIOL	ATION LOG (PVL) if form not complete, che	rk one):	DOI	MAIN: QS
☐ ₁ Participant un	available 🔲 2 Data co	lection error	3 Participant unable/unwilling	
Node #:	CTP Site ID #: _	SITEID	Participant ID #:	USUBJID
Assessm	ent Date:	ØSDTC /	Weel	#: VISITNUM

Containing Con	Date of violation: Violation type: Description of violation:	GSORRES/QSSTRESEnter code number from Violation Type Code List on next page If Other is indicated, please provide the specification: IDVAR = 'QSSEQ'; IDVARVAL = telt(put(qsseq,best.)); QNAM = 'PVL03'; QVAL = left(pvl03); QVAL = left(pvl03);
Comments:		If Other is indicated, please provide the specification: IDVAR = 'QSSEQ'; IDVARVAL = left(put(qsseq;best.)); QNAM = 'PCOMMENT BASED ON PVL02'; QVAL = left(pvl03);
DIVAR - GASEC DIVA	Description of violation:	IDVAR = 'QSSEQ'; IDVARVAL = teft(put(qsseq,best.)); QNAM = 'PVL03'; QLABEL = 'COMMENT BASED ON PVL02'; QVAL = left(pvl03);
DIVAR - GASEC DIVA	Description of violation:	IDVAR = 'QSSEQ'; IDVARVAL = teft(put(qsseq,best.)); QNAM = 'PVL03'; QLABE = 'COMMENT BASED ON PVL02'; QVAL = left(pvl03);
Obscription of violation: Obscription of violation been resolved?	Description of violation:	QNAM = 'PVL03'; QLABEL = 'COMMENT BASED ON PVL02'; QVAL = left(pvl03);
OVAL = Intiprova): IDVAN SGT = SGS = VISITALIAN	Description of violation:	QVAL = left(pvl03);
Description of violation: QSORRES/QSSTRES Gas this polocol violation been resolved? QSORRES/QSSTRES If Yes: Indicate resolution/corrective action below action: QSORRES/QSSTRES George S/QSSTRES	Description of violation:	DVIII OUT OUG T VISITION
as this p otocol violation been resolved? as this p otocol violation been resolved? as this p otocol violation resolution/corrective action below of the color. as this p otocol violation resolution/corrective action below of the color. as this p otocol violation resolution/corrective action below of the color. as this p otocol violation resolution/corrective action below of the color of the co	Description of Violation.	
las this protocol violation been resolved? Comments: Comments		I
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Protocol violation resolution/corrective action: QSORRES/QSSTRES Comments:		
Protocol violation resolution/corrective action: QSORRES/QSSTRES Comments:		
Protocol violation resolution/corrective action: QSORRES/QSSTRES Comments:	las this protocol violation been resolve	ed? OSORRES/OSSTRES If Yes: Indicate resolution/corrective action below
Comments:		
Comments:	Protocol violation resolution/corrective	OCCUPATION OF THE CONTRACT OF
	action:	QSORRES/QSSTRES
	as to	
DATA NOT STORED	Comments:	
	DATA NOT STO)RED

Form completion (if form not complete, check one):	3 Participant unable/unwilling to answer
Node #: CTP Site ID #:	Participant ID #:
Assessment Date://	Week #:

01 Informed Consent Procedures	OF Study Broad-up-/A	09 Behavioral Intervention
OI A No consent/assent obtained OIC Invalid/incomplete informed consent OID Unauthorized assessments and/or procedures conducted prior to obtaining informed consent OIE Other (specify):	O5 Study Procedures/Assessments O5A Protocol required procedures not obtained O5C Procedures/Assessments obtained outside the visit timeframes O5D Other (specify):	O9A Intervention not provided per protocol schedule or visit window timeframe O9C Other (specify):
02 Inclusion/Exclusion Criteria	06 Serious Adverse Event 06A SAE not reported 06B SAE reported out of time window 06C Other (specify):	99 Other Significant Violations 99C Using advertising materials or brochures without prior IRB approval 99D Other (specify):
03 Concomitant Medication/Therapy	07 Randomization Procedures 07A Randomization procedures not followed (e.g., outside window, out of sequence, etc.) 07B Ineligible participant randomized 07C Improper un-blinding procedures 07D Other (specify): 07E Incorrect treatment assignment	
04 Laboratory Assessments/Procedures 04A Required testing not obtained 04B Testing completed outside window 04D Unauthorized test/procedure obtained 04E Other (specify):	08 Study Drug Dosing 08A Ineligible participant dispensed medication 08B Incorrect medication dispensed 08C Incorrect medication dosage or amount of medication dispensed 08D Other (specify):	