

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

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4601 Adverse Events Source Document

1 AE symptom or diagnosis (one AE per form): _____ AETERM

1a If AE was a seizure, check here: ☐1

QNAM=AESEIZ
QLABEL=AE WAS A SEIZURE
IDVAR=AESEQ

2 Onset date (month in 3 letters, DD, YYYY): _____ / ^{AESTDTC} _____ / _____
month day year

3 Severity (check only one): ☐1 Mild
☐2 Moderate
☐3 Severe AEEV
☐4 Life-threatening
☐5 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: _____ ☐0 No ☐1 Yes AESER
Death? _____ ☐0 No ☐1 Yes AESDTH
A life-threatening event? _____ ☐0 No ☐1 Yes AESLIFE
Inpatient admission to hospital? _____ ☐0 No ☐1 Yes AESHOSP
Prolongation of hospitalization? _____ ☐0 No ☐1 Yes AESHOSP
A persistent or significant disability or incapacity? _____ ☐0 No ☐1 Yes AESDISAB
A congenital birth anomaly or defect? _____ ☐0 No ☐1 Yes AESCONG
Required significant intervention to prevent permanent
impairment/damage? _____ ☐0 No ☐1 Yes AESMIE

QNAM=AEHOSP1
QLABEL=AE INPATIENT ADMISSION
IDVAR=AESEQ

QNAM=AEHOSP2
QLABEL=AE PROLONG HOSPITALIZATION
IDVAR=AESEQ

5 Bupropion XL related (check only one)? ☐1 Unrelated ☐3 Probably related AEREL
☐2 Possibly related ☐4 Definitely related

5a Action(s) taken for Bupropion XL (check all that apply): ☐0 None AEACN ☐3 Temporarily stopped therapy
☐1 Decreased therapy ☐4 Permanently stopped therapy
☐2 Increased therapy ☐5 Participant terminated from study

6 Nicotine inhaler related (check only one)? ☐1 Unrelated ☐3 Probably related
☐2 Possibly related ☐4 Definitely related

QNAM=AEREL1
QLABEL=NICOTINE INHALER RELATED
IDVAR=AESEQ

6a Action(s) taken for nicotine inhaler (check all that apply): ☐0 None
☐1 Decreased therapy ☐3 Temporarily stopped therapy
☐2 Increased therapy ☐4 Permanently stopped therapy
☐5 Participant terminated from study

QNAM=AEACN1
QLABEL=NICOTINE INHALER ACTION TAKEN
IDVAR=AESEQ

7 Behavioral intervention related (check only one)? ☐1 Unrelated ☐3 Probably related
☐2 Possibly related ☐4 Definitely related

QNAM=AEREL2
QLABEL=BEHAVIORAL INT RELATED
IDVAR=AESEQ

7a Action(s) taken (check all that apply): ☐0 None
☐1 Decreased therapy ☐3 Temporarily stopped therapy
☐2 Increased therapy ☐4 Permanently stopped therapy
☐5 Participant terminated from study

QNAM=AEACN2
QLABEL=BEHAVIORAL INT ACTION TAKEN
IDVAR=AESEQ

8 Outcome (check only one): ☐1 Ongoing
☐2 Resolved AEOUT
☐3 Resolved with sequelae
☐4 Resolved by convention
☐5 Death

9 Resolution Date (month in 3 letters, DD, YYYY): _____ / _____ / _____
month day year AEENDTC

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: QS

Node #: _____ CTP Site ID #: _____ Participant ID #: _____

Assessment Date: _____ / _____ / _____ Visit #: _____
month day year

4602 CTN-ASI Lite v.1

Medical: _____	Drug: _____	Legal: _____	Psychiatric: _____
Employment: _____	Alcohol: _____	Family: _____	

Introducing the CTN-ASI Lite v. 1

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. Lifetime Data

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

1. 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).
3. 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.
5. 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:

Asl0d14, asl0d17, asl0d19, asl0d20, asl0d21, asl0d22, asl0d23, asl0d24, asl0d25, asl0d26, asl0d27, asl0e11, asl0e12, asl0e13, asl0e14, asl0e15, asl0e16, asl0e17, asl0e18, asl0e19, asl0e1a, asl0e1b, asl0e2a, asl0e2b, asl0e6a, asl0e6b, asl0f23S, asl0f30, asl0f31, asl0g20, asl0l10, asl0l11, asl0l12, asl0l13, asl0l14, asl0l15, asl0l16, asl0l17, asl0l18, asl0l19, asl0l20, asl0l21, asl0l25, asl0l26, asl0l27, asl0l4, asl0l5, asl0l6, asl0l7, asl0l8, asl0l9, asl0m1, asl0m6, asl0p12, asl0p1, asl0p2, asl0l3

4602 CTN-ASI Lite v. 1: 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)
- 3 = 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)
- 6 = 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.**
- 8 = Homemaker**
- 9 = Student/No Occupation/Disabled**

List of Commonly Used Drugs

- Alcohol:** Beer, wine, liquor
- Methadone:** Dolophine, LAAM
- Opiates:** Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4
Syrups = Robitussin, Fentanyl
- Barbiturates:** Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol
- Sed/Hyp/Tranq:** Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown,
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, Ecstasy
- 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

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC Visit #: _____ VISITNUM
month / day / year

QSTESTCD

EPOCH ?
QSSCAT=GENERAL INFORMATION

4602 CTN-ASI Lite v. 1: General Information

G14 How long have you lived at your current address? _____ / _____ ☐ Not answered
a. years b. months QSORRESU=YEARS QSORRESU=MONTHS

Comments: _____

DATA NOT STORED

G18 Do you have a religious preference? ☐ Protestant ☐ Catholic ☐ Jewish ☐ Islamic ☐ Other (specify): _____ ☐ None ☐ Not answered
QSTEST QSORRES/QSSTRESCC

G19 Have you been in a controlled environment in the past 30 days? (A place, theoretically, without access to drugs/alcohol) ☐ No ☐ Jail ☐ Alcohol or drug treatment ☐ Medical treatment ☐ Psychiatric treatment ☐ Other (specify): _____ ☐ Not answered

G20 How many days? _____ days OR ☐ Not answered ☐ Not applicable
(Refers to total number of days detained in the past 30 days)
Not applicable if question G19 is "No."
QSORRESU=DAYS

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSSCAT=MEDICAL STATUS

M1

M1 How many times in your _____ times OR ☐ Not answered

hospitalized for medical problems?

QSTEST

• Include O.D.'s and D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications).
• Enter the number of **overnight** hospitalizations for medical problems.

QSORRES/QSSTRESC

QSORRESU=TIMES HOSPITALIZED

Comments: _____

DATA NOT STORED

M2

M3 Do you have any chronic ☐ Not answered

medical problems which continue to interfere with your life?
☐ No☐ Yes → If Yes: Specify: _____

• A chronic medical condition is a serious physical or medical condition that requires regular care (i.e., medication, dietary restriction), preventing full advantage of their abilities.

M3SP

M4

M4 Are you taking any ☐ Not answered

prescribed medication on a regular basis for a physical problem?
☐ No☐ Yes → If Yes: Specify: _____

• Medication prescribed by a M.D. for medical conditions; **not psychiatric medicines**. • Include medicines prescribed, whether or not the participant is currently taking them.
• The intent is to verify chronic medical problems.

M4SP

M5

M5 Do you receive a ☐ Not answered

pension for a physical disability?
☐ No☐ Yes → If Yes: Specify: _____

• Include Workers' Compensation, exclude psychiatric disability.

M5SP

M6

M6 How many days have _____ days OR ☐ Not answered

you experienced medical problems in the past 30 days?

QSORRESU=DAYS

• Do not include ailments directly caused by drugs/alcohol.
• Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the participant were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.).

For questions M7 & M8, please ask participant to use the Participant Rating Scale.

M7

M7 How troubled or bothered ☐ Not at all

have you been by these medical problems in the past 30 days?
☐ Slightly☐ Moderately☐ Considerably☐ Extremely☐ Not answered

• Restrict response to problem days of question M6.

M8

M8 How important to you ☐ Not at all

now is treatment for these medical problems?
☐ Slightly☐ Moderately☐ Considerably☐ Extremely☐ Not answered

• Refers to the need for new or additional medical treatment by the participant.

Confidence Ratings: Is the above information significantly distorted by:

M10

M10 Participant's ☐ No

misrepresentation?
☐ Yes

M11

M11 Participant's inability ☐ No

to understand?
☐ Yes

CTN-0046 S-CAST

STUDYID = CTN0046

QSCAT=ADDITION SEVERITY INDEX LITE (ASL)

Data not collected

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

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

Fields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: CTP Site ID #: SITEID Participant ID #: USUBJID

Assessment Date: QSDTC / month day year Visit #: VISITNUM

QSTESTCD

QSSCAT=EMPLOYMENT/ SUPPORT STATUS

E1A/
E1B

E2A/
E2B

E4

E5

E6

E7
E7SP

E9

E10

E11

4602 CTN-ASI LITE v. 1: Employment/Support Status

E1 Education completed: ____ / ____ OR ☐ Not answered

a. years b. months

QSORRESU=YEARS

QSORRESU=MONTHS

* GED = 12 years

* Include formal education only.

QSTEST

QSORRES/QSSTRESC

E2 Training or technical education completed: ____ / ____ OR ☐ Not answered

a. years b. months

QSORRESU=YEARS

QSORRESU=MONTHS

* Formal/organized training only. For military training, only include training that can be used in civilian life, i.e., electronics or computers.

E4 Do you have a valid driver's license? ☐ No ☐ Yes ☐ Not answered

* Valid license; not suspended/revoked.

E5 Do you have an automobile available? ☐ No ☐ Yes ☐ Not answered

* (If answer to E4 is "No", then E5 must be "No".) Does not require ownership, only requires availability on a regular basis.

E6 How long was your longest full time job? ____ / ____ OR ☐ Not answered

a. years b. months

QSORRESU=YEARS

QSORRESU=MONTHS

* Full time = 35+ hours weekly; does not necessarily mean most recent job.

E7 Usual (or last) occupation? ____ OR ☐ Not answered
Specify: ____

* Use Hollingshead Categories Reference Sheet.

E9 Does someone contribute the majority of your support? ☐ No ☐ Yes ☐ Not answered ☐ Not applicable

* Is participant receiving any regular support (i.e., cash, food, housing) from family/friend? * Include spouse's contribution; exclude support by an institution.

E10 Usual employment pattern, past three years? ☐ Full time (35+ hrs/week) ☐ Part time (reg. hrs) ☐ Part time (irreg., day work) ☐ Student ☐ Military service ☐ Retired/disability ☐ Unemployed ☐ In controlled environment ☐ Not answered

* Answer should represent the **majority** of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents the more current situation.

E11 How many days were you paid for working in the past 30 days? ____ days OR ☐ Not answered

QSORRESU=DAYS

* Include "under the table" work, paid sick days, and vacation.

Comments: _____

DATA NOT STORED

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable☐ Data collection error☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____

CTP Site ID #: _____

SITEID

Participant ID #: _____

USUBJID

Assessment Date: _____

QSDTC

month / day / year

Visit #: VISITNUM

QSTESTCD

QSSCAT=EMPLOYMENT/SUPPORT STATUS

4602 CTN-ASI LITE v. 1: Employment/Support Status (continued)

For questions E12-E17: How much money did you receive from the following sources in the past 30 days? Max. = \$99999

Comments: _____

E12	E12 Employment (net income): QSTEST	\$ <u>QSORRESU=DOLLARS</u> OR <input type="checkbox"/> Not answered QSORRES/QSSTRESC <small>* Net or "take home" pay, include any "under the table" money.</small>
E13	E13 Unemployment compensation:	\$ <u>QSORRESU=DOLLARS</u> OR <input type="checkbox"/> Not answered
E14	E14 Welfare:	\$ <u>QSORRESU=DOLLARS</u> OR <input type="checkbox"/> Not answered <small>* Include food stamps, transportation money provided by an agency to go to and from treatment.</small>
E15	E15 Pensions, benefits, or Social Security:	\$ <u>QSORRESU=DOLLARS</u> OR <input type="checkbox"/> Not answered <small>* Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.</small>
E16	E16 Mate, family or friends:	\$ <u>QSORRESU=DOLLARS</u> OR <input type="checkbox"/> Not answered <small>* Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax refunds, etc.</small>
E17	E17 Illegal:	\$ <u>QSORRESU=DOLLARS</u> OR <input type="checkbox"/> Not answered <small>* Cash obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. * Do not attempt to convert drugs exchanged to a dollar value.</small>
E18	E18 How many people depend on you for the majority of their food, shelter, etc.?	_____ max = 99 OR <input type="checkbox"/> Not answered <small>* Must be regularly depending on participant; do include alimony/child support; do not include the participant or self-supporting spouse, etc.</small>
E19	E19 How many days have you experienced employment problems in the past 30 days?	QSORRESU=DAYS _____ days OR <input type="checkbox"/> Not answered <small>* Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.</small>

DATA NOT STORED

For questions E20-E21: Please ask participant to use the Participant Rating Scale.

The participant's ratings in questions E20 and E21 refer to question E19. Stress help in finding or preparing for a job, not giving them a job.

E20	E20 How troubled or bothered have you been by these employment problems in the past 30 days?	<input type="checkbox"/> Not at all <input type="checkbox"/> Slightly <input type="checkbox"/> Moderately <input type="checkbox"/> Considerably <input type="checkbox"/> Extremely <input type="checkbox"/> Not answered <input type="checkbox"/> Not applicable QSEVLINT=P30 <small>* If the participant has been incarcerated or detained during the past 30 days, they cannot have employment problems.</small>
E21	E21 How important to you now is counseling for these employment problems?	<input type="checkbox"/> Not at all <input type="checkbox"/> Slightly <input type="checkbox"/> Moderately <input type="checkbox"/> Considerably <input type="checkbox"/> Extremely <input type="checkbox"/> Not answered <input type="checkbox"/> Not applicable

Confidence Ratings: Is the above information significantly distorted by:

E23	E23 Participant's misrepresentation?	<input type="checkbox"/> No <input type="checkbox"/> Yes
-----	---------------------------------------------	----------------------------------------------------------

E24	E24 Participant's inability to understand?	<input type="checkbox"/> No <input type="checkbox"/> Yes
-----	---------------------------------------------------	----------------------------------------------------------

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable☐ Data collection error☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____

CTP Site ID #: _____

SITEID

Participant ID #: _____

USUBJID

Assessment Date: _____

QSDTC

month / day / year

Visit #: VISITNUM

QSTESTCD

QSSCAT=DRUG/ALCOHOL USE

4602 CTN-ASI LITE v. 1: Drug/Alcohol Use

Route of Administration:

1 - Oral 2 - Nasal 3 - Smoking 4 - Non-IV injection 5 - IV Injection

Note the **usual or most recent route**. For more than one route, choose the most severe.

The routes are listed from least severe to most severe. If Past 30 Days and Lifetime Use are zero, route should be "Not answered."

Comments:

DATA NOT STORED

QSTEST

QSORRES/QSSTRESC

Substance

A Past 30
(Days)B Lifetime
Use (Years)

C Route of Administration

D1 Alcohol (any use at all):QSORRESU
=DAYSQSORRESU
=YEARS**D2 Alcohol** (to intoxication):**D3 Heroin:**
☐ 1 Oral ☐ 4 Non IV injection
☐ 2 Nasal ☐ 5 IV injection
☐ 3 Smoking ☐ 6 Not applicable
☐ 7 Not answered
D4 Methadone/LAAM
(prescribed):
☐ 1 Oral ☐ 4 Non IV injection
☐ 2 Nasal ☐ 5 IV injection
☐ 3 Smoking ☐ 6 Not applicable
☐ 7 Not answered
D4a Methadone/LAAM
(illicit):
☐ 1 Oral ☐ 4 Non IV injection
☐ 2 Nasal ☐ 5 IV injection
☐ 3 Smoking ☐ 6 Not applicable
☐ 7 Not answered
**D5 Other Opiates/
Analgesics:**
☐ 1 Oral ☐ 4 Non IV injection
☐ 2 Nasal ☐ 5 IV injection
☐ 3 Smoking ☐ 6 Not applicable
☐ 7 Not answered
D6 Barbiturates:
☐ 1 Oral ☐ 4 Non IV injection
☐ 2 Nasal ☐ 5 IV injection
☐ 3 Smoking ☐ 6 Not applicable
☐ 7 Not answered
**D7 Other Sedatives/
Hypnotics/Tranquilizers:**
☐ 1 Oral ☐ 4 Non IV injection
☐ 2 Nasal ☐ 5 IV injection
☐ 3 Smoking ☐ 6 Not applicable
☐ 7 Not answered
D8 Cocaine:
☐ 1 Oral ☐ 4 Non IV injection
☐ 2 Nasal ☐ 5 IV injection
☐ 3 Smoking ☐ 6 Not applicable
☐ 7 Not answered

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSSCAT=DRUG/ALCOHOL USE

4602 CTN-ASI LITE v. 1: Drug/Alcohol Use (continued)

Route of Administration:

1 - Oral 2 - Nasal 3 - Smoking 4 - Non-IV injection 5 - IV Injection

Note the **usual or most recent route**. For more than one route, choose the most severe.
 The routes are listed from least severe to most severe. If Past 30 Days and Lifetime Use are zero, route should be "Not answered."

Comments: _____

DATA NOT STORED

Substance	A Past 30 (Days)	B Lifetime Use (Years)	C Route of Administration
D9 Amphetamines:	QSORRESU =DAYS	QSORRESU =YEARS	<input type="checkbox"/> 1 Oral <input type="checkbox"/> 4 Non IV injection <input type="checkbox"/> 2 Nasal <input type="checkbox"/> 5 IV injection <input type="checkbox"/> 3 Smoking <input type="checkbox"/> 96 Not applicable <input type="checkbox"/> 97 Not answered
D9a Methamphetamine:			<input type="checkbox"/> 1 Oral <input type="checkbox"/> 4 Non IV injection <input type="checkbox"/> 2 Nasal <input type="checkbox"/> 5 IV injection <input type="checkbox"/> 3 Smoking <input type="checkbox"/> 96 Not applicable <input type="checkbox"/> 97 Not answered
D10 Cannabis:			<input type="checkbox"/> 1 Oral <input type="checkbox"/> 4 Non IV injection <input type="checkbox"/> 2 Nasal <input type="checkbox"/> 5 IV injection <input type="checkbox"/> 3 Smoking <input type="checkbox"/> 96 Not applicable <input type="checkbox"/> 97 Not answered
D11 Hallucinogens:			<input type="checkbox"/> 1 Oral <input type="checkbox"/> 4 Non IV injection <input type="checkbox"/> 2 Nasal <input type="checkbox"/> 5 IV injection <input type="checkbox"/> 3 Smoking <input type="checkbox"/> 96 Not applicable <input type="checkbox"/> 97 Not answered
D12 Inhalants:			<input type="checkbox"/> 2 Nasal <input type="checkbox"/> 96 Not applicable <input type="checkbox"/> 97 Not answered
D13 More than 1 substance per day (including alcohol, excluding nicotine)			

D9A/
D9B/
D9CD9AA/
D9AB/
D9ACD10A/
D10B/
D10CD11A/
D11B/
D11CD12A/
D12B/
D12CD13A/
D13B

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable☐ Data collection error☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____

CTP Site ID #: _____

SITEID

Participant ID #: _____

USUBJID

QSSCAT=DRUG/ALCOHOL USE

Assessment Date: _____

QSDTC

month / day / year

Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

D14

4602 CTN-ASI LITE v. 1: Drug/Alcohol Use (continued)

D14 According to the interviewer, which substance(s) is/are the major problem?

_____ OR ☐ Not answered

• Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). Code the number next to the drug in questions 01 - 12 (code prescribed or illicit methadone as **04**). **00** - no problem, **15** - alcohol and one or more drugs; **16** - more than one drug but no alcohol. Ask participant when not clear.

Comments: _____

DATA NOT STORED

D17

D17 How many times have you had Alcohol DT's?

_____ OR ☐ Not answered

• Delirium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; they usually require medical attention.

How many times in your life have you been treated for:

Include detoxification, halfway houses, in/outpatient counseling and AA or NA (if 3+ meetings within one month period).

D19

D19 Alcohol abuse:

_____ OR ☐ Not answered

D20

D20 Drug abuse:

_____ OR ☐ Not answered

How many of these were detox only:

D21

D21 Alcohol:

_____ OR ☐ Not answered☐ Not applicable

• If D19 = 00, then question D21 is Not applicable.

D22

D22 Drugs:

_____ OR ☐ Not answered☐ Not applicable

• If D20 = 00, then question D22 is Not applicable.

How much money would you say you spent during the past 30 days on:

Max. = \$99999

D23

D23 Alcohol:

\$ QSORRESU=DOLLARS _____

OR ☐ Not answered

• Only count actual money spent. What is the financial burden caused by alcohol?

D24

D24 Drugs:

\$ QSORRESU=DOLLARS _____

OR ☐ Not answered

• Only count actual money spent. What is the financial burden caused by drugs?

D25

D25 How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?

QSORRESU=DAYS

_____ days OR ☐ Not answered

• Include AA/NA

D26

D26 How many days in the past 30 have you experienced alcohol problems?

QSORRESU=DAYS

_____ days OR ☐ Not answered

Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable☐ Data collection error☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____

CTP Site ID #: _____ SITEID

Participant ID #: _____ USUBJID

QSSCAT=DRUG/ALCOHOL USE

Assessment Date: _____

QSDTC

month / day / year

Visit #: _____ VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

D28

4602 CTN-ASI LITE v. 1: Drug/Alcohol Use (continued)

For questions D28-D31, please ask participant to use the Participant Rating Scale. The participant is rating the need for **additional** substance abuse treatment.

Comments: _____

DATA NOT STORED

D30

D28 How troubled or bothered have you been within the past 30 days by alcohol problems?

☐ Not at all
☐ Slightly
☐ Moderately

☐ Considerably
☐ Extremely
☐ Not answered

QSEVLINT=-P30

D27

D30 How important to you **now** is treatment for alcohol problems?

☐ Not at all
☐ Slightly
☐ Moderately

☐ Considerably
☐ Extremely
☐ Not answered

D27 How many days in the past 30 have you experienced drug problems? **QSORRESU=DAYS** days OR ☐ Not answered
 Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

QSEVLINT=-P30

D29

D29 How troubled or bothered have you been within the past 30 days by drug problems?

☐ Not at all
☐ Slightly
☐ Moderately

☐ Considerably
☐ Extremely
☐ Not answered

QSEVLINT=-P30

D31

D31 How important to you **now** is treatment for drug problems?

☐ Not at all
☐ Slightly
☐ Moderately

☐ Considerably
☐ Extremely
☐ Not answered

Confidence Ratings: Is the above information **significantly** distorted by:

D34

D34 Participant's misrepresentation?

☐ No ☐ Yes

D35

D35 Participant's inability to understand?

☐ No ☐ Yes

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

QSSCAT=LEGAL STATUS

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____
 month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC



L1

L2

L3

L4

L5

L6

L7

L8

L9

L10

L11

L12

L13

L14

L15

L16

L17

L18

L19

L20

4602 CTN-ASI LITE v. 1: Legal Status

L1 Was this admission prompted by the criminal justice system? ☐ No ☐ Yes ☐ Not answered
 * Judge, probation/parole officer, etc.

L2 Are you on parole or probation? ☐ No, neither ☐ Yes, parole or post release supervision ☐ Yes, probation or pre-sentencing diversion ☐ Not answered
 * Note duration and level in comments.

How many times in your life have you been arrested and charged with the following:
 Include total numbers of counts, not just convictions. Do not include juvenile [under age 18] crimes, unless they were charged as an adult. Include formal charges only.

L3 Shoplifting/vandalism: _____ OR ☐ Not answered

L4 Parole/probation violations: _____ OR ☐ Not answered

L5 Drug charges: _____ OR ☐ Not answered

L6 Forgery: _____ OR ☐ Not answered

L7 Weapons offense: _____ OR ☐ Not answered

L8 Burglary/larceny/B&E: _____ OR ☐ Not answered

L9 Robbery: _____ OR ☐ Not answered

L10 Assault: _____ OR ☐ Not answered

L11 Arson: _____ OR ☐ Not answered

L12 Rape: _____ OR ☐ Not answered

L13 Homicide/manslaughter: _____ OR ☐ Not answered

L14 Prostitution: _____ OR ☐ Not answered

L15 Contempt of court: _____ OR ☐ Not answered

L16 Other (specify): L16S _____ OR ☐ Not answered

L17 How many of these charges resulted in convictions? _____ OR ☐ Not answered ☐ Not applicable

* Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas.
 * If L3-L16 = 00, then L17 = Not applicable

How many times in your life have you been charged with the following:

L18 Disorderly conduct, vagrancy, public intoxication: _____ OR ☐ Not answered

L19 Driving while intoxicated (DWI): _____ OR ☐ Not answered

L20 Major driving violations: _____ OR ☐ Not answered

* Moving violation: speeding, reckless driving, no license, etc.

Comments: _____

DATA NOT STORED

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

QSSCAT=LEGAL STATUS

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year

Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

L21

4602 CTN-ASI LITE v. 1: Legal Status (continued)

L21 How many months were you incarcerated in your life? _____ months OR ☐ Not answered

QSORRESU=MONTHS

* If incarcerated **2 weeks or more**, round this up to 1 month. List total number of months incarcerated (up to 99). If more than 99, code 99 and enter the number in comments.

Comments: _____

DATA NOT STORED

L24

L24 Are you presently awaiting charges, trial or sentence? ☐ No ☐ Yes ☐ Not answered

L25

L25 What for (refers to L24)? _____ ☐ Not answered ☐ Not applicable

Use code 03-16, 18-20. If more than one, choose most severe. Don't include civil cases, unless a criminal offense is involved.

03 - Shoplifting	12 - Rape
04 - Probation violation	13 - Homicide
05 - Drug	14 - Prostitution
06 - Forgery	15 - Contempt
07 - Weapons	16 - Other
08 - Burglary	18 - Disorderly conduct
09 - Robbery	19 - DWI
10 - Assault	20 - Major driving violation
11 - Arson	

L26

L26 How many days in the past 30 were you detained or incarcerated? _____ days OR ☐ Not answered

QSORRESU=DAYS

* Include being arrested and released on the same day.

L27

L27 How many days in the past 30 have you engaged in illegal activities for profit? _____ days OR ☐ Not answered

QSORRESU=DAYS

* Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with question E17 under Employment/Family Support section.

For questions L28-29: Please ask participant to use the Participant Rating Scale.

L28

L28 How serious do you feel your present legal problems are? ☐ Not at all ☐ Slightly ☐ Moderately ☐ Considerably ☐ Extremely ☐ Not answered

* Exclude civil problems.

L29

L29 How important to you now is counseling or referral for these legal problems? ☐ Not at all ☐ Slightly ☐ Moderately ☐ Considerably ☐ Extremely ☐ Not answered

* Participant is rating a need for **additional** referral to legal counsel for defense against criminal charges.

Confidence Ratings: Is the above information significantly distorted by:

L31

L31 Participant's misrepresentation? ☐ No ☐ Yes

L32

L32 Participant's inability to understand? ☐ No ☐ Yes

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

QSSCAT=FAMILY/SOCIAL RELATIONSHIPS

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year

Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

F1

4602 CTN-ASI LITE v. 1: Family/Social Relationships

F1 Marital status

- ☐ Married ☐ Divorced
☐ Remarried ☐ Never married
☐ Widowed ☐ Not answered
☐ Separated

* Common-law marriage = 1: Specify in comments.

Comments: _____

DATA NOT STORED

F3

F3 Are you satisfied with this situation?

- ☐ No ☐ Yes ☐ Indifferent ☐ Not answered

* Satisfied = Generally liking the situation. Refers to question F1.

F4

F4 Usual living arrangements (past 3 yrs.):

- ☐ With sexual partner and children
☐ With sexual partner alone
☐ With children alone
☐ With parents
☐ With family
☐ With friends
☐ Alone
☐ Controlled environment
☐ No stable arrangements
☐ Not answered

* Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement.

F6

F6 Are you satisfied with these arrangements?

- ☐ No ☐ Yes ☐ Indifferent ☐ Not answered

* Refers to response in question F4.

Do you live with anyone who:

F7

F7 Has a current alcohol problem?

- ☐ No ☐ Yes ☐ Not answered

F8

F8 Uses non-prescribed drugs?

- ☐ No ☐ Yes ☐ Not answered

F9

F9 With whom do you spend most of your free time?

- ☐ Family ☐ Alone
☐ Friends ☐ Not answered

* If a girlfriend/boyfriend is considered as family by participant, then they must refer to them as family throughout this section, not as a friend. Family is not to be referred to as "friend."

F10

F10 Are you satisfied with spending your free time this way?

- ☐ No ☐ Yes ☐ Indifferent ☐ Not answered

* A satisfied response must indicate that the person generally likes the situation. Refers to question F9.

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

QSCAT=FAMILY/SOCIAL RELATIONSHIPS

Assessment Date: _____ QSDTC _____ / _____ / _____ Visit #: _____ VISITNUM _____

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4602 CTN-ASI LITE v. 1: Family/Social Relationships (continued)

Have you had significant periods in which you have experienced serious problems getting along with:

* "Serious problems" mean those that endangered the relationship.
A "problem" requires contact of some sort, either by telephone or in person.

QSEVLINT=P30

Comments: _____

DATA NOT STORED

F18A/
F18BF19A/
F19BF20A/
F20BF21A/
F21BF22A/
F22BF23A/
F23B
F23SF24A/
F24BF25A/
F25BF26A/
F26BF28A/
F28BF29A/
F29B

	A Past 30 Days	B Lifetime
F18 Mother:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F19 Father:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F20 Brother/sisters:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F21 Sexual partner/spouse:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F22 Children:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F23 Other significant family (specify): _____	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F24 Close friends:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F25 Neighbors:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
F26 Co-workers:	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable
Did anyone (F18-F26) abuse you?	A Past 30 Days	B Lifetime
F28 Physically (caused you physical harm)?	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes
F29 Sexually (forced sexual advances/acts)?	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Not answered <input type="checkbox"/> Yes

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=FAMILY/SOCIAL RELATIONSHIPS

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

F30

4602 CTN-ASI LITE v. 1: Family/Social Relationships (continued)

F30 How many days in the past 30 have you had serious conflicts with your family? QSORRESU=DAYS _____ days OR ☐_97 Not answered

QSEVLINT=-P30

Comments: _____

DATA NOT STORED

For questions F32 and F34, please ask participant to use the Participant Rating Scale.

F32

F32 How troubled or bothered have you been in the past 30 days by these family problems? ☐_0 Not at all ☐_3 Considerably
☐_1 Slightly ☐_4 Extremely
☐_2 Moderately ☐_97 Not answered

QSEVLINT=-P30

F34

F34 How important to you now is treatment or counseling for these family problems? ☐_0 Not at all ☐_3 Considerably
☐_1 Slightly ☐_4 Extremely
☐_2 Moderately ☐_97 Not answered
Participant is rating his/her need for counseling for family problems, not whether the family would be willing to attend.

F31

F31 How many days in the past 30 have you had serious conflicts with other people (excluding family)? QSORRESU=DAYS _____ days OR ☐_97 Not answered

QSEVLINT=-P30

For questions F33 and F35, please ask participant to use the Participant Rating Scale.

F33

F33 How troubled or bothered have you been in the past 30 days by these social problems? ☐_0 Not at all ☐_3 Considerably
☐_1 Slightly ☐_4 Extremely
☐_2 Moderately ☐_97 Not answered

QSEVLINT=-P30

F35

F35 How important to you now is treatment or counseling for these social problems? ☐_0 Not at all ☐_3 Considerably
☐_1 Slightly ☐_4 Extremely
☐_2 Moderately ☐_97 Not answered

** Include participant's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Participant rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if participant had no substance abuse.*

Confidence Ratings: Is the above information significantly distorted by:

F37

F37 Participant's misrepresentation? ☐_0 No ☐_1 Yes

F38

F38 Participant's inability to understand? ☐_0 No ☐_1 Yes

CTN-0046

S-CAST

Data not collected

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

☐ Participant unavailable☐ Data collection error☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____

CTP Site ID #: _____ SITEID

Participant ID #: _____ USUBJID

QSSCAT=PSYCHIATRIC STATUS

Assessment Date: _____

QSDTC

Visit #: _____ VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4602 CTN-ASI LITE v. 1: Psychiatric Status

How many times have you been treated for any psychological or emotional problems?

* Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in Comments if known.

Comments: _____

DATA NOT STORED

P1

P1 In a hospital or inpatient setting? _____

OR

☐ Not answered

P2

P2 As an outpatient/private patient? _____

OR

☐ Not answered

P3

P3 Do you receive a pension for a psychiatric disability? _____

☐ No☐ Yes☐ Not answered

Have you had a significant period of time (that was not a direct result of drug/alcohol use) in which you have:

QSORRES/QSSTRESC

P4A/
P4B

P4 Experienced serious depression—sadness, hopelessness, loss of interest, difficulty with daily function?

☐ No☐ Yes☐ Not answered

A Past 30 Days

B Lifetime

☐ No☐ Yes☐ Not answeredP5A/
P5B

P5 Experienced serious anxiety/tension—uptight, unreasonably worried, inability to feel relaxed?

☐ No☐ Yes☐ Not answered☐ No☐ Yes☐ Not answeredP6A/
P6B

P6 Experienced hallucinations—saw things or heard voices that other people did not hear or see?

☐ No☐ Yes☐ Not answered☐ No☐ Yes☐ Not answeredP7A/
P7B

P7 Experienced trouble understanding, concentrating, or remembering?

☐ No☐ Yes☐ Not answered☐ No☐ Yes☐ Not answered

For questions P8–P10, participant could have been under the influence of alcohol/drugs

P8A/
P8B

P8 Experienced trouble controlling violent behavior including episodes of rage, or violence?

☐ No☐ Yes☐ Not answered☐ No☐ Yes☐ Not answered

* Participant can be under the influence of alcohol/drugs.

P9A/
P9B

P9 Experienced serious thoughts of suicide?

* Participant seriously considered a plan for taking his/her life.

☐ No☐ Yes☐ Not answered☐ No☐ Yes☐ Not answeredP10A/
P10B

P10 Attempted suicide?

* Include actual suicidal gestures or attempts.

☐ No☐ Yes☐ Not answered☐ No☐ Yes☐ Not answeredP11A/
P11B

P11 Been prescribed medication for any psychological/emotional problem?

* Prescribed for the participant by MD.

Record "Yes" if a medication was prescribed even if the participant is not taking it.

☐ No☐ Yes☐ Not answered☐ No☐ Yes☐ Not answered

CTN-0046 S-CAST

Data not collected

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

QSSCAT=LEGAL STATUS

 Assessment Date: _____ QSDTC _____ / _____ / _____
 month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

P12

4602 CTN-ASI LITE v. 1: Psychiatric Status (continued)

P12 How many days in the past 30 _____ OR ☐₉₇ Not answered
 have you experienced these
 psychological or emotional
 problems?

* This refers to problems noted in questions
 P4-P10.

QSEVLINT=-P30

Comments: _____

DATA NOT STORED

For questions P13-P14, please ask participant to use the Participant Rating Scale.

P13

P13 How much have you been
 troubled or bothered by these
 psychological or emotional
 problems in the past 30 days?

☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

* Participant should be rating the problem days from
 question P12.

QSEVLINT=-P30

P14

P14 How important to you now is
 treatment for these psychological
 or emotional problems?

☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

Confidence Ratings: Is the above information significantly distorted by:

P22

P22 Participant's misrepresentation? ☐₀ No ☐₁ Yes

P23

P23 Participant's inability to
 understand? ☐₀ No ☐₁ Yes

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: QS

Node #: _____ CTP Site ID #: _____ Participant ID #: _____

Assessment Date: _____ / _____ / _____ Visit #: _____
month day year

4603 ASI-LITE Follow-up

Medical: _____	Drug: _____	Legal: _____	Psychiatric: _____
Employment: _____	Alcohol: _____	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

1. 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).
3. 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.
5. 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

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)**
- 3 = 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)**
- 6 = 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.**
- 8 = Homemaker**
- 9 = Student/No Occupation/Disabled**

List of Commonly Used Drugs

- Alcohol:** Beer, wine, liquor
- Methadone:** Dolophine, LAAM
- Opiates:** Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4
Syrups = Robitussin, Fentanyl
- Barbiturates:** Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol
- Sed/Hyp/Tranq:** Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown,
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, Ecstasy
- 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

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=GENERAL INFORMATION

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC



G19

G19S

G20

4603 ASI Lite Follow-up (ASF): General Information

G19 Have you been in a controlled environment in the past 30 days?

(A place, theoretically, without access to drugs/alcohol)

☐ No☐ Jail☐ Alcohol or drug treatment☐ Medical treatment☐ Psychiatric treatment☐ Other (specify): _____☐ Not answered

Comments: _____

DATA NOT STORED

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."

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

QSSCAT=MEDICAL STATUS

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC



M1

4603 ASI-Lite Follow-up (ASF): Medical Status

M1 How many times since your last ASI have you been hospitalized for medical problems?

_____ times OR ☐ 97 Not answered

• Include O.D.'s and D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications).
 • Enter the number of **overnight** hospitalizations for medical problems.

Comments: _____

DATA NOT STORED

M4

M4 Are you taking any prescribed medication on a regular basis for a physical problem?

☐ 97 Not answered☐ 0 No☐ 1 Yes → If Yes: Specify: _____

• Medication prescribed by a M.D. for medical conditions; **not psychiatric medicines**. • Include medicines prescribed, whether or not the participant is currently taking them.
 • The intent is to verify chronic medical problems.

M4SP

M5

M5 Do you receive a pension for a physical disability?

☐ 97 Not answered☐ 0 No☐ 1 Yes → If Yes: Specify: _____

• Include Workers' Compensation, exclude psychiatric disability.

M5SP

M6

M6 How many days have you experienced medical problems in the past 30 days?

_____ days OR ☐ 97 Not answered

• Do not include ailments directly caused by drugs/alcohol.
 • Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the participant were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.)

QSORRESU=DAYS

QSEVLINT=P30

For questions M7 & M8, please ask participant to use the Participant Rating Scale.

M7

M7 How troubled or bothered have you been by these medical problems in the past 30 days?

☐ 0 Not at all☐ 1 Slightly☐ 2 Moderately☐ 3 Considerably☐ 4 Extremely☐ 97 Not answered

• Restrict response to problem days of question M6.

QSEVLINT=P30

M8

M8 How important to you **now** is treatment for these medical problems?

☐ 0 Not at all☐ 1 Slightly☐ 2 Moderately☐ 3 Considerably☐ 4 Extremely☐ 97 Not answered

• Refers to the need for new or additional medical treatment by the participant.

Confidence Ratings:

Is the above information **significantly** distorted by:

M10

M10 Participant's misrepresentation?

☐ 0 No☐ 1 Yes

M11

M11 Participant's inability to understand?

☐ 0 No☐ 1 Yes

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=EMPLOYMENT/SUPPORT STATUS

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

E1A/
E1BE2A/
E2B

E4

E5

E7

E9

E11

4603 ASI-Lite Follow-up (ASF): Employment/Support Status		
E1 Education completed since your last ASI:	QSORRESU=YEARS _____ / _____ A-Years B-Months • GED = 12 years • Include formal education only.	OR <input type="checkbox"/> ₉₇ Not answered QSORRESU=MONTHS _____
E2 Training or technical education completed since your last ASI:	QSORRESU=YEARS _____ / _____ A-Years B-Months • Formal/organized training only. For military training, only include training that can be used in civilian life, i.e., electronics or computers.	OR <input type="checkbox"/> ₉₇ Not answered QSORRESU=MONTHS _____
E4 Do you have a valid driver's license?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₉₇ Not answered • Valid license; not suspended/revoked.	
E5 Do you have an automobile available?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₉₇ Not answered • If answer to E4 is "No", then E5 must be "No". Does not require ownership, only requires availability on a regular basis.	
E7 Usual (or last) occupation since your last ASI? Specify: <u>E7SP</u>	_____ OR <input type="checkbox"/> ₉₇ Not answered • Use Hollingshead Categories Reference Sheet.	
E9 Does someone contribute the majority of your support?	<input type="checkbox"/> ₀ No <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₉₇ Not answered • Is participant receiving any regular support (i.e., cash, food, housing) from family/friend? • Include spouse's contribution; exclude support by an institution.	
E11 How many days were you paid for working in the past 30 days?	_____ days OR <input type="checkbox"/> ₉₇ Not answered • Include "under the table" work, paid sick days, and vacation. QSORRESU=DAYS _____	

Comments: _____

DATA NOT STORED

CTN-0046

S-CAST

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

☐ Participant unavailable☐ Data collection error☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____

CTP Site ID #: _____

SITEID

Participant ID #: _____

USUBJID

QSSCAT=EMPLOYMENT/SUPPORT STATUS

Assessment Date: _____

QSDTC

month / day / year

Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4603 ASI-Lite Follow-up (ASF): Employment/Support Status (continued)

For questions E12-E17: How much money did you receive from the following sources in the past 30 days?

Comments: _____

DATA NOT STORED

E12

E12 Employment (net income):

\$ QSORRESU=DOLLARS

OR ☐ Not answered

* Net or "take home" pay, include any "under the table" money.

E13

E13 Unemployment compensation

\$ QSORRESU=DOLLARS

OR ☐ Not answered

E14

E14 Welfare:

\$ QSORRESU=DOLLARS

OR ☐ Not answered

* Include food stamps, transportation money provided by an agency to go to and from treatment.

E15

E15 Pensions, benefits, or Social Security:

\$ QSORRESU=DOLLARS

OR ☐ Not answered

* Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

E16

E16 Mate, family or friends:

\$ QSORRESU=DOLLARS

OR ☐ Not answered

* Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.

E17

E17 Illegal:

\$ QSORRESU=DOLLARS

OR ☐ Not answered* **Cash** obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc.* **Do not** attempt to convert drugs exchanged to a dollar value.

E18

E18 How many people depend on you for the majority of their food, shelter, etc.?

QSORRESU=PEOPLE

____ 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

E19 How many days have you experienced employment problems in the past 30 days?

QSORRESU=DAYS

____ days OR ☐ Not answered

QSEVLINT=P30

* Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

For questions E20-E21: Please ask participant to use the Participant Rating Scale. The participant's ratings in questions E20 and E21 refer to question E19. Stress help in finding or preparing for a job, not giving them a job.

E20

E20 How troubled or bothered have you been by these employment problems in the past 30 days?

☐ Not at all☐ Slightly☐ Moderately

QSEVLINT=P30

☐ Considerably☐ Extremely☐ Not applicable☐ Not answered

* If the participant has been incarcerated or detained during the past 30 days, they cannot have employment problems.

E21

E21 How important to you now is counseling for these employment problems?

☐ Not at all☐ Slightly☐ Moderately☐ Considerably☐ Extremely☐ Not applicable☐ Not answered

Confidence Ratings: Is the above information significantly distorted by:

E23

E23 Participant's misrepresentation?

☐ No☐ Yes

E24

E24 Participant's inability to understand?

☐ No☐ Yes

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

QSSCAT=ALCOHOL/DRUGS

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4603 ASI-Lite Follow-up (ASF): Alcohol/Drugs

Route of Administration:

1 - Oral 2 - Nasal 3 - Smoking 4 - Non-IV injection 5 - IV Injection

 Note the **usual or most recent route**. For more than one route, choose the most severe.
 The routes are listed from least severe to most severe.

Comments: _____

DATA NOT STORED

D1A

D1 Alcohol (any use at all):

QSEVLINT=P30

D2A

D2 Alcohol (to intoxication):

D3A/
D3C**D3 Heroin:**

☐ Oral ☐ Non IV injection
☐ Nasal ☐ IV injection
☐ Smoking ☐ Not applicable
☐ Not answered
D4A/
D4C**D4 Methadone/LAAM**
(prescribed):

☐ Oral ☐ Non IV injection
☐ Nasal ☐ IV injection
☐ Smoking ☐ Not applicable
☐ Not answered
D4AA/
D4AC**D4a Methadone/LAAM**
(illicit):

☐ Oral ☐ Non IV injection
☐ Nasal ☐ IV injection
☐ Smoking ☐ Not applicable
☐ Not answered
D5A/
D5C**D5 Other opiates/
analgesics:**

☐ Oral ☐ Non IV injection
☐ Nasal ☐ IV injection
☐ Smoking ☐ Not applicable
☐ Not answered
D6A/
D6C**D6 Barbiturates:**

☐ Oral ☐ Non IV injection
☐ Nasal ☐ IV injection
☐ Smoking ☐ Not applicable
☐ Not answered
D7A/
D7C**D7 Other sedatives/
hypnotics/tranquilizers:**

☐ Oral ☐ Non IV injection
☐ Nasal ☐ IV injection
☐ Smoking ☐ Not applicable
☐ Not answered

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

QSSCAT=ALCOHOL/DRUGS

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4603 ASI-Lite Follow-up (ASF): Alcohol/Drugs (continued)

Route of Administration:

1 - Oral 2 - Nasal 3 - Smoking 4 - Non-IV injection 5 - IV Injection
Note the **usual or most recent route**. For more than one route, choose the most severe.

The routes are listed from least severe to most severe.

Comments:

DATA NOT STORED

Substance	A Past 30 (Days)	Route of Administration
D8 Cocaine:	QSEVLINT=P30 ____	<input type="checkbox"/> ₁ Oral <input type="checkbox"/> ₄ Non IV injection <input type="checkbox"/> ₂ Nasal <input type="checkbox"/> ₅ IV injection <input type="checkbox"/> ₃ Smoking <input type="checkbox"/> ₆ Not applicable <input type="checkbox"/> ₇ Not answered
D9 Amphetamines:	____	<input type="checkbox"/> ₁ Oral <input type="checkbox"/> ₄ Non IV injection <input type="checkbox"/> ₂ Nasal <input type="checkbox"/> ₅ IV injection <input type="checkbox"/> ₃ Smoking <input type="checkbox"/> ₆ Not applicable <input type="checkbox"/> ₇ Not answered
D9a Methamphetamine:	____	<input type="checkbox"/> ₁ Oral <input type="checkbox"/> ₄ Non IV injection <input type="checkbox"/> ₂ Nasal <input type="checkbox"/> ₅ IV injection <input type="checkbox"/> ₃ Smoking <input type="checkbox"/> ₆ Not applicable <input type="checkbox"/> ₇ Not answered
D10 Cannabis:	____	<input type="checkbox"/> ₁ Oral <input type="checkbox"/> ₄ Non IV injection <input type="checkbox"/> ₃ Smoking <input type="checkbox"/> ₅ IV injection <input type="checkbox"/> ₆ Not applicable <input type="checkbox"/> ₇ Not answered
D11 Hallucinogens:	____	<input type="checkbox"/> ₁ Oral <input type="checkbox"/> ₄ Non IV injection <input type="checkbox"/> ₂ Nasal <input type="checkbox"/> ₅ IV injection <input type="checkbox"/> ₃ Smoking <input type="checkbox"/> ₆ Not applicable <input type="checkbox"/> ₇ Not answered
D12 Inhalants:	____	<input type="checkbox"/> ₂ Nasal <input type="checkbox"/> ₆ Not applicable <input type="checkbox"/> ₇ Not answered
D13 More than 1 substance per day (including alcohol, excluding nicotine)	____	

CTN-0046

S-CAST

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

☐ ₁ Participant unavailable ☐ ₂ Data collection error ☐ ₃ Participant unable/unwilling to answer
 Fields affected: ☐ ₀ Entire CRF ☐ ₁ Questions (specify): _____

QSSCAT=ALCOHOL/DRUGS

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____
 month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

D14

4603 ASI Lite Follow-up (ASF): Alcohol/Drugs (continued)

D14 According to the interviewer, which substance(s) is/are the major problem?

_____ OR ☐ ₉₇ Not answered

• Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). Code the number next to the drug in questions 01 - 12 (code prescribed or illicit methadone as **04**).
00 - no problem, **15** - alcohol and one or more drugs; **16** - more than one drug but no alcohol. Ask participant when not clear.

Comments: _____

DATA NOT STORED

D17

D17 How many times, since your last ASI, have you had Alcohol DT's?

_____ OR ☐ ₉₇ Not answered

• Delirium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; they usually require medical attention.

How many times since your last ASI have you been treated for:

Include detoxification, halfway houses, in/outpatient counseling and AA or NA (if 3+ meetings within one month period.)

D19

D19 Alcohol abuse:

_____ OR ☐ ₉₇ Not answered

D20

D20 Drug abuse:

_____ OR ☐ ₉₇ Not answered

How many of these were detox only:

D21

D21 Alcohol:

_____ OR ☐ ₉₇ Not answered
☐ ₉₆ Not applicable

• If D19 = 00, then question D21 is Not applicable.

D22

D22 Drugs:

_____ OR ☐ ₉₇ Not answered
☐ ₉₆ Not applicable

• If D20 = 00, then question D22 is Not applicable.

How much money would you say you spent during the past 30 days on:

Max. = \$99999

D23

D23 Alcohol:

\$ QSORRESU=DOLLARS _____

QSEVLINT=P30

OR ☐ ₉₇ Not answered

• Only count actual money spent. What is the financial burden caused by alcohol?

D24

D24 Drugs:

\$ QSORRESU=DOLLARS _____

QSEVLINT=P30

OR ☐ ₉₇ Not answered

• Only count actual money spent. What is the financial burden caused by drugs?

D25

D25 How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?

QSORRESU=DAYS _____ days OR ☐ ₉₇ Not answered

• Include AA/NA

QSEVLINT=P30

D26

D26 How many days in the past 30 have you experienced alcohol problems?

_____ days OR ☐ ₉₇ Not answered

Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

QSEVLINT=P30

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=GENERAL INFORMATION

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

G28

D30

D27

D29

D31

D34

D35

4603 ASI-LITE Follow-up (ASF): Alcohol/Drugs (continued)

For questions D28-D31, please ask participant to use the Participant Rating Scale. The participant is rating the need for additional substance abuse treatment.

Comments: _____

DATA NOT STORED

D28 How troubled or bothered have you been within the past 30 days by alcohol problems?

☐ Not at all ☐ Considerably
☐ Slightly ☐ Extremely
☐ Moderately ☐ Not answered

QSEVLINT=-P30

D30 How important to you now is treatment for alcohol problems?

☐ Not at all ☐ Considerably
☐ Slightly ☐ Extremely
☐ Moderately ☐ Not answered

D27 How many days in the past 30 have you experienced drug problems? QSORRESU=DAYS days OR ☐ Not answered

QSEVLINT=-P30

*Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

D29 How troubled or bothered have you been within the past 30 days by drug problems?

☐ Not at all ☐ Considerably
☐ Slightly ☐ Extremely
☐ Moderately ☐ Not answered

QSEVLINT=-P30

D31 How important to you now is treatment for drug problems?

☐ Not at all ☐ Considerably
☐ Slightly ☐ Extremely
☐ Moderately ☐ Not answered

Confidence Ratings: Is the above information significantly distorted by:

D34 Participant's misrepresentation? ☐ No ☐ Yes

D35 Participant's inability to understand? ☐ No ☐ Yes

CTN-0046
S-CAST

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

☐1 Participant unavailable ☐2 Data collection error ☐3 Participant unable/unwilling to answer
Fields affected: ☐0 Entire CRF ☐1 Questions (specify): _____

Node #: CTP Site ID #: SITEID Participant ID #: USUBJID

QSSCAT=LEGAL STATUS

Assessment Date: **QSDTC** / / Visit #: **VISITNUM**
month day year

OSTESTCD	OSTEST	OSORRES/OSSTRESC	month	day	year
-----------------	---------------	-------------------------	--------------	------------	-------------

OSTESTCD	OSTEST	OSORRES/OSSTRESC	month	day	year
-----------------	---------------	-------------------------	--------------	------------	-------------

OSTESTCD	OSTEST	OSORRES/OSSTRESC	month	day	year
-----------------	---------------	-------------------------	--------------	------------	-------------

4603 ASI-Lite Follow-up (ASF): Legal Status			
L2	L2 Are you on probation or parole? <input type="checkbox"/> No, neither <input type="checkbox"/> Yes, parole or post release supervision <input type="checkbox"/> Yes, probation or pre-sentencing diversion <input type="checkbox"/> Not answered <small>* Note duration and level in comments.</small>	Comments: <div>DATA NOT STORED</div>	
How many times since your last ASI have you been arrested and charged with the following: <small>Include total numbers of counts, not just convictions. Do not include juvenile [under age 18] crimes, unless they were charged as an adult. Include formal charges only.</small>			
L3	L3 Shoplifting/vandalism:	___ OR <input type="checkbox"/> Not answered	
L4	L4 Parole/probation violations:	___ OR <input type="checkbox"/> Not answered	
L5	L5 Drug charges:	___ OR <input type="checkbox"/> Not answered	
L6	L6 Forgery:	___ OR <input type="checkbox"/> Not answered	
L7	L7 Weapons offense:	___ OR <input type="checkbox"/> Not answered	
L8	L8 Burglary/larceny/B&E:	___ OR <input type="checkbox"/> Not answered	
L9	L9 Robbery:	___ OR <input type="checkbox"/> Not answered	
L10	L10 Assault:	___ OR <input type="checkbox"/> Not answered	
L11	L11 Arson:	___ OR <input type="checkbox"/> Not answered	
L12	L12 Rape:	___ OR <input type="checkbox"/> Not answered	
L13	L13 Homicide/manslaughter:	___ OR <input type="checkbox"/> Not answered	
L14	L14 Prostitution:	___ OR <input type="checkbox"/> Not answered	
L15	L15 Contempt of court:	___ OR <input type="checkbox"/> Not answered	
L16	L16 Other (specify): _____	___ OR <input type="checkbox"/> Not answered	
L17	L17 How many of these charges resulted in convictions? ___ OR <input type="checkbox"/> Not applicable <input type="checkbox"/> Not answered <small>Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarceration, suspended sentences, and guilty pleas.</small>		
How many times since your last ASI have you been charged with the following:			
L18	L18 Disorderly conduct, vagrancy, public intoxication:	___ OR <input type="checkbox"/> Not answered	
L19	L19 Driving while intoxicated (DWI):	___ OR <input type="checkbox"/> Not answered	
L20	L20 Major driving violations:	___ OR <input type="checkbox"/> Not answered	
<small>* Moving violations: speeding, reckless driving, no license, etc.</small>			

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

QSSCAT=LEGAL STATUS

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC



L21

4603 ASI-Lite Follow-up (ASF): Legal Status (continued)

L21 How many months were you incarcerated since your last ASI?

_____ OR ☐ 97 Not answered

* If incarcerated **2 weeks or more**, round this up to 1 month. List total number of months incarcerated (up to 99). If more than 99, code 99 and enter the number in Comments.

QSORRESU=MONTHS

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)?

_____ ☐ 97 Not answered ☐ 96 Not applicable

Use code 03-16, 18-20. If more than one, choose most severe. Don't include civil cases, unless a criminal offense is involved.

03 - Shoplifting	12 - Rape
04 - Probation violation	13 - Homicide
05 - Drug	14 - Prostitution
06 - Forgery	15 - Contempt
07 - Weapons	16 - Other
08 - Burglary	18 - Disorderly conduct
09 - Robbery	19 - DWI
10 - Assault	20 - Major driving violation
11 - Arson	

L26

L26 How many days in the past 30 were you detained or incarcerated?

_____ days OR ☐ 97 Not answered

* Include being arrested and released on the same day.

QSORRESU=DAYS

QSEVLINT=-P30

L27

L27 How many days in the past 30 have you engaged in illegal activities for profit?

_____ days OR ☐ 97 Not answered

* Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with question E17 under Employment/Family Support section.

QSORRESU=DAYS

QSEVLINT=-P30

For questions L28-29: Please ask participant to use the Participant Rating Scale.

L28

L28 How serious do you feel your present legal problems are?

☐ 0 Not at all ☐ 3 Considerably
☐ 1 Slightly ☐ 4 Extremely
☐ 2 Moderately ☐ 97 Not answered

* Exclude civil problems.

L29

L29 How important to you now is counseling or referral for these legal problems?

☐ 0 Not at all ☐ 3 Considerably
☐ 1 Slightly ☐ 4 Extremely
☐ 2 Moderately ☐ 97 Not answered

* Participant is rating a need for **additional** referral to legal counsel for defense against criminal charges.

Confidence Ratings: Is the above information significantly distorted by:

L31

L31 Participant's misrepresentation?

☐ 0 No ☐ 1 Yes

L32

L32 Participant's ability to understand?

☐ 0 No ☐ 1 Yes

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=FAMILY/SOCIAL RELATIONSHIPS

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC



F1

4603 ASI-LITE Follow-up (ASF): Family/Social Relationships

F1 Marital status

- ☐ Married ☐ Divorced
☐ Remarried ☐ Never married
☐ Widowed ☐ Not answered
☐ Separated

* Common-law marriage - 1: Specify in Comments.

Comments: _____

DATA NOT STORED

F3

F3 Are you satisfied with this situation?

- ☐ No ☐ Yes ☐ Indifferent ☐ Not answered

* Satisfied - Generally liking the situation. Refers to question F1.

F4

F4 Usual living arrangements (since last ASI):

- ☐ With sexual partner and children
☐ With sexual partner alone
☐ With children alone
☐ With parent
☐ With family
☐ With friends
☐ Alone
☐ Controlled environment
☐ No stable arrangements
☐ Not answered

F6

F6 Are you satisfied with these arrangements?

- ☐ No ☐ Yes ☐ Indifferent ☐ Not answered

* Refers to response in question F4.

Do you live with anyone who:

F7

F7 Has a current alcohol problem?

- ☐ No ☐ Yes ☐ Not answered

F8

F8 Uses non-prescribed drugs?

- ☐ No ☐ Yes ☐ Not answered

F9

F9 With whom do you spend most of your free time?

- ☐ Family ☐ Alone
☐ Friends ☐ Not answered

* If a girlfriend/boyfriend is considered as family by participant, then they must refer to them as family throughout this section, not as a friend. Family is not to be referred to as "friend."

F10

F10 Are you satisfied with spending your free time this way?

- ☐ No ☐ Yes ☐ Indifferent ☐ Not answered

* A satisfied response must indicate that the person generally likes the situation. Refers to question F9.

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=FAMILY/SOCIAL RELATIONSHIPS

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4603 ASI-LITE Follow-up (ASF): Family/Social Relationships (continued)

Have you had significant periods in which you have experienced serious problems getting along with:

* Serious problems mean those that endangered the relationship.

A "problem" requires contact of some sort, either by telephone or in person.

QSEVLINT=P30

Comments: _____

DATA NOT STORED

F18

F18 Mother:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F19

F19 Father:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F20

F20 Brothers/sisters:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F21

F21 Sexual partner/spouse:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F22

F22 Children:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F23

F23 Other significant family (specify):
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F23S

F24

F24 Close friends:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F25

F25 Neighbors:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable

F26

F26 Co-workers:
☐ No ☐ Not answered
☐ Yes ☐ Not applicable
Did anyone abuse you?**Past 30 Days**

F28

F28 Physically (cause you physical harm)?
☐ No ☐ Not answered
☐ Yes

F29

F29 Sexually (force sexual advances/acts)?
☐ No ☐ Not answered
☐ Yes

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=FAMILY/SOCIAL RELATIONSHIPS

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRES



F30

4603 ASI-LITE Follow-up (ASF): Family/Social Relationships (continued)

F30 How many days in the past 30 _____ days OR ☐₉₇ Not answered
 have you had serious conflicts with your family?
 QSORRESU=DAYS
 QSEVLINT=-P30

Comments: _____

DATA NOT STORED

For questions F32 and F34, please ask participant to use the Participant Rating Scale.

F32

F32 How troubled or bothered have you been in the past 30 days by these family problems?
☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

QSEVLINT=-P30

F34

F34 How important to you now is treatment or counseling for these family problems?
☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

* Participant is rating his/her need for counseling for family problems, not whether the family would be willing to attend.

F31

F31 How many days in the past 30 _____ days OR ☐₉₇ Not answered
 have you had serious conflicts with other people
 (excluding family)?
 QSORRESU=DAYS
 QSEVLINT=-P30

For questions F33 and F35, please ask participant to use the Participant Rating Scale.

F33

F33 How troubled or bothered have you been in the past 30 days by these social problems?
☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

QSEVLINT=-P30

F35

F35 How important to you now is treatment or counseling for these social problems?
☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

* Include participant's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Participant rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if participant had no substance abuse

Confidence Ratings: Is the above information significantly distorted by:

F37

F37 Participant's misrepresentation? ☐₀ No ☐₁ Yes

F38

F38 Participant's inability to understand? ☐₀ No ☐₁ Yes

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

QSSCAT=PSYCHIATRIC STATUS

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year

Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4603 ASI-LITE Follow-up (ASF): Psychiatric Status

How many times since your last ASI have you been treated for any psychological or emotional problems?

* Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in Comments if known.

Comments: _____

DATA NOT STORED

P1

P1 In a hospital or inpatient setting?

____ OR ☐ 97 Not answered

P2

P2 As an outpatient/private patient?

____ OR ☐ 97 Not answered

P3

P3 Do you receive a pension for a psychiatric disability?

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

Have you had a significant period of time (that was not a direct result of drug/alcohol use) in which you have:

Past 30 Days

P4

P4 Experienced serious depression—sadness, hopelessness, loss of interest, difficulty with daily function?

☐ 0 No ☐ 1 Yes ☐ 97 Not answered
QSEVLINT=-P30

P5

P5 Experienced serious anxiety/tension—uptight, unreasonably worried, inability to feel relaxed?

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

P6

P6 Experienced hallucinations—saw things or heard voices that other people did not hear or see?

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

P7

P7 Experienced trouble understanding, concentrating, or remembering?

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

For questions P8–P10, participant could have been under the influence of alcohol/drugs

P8

P8 Experienced trouble controlling violent behavior including episodes of rage, or violence?

* Participant can be under the influence of alcohol/drugs.

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

P9

P9 Experienced serious thoughts of suicide?

* Participant seriously considered a plan for taking his/her life.

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

P10

P10 Attempted suicide?

* Include actual suicidal gestures or attempts.

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

P11

P11 Been prescribed medication for any psychological/emotional problem?

* Prescribed for the participant by M.D.

Record "Yes" if a medication was prescribed **even if** the participant is not taking it.

☐ 0 No ☐ 1 Yes ☐ 97 Not answered

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

QSSCAT=PSYCHIATRIC STATUS

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC



P12

4603 ASI-Lite Follow-up (ASF): Psychiatric Status (continued)

P12 How many days in the past 30 **QSORRESU=DAYS** **OR** ☐₉₇ Not answered
 have you experienced these
 psychological or emotional
 problems?
 • This refers to problems noted in questions
 P4-P10. **QSEVLINT=-P30**

Comments: _____

DATA NOT STORED

For questions P13-P14, please ask participant to use the Participant Rating Scale.

P13

P13 How much have you been
 troubled or bothered by these
 psychological or emotional
 problems in the past 30 days? **QSEVLINT=-P30**

☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

P14

P14 How important to you **now** is
 treatment for these psychological
 or emotional problems?

☐₀ Not at all ☐₃ Considerably
☐₁ Slightly ☐₄ Extremely
☐₂ Moderately ☐₉₇ Not answered

Confidence Ratings: Is the above information **significantly** distorted by:

P22

P22 Participant's misrepresentation? ☐₀ No ☐₁ Yes

P23

P23 Participant's inability to
 understand? ☐₀ No ☐₁ Yes

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: LB

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ LBDTC
month / day / year Visit #: VISITNUM

LBCAT=CHEMISTRY

4604 Blood Chemistry

Sequence #: _____ LBGRPID

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	_____	mg/dL	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Abnormal/Excludes <input type="checkbox"/> Not Done
2 Creatinine	_____	mg/dL	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Abnormal/Excludes <input type="checkbox"/> Not Done
3 Alanine Aminotransferase (ALT/SGPT)	_____	U/L	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Abnormal/Excludes <input type="checkbox"/> Not Done
4 Aspartate Aminotransferase (AST/SGOT)	_____	U/L	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Abnormal/Excludes <input type="checkbox"/> Not Done
5 Gamma Glutamyl Transpeptidase (GGT)	_____	U/L	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Abnormal/Excludes <input type="checkbox"/> Not Done
6 Blood Urea Nitrogen (BUN)	_____	mg/dL	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	<input type="checkbox"/> Abnormal/Excludes <input type="checkbox"/> Not Done

7 Provide comments for any abnormal value(s): _____ DATA NOT STORED

QNAM=ABNORMAL
QLABEL=TEST VALUE IS ABNORMAL
IDVAR=LBSEQ

QNAM=EXCLUDES
QLABEL=TEST VALUE IS
ABNORMAL/EXCLUDES
IDVAR=LBSEQ

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC



4605 Brief Substance Craving Scale

BSCS01

- 1 Please indicate your primary drug of choice (check only one):** ☐ Cocaine
☐ Methamphetamine

BSCS02

Answer the following questions with regard to your craving for your primary drug (check one per question):

- 2 The INTENSITY of my craving, that is, how much I desired this drug in the past 24 hours was:**

- ☐ None at all
☐ Slight
☐ Moderate
☐ Considerable
☐ Extreme

QSEVLINT=-H24

BSCS03

- 3 The FREQUENCY of my craving, that is, how often I desired this drug in the past 24 hours was:**

- ☐ Never
☐ Almost Never
☐ Several Times
☐ Regularly
☐ Almost Constantly

BSCS04

- 4 The LENGTH of time I spent in craving this drug during the past 24 hours was:**

- ☐ None at all
☐ Very Short
☐ Short
☐ Somewhat Long
☐ Very Long

BSCS05

- 5 Write in the NUMBER of times you think you had craving for this drug during the past 24 hours: _____**

BSCS06

- 6 A second craved substance during the past 24 hours was (check only one):**

- ☐ None (STOP)
☐ Alcohol
☐ Amphetamine
☐ Cannabis (Marijuana)
☐ Cocaine
☐ Hallucinogens (including Ecstasy)
☐ Inhalants
☐ Methamphetamine
☐ Opiates (Heroin, Morphine, prescription opioids such as Oxycontin, etc.)
☐ PCP
☐ Sedatives/Benzodiazepines (Barbiturates, downers, Valium, Xanax)
☐ Other (specify): _____

QSTESTCD=BSCS06S

QSTEST=2ND CRAVED SUBSTANCE

QSORRES/QSXTRESC

OTHER SPECIFY

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year

Visit #: _____ VISITNUM

QSTESTCD

QSTEST

QSORRES/QSSTRESC

4605 Brief Substance Craving Scale (continued)

Please answer the following questions with regard to a second craved drug (check one per question):

7 The INTENSITY of my craving, that is, how much I desired this drug in the past 24 hours was:

- ☐ None at all
☐ Slight
☐ Moderate
☐ Considerable
☐ Extreme

QSEVLINT=-H24

8 The FREQUENCY of my craving, that is, how often I desired this drug in the past 24 hours was:

- ☐ Never
☐ Almost Never
☐ Several Times
☐ Regularly
☐ Almost Constantly

9 The LENGTH of time I spent in craving this drug during the past 24 hours was:

- ☐ None at all
☐ Very Short
☐ Short
☐ Somewhat Long
☐ Very Long

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

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: LB

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ LBDTC
month / day / year Visit #: VISITNUM

LBCAT=CARBON MONOXIDE ASSESSMENT

4606 Carbon Monoxide (CO) Assessment

1 Carbon monoxide reading: LBTEST=CARBON MONOXIDE

1a Current time: _____ LBDTC
00:00 to 23:59

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? ☐ No QNAM=LBAVGCO
☐ Yes QLABEL=AVERAGE OF 2 CO2 LEVELS < 4 PPM
IDVAR=LBSEQ

3 Was the CO level (Trial #1 or Trial #2) above 8 ppm? ☐ No QNAM=LBCOGT8
☐ Yes QLABEL=CO LEVEL > 8 PPM FOR EITHER TRIAL
IDVAR=LBSEQ

3a If Yes, does the participant report having smoked any tobacco in the past 7 days? ☐ No
☐ Yes QNAM=LBSMOKE
QLABEL=SMOKED TOBACCO IN PAST 7 DAYS
IDVAR=LBSEQ

3b If No, please ask the following:

1 Have you smoked anything else besides tobacco products in the past 7 days (for example, herbal cigarettes, marijuana joints, etc.)? ☐ No QNAM=LBSMOKE2
☐ Yes QLABEL=SMOKED OTHER THAN TOBACCO IN PAST 7 DAYS
IDVAR=LBSEQ

2 Do you work, or have you been, in an area where there is quite a bit of car exhaust (for example, garage, etc.)? ☐ No QNAM=LBEXHAUS
☐ Yes QLABEL=NEAR QUITE A BIT OF EXHAUST
IDVAR=LBSEQ

3 Do you know if you have a defective furnace at home that could be giving out a higher-than-normal reading of CO? ☐ No QNAM=LBFURNAC
☐ Yes QLABEL=HAVE A DEFECTIVE FURNACE AT HOME
IDVAR=LBSEQ

4 Comments (print; limit 200 characters): _____
DATA NOT STORED

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: MH

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ MHDTC
month / day / year Visit #: VISITNUM

MHCAT=CIDI SUMMARY

4607 CIDI Summary

A Substance Dependence		MHSCAT=SUBSTANCE DEPENDENCE	MHOCCUR=0	MHOCCUR=1		
MHTERM	Diagnosis		Neg	Life	12 mo	30 days
1	Nicotine Dependence [TBD]	QNAM=MHDUR_LF QLABEL=HISTORICAL OCCURANCE LIFE IDVAR=MHSEQ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Alcohol Dependence [ALD] (past 30 excludes; 4631 Q-8)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Sedatives/Tranquilizers Dep [SEDD] (past 30 excludes; 4631 Q-8)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Stimulants Dep—Meth Only [STIMD] (past 12 or 30 required; 4631 Q-3)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Analgesics Dependence [PAIND]	QNAM=MHDUR_YR QLABEL=HISTORICAL OCCURANCE 12MO IDVAR=MHSEQ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Marijuana/Hashish Dependence [MARD]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Cocaine Dependence [COCD] (past 12 or 30 required; 4631 Q-3)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Club Drugs Dependence [CLUBD]	QNAM=MHDUR_MH QLABEL=HISTORICAL OCCURANCE 30 DAYS IDVAR=MHSEQ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Hallucinogens Dependence [HALD]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Heroin/Opium Dependence [OPID]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Inhalants/Solvents Dependence [INHD]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Other Dependence—Other (non-meth) stimulants [OTHD]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B Substance Abuse		MHSCAT=SUBSTANCE ABUSE				
MHTERM	Diagnosis		Neg	Life	12 mo	30 days
13	Alcohol Abuse [ALA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Sedatives/Tranquilizers Abuse [SEDA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Stimulants Abuse—Methamphetamine Only [STIMA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	Analgesics Abuse [PAINA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17	Marijuana/Hashish Abuse [MARA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18	Cocaine Abuse [COCA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19	Club Drugs Abuse [CLUBA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20	Hallucinogens Abuse [HALA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21	Heroin/Opium Abuse [OPIA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22	Inhalants/Solvents Abuse [INHA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23	Other Abuse—Other (non-meth) stimulants [OTHA]		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: MH

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ MHDTC
month / day / year Visit #: VISITNUM

MHCAT=CIDI SUMMARY

4607 CIDI Summary (continued)

C Non-Substance Use Disorders		MHSCAT=NON-SUBSTANCE USE DISORDERS			
		MHOCUR=0		MHOCUR=1	
MHTERM	Diagnosis	Neg	Life	12 mo	30 days
24	Agoraphobia without Panic Disorder [AGP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25	Anorexia [ANO] (Excludes; 4631 Q-10)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26	Attention Deficit Disorder [ADD]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27	Bipolar I Disorder [BIPOLARI] (12 or 30 excludes; 4631 Q-10)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28	Bipolar II Disorder [BIPOLARII] (12 or 30 excludes; 4631 Q-10)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29	Bulimia [BUL] (Excludes; 4631 Q-10)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30	Dysthymia [DYS]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31	Generalized Anxiety Disorder [GAD]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32	Major Depressive Disorder [MDD]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33	Obsessive Compulsive Disorder [OCD]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34	Panic Disorder [PDS]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35	Pathological Gambling [GAM]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36	Posttraumatic Stress Disorder [PTS]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37	Premenstrual Syndrome [PMS] females only; if male ✓ "Neg"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38	Social Phobia [SO]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39	Specific Phobia [SP]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D Psychosis Screen

MHSCAT=PSYCHOSIS SCREEN

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

MHOCUR

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: DA, EX

USUBJID

Node #: _____

CTP Site ID #: _____

Participant ID #: _____

Assessment Date: ____/____/____
month day year

Visit #: VISITNUM

Sequence #: _____

DACAT/EXCAT=COMPLIANCE-MEDICATION-PARTICIPATION REPORT

4608 Compliance—Medication—Participant Report

1 Study week being assessed: VISITNUM

Medication Day	A Date ____/____/____ month day year	Bupropion XL		Nicotine Inhaler	F Comments (Print; 200 character limit)
		DA.DATEST B mg Prescribed	EX.EXTRT C mg Taken	EX.EXTRT D Carts. Used	
2 Day 1	DA.DADTC / EX.EXDTC ____/____/____ month day year	DA.DAORRES _____	EX.EXDOSE _____ EX.EXDOSU _____ EX.EXDOSFRM _____	EX.EXDOSE _____ EX.EXDOSU _____ EX.EXDOSFRM _____	DATA NOT STORED
3 Day 2	____/____/____ month day year	_____	_____	_____	
4 Day 3	____/____/____ month day year	_____	_____	_____	
5 Day 4	____/____/____ month day year	_____	_____	_____	
6 Day 5	____/____/____ month day year	_____	_____	_____	
7 Day 6	____/____/____ month day year	_____	_____	_____	
8 Day 7	____/____/____ month day year	_____	_____	_____	

USUBJID

Node #: _____

CTP Site ID #: _____

Participant ID #: _____

Assessment Date: _____

month / day / year

Visit #: _____

VISITNUM

Sequence #: _____

DACAT=COMPLIANCE-MEDICATION-PARTICIPATION-PILL COUNT

4609 Compliance—Medication—Pill Count

1 Study week being assessed: VISITNUM

Section I: Scheduled Bupropion XL

DASCAT=SECTION 1: SCHEDULED BUPROPION XL

DATEST=BOTTLE DISPENSED

DADTC

2 Date bottle dispensed: _____

month / day / year

DATEST=PILLS RETURNED-EXPECTED

3 Number of pills returned—expected: _____

DAORRES

DATEST=PILLS RETURNED-ACTUAL

4 Number of pills returned—actual: _____

DAORRES

DATEST=PILLS REPORTED LOST

5 Number of pills reported lost: _____

DAORRES

6 Date bottle returned: _____

month / day / year OR ☐ NA

DADTC

7 Was replacement Bupropion XL dispensed? ☐ No

DAORRES

DATEST=REPLACEMENT BUPROPION DISPENSED

☐ Yes

→ If Yes: Complete Section II below

8 Are there any inconsistencies between pill count and self-reported administration of pills (see CRF 4608)?

☐ No
☐ Yes

DAORRES

DATEST=INCONSISTENCY ACTUAL/ REPORTED PILL CNT

Section II: Replacement Bupropion XL

DASCAT=SECTION 2: REPLACEMENT BUPROPION XL

DATEST=BOTTLE DISPENSED

DADTC

9 Date replacement bottle dispensed: _____

month / day / year

10 Number of pills dispensed: _____

DAORRES

DATEST=NUMBER OF PILLS RETURNED-EXPECTED

11 Number of pills returned—expected: _____

DAORRES

DATEST=NUMBER OF PILLS RETURNED-ACTUAL

12 Number of pills returned—actual: _____

DAORRES

DATEST=NUMBER OF PILLS REPORTED-LOST

13 Number of pills reported lost: _____

DAORRES

14 Date replacement bottle returned: _____

month / day / year OR ☐ NA

DADTC

USUBJID

Node #: _____

CTP Site ID #: _____

Participant ID #: _____

Assessment Date: _____ / _____ / _____

Visit #: _____

VISITNUM

Sequence #: _____

DACAT=COMPLIANCE-MEDICATION-PARTICIPATION-CARTRIDGE COUNT

4610 Compliance—Medication—Cartridge Count

1 Study week being assessed: VISITNUM

DASCAT=SECTION 1: SCHEDULED NICOTINE CARTRIDGES

Section I: Scheduled Nicotine Cartridges

2 Date cartridges dispensed: _____

DADTC

DATEST=CARTRIDGES DISPENSED

3 Number of cartridges dispensed: _____

DAORRES

DATEST=USED CARTRIDGES RETURNED

4 Number of used cartridges returned: _____

DAORRES

DATEST=UNUSED CARTRIDGES RETURNED

5 Number of unused cartridges returned: _____

DAORRES

DATEST=CARTRIDGES REPORTED LOST

6 Number of cartridges reported lost: _____

DAORRES

7 Date cartridges returned: _____

DADTC

DATEST=REPLACEMENT CARTRIDGES DISPENSED

OR ☐ NA

8 Were replacement cartridges dispensed? ☐ No

DAORRES

☐ Yes

→ If Yes: Complete Section II below

DATEST=INCONSISTENCY ACTUAL/ REPORTED CART CNT

9 Are there any inconsistencies between cartridge count and self-reported administration of cartridges (see CRF 4608)?

☐ No

DAORRES

☐ Yes

DASCAT=SECTION 2: REPLACEMENT CARTRIDGES

Section II: Replacement Nicotine Cartridges

10 Date replacement cartridges dispensed: _____

DADTC

DATEST=CARTRIDGES DISPENSED

11 Number of cartridges dispensed: _____

DAORRES

DATEST=USED CARTRIDGES RETURNED

12 Number of used cartridges returned: _____

DAORRES

DATEST=UNUSED CARTRIDGES RETURNED

13 Number of unused cartridges returned: _____

DAORRES

DATEST=CARTRIDGES REPORTED LOST

14 Number of cartridges reported lost: _____

DAORRES

15 Date replacement cartridges returned: _____

DADTC

OR ☐ NA

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: EX/DA

USUBJID Node #: _____ CTP Site ID #: _____ Participant ID #: _____

Assessment Date: _____ EXDTC / DADTC
month / day / year

DACAT/EXCAT=COMPLIANCE-SMOKING-CESSATION COUNSELING

4611 Compliance—Smoking-Cessation Counseling

- 1 Study week for which compliance is being assessed: VISITNUM
- 2 How many sessions were scheduled during the study week? DA.DAORRES DA.DATEST=SCHEDULED SESSIONS
DA.DAORRESU=SESSION
- 3 How many sessions were attended during the study week? EX.EXDOSE EX.EXTRT=SMOKING CESSATION COUNSELING
EX.EXDOSU=SESSION
- 4 How many scheduled sessions did the participant miss? DA.DAORRES DA.DATEST=SESSIONS MISSED
DA.DAORRESU=SESSION
- 5 How many sessions did you cancel? DA.DAORRES DA.DATEST=SESSIONS CANCELLED
DA.DAORRESU=SESSION
- 6 Based on the participant's session participation and completion of homework assignments, how compliant was the participant (check only one)?
- ☐ Participant did not attend
- ☐ Not at all
- ☐ Slightly
- ☐ Moderately
- ☐ Considerably
- ☐ Extremely
- SUPPEX
QNAM=EXCOMPLY
QLABEL=HOW COMPLIANT WAS THE PARTICIPANT
IDVAR=EXSEQ

7 Comments (print; limit 200 characters): _____
DATA NOT STORED

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: EX/DA

USUBJID Node #: _____ CTP Site ID #: _____ Participant ID #: _____

Assessment Date: _____ EXDTC / DADTC _____ Visit #: _____
month day year

DACAT/EXCAT=CONTINGENCY MANAGEMENT TRACKING FORM

4612 Contingency Management Tracking Form

1 Study week being assessed: VISITNUM

First CM Visit for the Study Week EX.EXGRPID / DA.DAGRPID = FIRST CM VISIT

2 Number of draws earned (If 0 then enter "00"): DA.DAORRES DA.DATEST=DRAWS EARNED
DA.DAORRESU=DRAW

3 If no draws earned, indicate the reason (check only one): ☐ Was not abstinent
☐ Unexcused absence
☐ Excused absence

SUPPDA
QNAM=DADRAWC1
QLABEL=REASON NO DRAWS EARNED
IDVAR=DASEQ

EX.EXTRT

4 If draws were earned, please indicate the number of prizes won in each of the following categories:

a "Good Jobs": EX.EXDOSE

b "Small" prizes: _____

c "Medium" prizes: _____

d "Large" prizes: _____

e "Jumbo" prizes: _____ EX.EXDOSU=PRIZE

Second CM Visit for the Study Week: EX.EXGRPID / DA.DAGRPID = SECOND CM VISIT

5 Number of draws earned (If 0 then enter "00"): DA.DAORRES DA.DATEST=DRAWS EARNED
DA.DAORRESU=DRAW

6 If no draws earned, indicate the reason (check only one): ☐ Was not abstinent
☐ Unexcused absence
☐ Excused absence

SUPPDA
QNAM=DADRAWC2
QLABEL=REASON NO DRAWS EARNED
IDVAR=DASEQ

EX.EXTRT

7 If draws were earned, please indicate the number of prizes won in each of the following categories:

a "Good Jobs": EX.EXDOSE

b "Small" prizes: _____

c "Medium" prizes: _____

d "Large" prizes: _____

e "Jumbo" prizes: _____ EX.EXDOSU=PRIZE

8 Comments (print; limit 200 characters): _____

DATA NOT STORED

USUBJID Node #: _____ CTP Site ID #: _____ Participant ID #: _____
Assessment Date: _____ / _____ / _____ DM.DMDTC / SC.SCDTC
month day year Visit #: _____

4613 Demographics

- 1 Date of birth:** _____ / _____ / _____ DM.BRTHDTC
month day year
- 2 Sex:** ☐ ₁ Male ☐ ₂ Female ☐ ₉₈ Participant chooses not to answer DM.SEX
- 3 Ethnicity:** DM.ETHNIC
☐ ₁ Hispanic or Latino
☐ ₂ Not Hispanic or Latino
☐ ₉₈ 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): _____ SC.SCTEST / SC.SCORRES
SC.SCCAT = DEMOGRAPHICS
- OR**
☐ Participant chooses not to answer
☐ Unknown

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: EG

USUBJID Node #: _____ CTP Site ID #: _____ Participant ID #: _____

Assessment Date: _____ / _____ / _____ VISITNUM Visit #: _____
month day year

4614 Electrocardiogram (ECG)

- 1 ECG overall results: ☐ ^{EGTEST} Normal → If Normal: Skip to question 34
☐ ^{EGORRES} Abnormal → If Abnormal: Answer questions 2-34: Indicate if any result was ABNORMAL but does not exclude the participant from participation in the study, or ABNORMAL EXCLUDES and does exclude participation in the study (4631 Study Eligibility, Q-14).

^{EGTEST}	Specific ECG Abnormality	^{EGORRES} Abnormal	^{EGORRES} Abnormal / Excludes	^{EGTEST}	Specific ECG Abnormality	^{EGORRES} Abnormal	^{EGORRES} Abnormal / Excludes
2	Increased QRS voltage	<input type="checkbox"/>	<input type="checkbox"/>	18	Supraventricular premature beat	<input type="checkbox"/>	<input type="checkbox"/>
3	QTc prolongation	<input type="checkbox"/>	<input type="checkbox"/>	19	Ventricular premature beat	<input type="checkbox"/>	<input type="checkbox"/>
4	Left atrial hypertrophy	<input type="checkbox"/>	<input type="checkbox"/>	20	Supraventricular tachycardia	<input type="checkbox"/>	<input type="checkbox"/>
5	Right atrial hypertrophy	<input type="checkbox"/>	<input type="checkbox"/>	21	Ventricular tachycardia	<input type="checkbox"/>	<input type="checkbox"/>
6	Left ventricular hypertrophy	<input type="checkbox"/>	<input type="checkbox"/>	22	Atrial fibrillation	<input type="checkbox"/>	<input type="checkbox"/>
7	Right ventricular hypertrophy	<input type="checkbox"/>	<input type="checkbox"/>	23	Atrial flutter	<input type="checkbox"/>	<input type="checkbox"/>
8	Acute infarction	<input type="checkbox"/>	<input type="checkbox"/>	24	Other rhythm abnormalities	<input type="checkbox"/>	<input type="checkbox"/>
9	Subacute infarction	<input type="checkbox"/>	<input type="checkbox"/>	25	Implanted pacemaker	<input type="checkbox"/>	<input type="checkbox"/>
10	Old infarction	<input type="checkbox"/>	<input type="checkbox"/>	26	First degree A-V block	<input type="checkbox"/>	<input type="checkbox"/>
11	Myocardial ischemia	<input type="checkbox"/>	<input type="checkbox"/>	27	Second degree A-V block	<input type="checkbox"/>	<input type="checkbox"/>
12	Digitalis effect	<input type="checkbox"/>	<input type="checkbox"/>	28	Third degree A-V block	<input type="checkbox"/>	<input type="checkbox"/>
13	Symmetrical T-wave inversions	<input type="checkbox"/>	<input type="checkbox"/>	29	LBB block	<input type="checkbox"/>	<input type="checkbox"/>
14	Poor R-wave progression	<input type="checkbox"/>	<input type="checkbox"/>	30	RBB block	<input type="checkbox"/>	<input type="checkbox"/>
15	Other nonspecific ST/T	<input type="checkbox"/>	<input type="checkbox"/>	31	Pre-excitation syndrome	<input type="checkbox"/>	<input type="checkbox"/>
16	Sinus tachycardia	<input type="checkbox"/>	<input type="checkbox"/>	32	Other intraventricular condition block	<input type="checkbox"/>	<input type="checkbox"/>
17	Sinus bradycardia	<input type="checkbox"/>	<input type="checkbox"/>				

33 Other abnormality (print; limit 200 characters): ^{EGTEST} ^{EGORRES} _____

34 Ventricular rate: ^{EGTEST} ^{EGORRES} bpm ^{EGORRESU}
35 QRS: ^{EGORRES} ms ^{EGORRESU}
36 PR: ^{EGORRES} ms ^{EGORRESU}
37 QTc: ^{EGORRES} ms ^{EGORRESU}

Cardiologist's Signature

38 Cardiologist name (please print): _____

QNAM=EGCNAME
QLABEL=EG CARDIOLOGIST NAME
IDVAR=VISITNUM

39 Date signed: _____ / _____ / _____
month day year

QNAM=EGSIGDTC
QLABEL=EG SIGNATURE DATE
IDVAR=VISITNUM

40 Cardiologist signature: DATA NOT STORED

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S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

QSTESTCD

4615 Fagerström Test for Nicotine Dependence (FTND)

Please read each question below. For each question enter the answer choice which best describes your responses.

QSTEST

FTN001

1 How soon after you wake do you smoke your first cigarette (check only one)?

- ☐ Within 5 minutes
- ☐ Within 6 - 30 minutes
- ☐ Within 31 - 60 minutes
- ☐ After 60 minutes

QSORRES/QSSTRES

ADDITIONAL QUESTION ADDED TO FORM:

QSTEST= DO YOU SMOKE AT ALL?

QSTESTCD = FTN007

FTN002

2 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)?

- ☐ No
- ☐ Yes

QSORRES/QSSTRES

FTN003

3 Which cigarette would you hate most to give up (check only one)?

- ☐ The first one in the morning
- ☐ All others

QSORRES/QSSTRES

FTN004

4 How many cigarettes per day do you smoke (check only one)?

- ☐ 10 or less
- ☐ 11-20
- ☐ 21-30
- ☐ 31 or more

QSORRES/QSSTRES

FTN005

5 Do you smoke more frequently during the first hours after waking than during the rest of the day (check only one)?

- ☐ No
- ☐ Yes

QSORRES/QSSTRES

FTN006

6 Do you smoke if you are so ill that you are in bed most of the day (check only one)?

- ☐ No
- ☐ Yes

QSORRES/QSSTRES

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____ Visit #: _____ VISITNUM
month day year

QSTESTCD

QSTESTCD

4616 Hospital Anxiety and Depression Scale (HADS)

This questionnaire will help your doctor to know how you feel. Read each item and place an "X" next to the reply which comes closest to how you have been feeling in the past week. Don't take too long in thinking about your replies; your immediate reaction to each item will probably be more accurate than a long thought-out response.

HAD1

1 I feel tense or "wound up":

HAD8

- ☐ Most of the time
- ☐ A lot of the time
- ☐ From time to time, occasionally
- ☐ Not at all

QSORRES/QSSTRES

HAD2

2 I still enjoy the things I used to enjoy:

HAD9

- ☐ Definitely as much
- ☐ Not quite so much
- ☐ Only a little
- ☐ Hardly at all

QSORRES/QSSTRES

HAD3

3 I get a sort of frightened feeling as if something awful is about to happen:

HAD10

- ☐ Very definitely and quite badly
- ☐ Yes, but not too badly
- ☐ A little, but it doesn't worry me
- ☐ Not at all

QSORRES/QSSTRES

HAD4

4 I can laugh and see the funny side of things:

HAD11

- ☐ As much as I always could
- ☐ Not quite so much now
- ☐ Definitely not so much
- ☐ Not at all

QSORRES/QSSTRES

HAD5

5 Worrying thoughts go through my mind:

HAD12

- ☐ A great deal of the time
- ☐ A lot of the time
- ☐ From time to time but not too often
- ☐ Only occasionally

QSORRES/QSSTRES

HAD6

6 I feel cheerful:

HAD13

- ☐ Not at all
- ☐ Not often
- ☐ Sometimes
- ☐ Most of the time

QSORRES/QSSTRES

HAD7

7 I can sit at ease and feel relaxed:

HAD14

- ☐ Definitely
- ☐ Usually
- ☐ Not often
- ☐ Not at all

QSORRES/QSSTRES

8 I feel as if I am slowed down:

- ☐ Nearly all the time
- ☐ Very often
- ☐ Sometimes
- ☐ Not at all

QSORRES/QSSTRES

9 I get a sort of frightened feeling like "butterflies" in the stomach:

- ☐ Not at all
- ☐ Occasionally
- ☐ Quite often
- ☐ Very often

QSORRES/QSSTRES

10 I have lost interest in my appearance:

- ☐ 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

QSORRES/QSSTRES

11 I feel restless, as if I have to be on the move:

- ☐ Very much indeed
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all

QSORRES/QSSTRES

12 I look forward with enjoyment to things:

- ☐ As much as I ever did
- ☐ Rather less than I used to
- ☐ Definitely less than I used to
- ☐ Hardly at all

QSORRES/QSSTRES

13 I get sudden feelings of panic:

- ☐ Very often indeed
- ☐ Quite often
- ☐ Not very often
- ☐ Not at all

QSORRES/QSSTRES

14 I can enjoy a good book or radio or TV program:

- ☐ Often
- ☐ Sometimes
- ☐ Not often
- ☐ Very seldom

QSORRES/QSSTRES

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S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: _____ VISITNUM

4617 Initial Quit

1 Date of the participant's scheduled quit day: _____
month day year

QSTESTCD=IQ4DT

IQ4SDT

IQ5DT

IQ5SDT

IQ6DT

IQ6SDT

Achieving an Initial Quit

Study Week 4 Assessment

2a Since your quit date on (see question 1) have you had a period of 24 hours or more in which you did not smoke at all?

☐ No → If No: Assess success of initial quit again during week 5.
☐ Yes → If Yes: 2b On what date did this abstinence period begin: _____
month day year

QSTESTCD=IQ4ABST
IQ4SABST

QSORRES/QSSTRES

QSTEST

QSTESTCD=IQ4ABSDT
IQ4SABSDT

Study Week 5 Assessment

2c Since your quit date on (see question 1) have you had a period of 24 hours or more in which you did not smoke at all?

☐ No → If No: Assess success of initial quit again during week 6.
☐ Yes → If Yes: 2d On what date did this abstinence period begin: _____
month day year

QSTESTCD=IQ5ABST
IQ5SABST

QSORRES/QSSTRES

QSTEST

QSTESTCD=IQ5ABSDT
IQ5SABSDT

Study Week 6 Assessment

2e Between your quit date on (see question 1) and (end date for initial quit time-frame from the Visit Window and TLFB Time-Frames Worksheet), did you have a period of 24 hours or more in which you did not smoke at all?

☐ No
☐ Yes → If Yes: 2f On what date did this abstinence period begin: _____
month day year

QSTESTCD=IQ6ABST
IQ6SABST

QSORRES/QSSTRES

QSTEST

QSTESTCD=IQ6ABSDT
IQ6SABSDT

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: MH

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ MHDTC
month / day / year Visit #: VISITNUM

MHCAT=MEDICAL HISTORY

MHGRPID=1

4618 Medical History

Complete Medical and Surgical History below. Indicate medical history for each condition listed below by checking the box next to the appropriate response (Yes, No, Unknown). If the response is Yes, specify the medical problem and indicate if the condition is present currently and whether the condition excludes the participant from the study.

MHTERM

MHOCCUR

Condition	History of the Condition?	If Yes: Specify	Condition Present Currently?	Condition Excludes Participant?
1 Asthma	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAME=MHSPEC QLABEL=MEDICAL HISTORY SPECIFIED IDVAR=MHSEQ	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
2 Cardiovascular	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
3 Dermatologic	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
4 Drug Allergies	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAME=MHCURREN QLABEL=CONDITION PRESENT CURRENTLY IDVAR=MHSEQ	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
5 Endocrine	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
6 Gastrointestinal	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
7 Genitourinary	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAME=MHEXCLUD QLABEL=CONDITION EXCLUDES PATIENT IDVAR=MHSEQ	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
8 Head Injury	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
9 HEENT	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
10 Hematologic	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
11 Hepatic	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
12 Infectious Disease	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
13 Metabolic	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
14 Musculoskeletal	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
15 Other Allergies	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
16 Pulmonary	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
17 Renal	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
18 Reproductive System	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: MH

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ MHDTC
month / day / year Visit #: VISITNUM

MHCAT=MEDICAL HISTORY

MHGRPID=1

4618 Medical History (continued)

Condition	History of the Condition?	If Yes: Specify	Condition Present Currently?	Condition Excludes Participant?
MHSCAT= PSYCHIATRIC/NEUROLOGICAL HISTORY Psychiatric/Neurological History (Indicate history of disorders listed below)				
	MHTERM	MHOCCUR		
19 Anxiety or Panic Disorder	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAM=MHSPEC QLABEL=MEDICAL HISTORY SPECIFIED IDVAR=MHSEQ	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
20 Attention Deficit Hyperactivity Disorder	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
21 Bipolar Disorder	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
22 Clinically significant Neurological Damage	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAM=MHCURREN QLABEL=CONDITION PRESENT CURRENTLY IDVAR=MHSEQ	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
23 Epilepsy or Seizure Disorder (4631 Study Eligibility, Q 12)	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
24 Major Depressive Disorder	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAM=MHEXCLUD QLABEL=CONDITION EXCLUDES PATIENT IDVAR=MHSEQ	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
25 Schizophrenia	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
26 Tourette's Syndrome	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
27 Suicidal Ideation	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
28 Suicidal Behavior	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
29 Homicidal Ideation	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
30 Homicidal Behavior	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
31 Violent Behavior	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
32 Psychotic Episodes	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
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				
33	MHOCCUR=Y		<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
34			<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
35			<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: MH

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ MHDTC
month / day / year Visit #: VISITNUM

MHCAT=MEDICAL HISTORY

MHGRPID=1

4618 Medical History (continued)

Surgical History

MHSCAT=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

Type of Surgery (limit 50 characters per line)	Surgery Date (partial dates allowable)	OR Date Unknown
37 MHTERM / MHOCCUR=1	MHSTDTC month / day / year	<input type="checkbox"/>
38	month / day / year	<input type="checkbox"/>
39	month / day / year	<input type="checkbox"/>
40	month / day / year	<input type="checkbox"/>
41	month / day / year	<input type="checkbox"/>

42 Clinician name and degree (please print): _____

QNAME=MHNAME
QLABEL=MH CLINICIAN NAME
IDVAR=MHGRPID

43 Date signed: month / day / year

QNAME=MHSIGDTC
QLABEL=MH SIGNATURE DATE
IDVAR=MHGRPID

44 Clinician signature: DATA NOT STORED

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: MH

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ MHDTC
month / day / year Visit #: VISITNUM

MHCAT=MEDICAL HISTORY

MHGRPID=2

4619 Medical History Addendum

I Cardiovascular History (4631 Study Eligibility, Q-14)

A Personal History

MHSCAT=PERSONAL CARDIOVASCULAR HISTORY

QNAM=MHAGE

QLABEL=MH PARTICIPANT AGE

IDVAR=VISITNUM

Condition	History of the Condition?	If Yes: Specify	Condition Present Currently?
1 Participant age: _____	MHTERM MHOCCUR		MHOCCUR
2 Hypertension	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAM=MHSPEC QLABEL=MEDICAL HISTORY SPECIFIED IDVAR=MHSEQ	<input type="checkbox"/> No <input type="checkbox"/> Yes
3 Coronary artery disease	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes
4 Chest pain	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes
5 Palpitations	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes
6 Shortness of breath	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes
7 Dizziness	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes
8 Syncope	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes
9 History of CHF	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes
10 History of MI	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown		<input type="checkbox"/> No <input type="checkbox"/> Yes

B Family History

MHSCAT=FAMILY CARDIOVASCULAR HISTORY

Condition	History of the Condition?	If Yes: Specify
11 History of early MI	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	QNAM=MHSPEC QLABEL=MEDICAL HISTORY SPECIFIED IDVAR=MHSEQ
12 History of sudden cardiac death	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	
13 History of significant arrhythmias	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	
14 History of congenital heart disease (particularly cardiomyopathy)	<input type="checkbox"/> No <input type="checkbox"/> Yes → <input type="checkbox"/> Unknown	

15 Comments (print; limit 200 characters): _____
DATA NOT STORED

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: MH

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ MHDTC
month / day / year Visit #: VISITNUM

MHCAT=MEDICAL HISTORY

MHGRPID=2

4619 Medical History Addendum (continued)

MHSCAT=OTHER STUDY ELIGIBILITY CRITERIA

II Assessment of Other Study Eligibility Criteria:

16 Has the participant been smoking for at least 3 months (4631 Study Eligibility, Q 4)? MHTERM

☐ No MHOCUR
☐ Yes

17 Does the participant have a physiological dependence on alcohol or sedatives requiring medical detoxification (4631 Study Eligibility, Q 8)?

☐ No
☐ Yes

18 Does the participant have a history of closed head trauma with > 30 minutes loss of consciousness (4631 Study Eligibility, Q 13)?

☐ No
☐ Yes

19 Does the participant have AIDS according to the current CDC criteria for AIDS (4631 Study Eligibility, Q 14)?

☐ No
☐ Yes

20 Does the participant have diabetes treated with hypoglycaemics or insulin (4631 Study Eligibility, Q 14)?

☐ No
☐ Yes

21 Does the participant have a known or suspected hypersensitivity to bupropion, nicotine, or menthol (4631 Study Eligibility, Q 16)?

☐ No
☐ Yes

22 Comments (print; limit 200 characters): _____

DATA NOT STORED

Clinician Signature

23 Clinician name and degree (please print): _____

QNAM=MHNAME
QLABEL=MH CLINICIAN NAME
IDVAR=MHGRPID

24 Date signed: _____ / _____ / _____
month day year

QNAM=MHSIGDTC
QLABEL=MH SIGNATURE DATE
IDVAR=MHGRPID

25 Clinician signature: _____

DATA NOT STORED

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S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

4620 Non-Study Smoking Treatment

1 Since the last research visit, have you used ANY non-study 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, counseling, or self-help materials?

- ☐ No → If No: STOP. This form is complete.
☐ Yes → If Yes: Answer questions 2-7 below.

2 Have you used any medications, like the nicotine patch, Zyban® or Chantix®?

- ☐ No
☐ Yes → If Yes: Please check all medications used:

- NSST02A_0 ☐ Zyban® (bupropion SR)
 NSST02A_1 ☐ Nicotine nasal spray
 NSST02A_2 ☐ Nicotine gum
 NSST02A_3 ☐ Nicotine patch
 NSST02A_4 ☐ Nicotine inhaler
 NSST02A_5 ☐ Chantix® (varenicline)
 NSST02A_6 ☐ Nicotine lozenge

OTHER MEDICATION USED:
 QSTESTCD=NSST02A_7

OTHER MEDICATION USED SPECIFY:
 QSTESTCD = NSST02_OT

3 Have you attended an in-person smoking cessation program (e.g., classes, group/individual discussions, etc.)?

- ☐ No
☐ Yes

4 Have you used telephone smoking-cessation treatment (e.g., the smoking quitline, etc.)?

- ☐ No
☐ Yes

5 Have you used self-help material to stop smoking (e.g., American Lung Association material, materials from your doctor, tapes, books, etc.)?

- ☐ No
☐ Yes

6 Have you received any other smoking cessation treatment not listed above?

- ☐ No
☐ Yes → If Yes: Please describe briefly: _____

7 Comments (print; limit 200 characters): _____

DATA NOT STORED

DSCAT = DISPOSITION

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID
Assessment Date: _____ / _____ / _____ DSDTC
month day year Visit #: VISITNUM

4621 Participant Status at the End of the Active Study Phase

1 Date last research visit attended: _____ / _____ / _____ DSSTDTC
month day year

2 Please indicate the participant's status at the end of his or her participation in the active study phase (check only one):

Completer: ☐ 1 Participant completed at least one week 10 research visit

Withdrawn: ☐ 2 Significant psychiatric risk (suicidal, homicidal, psychotic)

☐ 3 Death

☐ 4 Administrative discharge (specify below)*

☐ 5 Other type of clinical deterioration

Non-completer: ☐ 6 Withdrew consent

☐ 7 Moving from area

☐ 8 Practical problems (no childcare, transportation, other)

☐ 9 Medical problems (hospitalization, other)

☐ 10 Incarceration

☐ 11 Pressure or advice from outsiders

☐ 12 Feels treatment no longer necessary, cured

☐ 13 Feels treatment no longer necessary, not working

☐ 14 Failed to return to clinic and unable to contact

☐ 15 Other (specify below)*

DSTERM

QNAM=DSPECIFY
QLABEL=ADMIN DISCHARGE SPECIFIED
IDVAR=DSSEQ

2a *Specify (for administrative discharge or other) (print; limit 200 characters): _____

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: PE

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ PEDTC
month / day / year Visit #: VISITNUM

4622 Physical Examination

Body System	Evaluation				Comments (data entry only for abnormal results)
	Normal	Abnormal	Abnormal Excludes (4631 Study Eligibility, Q 14g)	Not Done	
1 General Appearance:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	DATA NOT STORED
2 Head/Neck:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3 Ears, Eyes, Nose and Throat:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4 Cardiovascular and Pulse:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5 Lymph Nodes:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6 Respiratory:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7 Musculoskeletal:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8 Gastrointestinal and Abdomen:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9 Extremities:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10 Neurological:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11 Skin:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12 Other (specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

PETEST

PEORRES

If 'Not Done' then
PESTAT=NOT DONE and
PEREASND=NA

QNAM=OTHER
QLABEL=OTHER BODY SYSTEM
IDVAR=PESEQ

Clinician's Signature

13 Clinician name and degree (print): _____

QNAM=PENAME
QLABEL=PE CLINICIAN NAME
IDVAR=VISITNUM

14 Date: _____ / _____ / _____
month day year

15 Clinician signature: _____

DATA NOT STORED

QNAM=PESIGDTC
QLABEL=PE SIGNATURE DATE
IDVAR=VISITNUM

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year Visit #: VISITNUM

4623 Pittsburgh Sleep Quality Index (PSQI)

Instructions: The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1 During the past month, what time have you usually gone to bed at night? QSTEST=BEDTIME AM/PM QSTESTCD=PSQI1 QSTESTCD=PSQI1A QSORRES/QSSTRES	Bed time: QSORRES/QSSTRES → <input type="checkbox"/> AM <input type="checkbox"/> PM
2 During the past month, how long (in minutes) has it usually taken you to fall asleep each night? QSTEST QSTESTCD=PSQI2 QSORRESU=MINUTES	Number of minutes: QSORRES/QSSTRES
3 During the past month, what time have you usually gotten up in the morning? QSTEST=WAKEUP AM/PM QSTESTCD=PSQI3 QSTESTCD=PSQI3A QSORRES/QSSTRES	Getting up time: QSORRES/QSSTRES → <input type="checkbox"/> AM <input type="checkbox"/> PM
4 During the past month, how many hours of <u>actual sleep</u> did you get at night? (This may be different than the number of hours you spent in bed.) QSTEST QSTESTCD=PSQI4 QSORRESU=HOURS	Hours of sleep per night: QSORRES/QSSTRES

For each of the remaining questions, check the one best response. Please answer all questions.

5 During the past month, how often have you had trouble sleeping because you...	
a Cannot get to sleep within 30 minutes QSTEST QSTESTCD=PSQI5A QSORRES/QSSTRES	<input type="checkbox"/> Not during the past month <input type="checkbox"/> Less than once a week <input type="checkbox"/> Once or twice a week <input type="checkbox"/> Three or more times a week
b Wake up in the middle of the night or early morning QSTEST QSTESTCD=PSQI5B QSORRES/QSSTRES	<input type="checkbox"/> Not during the past month <input type="checkbox"/> Less than once a week <input type="checkbox"/> Once or twice a week <input type="checkbox"/> Three or more times a week
c Have to get up to use the bathroom QSTEST QSTESTCD=PSQI5C QSORRES/QSSTRES	<input type="checkbox"/> Not during the past month <input type="checkbox"/> Less than once a week <input type="checkbox"/> Once or twice a week <input type="checkbox"/> Three or more times a week
d Cannot breathe comfortably QSTEST QSTESTCD=PSQI5D QSORRES/QSSTRES	<input type="checkbox"/> Not during the past month <input type="checkbox"/> Less than once a week <input type="checkbox"/> Once or twice a week <input type="checkbox"/> Three or more times a week
e Cough or snore loudly QSTEST QSTESTCD=PSQI5E QSORRES/QSSTRES	<input type="checkbox"/> Not during the past month <input type="checkbox"/> Less than once a week <input type="checkbox"/> Once or twice a week <input type="checkbox"/> Three or more times a week
f Feel too cold QSTEST QSTESTCD=PSQI5F QSORRES/QSSTRES	<input type="checkbox"/> Not during the past month <input type="checkbox"/> Less than once a week <input type="checkbox"/> Once or twice a week <input type="checkbox"/> Three or more times a week

Buyse, 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.

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S-CAST

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

☐ ₁ Participant unavailable ☐ ₂ Data collection error ☐ ₃ Participant unable/unwilling to answer
Fields affected: ☐ ₀ Entire CRF ☐ ₁ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____ Visit #: _____ VISITNUM
month day year

QSTEST

4623 Pittsburgh Sleep Quality Index (PSQI) (continued)

5 During the past month, how often have you had trouble sleeping because you... (continued)

g Feel too hot

QSTEST

QSTESTCD=PSQI5G

QSORRES/QSSTRES

- ☐
- Not during the past month
-
- ☐
- Less than once a week
-
- ☐
- Once or twice a week
-
- ☐
- Three or more times a week

h Had bad dreams

QSTEST

QSTESTCD=PSQI5H

QSORRES/QSSTRES

- ☐
- Not during the past month
-
- ☐
- Less than once a week
-
- ☐
- Once or twice a week
-
- ☐
- Three or more times a week

i Have pain

QSTEST

QSTESTCD=PSQI5I

QSORRES/QSSTRES

- ☐
- Not during the past month
-
- ☐
- Less than once a week
-
- ☐
- Once or twice a week
-
- ☐
- Three or more times a week

j Other reason(s), please describe: _____

QSTEST

QSTESTCD=PSQI5J

QSORRES/QSSTRES

How often during the past month have you had trouble sleeping because of this?

QSTEST

QSTESTCD=PSQI5J

QSORRES/QSSTRES

- ☐
- Not during the past month
-
- ☐
- Less than once a week
-
- ☐
- Once or twice a week
-
- ☐
- Three or more times a week

6 During the past month, how would you rate your sleep quality?

QSTEST

QSTESTCD=PSQI6

QSORRES/QSSTRES

- ☐
- Very good
-
- ☐
- Fairly good
-
- ☐
- Fairly bad
-
- ☐
- Very bad

7 During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

QSTEST

QSTESTCD=PSQI7

QSORRES/QSSTRES

- ☐
- Not during the past month
-
- ☐
- Less than once a week
-
- ☐
- Once or twice a week
-
- ☐
- Three or more times a week

8 During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

QSTEST

QSTESTCD=PSQI8

QSORRES/QSSTRES

- ☐
- Not during the past month
-
- ☐
- Less than once a week
-
- ☐
- Once or twice a week
-
- ☐
- Three or more times a week

9 During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

QSTEST

QSTESTCD=PSQI9

QSORRES/QSSTRES

- ☐
- Not a problem at all
-
- ☐
- Only a very slight problem
-
- ☐
- Somewhat of a problem
-
- ☐
- A very big problem

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S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: _____ VISITNUM

4624 Pregnancy and Outcome

Information about Pregnancy

OR ☐ NA QSSCAT

QSTEST

QSORRES/QSSTRES

QSTESTCD

- 1 Who discovered the pregnancy? ☐ Study participant ☐ Study staff ☐ Unknown POA101
- 2 How was the pregnancy verified (select all that apply)?
☐ Urine pregnancy test POA12U
☐ Serum pregnancy test POA12S
☐ Ultrasound POA12T
☐ Unknown POA12UNK
- 3 Date on which the pregnancy was verified: _____ / _____ / _____ ☐ Unknown POA103R/ POA103DT
- 4 Date on which study staff was aware of pregnancy: _____ / _____ / _____ ☐ Unknown POA104R/ POA104DT
- 4a How was the pregnancy verified by study staff (check only one)? ☐ Urine pregnancy test POA14AR
☐ Participant clinic records
☐ Unknown
- 4b Date on which study staff verified pregnancy: _____ / _____ / _____ ☐ Unknown POA14BR/ POA14BDT
- 5 Date on which study medication was discontinued: _____ / _____ / _____ ☐ Unknown POA105R/ POA105DT
- 6 Approximate due date: _____ / _____ / _____ ☐ Unknown POA106R/ POA106DT

Outcome of Pregnancy

QSSCAT

- 7 Outcome of pregnancy: POA107R
☐ Normal
☐ Abnormal → If Abnormal: Specify abnormality: _____ POA17ASP
☐ Miscarriage → STOP. This form is complete.
☐ Terminated → STOP. This form is complete.
☐ Other (specify): _____ POA17BSP
☐ Unknown
- 8 Date of delivery: _____ / _____ / _____ ☐ Unknown POA08R/ POA08DT
- 9 Number of live births (this pregnancy): POA09R
☐ 0 → If 0 live births, indicate reason: _____ POA09SP
☐ 1
☐ 2
☐ 3
☐ Unknown
- 10 Type of delivery: POA10
☐ Vaginal
☐ Cesarean section
☐ Unknown

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: QS

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

4624 Pregnancy and Outcome (continued)

Newborn #1 Information

- 1 Gender: ☐ Male ☐ Female ☐ Unknown
- 2 Gestational age at delivery: _____ / _____ ☐ Unknown
weeks days
- 3 Weight: _____ / _____ ☐ Unknown
lbs oz
- 4 Length: _____ cm ☐ Unknown
- 5 Head circumference: _____ cm ☐ Unknown
- 6 APGAR score at 1 minute: _____ 1 min ☐ Unknown
- 7 APGAR score at 5 minute: _____ 5 min ☐ Unknown
- 8 APGAR score at 24 hours: _____ 24 hrs ☐ Unknown

9 Normal infant?

☐ No → If No: Specify abnormality: _____

Contributing factors to abnormality: _____

Is this a congenital abnormality? ☐ No ☐ Yes ☐ Unknown

☐ Yes

☐ Unknown

QSSCAT=NEWBORNn where n = birth number (in case of multiple births (e.g. twins))

QSORRES/QSSTRES

QSTESTCD
POAN01

POAN02R/ POAN2WK

POAN02R/ POAN2DAY

POANO3R/ POAN3LBS

POAN3OZS

POAN4LNG

POAN5CIR

POAN61MN

POAN75MN

POAN824H

POAN9R

POAN9BSP

POAN9CSP

POAN9BR

Newborn #2 Information

- 1 Gender: ☐ Male ☐ Female ☐ Unknown
- 2 Gestational age at delivery: _____ / _____ ☐ Unknown
weeks days
- 3 Weight: _____ / _____ ☐ Unknown
lbs oz
- 4 Length: _____ cm ☐ Unknown
- 5 Head circumference: _____ cm ☐ Unknown
- 6 APGAR score at 1 minute: _____ 1 min ☐ Unknown
- 7 APGAR score at 5 minute: _____ 5 min ☐ Unknown
- 8 APGAR score at 24 hours: _____ 24 hrs ☐ Unknown

9 Normal infant?

☐ No → If No: Specify abnormality: _____

Contributing factors to abnormality: _____

Is this a congenital abnormality? ☐ No ☐ Yes ☐ Unknown

☐ Yes

☐ Unknown

THE ABOVE FIELDS ARE
REPEATED ON SEPARATE
RECORD FOR EACH BIRTH

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ Participant ID #: _____

Assessment Date: _____ / _____ / _____ Visit #: _____
month day year

4624 Pregnancy and Outcome (continued)

Newborn #3 Information

1 Gender: ☐ Male ☐ Female ☐ Unknown

2 Gestational age at delivery: _____ / _____ ☐ Unknown
weeks days

3 Weight: _____ / _____ ☐ Unknown
lbs oz

4 Length: _____ cm ☐ Unknown

5 Head circumference: _____ cm ☐ Unknown

6 APGAR score at 1 minute: _____ 1 min ☐ Unknown

7 APGAR score at 5 minute: _____ 5 min ☐ Unknown

8 APGAR score at 24 hours: _____ 24 hrs ☐ Unknown

9 Normal infant?

☐ No → If No: Specify abnormality: _____

Contributing factors to abnormality: _____

Is this a congenital abnormality? ☐ No ☐ Yes ☐ Unknown

☐ Yes

☐ Unknown

Comments: _____

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Form completion: ☐ Complete ☐ Participant unavailable ☐ Data collection error
☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

USUBJID Node #: _____ CTP Site ID #: _____ Participant ID #: _____

CMCAT = PRIOR AND CONCOMITANT MEDICATIONS

4625 Prior and Concomitant Medications

Assessment Date	Medication Name (Generic preferred)	Purpose/Indication	Treating an AE?	Start Date	Stop Date	Comments
CMDDTC ____/____/____ month/day/year	CMTRT	CMINDC	<input type="checkbox"/> Yes <input type="checkbox"/> No	CMSTDTC ____/____/____ month/day/year	CMENDTC ____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	DATA NOT STORED
____/____/____ month/day/year			<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	
____/____/____ month/day/year	QNAME=TRTFORAE QLABEL=DRUG GIVEN AS TREATMENT FOR AE IDVAR=CMSEQ		<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	
____/____/____ month/day/year			<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	
____/____/____ month/day/year			<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	
____/____/____ month/day/year	QNAME=CMACTIVE QLABEL=ACTIVE TX PHASE ENDED IDVAR=CMSEQ		<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	
____/____/____ month/day/year			<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	
____/____/____ month/day/year			<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	
____/____/____ month/day/year			<input type="checkbox"/> Yes <input type="checkbox"/> No	____/____/____ month/day/year	____/____/____ month/day/year <input type="checkbox"/> Active Tx phase ended	

CMSEQ

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S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: VISITNUM

4626 PRISM Suicidal and Homicidal Intent (PRISM)

1 Recurrent Thoughts of Death

Did you ever find yourself thinking about death or dying? QSTEST=.RATING
 Do you think you would be better off dead? QSTESTCD=PRISM1A
 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.

A Rating Scale:

Absent	Sub Threshold	Present	Not Answered
<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4

QSORRES/QSSTRES

B Most Recent Occurrence:

- ☐ Prior to the past 6 months
☐ In the past 6 months

QSORRES/QSSTRES

2 Recurrent Suicidal Ideation

Did you ever think about suicide or killing yourself? (What did you think of? How often did you have that thought?)

IF YES: Do you still think about killing yourself at the present time?

How often?

For how long have you been having these thoughts? QSTEST=.RATING
 QSTESTCD=PRISM2A
 QSTEST=.MOST RECENT
 QSTESTCD=PRISM2B

Must have a thought about this at least three times in a week.

Must think actively of killing oneself, even if ambivalent.

Can have suicidal ideation without having suicidal plan.

A Rating Scale:

Absent	Sub Threshold	Present	Not Answered
<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4

QSORRES/QSSTRES

B Most Recent Occurrence:

- ☐ Prior to the past 6 months
☐ In the past 6 months

QSORRES/QSSTRES

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S-CAST

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

☐ ₁ Participant unavailable ☐ ₂ Data collection error ☐ ₃ Participant unable/unwilling to answer
 Fields affected: ☐ ₈ Entire CRF ☐ ₁ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: _____ VISITNUM

4626 PRISM Suicidal and Homicidal Intent (PRISM) (continued)

3 Specific Suicide Plan

Did you ever think of any specific plan for committing suicide? QSTEST=.RATING
QSTESTCD=PRISM3A

What did you think of doing?

IF YES: When was that?

For how long did you think of this plan?

How often would you think about this plan? QSTEST=.MOST RECENT
QSTESTCD=PRISM3B

IF YES: Do you think of any specific plan for committing suicide at the present time?

What do you think of doing?

How often do you think about it?

For how long have you been thinking about this plan?

Must be thinking of actual method of suicide.

Intent to carry out the plan is not required; formulation of a specific plan is enough.

Include even if fleeting plan.

Need not have been recurrent or feasible

A Rating Scale:

Absent	Sub Threshold	Present	Not Answered
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ QSORRES/QSSTRES	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄

B Most Recent Occurrence:

- ☐ Prior to the past 6 months
☐ In the past 6 months (4631 Study Eligibility, Q-22) QSORRES/QSSTRES

4 Suicide Gesture

Did you start to do something in order to kill yourself, even if you changed your mind and stopped, or if someone else stopped you? QSTEST=.RATING
QSTESTCD=PRISM4A

What did you do? QSTEST=.MOST RECENT
QSTESTCD=PRISM4B

What happened then?

What were you thinking of when you did that?

If Yes: When was that?

How many times did this happen?

Must be thinking about suicide at the time of act but believe that the extent of action taken would not actually result in death.

Include apparent suicide gesture even if subject claims intent was only attention-seeking.

Exclude self-mutilation for tension relief.

Exclude preparation for attempt.

A Rating Scale:

Absent	Sub Threshold	Present	Not Answered
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ QSORRES/QSSTRES	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄

B Most Recent Occurrence:

- ☐ Prior to the past 6 months
☐ In the past 6 months QSORRES/QSSTRES

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
 month day year Visit #: VISITNUM

4626 PRISM Suicidal and Homicidal Intent (PRISM) (continued)

5 Suicide Attempt

Did you ever do anything to hurt or kill yourself? (4631 Study Eligibility, Q 22)

Did you do anything on purpose that you knew could have killed you? (What did you do? What happened then? Did you think you could die as a result?)

If Yes: When was that? QSTEST=.RATING
 QSTESTCD=PRISM5A

How many times did you do anything to kill yourself?

QSTEST=.MOST RECENT
 QSTESTCD=PRISM5B

Need not have been planned or pre-meditated; include totally impulsive attempts.

Very impulsive suicidal behavior can occur even when other death/suicide items are negative.

Include if completed act was believed to be lethal but subject was discovered and saved.

Must have believed that the act was lethal, regardless of objective reality.

A Rating Scale:

Absent	Present	Not Answered
<input type="checkbox"/> _1	<input type="checkbox"/> _3	<input type="checkbox"/> _4

QSORRES/QSSTRES

B Most Recent Occurrence:

- ☐ Prior to the past 6 months
☐ In the past 6 months (4631 Study Eligibility, Q 22)

QSORRES/QSSTRES

6 Recurrent Homicidal Ideation

Did you ever think about harming or killing someone? (What did you think of? How often did you have that thought?)

QSTEST=.RATING
 QSTESTCD=PRISM6A

IF YES: Do you still think about harming or killing someone at the present time?

How often? QSTEST=.MOST RECENT
 QSTESTCD=PRISM6B

For how long have you been having these thoughts?

Must think actively of harming or killing someone, even if ambivalent.

Can have homicidal ideation without having homicidal plan

A Rating Scale:

Absent	Sub Threshold	Present	Not Answered
<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _3	<input type="checkbox"/> _4

QSORRES/QSSTRES

B Most Recent Occurrence:

- ☐ Prior to the past 6 months → STOP. This form is complete.
☐ In the past 6 months → Proceed to question 7.

QSORRES/QSSTRES

7 Specific Homicide Plan

Have you taken any steps toward carrying out this plan (4631 Study Eligibility, Q-22)?

QSTEST=.RATING
 QSTESTCD=PRISM7A

IF YES: What have you done?

Must be thinking of actual method of harming or killing someone. Intent to carry out the plan is not required, for formulation of a specific plan is enough.

Include even if fleeting plan. Need not have been recurrent or feasible.

A Rating Scale:

Absent	Present	Not Answered
<input type="checkbox"/> _1	<input type="checkbox"/> _3	<input type="checkbox"/> _4

QSORRES/QSSTRES

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID
Assessment Date: _____ DS.DSDTC / SC.SCDTC
month / day / year Visit #: VISITNUM

4627 Randomization

Section 1: Must be completed prior to randomizing the study candidate.

- 1 Has it been determined that the individual is eligible for the study, as defined by the inclusion/exclusion criteria (4631 Study Eligibility Form)? ☐ No ☐ Yes **SCCAT=RANDOMIZATION** **SCORRES** **SCTEST**
- 2 Did the participant have a stimulant-positive UDS result during baseline/screening? ☐ No ☐ Yes **SCORRES** **SCTEST**

Section 2: Complete Randomization procedure

- 3 Treatment assignment (check only one): ☐ TAU **DM.ARM** ☐ TAU + SCT
- 4 Date of randomization: _____ / _____ / _____ **DM.RFSTDTC** **DSCAT=DISPOSITION EVENT** month / day / year
- 5 If participant was eligible, but not randomized, please mark reason (check only one): **DSTERM**
- ☐ 1 No longer interested in participating in the study
- ☐ 2 Left prior to randomization and failed to return
- ☐ 3 Other (specify): _____ **DSDECOD**

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

☐ ₁ Participant unavailable ☐ ₂ Data collection error ☐ ₃ Participant unable/unwilling to answer
 Fields affected: ☐ ₀ Entire CRF ☐ ₁ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____
month day year Visit #: VISITNUM

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.

QSTEST

A Past Month Drug and Alcohol Use

QSORRES/QSSTRES

Please fill in the most correct response

QSEVLINT=-P30

QSTESTCD

RAB1

1 In the past month, how often have you injected cocaine and heroin together (speedball)?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB2

2 In the past month, how often have you injected heroin (not mixed)?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB3

3 In the past month, how often have you snorted heroin (not mixed)?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB4

4 In the past month, how often have you smoked heroin?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB5

5 In the past month, how often have you injected cocaine (not mixed)?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB6

6 In the past month, how often have you snorted cocaine (not mixed)?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB7

7 In the past month, how often have you smoked crack, rock, or freebase cocaine?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB8

8 In the past month, how often have you injected amphetamines, meth, speed, crank, or crystal?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB9

9 In the past month, how often have you snorted amphetamines, meth, speed, crank, or crystal?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB10

10 In the past month, how often have you smoked amphetamines, meth, speed, crank, or crystal?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB11

11 In the past month, how often have you used benzodiazepines, (benzos, benzie) such as Xanax, Valium, Klonopin, or Ativan?

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB12

12 In the past month, how often have you taken painkillers—pills such as Percodan, Percocet, Vicodin, Demerol, Dilaudid, Darvon, Darvocet, or syrup (Codeine)??

☐ Not at all ☐ A few times ☐ A few times each week ☐ Everyday

RAB12_3A

12a Which types of painkillers did you use? _____

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____ month _____ Visit #: _____ VISITNUM _____

QSTESTCD

QSTEST

QSEVLINT=P30

QSORRES/QSSTRES

4628 Risk Assessment Battery (RAB) (continued)

RAB13	13 In the past month, how often have you injected Dilaudid?	<input type="checkbox"/> Not at all <input type="checkbox"/> A few times <input type="checkbox"/> A few times each week <input type="checkbox"/> Everyday
RAB12	14 In the past month, how often have you used acid, LSD or other hallucinogens?	<input type="checkbox"/> Not at all <input type="checkbox"/> A few times <input type="checkbox"/> A few times each week <input type="checkbox"/> Everyday
RAB15	15 In the past month, how often have you used marijuana?	<input type="checkbox"/> Not at all <input type="checkbox"/> A few times <input type="checkbox"/> A few times each week <input type="checkbox"/> Everyday
RAB16	16 In the past month, how often have you used beer, wine, or liquor?	<input type="checkbox"/> Not at all <input type="checkbox"/> A few times <input type="checkbox"/> A few times each week <input type="checkbox"/> Everyday
B Needle Use		
RAB17	17 In the past month, have you injected drugs?	<input type="checkbox"/> No <input type="checkbox"/> Yes
RAB18	18 In the past month, have you shared needles or works?	<input type="checkbox"/> No or I have not shot up in the past month <input type="checkbox"/> Yes
RAB19	19 With how many different people did you share needles in the past month?	<input type="checkbox"/> Zero or I have not shot up or shared in the past month <input type="checkbox"/> 1 other person <input type="checkbox"/> 2 or 3 different people <input type="checkbox"/> 4 or more different people
RAB20	20 In the past month, how often have <u>you</u> used a needle after someone (with or without cleaning)?	<input type="checkbox"/> Never or I have not shot up or shared in the past month <input type="checkbox"/> A few times (1 or 2 times) <input type="checkbox"/> About once a week (3 or 4 times) <input type="checkbox"/> More than once a week (5 or more times)
RAB21	21 In the past month, how often have <u>others</u> used after you (with or without cleaning)?	<input type="checkbox"/> Never or I have not shot up or shared in the past month <input type="checkbox"/> A few times (1 or 2 times) <input type="checkbox"/> About once a week (3 or 4 times) <input type="checkbox"/> More than once a week (5 or more times)
RAB22	22 During the past month, how often have you shared needles with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?	<input type="checkbox"/> Never or I have not shot up or shared in the past month <input type="checkbox"/> A few times (1 or 2 times) <input type="checkbox"/> About once a week (3 or 4 times) <input type="checkbox"/> More than once a week (5 or more times)
RAB23	23 Where did you get your needles in the past month (check ALL that apply)?	<input type="checkbox"/> I have not shot up in the past month <input type="checkbox"/> From a diabetic <input type="checkbox"/> On the street <input type="checkbox"/> Drugstore <input type="checkbox"/> Shooting gallery or other place where users go to shoot up <input type="checkbox"/> Needle Exchange Program <input type="checkbox"/> Other (specify): _____
RAB24	24 In the past month, how often have you been to a shooting gallery/house or other place where users go to shoot up?	<input type="checkbox"/> Never <input type="checkbox"/> A few times (1 or 2 times) <input type="checkbox"/> About once a week (3 or 4 times) <input type="checkbox"/> More than once a week (5 or more times)
RAB25	25 In the past month, how often have you been to a crack house or other place where people go to smoke crack?	<input type="checkbox"/> Never <input type="checkbox"/> A few times (1 or 2 times) <input type="checkbox"/> About once a week (3 or 4 times) <input type="checkbox"/> More than once a week (5 or more times)

RAB23_err
has no data,
not collected

QSTESTCD → RAB23_0 → RAB23_1 → RAB23_2 → RAB23_3 → RAB23_4 → RAB23_5 → RAB23_6 → QSTESTCD=RAB23_6A

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____ Visit #: _____ VISITNUM _____

QSTESTCD _____ QSTEST= MOST RECENT

QSEVLINT=P30

QSORRES/QSSTRES

4628 Risk Assessment Battery (RAB) (continued)

RAB26

26 Which statement best describes the way you cleaned your needles during the past month (please choose ONE)?

- ☐ I have not shot up in the past month
- ☐ I always use new needles
- ☐ I always clean my needle just before I shoot up
- ☐ After I shoot up, I always clean my needle
- ☐ Sometimes I clean my needle, sometimes I don't
- ☐ I never clean my needle

RAB27

27 If you cleaned your needles and works in the past month, how did you clean them (check ALL that apply)?

- ☐ I have not shot up in the past month
- ☐ Soap and water only
- ☐ Alcohol
- ☐ Bleach
- ☐ Boiling water
- ☐ Other
- ☐ I did not clean my needles in the past month
- ☐ I ALWAYS used new needles in the past month

QSTESTCD

RAB23_err
has no data,
not collected

RAB28

28 In the past month, how often have you shared rinse-water?

- ☐ Never or I have not shot up or shared in the past month
- ☐ A few times (1 or 2 times)
- ☐ About once a week (3 or 4 times)
- ☐ More than once a week (5 or more times)

RAB29

29 In the past month, how often have you shared a cooker?

- ☐ Never or I have not shot up or shared in the past month
- ☐ A few times (1 or 2 times)
- ☐ About once a week (3 or 4 times)
- ☐ More than once a week (5 or more times)

RAB30

30 In the past month, how often have you shared a cotton?

- ☐ Never or I have not shot up or shared in the past month
- ☐ A few times (1 or 2 times)
- ☐ About once a week (3 or 4 times)
- ☐ More than once a week (5 or more times)

RAB31

31 In the past month, how often have you divided or shared drugs with others by using one syringe (yours or somebody else's) to squirt or load the drugs into the other syringe(s) (backloading, for example)?

- ☐ Never
- ☐ A few times (1 or 2 times)
- ☐ About once a week (3 or 4 times)
- ☐ More than once a week (5 or more times)

C Sexual Practices

RAB32_0

32 How would you describe yourself? ☐ Straight or Heterosexual ☐ Gay or Homosexual ☐ Bisexual

PLEASE NOTE: For the following questions, sex means any vaginal intercourse, anal intercourse (in the butt) or oral sex (blowjobs, for example).

RAB33

33 With how many men have you had sex with in the past month?

- ☐ 0 men ☐ 2 or 3 men
- ☐ 1 man ☐ 4 or more men

RAB34

34 With how many women have you had sex with in the past month?

- ☐ 0 women ☐ 2 or 3 women
- ☐ 1 woman ☐ 4 or more women

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ Visit #: _____ VISITNUM _____

QSTESTCD

QSTEST

QSEVLINT=P30

QSORRES/QSSTRES

4628 Risk Assessment Battery (RAB) (continued)

RAB35

35 In the past month, how often have you had sex so you could get drugs?

- ☐ 0 Never
☐ 1 A few times (1 or 2 times)
☐ 2 About once a week (3 or 4 times)
☐ 3 More than once a week (5 or more times)

RAB36

36 In the past month, how often have you given drugs to someone so you could have sex with them?

- ☐ 0 Never
☐ 1 A few times (1 or 2 times)
☐ 2 About once a week (3 or 4 times)
☐ 3 More than once a week (5 or more times)

RAB37

37 In the past month, how often were you paid money to have sex with someone?

- ☐ 0 Never
☐ 1 A few times (1 or 2 times)
☐ 2 About once a week (3 or 4 times)
☐ 3 More than once a week (5 or more times)

RAB38

38 In the past month, how often did you give money to someone so you could have sex with them?

- ☐ 0 Never
☐ 1 A few times (1 or 2 times)
☐ 2 About once a week (3 or 4 times)
☐ 3 More than once a week (5 or more times)

RAB39

39 In the past month, how often had you had sex with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?

- ☐ 0 Never
☐ 1 A few times (1 or 2 times)
☐ 2 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 when you had sex?

- ☐ 0 I have not had sex in the past month
☐ 1 All the time
☐ 2 Most of the time
☐ 3 Some of the time
☐ 4 None of the time

RABH

D Concerns about HIV and Testing

If you know that you are HIV positive, skip to question 44.

RAB41

41 How worried are you about getting HIV or AIDS?

- ☐ 0 Not at all ☐ 3 Considerably
☐ 1 Slightly ☐ 4 Extremely
☐ 2 Moderately

RAB42

42 How worried are you that you may have already been exposed to the HIV or AIDS virus?

- ☐ 0 Not at all ☐ 3 Considerably
☐ 1 Slightly ☐ 4 Extremely
☐ 2 Moderately

RAB43

43 How many times have you had a blood test for the AIDS virus (HIV)?

- ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 or more times

RAB44

44 When were you last tested for HIV? Please write the month and year of your most recent test.

____ / ____
 month year

RAB45

45 Were you ever told you had HIV, the AIDS virus?

- ☐ 0 No ☐ 1 Yes ☐ 2 I never got the results

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

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: AE, CM, LB

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

AEDTC

Assessment Date: _____ / _____ / _____
month day year

Week #: VISITNUM Sequence #: _____

AESER=Y

4629 Serious Adverse Events

AESEQ

1 Corresponding AE symptom or diagnosis: AETERM

2 Narrative description of serious adverse event and any sequelae (if associated with hospitalization, include the dates of hospitalization):

QNAE=AESNAR

QLABEL=SAE NARRATIVE DESCRIPTION

IDVAR=AESEQ

3 Known medical history including pre-existing medical conditions (allergies, pregnancy, smoking and alcohol use, hypertension, diabetes, epilepsy, depression, etc.): OR ☐ Unknown

QNAE=AESMH

QLABEL=SAE MEDICAL HISTORY

IDVAR=AESEQ

CMCAT = 'SAE CONCOMITANT DRUGS USING'

4 What concomitant medications was the participant using at the time of this event? (Include name of medication, indication for medication, dose and date last taken if known) OR ☐ Unknown ☐ None

CMSEQ

Medication Name	Indication	Dosage	Date Last Taken
CMTRT	CMINDC	CMDOSE	CMSTDTC / / month day year
			/ / month day year
			/ / month day year
			/ / month day year
			/ / month day year

CMCAT = 'SAE CONCOMITANT DRUGS ENGAGED'

5 What concomitant treatment was the participant engaged in at the time of this event? (Include name of treatment, indication for treatment, and date last treated if known) OR ☐ Unknown ☐ None

CMSEQ

Treatment Name	Indication	Date Last Treated
CMTRT	CMINDC	CMSTDTC / / month day year
		/ / month day year
		/ / month day year
		/ / month day year
		/ / month day year

LBCAT = 'SAE LAB TESTS PERFORMED'

6 What tests/labs were performed in conjunction with this event? OR ☐ Unknown ☐ None

Lab/Test Data	Date of Test
LBTEST = SAE RELATED LBTESTCD = SAE LAB LBORRES	LBDTC / / month day year
	/ / month day year
	/ / month day year
	/ / month day year

CTN-0046
S-CAST

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

☐₁ Participant unavailable ☐₂ Data collection error ☐₃ Participant unable/unwilling to answer

Fields affected: ☐ Entire CRF ☐ Questions (specify):

Node #: CTP Site ID #: SITEID Participant ID #: USUBJID

Assessment Date: ^{QSDTC} / / Visit #: VISITNUM
month day year

4630 Smoking History Survey (SHS)

This 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 ← OSSTRESII-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 (4631 Study Eligibility, Q 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

SHS06A **6a** What brand of cigarettes or tobacco do you smoke most? Specify brand (print): _____

SHS06B **6b Length** (check only one): ☐₁ Regular
☐₂ 100's
☐₃ Other (specify in 6c)

SHS06C 6c If 6b = other (3), then specify other length (print): _____

SHS06D **6d Pack style** (check only one): ☐ 1 Hard pack
☐ 2 Soft pack

SHS06E **6e Mentholated** (check only one): ☐ Non-mentholated
☐ Mentholated

SHS07 **7** Among your close friends and family, what percentage would you say smoke cigarettes (check only one)?

☐ ₀ None

☐ ₁ Few

☐ ₂ Approximately 25%

☐ ₃ Approximately 50%

☐ ₄ Approximately 75%

☐ ₅ Approximately 100%

SHS08A **8a** Are there any other cigarette smokers in your household/living arrangements?

☐ ₀ No

SHS08B ☐ ₁ Yes → If Yes: Answer 8b: How many? ____

SHS09 9 How much do the people closest to you want you to stop smoking (check only one)?

☐0 Not at all

☐1 Not much

☐2 Neutral

☐3 Somewhat

☐4 Very much

SHS010

10 If you were to stop, how helpful would the people closest to you be?

☐ ₀ Not helpful

☐ ₁ Not much help

☐ ₂ Neutral

☐ ₃ Somewhat helpful

☐ ₄ Very helpful

SHSCRIS

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year Visit #: _____ VISITNUM

4630 Smoking History Survey (continued)

11a Have you ever used non-cigarette tobacco products?

☐ No☐ Yes → If Yes: Check an answer for each of the following:

11b Cigars ☐ No ☐ Yes

11c Pipes ☐ No ☐ Yes

11d Bidis (tobacco wrapped in a temburni leaf) ☐ No ☐ Yes

11e Smokeless tobacco (pan, chewing tobacco, snuff) ☐ No ☐ Yes

12 How many times have you attempted to quit smoking? → If zero times, enter 000 and then answer questions 13 and 14; then stop.) _____

13 Since you started smoking regularly, what is the longest time that you have gone without smoking any cigarettes (check only one)? ☐ Never gone without smoking

☐ Less than a day☐ At least one day, but less than a week☐ At least one week, but less than a month☐ At least one month, but less than a year☐ One year or more

14a Have you ever experienced uncomfortable symptoms when you stopped smoking (check only one)?

☐ Does not apply—I have never stopped smoking☐ I have stopped smoking in the past but never experienced uncomfortable symptoms

☐ I have stopped smoking in the past and have experienced uncomfortable symptoms → If answered: What symptoms (check an answer for each of the following)?

14b Craving ☐ No ☐ Yes

14c Decreased heart rate ☐ No ☐ Yes

14d Irritability ☐ No ☐ Yes

14e Anxiety ☐ No ☐ Yes

14f Increased eating ☐ No ☐ Yes

14g Restlessness ☐ No ☐ Yes

14h Difficulty concentrating ☐ No ☐ Yes

14i Other (specify in 14j) ☐ No ☐ Yes

14j Other, specify (print; limit 200 characters): _____

15 Enter the number of times you have tried the following methods to stop smoking (if zero, enter 000):

15a Self-help material (for example American Lung Association material, materials from your doctor, etc.): _____ times

15b A formal cessation program (for example with classes, group discussions, etc.): _____ times

15c A private consultation with your doctor or mental health physician: _____ times

15d Hypnosis/acupuncture: _____ times

15e Nicotine medicated gum: _____ times

15f Zyban® (bupropion SR): _____ times

15g Chantix® (varenicline): _____ times

15h Nicotine inhaler, spray, or lozenge: _____ times

15i On your own (cold turkey): _____ times

15j Other (if not 000, specify in 15k): _____ times

15k Other, specify (print; limit 200 characters): _____

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year

Visit #: _____ VISITNUM

4630 Smoking History Survey (continued)

16a Have you ever used nicotine skin patches?

☐ No☐ Yes → If Yes: Answer 16b–16d below.**16b** If you have used nicotine skin patches, how many times? _____**16c** If you have used nicotine skin patches, did you have any problems with the patch?☐ No☐ Yes → **16d** Please describe (print; limit 200 characters): _____

17a When was your last attempt to stop/quit smoking?

☐ Never attempted → If Never attempted: STOP. This form is complete.☐ Hours ago☐ Days ago☐ Weeks ago☐ Months ago☐ Years ago

17b When was the date of the last attempt to quit smoking (4631 Study Eligibility, Q 15): _____ / _____ / _____
month day year

17c Did you use a smoking cessation counseling program or medication to help you quit smoking (4631 Study Eligibility, Q 15):

☐ No ☐ Yes

17d For how long did you go without smoking at that time?

☐ Never stopped☐ Hours☐ Days☐ Weeks☐ Months☐ Years

17e How did you stop? Please describe (print; limit 200 characters): _____

17f Why did you start again? Please describe (print; limit 200 characters): _____

18 What is the longest period of time you have gone without smoking?

☐ Hours☐ Days☐ Weeks☐ Months☐ Years

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: IE

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ IEDTC
month / day / year Visit #: VISITNUM

4631 Study Eligibility

Inclusion Criteria: Is the individual: (include if Yes)

IECAT = INCLUSION CRITERIA

IE TEST

1	An adult, age 18 or older (see 4613 Demographics, Q 1)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed	IEORRES
2	Able to understand and provide written informed consent in English (see signed consent form)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed	
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)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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 \geq 8 ppm (see 4606 Carbon Monoxide Assessment, Q 1)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed	

Exclusion 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)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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) OR current or lifetime anorexia nervosa or bulimia (see 4607 CIDI Summary, Q 25 and Q 29)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed	
12	Have a history of seizure disorder (see 4618 Medical History, Q 23)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed	
13	Have a history of a closed head trauma with > 30 minutes loss of consciousness (see 4619 Medical History Addendum, Q 18)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed	

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: IE

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ IEDTC
month / day / year Visit #: VISITNUM

4631 Study Eligibility (continued)

Exclusion Criteria: Does the individual: (Exclude if Yes)

IECAT = EXCLUSION CRITERIA

IEORRES

IE TEST

14 Have a potentially life-threatening or progressive medical illness other than addiction that may compromise participant safety or study conduct?

If Yes, specify whether the participant met each of the following:

14.1 Uncontrolled hypertension (i.e., blood pressure readings $\geq 140/90$ on two clinic visits) (see 4644 Vital Signs) ☐ No ☐ Yes
☐ Not assessed

14.2 Known coronary artery disease including myocardial infarction or angina (see 4619 Medical History Addendum, Section I), **or an ECG with significant conduction abnormality** (see 4614 ECG) ☐ No ☐ Yes
☐ Not assessed

14.3 AIDS according to the current CDC criteria for AIDS (see 4619 Medical History Addendum, Q 19) ☐ No ☐ Yes
☐ Not assessed

14.4 Liver function tests greater than 3X upper limit of normal (see 4604 Blood Chemistry) ☐ No ☐ Yes
☐ Not assessed

14.5 Serum creatinine greater than 2 mg/dL (see 4604 Blood Chemistry) ☐ No ☐ Yes
☐ Not assessed

14.6 Diabetes treated with hypoglycaemics or insulin (see 4619 Medical History Addendum, Q 20) ☐ No ☐ Yes
☐ Not assessed

14.7 Other (see 4622 Physical Exam, etc.) ☐ No ☐ Yes
If Yes, specify: _____ ☐ Not assessed

☐ No ☐ Yes
☐ Not assessed

☐ No ☐ Yes
☐ Not assessed

☐ No ☐ Yes
☐ Not assessed

☐ No ☐ Yes
☐ Not assessed

☐ No ☐ Yes
☐ Not assessed

☐ No ☐ Yes
☐ Not assessed

15 Report using or having used other smoking-cessation programs or medication treatments currently, or within the last 30 days (see 4630 Smoking History Survey, Q 17b–17c)?

16 Have a known or suspected hypersensitivity to bupropion, nicotine, or menthol (see 4619 Medical History Addendum, Q 21)?

17 If female, have a positive pregnancy test or report being pregnant or breastfeeding (see 4643 Urine Pregnancy Test, Q 3 and Q 4)?

18 Report using any of the following medications within 14 days of randomization: monoamine oxidase (MAO) inhibitors, antimalarials, tramadol, theophylline, systemic steroids, quinolones, bupropion, any investigational drug, or any drug with known potential for toxicity to a major organ system (e.g., isoniazid, methotrexate) and/or have used sedating antihistamines within 7 days of randomization (see 4625 Prior and Concomitant Medications)?

19 Report taking any medications which, in the judgment of the study medical clinician, may produce interactions with bupropion XL that are sufficiently dangerous so as to exclude the patient from participating in the study (see 4625 Prior and Concomitant Medications)?

CTN-0046 S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: IE

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ IEDTC
month / day / year Visit #: VISITNUM

4631 Study Eligibility (continued)

Exclusion Criteria: Does the individual: (Exclude if Yes)

IECAT = EXCLUSION CRITERIA

IEORRES

IE TEST

20 In the judgement of the investigator, seems unlikely to complete the study protocol (see RA checklist for Visit 101)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed
21 Report having used tobacco products, other than cigarettes, in the past week (see 4638 TLFB Pre-Study)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed
22 Represent a significant suicidal/homicidal risk (see 4626 PRISM, Q 3b, Q 5b, Q 7a)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed
24 Have all stimulant-positive UDS results during screening/baseline (see 4642 Urine Drug Screen)	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Not assessed
25 Is the individual eligible for the study?	<input type="checkbox"/> No <input type="checkbox"/> Yes

26 Investigator name (print legibly): _____

QNAME=IENAME
QLABEL=IE CLINICIAN NAME
IDVAR=VISITNUM

27 Date signed: _____
month / day / year

QNAME=IESIGDTC
QLABEL=IE SIGNATURE DATE
IDVAR=VISITNUM

28 Investigator signature: DATA NOT STORED

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ Visit #: VISITNUM

QSTEST

QSORRES/QSSTRES

4632 Study Questionnaire

This questionnaire is designed to help us better understand the relationship between cigarette smoking and crack/cocaine or methamphetamine use. Please answer the questions for the last period of time when you were using crack/cocaine or methamphetamine at least once a week.

1 How often did you smoke cigarettes to try to avoid using crack/cocaine or methamphetamine?

☐ Not at all☐ A few times☐ A few times each week☐ Everyday

2 How often did you use crack/cocaine or methamphetamine to avoid smoking cigarettes?

☐ Not at all☐ A few times☐ A few times each week☐ Everyday

3 How often did your use of crack/cocaine or methamphetamine increase your desire/craving for cigarettes?

☐ Not at all☐ A few times☐ A few times each week☐ Everyday

4 How often did smoking a cigarette increase your desire/craving for crack/cocaine or methamphetamine?

☐ Not at all☐ A few times☐ A few times each week☐ Everyday

5 How often did your use of crack/cocaine or methamphetamine increase your use of cigarettes?

☐ Not at all☐ A few times☐ A few times each week☐ Everyday

6 How often did smoking a cigarette increase your use of crack/cocaine or methamphetamine?

☐ Not at all☐ A few times☐ A few times each week☐ Everyday

7 If you smoked cigarettes while also using crack/cocaine or methamphetamine, please choose all of the responses that explain why you used cigarettes with crack/cocaine or methamphetamine:

☐ NA (did not use both together)☐ Cigarette smoking helps to feel more relaxed/calm☐ Cigarette smoking helps the high from crack/cocaine or methamphetamine to last longer☐ Smoking cigarettes slows down crack/cocaine/methamphetamine use so that the crack/cocaine/methamphetamine lasts longer☐ Cigarette smoking is just a habit—no particular reason for using cigarettes with crack/cocaine or methamphetamine☐ Everyone else is smoking cigarettes and I want to be social☐ Other (specify) _____

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

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____ Visit #: _____ VISITNUM _____

QSTEST

QSORRES/QSSTRES

4633 Substance Abuse Treatment Status

1 Are you currently enrolled in outpatient or intensive outpatient substance abuse treatment (4631 Study Eligibility, Q 6)?

- ☐ Not enrolled → If NO: STOP. Participant is not eligible for CTN-0046.
☐ Outpatient
☐ Intensive outpatient (IOP)

2 When did you enroll in your present outpatient/IOP treatment: _____ / _____ / _____
month day year

3a Are you scheduled to attend at least one treatment session per week (4631 Study Eligibility, Q 6)?

- ☐ No → If NO: STOP. Participant is not eligible for CTN-0046.
☐ Yes → If Yes: Answer question 3b.

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.
☐ Yes → If Yes: Answer question 3c.

3c How many weeks will you be scheduled to attend treatment as of [give estimated date of randomization]?

_____ weeks ☐ Ongoing treatment (no end date set)

SATS03c = 1 for # of weeks, =2 for ongoing

SATS03cr = the number of weeks

4 Did you complete residential treatment within two weeks of starting your present outpatient/IOP treatment?

- ☐ No
☐ Yes

5a Are you receiving methadone or buprenorphine (Subutex®), buprenorphine naloxone (Suboxone®), or naltrexone (4631 Study Eligibility, Q 11)?

- ☐ No → If NO: Answer question 5b.
☐ Yes → If Yes: STOP. Participant is not eligible for CTN-0046.

5b Are you trying to get into treatment in which you would receive methadone, buprenorphine naloxone, or naltrexone (4631 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:

- | | | | |
|---------------------------------------------------------------------------------------------------------------------------------------|-------|-----------------------------|------------------------------|
| 6a Are you currently on probation? | _____ | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 6b Are you court ordered to substance abuse treatment? | _____ | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 6c Have you been formally notified that you will go to jail if you fail to attend treatment? | _____ | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 6d Have you been formally notified that a child will be removed from you if you fail to attend treatment? | _____ | <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| 6e Have you been formally notified that the housing that you are living in will be taken away if you fail to attend treatment? | _____ | <input type="checkbox"/> No | <input type="checkbox"/> Yes |

7 Will you be trying to get into residential/inpatient treatment within the next 2 to 3 months (4631 Study Eligibility, Q 23)?

- ☐ No
☐ Yes → If Yes: The RA will need to speak with the clinic staff to assess the likelihood of the participant getting into residential/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

CTN-0046

S-CAST

QSSCAT=CLINICIAN RATINGS

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID _____ Participant ID #: _____ USUBJID _____

Assessment Date: _____ QSDTC _____ / _____ / _____ Visit #: _____ VISITNUM _____
month day year

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

4634 Supervisor Tape Rating—Smoking Cessation

Clinician ID: _____ SQ 1 _____ Supervisor ID: _____ SQ 2 _____ Supervisor Node: _____ SQ 3 _____ Supervisor Site: _____ SQ 4 _____

Check if Independent Rater (IR): ☐ → IR ID: _____ SQ 5 _____ IR Node: _____ SQ 6 _____ IR Site: _____ SQ 7 _____Session # _____ SQ 8 _____ Session date: _____ SQ 9 _____
month day year

QSTESTCD

QSTEST

Meets
ExpectationsNeeds
ImprovementExpectations
Not Met:
Additional Training
Required

QSORRES/QSSTRES

STR001/
ITR001

1 Familiarity with each of the intervention topics.

☐_1☐_2☐_3STR002/
ITR002

2 Ability to effectively guide study participant through key points in the 10 minute time allowed.

☐_1☐_2☐_3STR003/
ITR003

3 Ability to make and maintain eye contact.

☐_1☐_2☐_3STR004/
ITR004

4 Ability to listen.

☐_1☐_2☐_3STR005/
ITR005

5 Ability to identify individual needs and provide the appropriate intervention.

☐_1☐_2☐_3STR006/
ITR006

6 Ability to remain non-judgmental and encouraging.

☐_1☐_2☐_3STR007/
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.

☐_1☐_2☐_3

SUBSTITUTE 'STR' FOR 'ITR' WHEN USING STR FORM

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=SESSION NUMBER Also in STR

SQ9 QNAM=ITR001DT QLABEL=SESSION DATE Also in STR

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____
Node #: _____ CTP Site ID #: SITEID Participant ID #: USUBJIDAssessment Date: _____ / _____ / _____
month day year Visit #: VISITNUM

4635 Thoughts About Abstinence—Alcohol

Section 1

QSTEST

QSORRES/QSSTRES

This section asks about how you feel about **stopping all alcohol use** at this time in your life. On the scales below, circle the number that best represents how you feel about **stopping**, how **successful** you will be, and **how you will do** after you quit.

1 Have you used alcohol in the past 90 days?

- ☐ No → If No: STOP
☐ Yes → If Yes: Continue to question 2

QSEVLINT=-D90

2 Using the scale at right, how would you describe your **desire to quit using alcohol** at this time in your life?

No desire to quit										Greatest desire to quit
0	1	2	3	4	5	6	7	8	9	

3 Using the scale at right, how would you describe **how successful you expect to be** in quitting?

Very low chance of success										Very high chance of success
0	1	2	3	4	5	6	7	8	9	

4 Using the scale at right, how would you describe how **difficult** it will be **to keep from using alcohol** at this time in your life?

Very easy										Very difficult
0	1	2	3	4	5	6	7	8	9	

Section 2

5 What is the **GOAL** you have chosen for yourself about using alcohol at this time?

Please read the goals listed below and choose which goal best represents your own goal at this time by checking the box next to your choice. Please read all of them before you pick one.

- ☐ 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.
- ☐ 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.
- ☐ 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 the urge.
- ☐ 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.
- ☐ 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 life.
- ☐ None of the above – None of the above applies exactly to me. My own goal is (print; limit 200 characters):

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____
Node #: _____ CTP Site ID #: SITEID Participant ID #: USUBJIDAssessment Date: _____ / _____ / _____
month day year Visit #: VISITNUM

4636 Thoughts About Abstinence—Cigarettes

Section 1

QSTEST

QSORRES/QSSTRES

This section asks about how you feel about **stopping all cigarette smoking** at this time in your life. On the scales below, circle the number that best represents how you feel about **stopping**, how **successful** you will be, and **how you will do** after you quit.

1 Using the scale at right, how would you describe your **desire to quit smoking cigarettes** at this time in your life (4631 Study Eligibility, Q 5)?

No
desire to
quitGreatest
desire to
quit

0 1 2 3 4 5 6 7 8 9

2 Using the scale at right, how would you describe **how successful you expect to be** in quitting?

Very low
chance of
successVery high
chance of
success

0 1 2 3 4 5 6 7 8 9

3 Using the scale at right, how would you describe how **difficult** it will be to **keep from smoking cigarettes** at this time in your life?

Very
easyVery
difficult

0 1 2 3 4 5 6 7 8 9

Section 2

4 What is the **GOAL** you have chosen for yourself about smoking cigarettes at this time?

Please read the goals listed below and choose which goal best represents your own goal at this time by checking the box 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 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.
- ☐ **4. 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 the urge.
- ☐ **5. 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.
- ☐ **6. 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 life.
- ☐ **7. None of the above** – None of the above applies exactly to me. My own goal is (print; limit 200 characters):

CTN-0046

S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
 Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ Q\$DTC / _____ / _____
month day year Visit #: _____ VISITNUM

4637 Thoughts About Abstinence—Drugs

Section 1

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 the number that best represents how you feel about **stopping**, how **successful** you will be, and **how you will do** after you quit.

1 Using the scale at right, how would you describe your desire to quit using drugs at this time in your life?	No desire to quit	Greatest desire to quit
	0 1 2 3 4 5 6 7 8 9	
2 Using the scale at right, how would you describe how successful you expect to be in quitting?	Very low chance of success	Very high chance of success
	0 1 2 3 4 5 6 7 8 9	
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?	Very easy	Very difficult
	0 1 2 3 4 5 6 7 8 9	

Section 2

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 box next to your choice. Please read all of them before you pick one.

- ☐ 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.
- ☐ 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.
- ☐ 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 the urge.
- ☐ 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.
- ☐ 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 life.
- ☐ None of the above – None of the above applies exactly to me. My own goal is (print; limit 200 characters):

CTN-0046

S-CAST

SUCAT=TIMELINE FOLLOW-BACK PRE-STUDY

Form completion (if form not complete, check one): ☐ 1 Participant unavailable ☐ 2 Data collection error ☐ 3 Participant unable/unwilling to answer
Fields affected: ☐ 0 Entire CRF ☐ 1 Questions (specify): _____

USUBJID _____ CTP ID #: _____ Node #: _____

VISITNUM _____ Assessment Date: _____ month / day / year

SUDTC

4638 Timeline Follow-Back—Pre-Study

Visit number:	VISITNUM	1	2	3	4	5	6	7
Day								
1 Date	SUSTDTC	month / day / year	month / day / year	month / day / year	month / day / year	month / day / year	month / day / year	month / day / year
2 Alcohol	SUTRT	# Standard drinks: SUDOSE	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
3 Marijuana	SUTRT	# Joints: SUDOSE	# Joint:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4 Cigarettes	SUTRT	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
5 Other tobacco	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
5a If Yes: Specify other tobacco (check all used)	SUTRT	SUTRT	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
6 Cocaine	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
7 Amphetamine	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
8 Methamphetamine	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
9 Sedatives	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
10 Opiates	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
11 Other 1 (specify)	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
12 Other 2 (specify)	SUTRT	SUOCCUR	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:

* Route 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

VISITUM

Node #: _____ CTP ID #: _____ USUBID

Participant ID #: _____

Visit #: _____ Assessment Date: _____ SUDTC

month

day

year

4638 Timeline Follow-Back—Pre-Study (continued)

Day	SUSPID	8	9	10	11	12	13	14
1 Date		SUSTDTC / month / day						
2 SUTRT Alcohol		# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE
3 SUTRT Marijuana		# Joints: SUDOSE	# Joints: SUDOSE	# Joints: SUDOSE	# Joints: SUDOSE	# Joints: SUDOSE	# Joints: SUDOSE	# Joints: SUDOSE
4 SUTRT Cigarettes		# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE
5 Other tobacco		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes →	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes →	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes →	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes →	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes →	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes →	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes →
5a If Yes: Specify other tobacco (check all used)		<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> SUTRT Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> SUTRT Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> SUTRT Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> SUTRT Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> SUTRT Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> SUTRT Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> SUTRT Dip <input type="checkbox"/> Pipe
6 SUTRT Cocaine		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE
7 SUTRT Amphetamine		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE
8 SUTRT Methamphetamine		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE
9 SUTRT Sedatives		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes
10 SUTRT Opiates		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE
11 Other 1 (specify) SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE
12 Other 2 (specify) SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SUDROUTE

* Route 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-UP-BACK PRE-STUDY

VISITUM

Node #: _____ CTP ID #: _____ USUBID _____ Participant ID #: _____ Assessment Date: _____ / _____ / _____ SUDTC _____
 Visit #: _____ / _____ / _____ day _____ month _____ year _____

4638 Timeline Follow-Back—Pre-Study (continued)

Day	SUSPID	15	16	17	18	19	20	21
1 Date		SUSTDTC / month / day	month / day	month / day	month / day	month / day	month / day	month / day
2 SUTRT Alcohol		# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks: SUDOSE
3 SUTRT Marijuana		# Joint s: SUDOSE	# Joint s: SUDOSE	# Joint s: SUDOSE	# Joint s: SUDOSE	# Joint s: SUDOSE	# Joint s: SUDOSE	# Joint s: SUDOSE
4 SUTRT Cigarettes		# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE	# Cigarettes/day: SUDOSE
5 Other tobacco		SUOCCUR No Yes → Chew SUTRT Cigar Dip Pipe	SUOCCUR No Yes → Chew SUTRT Cigar Dip Pipe	SUOCCUR No Yes → Chew SUTRT Cigar Dip Pipe	SUOCCUR No Yes → Chew SUTRT Cigar Dip Pipe	SUOCCUR No Yes → Chew SUTRT Cigar Dip Pipe	SUOCCUR No Yes → Chew SUTRT Cigar Dip Pipe	SUOCCUR No Yes → Chew SUTRT Cigar Dip Pipe
5a If Yes: Specify other tobacco (check all used)								
6 SUTRT Cocaine		SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE
7 SUTRT Amphetamine		SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE
8 SUTRT Methamphetamine		SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE
9 SUTRT Sedatives		SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE
10 SUTRT Opiates		SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE
11 Other 1 (specify) SUTRT		SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE
12 Other 2 (specify) SUTRT		SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE	SUOCCUR No Yes → Route*: SUROUTE

*Route Code list	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-UP BACK PRE-STUDY

VISITUM

 Visit #: _____ / _____ / _____
 Assessment Date: _____ month _____ day _____ year

Node #: _____ CTP ID #: _____

USUBID

Participant ID #: _____

Assessment Date: _____

SUDTC

4638 Timeline Follow-Back—Pre-Study (continued)

Day	SUSPID	22	23	24	25	26	27	28
1 Date		SUSTDTC / _____ month _____ day _____	_____ / _____ month _____ day _____	_____ / _____ month _____ day _____	_____ / _____ month _____ day _____	_____ / _____ month _____ day _____	_____ / _____ month _____ day _____	_____ / _____ month _____ day _____
2 SUTRT Alcohol		# Standard drinks: SUDOSE _____	# Standard drinks: SUDOSE _____	# Standard drinks: SUDOSE _____	# Standard drinks: SUDOSE _____	# Standard drinks: SUDOSE _____	# Standard drinks: SUDOSE _____	# Standard drinks: SUDOSE _____
3 SUTRT Marijuana		# Joints: SUDOSE _____	# Joints: SUDOSE _____	# Joints: SUDOSE _____	# Joints: SUDOSE _____	# Joints: SUDOSE _____	# Joints: SUDOSE _____	# Joints: SUDOSE _____
4 SUTRT Cigarettes		# Cigarettes/day: SUDOSE _____	# Cigarettes/day: SUDOSE _____	# Cigarettes/day: SUDOSE _____	# Cigarettes/day: SUDOSE _____	# Cigarettes/day: SUDOSE _____	# Cigarettes/day: SUDOSE _____	# Cigarettes/day: SUDOSE _____
5 Other tobacco		SUOCCUR _____ No _____ Yes →	SUOCCUR _____ No _____ Yes →	SUOCCUR _____ No _____ Yes →	SUOCCUR _____ No _____ Yes →	SUOCCUR _____ No _____ Yes →	SUOCCUR _____ No _____ Yes →	SUOCCUR _____ No _____ Yes →
5a If Yes: Specify other tobacco (check all used)		Chew SUTRT _____ Dip _____	Chew SUTRT _____ Dip _____	Chew SUTRT _____ Dip _____	Chew SUTRT _____ Dip _____	Chew SUTRT _____ Dip _____	Chew SUTRT _____ Dip _____	Chew SUTRT _____ Dip _____
6 SUTRT Cocaine		SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____
7 SUTRT Amphetamine		SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____
8 SUTRT Methamphetamine		SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____
9 SUTRT Sedatives		SUOCCUR _____ No _____ Yes	SUOCCUR _____ No _____ Yes	SUOCCUR _____ No _____ Yes	SUOCCUR _____ No _____ Yes	SUOCCUR _____ No _____ Yes	SUOCCUR _____ No _____ Yes	SUOCCUR _____ No _____ Yes
10 SUTRT Opiates		SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____
11 Other 1 (specify) SUTRT		SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____
12 Other 2 (specify) SUTRT		SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____	SUOCCUR _____ No _____ Yes Route*: SUDROUTE _____
* Route Code list		01 = oral 06 = shot up through skin	02 = nasal 07 = dissolved under tongue	03 = inhaled/smoked 08 = topical	04 = shot up through vein 09 = rectal	05 = shot up through muscle 10 = vaginal		

CTN-0046

S-CAST

SUCAT=TIMELINE FOLLOW-BACK ACTIVE STUDY

Form completion (if form not complete, check one): ☐ 1 Participant unavailable ☐ 2 Data collection error ☐ 3 Participant unable/unwilling to answer
Fields affected: ☐ 0 Entire CRF ☐ 1 Questions (specify):

VISITUM

USUBJID

SUDTC

Node #: _____ CTP ID #: _____ Participant ID #: _____ Visit #: _____ / _____ / _____
Assessment Date: _____ month _____ day _____ year

4639 Timeline Follow-Back—Active Study

Day	1	2	3	4	5	6	7
1 Date	SUSPID ____/____/20____ month day year						
2 SUTRT Alcohol	# Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
3 SUTRT Marijuana	# Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
4 SUTRT Cigarettes	# Cigarettes/day: SUDOSE	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:
5 Other tobacco	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes → # Joints: SUDOSU	<input type="checkbox"/> No <input type="checkbox"/> Yes → # Joints:	<input type="checkbox"/> No <input type="checkbox"/> Yes → # Joints:	<input type="checkbox"/> No <input type="checkbox"/> Yes → # Joints:	<input type="checkbox"/> No <input type="checkbox"/> Yes → # Joints:	<input type="checkbox"/> No <input type="checkbox"/> Yes → # Joints:	<input type="checkbox"/> No <input type="checkbox"/> Yes → # Joints:
5a If Yes: Specify other tobacco (check all used)	SUTRT <input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe
6 SUTRT Cocaine	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:
7 SUTRT Amphetamine	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:
8 SUTRT Methamphetamine	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:
9 SUTRT Sedatives	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
10 SUTRT Opiates	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:
11 Other 1 (specify) SUTRT	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:
12 Other 2 (specify) SUTRT	SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*:

* Route Code list	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 FOLLOW-UP

Form completion (if form not complete, check one): ☐ Data collection error ☐ Participant unavailable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify):

USUBJID

Node #: CTP ID #:

Participant ID #:

Visit #:

Assessment Date:

SUDTC

4640 Timeline Follow-Back—Follow-Up

Day	1	2	3	4	5	6	7
1 Date	SUSPID month / day / year						
2 Alcohol	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
3 Marijuana	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
4 Cigarettes	SUTRT # Cigarettes/day: SUDOSE	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:	# Cigarettes/day: # Joints:
5 Other tobacco	SUOCCUR # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
5a If Yes: Specify other tobacco (check all used)	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
6 Cocaine	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
7 Amphetamine	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
8 Methamphetamine	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
9 Sedatives	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
10 Opiates	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
11 Other 1 (specify)	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:
12 Other 2 (specify)	SUTRT # Standard drinks: SUDOSE # Joints: SUDOSU	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:	# Standard drinks: # Joints:

*Route Code list	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-UP FOLLOW-UP

VISITUM

Node #: _____ CTP ID #: _____ USUBID _____

Participant ID #: _____

Assessment Date: _____ / _____ / _____
 SUTDC _____ / _____ / _____

4640 Timeline Follow-Back—Follow-Up (continued)

Day	SUSPID 8	9	10	11	12	13	14
1 Date	SUTDTC month / day	month / day	month / day	month / day	month / day	month / day	month / day
2 ^{SUTRT} Alcohol	# Standard drinks: SUDOSE	# Standard drinks: SUDOSU	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
3 ^{SUTRT} Marijuana	# Joint: SUDOSE	# Joint: SUDOSU	# Joint:	# Joint:	# Joint:	# Joint:	# Joint:
4 ^{SUTRT} Cigarettes	# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
5 Other tobacco	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →
5a If Yes: Specify other tobacco (check all used)	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar ^{SUTRT} <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe	<input type="checkbox"/> Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe
6 ^{SUTRT} Cocaine	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: <u>SURROUTE</u>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____
7 ^{SUTRT} Amphetamine	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: <u>SURROUTE</u>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____
8 ^{SUTRT} Methamphetamine	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: <u>SURROUTE</u>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____
9 ^{SUTRT} Sedatives	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> →
10 ^{SUTRT} Opiates	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: <u>SURROUTE</u>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____
11 Other 1 (specify) ^{SUTRT}	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: <u>SURROUTE</u>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____
12 Other 2 (specify) ^{SUTRT}	^{SUDCCUR} No <input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: <u>SURROUTE</u>	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> → Route*: _____

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

CTN-0046

S-CAST

SUCAT=TIMELINE FOLLOW-BACK FOLLOW-UP

VISITUM

USUBJID

Node#:

CTP ID #:

Participant ID #:

Visit #:

Assessment Date:

SUDTC

year

month

day

4640 Timeline Follow-Back—Follow-Up (continued)

Day	SUSPID	15	16	17	18	19	20	21
1 Date		SUSTDTC month / day	month / day	month / day	month / day	month / day	month / day	month / day
2 Alcohol SUTRT		# Standard drinks: SUDOSE SUDOSU	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
3 Marijuana SUTRT		# Joints: SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4 Cigarettes SUTRT		# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
5 Other tobacco SUTRT		<input type="checkbox"/> No <input type="checkbox"/> Yes → Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe SUTRT	<input type="checkbox"/> No <input type="checkbox"/> Yes → Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe SUTRT	<input type="checkbox"/> No <input type="checkbox"/> Yes → Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe SUTRT	<input type="checkbox"/> No <input type="checkbox"/> Yes → Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe SUTRT	<input type="checkbox"/> No <input type="checkbox"/> Yes → Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe SUTRT	<input type="checkbox"/> No <input type="checkbox"/> Yes → Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe SUTRT	<input type="checkbox"/> No <input type="checkbox"/> Yes → Chew <input type="checkbox"/> Cigar <input type="checkbox"/> Dip <input type="checkbox"/> Pipe SUTRT
5a If Yes: Specify other tobacco (check all used)								
6 Cocaine SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE
7 Amphetamine SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE
8 Methamphetamine SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE
9 Sedatives SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes
10 Opiates SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE
11 Other 1 (specify) SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE
12 Other 2 (specify) SUTRT		SUOCCUR <input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE	<input type="checkbox"/> No <input type="checkbox"/> Yes Route*: SURROUTE

* Route Codelist	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

S-CAST

SUCAT=TIMELINE FOLLOW-BACK FOLLOW-UP

VISITUM

 Node #: _____ CTP ID #: _____ USUBJID _____ Participant ID #: _____ Assessment Date: _____ / _____ / _____
 SUTDC / _____ / _____
 SUTDC / _____ / _____

4640 Timeline Follow-Back—Follow-Up (continued)

Day	SUSPID	22	23	24	25	26	27	28
1 Date		SUTDTC month / day						
2 SUTRT Alcohol		# Standard drinks: SUDOSE	# Standard drinks: SUDOSE	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:	# Standard drinks:
3 SUTRT Marijuana		# Joints: SUDOSE	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:	# Joints:
4 SUTRT Cigarettes		# Cigarettes/day: SUDOSE	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:	# Cigarettes/day:
5 Other tobacco		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →
5a If Yes: Specify other tobacco (check all used)		Chew SUTRT Dip SUTRT	Cigar Pipe	Cigar Pipe	Cigar Pipe	Cigar Pipe	Cigar Pipe	Cigar Pipe
6 SUTRT Cocaine		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →
7 SUTRT Amphetamine		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →
8 SUTRT Methamphetamine		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →
9 SUTRT Sedatives		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →
10 SUTRT Opiates		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →
11 Other 1 (specify) SUTRT		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →
12 Other 2 (specify) SUTRT		SUOCCR No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →	No Yes →

*Route Code list	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

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: EX

Node #: _____ CTP Site ID #: _____ Participant ID #: _____
Assessment Date: _____
month / day / year

USUBJID

EXDTC

EXCAT=TREATMENT TRACKING FORM

4641 Treatment Tracking Form

Study week number: VISITNUM

EXSTDTC

Week start date: _____
month / day / year

Week end date: EXENDTC

month / day / year

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:

	Scheduled Hours	Actual Hours EXDOSU
1 Total outpatient/IOP treatment hours EXTRT	<u>EXDOSRGM</u> _____	<u>EXDOSE</u> _____
2 Individual outpatient/IOP treatment hours EXTRT	<u>EXDOSRGM</u> _____	<u>EXDOSE</u> _____
3 Group outpatient/IOP treatment hours EXTRT	<u>EXDOSRGM</u> _____	<u>EXDOSE</u> _____

4 Did the participant attend other substance abuse treatment at the CTP?

- ☐ No If No: STOP. This form is complete. 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 (check all that apply)	Scheduled Hours	Actual Hours EXDOSU
<input type="checkbox"/> Outpatient detox EXTRT	<u>EXDOSRGM</u> _____	<u>EXDOSE</u> _____
<input type="checkbox"/> Inpatient detox EXTRT	<u>EXDOSRGM</u> _____	<u>EXDOSE</u> _____
<input type="checkbox"/> Residential EXTRT	<u>EXDOSRGM</u> _____	<u>EXDOSE</u> _____
<input type="checkbox"/> Methadone EXTRT	<u>EXDOSRGM</u> _____	<u>EXDOSE</u> _____

6 Comments: DATA NOT STORED

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

DOMAIN: LB

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID

Assessment Date: _____ LBDTC
month / day / year Visit #: VISITNUM

LBCAT=DRUG SCREEN

4642 Urine Drug Screen

Section I: Urine Collection

1 Was a urine sample obtained?

☐ No → If No: 1a Why was a urine sample not obtained (check only one)?

LBSTAT/LBREASND

- ☐ Participant reported being unable to provide sample
☐ Participant refused to provide sample
☐ Study staff error
☐ Other (specify): _____

☐ Yes

QNAM=LBTEMP

QLABEL= URINE TEMP WITHIN EXPECTED RANGE

IDVAR=LBSEQ

2 Urine temperature within expected range (between 90° and 99° F)?

☐ No* →
☐ Yes

* If the urine sample was not within the expected range or was not valid on the adulterant test, please collect another sample from the participant. Do not test samples that are not within the expected range or are not valid.

3 Does the adulterant test indicate that the test was valid?

☐ No* →
☐ Yes

QNAM=LBABNORM
QLABEL= URINE POTENTIALLY ABNORMAL
IDVAR=LBSEQ

Section II: Urine Drug Screen Results

LBORRES

LBTEST	Negative	Positive	Unknown	Agree with TLFB?
4 Methamphetamine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes
5 THC (marijuana)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes
6 Cocaine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes
7 Opioids (2000)*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes
8 Amphetamine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes
9 Benzodiazepine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> No <input type="checkbox"/> Yes

10 Comments: DATA NOT STORED

QNAM=LBAGREE
QLABEL= LAB AGREES WITH TLFB
IDVAR=LBSEQ

4643 Urine Pregnancy Test and Birth Control Assessment

LBCAT=PREGNANCY TEST

ONLY COMPLETE THIS FORM FOR FEMALES

Pregnancy Test

LB.LBTEST

1 Was a pregnancy test performed? ☐ No ☐ Yes LB.LBSTAT

2 Date of pregnancy test: _____ / _____ / _____ LB.LBDTC
month day year

3 Pregnancy test result (4631 Study Eligibility, Q 17): ☐ Negative ☐ Positive LB.LBORRES

Breastfeeding—Complete only during Baseline/Screening

SC.SCCAT=BIRTH CONTROL ASSESSMENT

4 Is the participant breastfeeding (4631 Study Eligibility, Q 17)? ☐ No ☐ Yes
SC.SCTEST

SC.SCORRES

Birth Control Method—Complete only during Baseline/Screening

SC.SCTEST

5 Does the participant agree to use an acceptable method of birth control (4631 Study Eligibility, Q 7)?

☐ No

SC.SCTEST

☐ Yes

→ Indicate all methods of birth control the participant agrees to use (answer all questions):

SC.SCORRES

SC.SCORRES

5b Abstinence	<input type="checkbox"/> No <input type="checkbox"/> Yes
5c Barrier	<input type="checkbox"/> No <input type="checkbox"/> Yes
5d IUD	<input type="checkbox"/> No <input type="checkbox"/> Yes
5e Levonorgestrel implant	<input type="checkbox"/> No <input type="checkbox"/> Yes
5f Medroxyprogesterone acetate injection	<input type="checkbox"/> No <input type="checkbox"/> Yes
5g Oral contraceptives	<input type="checkbox"/> No <input type="checkbox"/> Yes
5h Patch	<input type="checkbox"/> No <input type="checkbox"/> Yes
5i Surgical sterilization	<input type="checkbox"/> No <input type="checkbox"/> Yes
5j Other	<input type="checkbox"/> No <input type="checkbox"/> Yes
5k Specify: _____	

Value is SC.SCORRES for question 5j

6 Comments (print; limit 200 characters): _____

DATA NOT STORED

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

☐ ₁ Participant unavailable ☐ ₂ Data collection error ☐ ₃ Participant unable/unwilling to answer
Fields affected: ☐ ₀ Entire CRF ☐ ₁ Questions (specify): _____

DOMAIN: VS

Node #: _____ CTP Site ID #: _____ Participant ID #: _____ USUBJID
Assessment Date: _____ VSDTC
month / day / year Visit #: VISITNUM

4644 Vital Signs and Weight

Reading	A Pulse VSTEST	Blood Pressure (sitting) (4631 Study Eligibility, Q 14)		D Weight VSTEST (Screening, Weeks 5, 10)	E Height VSTEST (Screening)
		B Systolic VSTEST	C Diastolic VSTEST		
VSSPID 1	VSORRES _____	VSORRES _____	VSORRES _____	VSORRES _____ lbs VSORRESU	VSORRES _____ in VSORRESU
If the systolic blood pressure for the first reading is ≥ 140 or < 90 OR the diastolic blood pressure for the first reading is ≥ 90 or < 65 then wait for five minutes and then repeat the assessment.					
		Blood Pressure (sitting) VSTEST (4631 Study Eligibility, Q 14) VSTEST			
		B Systolic	C Diastolic		
VSSPID 2		VSORRES _____	VSORRES _____		
If two blood pressure readings were completed then average the systolic readings and average the diastolic readings and record the averages in the appropriate fields below.					
VSSPID 3	Average of 1 and 2	VSORRES _____	VSORRES _____		
F Comments (print; limit, 200 characters): DATA NOT STORED _____ _____ _____ _____					

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S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ SITEID Participant ID #: _____ USUBJID

Assessment Date: _____ QSDTC / _____ / _____
month day year

Visit #: _____ VISITNUM

4645 Withdrawal Scale—Tobacco

Please rate the following items based on how you have felt or what you have noticed over the last 24 hours. Rate the items by checking the box by the number that best reflects how you have generally felt during this time.

QSTEST

QSORRES/QSSTRES

QSEVLINT=P24

QSTESTCD

WST01

WST02

WST03

WST04

WST05

WST06

WST07

WST08

		None	Slight	Mild	Moderate	Severe
1	Desire to smoke	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
2	Anger, irritability, frustration	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
3	Anxiety, nervousness	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
4	Difficulty concentrating	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
5	Impatience, restlessness	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
6	Hunger	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
7	Awakening at night	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
8	Depression	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4

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S-CAST

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answerFields affected: ☐ Entire CRF ☐ Questions (specify): _____Node #: _____ CTP Site ID #: SITEID Participant ID #: USUBJIDAssessment Date: _____ QSDTC / _____ / _____
month day year Week #: VISITNUM

4646 Protocol Violation Log (PVL)

To be filled in by person(s) reporting this protocol violation:

Date of violation:	____ / ____ / ____ <small>month day year</small>
Violation type:	<u>QSORRES/QSSTRES</u> Enter code number from Violation Type Code List on next page. If Other is indicated, please provide the specification: _____ <div><u>IDVAR = 'QSSEQ';</u> <u>IDVARVAL = left(pat(qsseq,best));</u> <u>QNAM = 'PVL03';</u> <u>QLABEL = 'COMMENT BASED ON PVL02';</u> <u>QVAL = left(pvl03);</u> <u>IDVAR - SQ1 - SQ9 = VISITNUM</u></div>
Description of violation:	<u>QSORRES/QSSTRES</u>
Has this protocol violation been resolved?	<input type="checkbox"/> No <input type="checkbox"/> Yes <u>QSORRES/QSSTRES</u> If Yes: Indicate resolution/corrective action below.
Protocol violation resolution/corrective action:	<u>QSORRES/QSSTRES</u>

Comments:

DATA NOT STORED

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

☐ Participant unavailable ☐ Data collection error ☐ Participant unable/unwilling to answer
Fields affected: ☐ Entire CRF ☐ Questions (specify): _____

Node #: _____ CTP Site ID #: _____ Participant ID #: _____

Assessment Date: ____/____/____
month day year Week #: _____

4646 Violation Type Code List (PVL) (continued)

01 Informed Consent Procedures 01A No consent/assent obtained 01C Invalid/incomplete informed consent 01D Unauthorized assessments and/or procedures conducted prior to obtaining informed consent 01E Other (specify): _____	05 Study Procedures/Assessments 05A Protocol required procedures not obtained 05C Procedures/Assessments obtained outside the visit timeframes 05D Other (specify): _____	09 Behavioral Intervention 09A Intervention not provided per protocol schedule or visit window timeframe 09C 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): _____	