

# Form 226—Adverse Event

Page 1 of 1

DOMAIN: AE

Study Number: STUDYID

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Node:

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Site:

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Evaluator #:

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ID #: USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment: AEDTC (MM/DD/YYYY)																						
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Treatment phase: (Mark one only)	<input type="radio"/> Screening <input type="radio"/> Induction/stabilization <input type="radio"/> Post Study <input type="radio"/> Early termination	VISITNUM	<input type="radio"/> Taper <input type="radio"/> End of taper <input type="radio"/> Post taper	<input type="radio"/> 1 Month post taper <input type="radio"/> 3 Months post randomization <input type="radio"/> 3 Months post taper																						
EPOCH																										

1. Adverse event number  
(Start with 001, and continue through the end of the study):

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AESPID

9. Date of onset: AESTDTC

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2. Description (200 characters):

AETERM
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OPENED:



MD signature and date:  
THIS DATA NOT ENTERED

3. Type of report:

- ☐ Anticipated  
☐ Unanticipated  
☐ Intercurrent illness  
☐ Withdrawal

4. Study drug related: AEREL

- ☐ Definitely  
☐ Probably  
☐ Possibly  
☐ Remotely  
☐ Definitely not  
☐ Unknown

10. Date of resolution/Change in severity: AEENDTC

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☐ Unresolved at the end of study participation

AEENRF

5. Severity: AESEV

- ☐ Mild  
☐ Moderate  
☐ Severe  
☐ Life threatening \*

6. Action taken regarding study drug:

- ☐ None  
☐ Discontinued permanently  
☐ Discontinued temporarily (>24 hour delay)  
☐ Reduced dose  
☐ Increased dose  
☐ Delayed dose (24 hour delay or less)

11. Outcome: AEOUT

- ☐ Resolved, no sequelae  
☐ Not yet resolved, but improving  
☐ Not yet resolved, no change  
☐ Resulted in chronic condition, severe and/or permanent  
☐ Not yet resolved, worsening  
☐ Deceased \*  
☐ Unknown

7. Other action taken (mark all that apply):

- ☐ None  
☐ Therapy pharm. (OTC or RX) \*\*  
☐ Therapy non-pharm.  
☐ Hospitalization \*

CLOSED:



MD signature and date:  
THIS DATA NOT ENTERED

8. Serious: AESER

- ☐ Yes \*  
☐ No

THIS DATA NOT ENTERED

52725

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Serial Number:

AEF003-08/02/04-Final v.2

\* Complete Serious Adverse Event form

\*\* Complete ConMed form

## Form 286—Adjective Rating Scale for Withdrawal

Study Number: STUDYID

Node:

Site:

Evaluator #: QSEVAL

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ID #: USUBJID

Name Code:

Week #:

Study Day:

Date of Assessment: QSDTC (MM/DD/YYYY)

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Treatment phase:  
(Mark one only)

EPOCH

- ☐ Screening  
☐ Induction/stabilization  
☐ Early termination

VISITNUM

- ☐ Taper  
☐ End of taper  
☐ Post taper

- ☐ 1 Month post taper  
☐ 3 Months post randomization  
☐ 3 Months post taper

Please fill in the circle which best describes how you have been feeling in the last 24 hours.

QSEVLINT=-PT24H

QSORRES

NONEMODERATESEVERE

QSTEST

	0	1	2	3	4	5	6	7	8	9
1. Muscle cramps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Depressed or sad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Painful joints	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Excessive yawning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Hot or cold flashes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Trouble getting to sleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Sick to stomach	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Irritable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Runny nose	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Poor appetite	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Weak knees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Excessive sneezing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Tense, jittery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Watery eyes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Abdominal cramps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Fitful sleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2	3	4	5	6	7	8	9

Please mark bubbles FULLY

Correct



Incorrect



53614

THIS DATA NOT ENTERED

Serial Number:

QSCAT=ADDICTION SEVERITY INDEX LITE  
Form 293—Addiction Severity Index Lite CF

Page 1 of 16

DOMAIN: QS

StudyNumber: STUDYID

Node:

Site:

Evaluator#:

QSEVAL

ID #:	USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment:	QSDTC
Treatment phase: (Mark one only)	<input type="radio"/> Screening <input type="radio"/> Induction/stabilization <input type="radio"/> Early termination	VISITNUM	<input type="radio"/> Taper <input type="radio"/> End of taper <input type="radio"/> Post taper	<input type="radio"/> 1 Month post taper <input type="radio"/> 3 Months post randomization <input type="radio"/> 3 Months post taper		
EPOCH						

See page 16 for instructions and codes

Circled items asked at follow-up  
\* Starred items rephrased at follow-up as "Since the last ASI interview,..."

QSSCAT=GENERAL INFORMATION

Comments:

THIS DATA NOT ENTERED

QSTEST

QSORRES

G4. Date of admission:

		/			/				
(MM)			(DD)			(YYYY)			

G8.

Class:

- ☐ 1-Intake  
☐ 2-Follow-up

G9.

Contact code:

- ☐ 1-In Person  
☐ 2-Telephone (Intake ASI must be in person)  
☐ 3-Mail

G10.

Gender:

- ☐ 1-Male  
☐ 2-Female

G12.

Special:

- ☐ 1-Patient terminated  
☐ 2-Patient refused  
☐ 3-Patient unable to respond  
☐ -98-NA

1	2	3	4	5	6	7	8	9	0
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Serial Number:

ASI003-02/18/2003-Final V.1

30629

**GENERAL INFORMATION**  
(continued)

Page 2 of 16

DOMAIN: QS

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment: <b>QSDTC</b> (MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>

G14. How long have you lived at your current address?  
**QSTEST**  /  **QSORRES**

**QSORRESU='YEAR'** **QSORRESU='MONTH'**

G16. Date of birth:  
 /  /   
(MM) (DD) (YYYY)

G17. Of what race do you consider yourself?

- ☐ 1-White (Not Hispanic)
- ☐ 2-Black (Not Hispanic)
- ☐ 3-American Indian
- ☐ 4-Alaskan Native
- ☐ 5-Asian/Pacific
- ☐ 6-Hispanic - Mexican
- ☐ 7-Hispanic - Puerto Rican
- ☐ 8-Hispanic - Cuban
- ☐ 9-Other Hispanic

G18. Do you have a religious preference?

- ☐ 1-Protestant
- ☐ 2-Catholic
- ☐ 3-Jewish
- ☐ 4-Islamic
- ☐ 5-Other: \_\_\_\_\_
- ☐ 6-None

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

- ☐ 1-No **QSEVLNT=-P30D**
- ☐ 2-Jail
- ☐ 3-Alcohol or Drug Treat.
- ☐ 4-Medical Treatment
- ☐ 5-Psychiatric Treatment
- ☐ 6-Other: \_\_\_\_\_
  - A place, theoretically, without access to drugs/alcohol.

G20. How many days?

**QSEVLNT=-P30D**  **QSORRESU='DAY'**

- "NN" if question G19 is "No". Refers to total number of days detained in the past 30 days.

Comments:

THIS DATA NOT ENTERED

THIS DATA NOT ENTERED

Serial Number:

30629  
ASI003-02/18/2003-Final V.1

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment: <b>QSDTC</b> (MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**QSTEST****QSORRES**

- \* M1. How many times in your life have you been hospitalized for medical problems?    
• Include O.D.'s & D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications). Enter the number of **overnight** hospitalizations for medical problems.
- M3. Do you have any chronic medical problems which continue to interfere with your life? ☐ 1-Yes ☐ 0-No  
• If "Yes", specify in comments.  
• A chronic medical condition is a serious physical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities.
- M4. Are you taking any prescribed medication on a regular basis for a physical problem? ☐ 1-Yes ☐ 0-No  
• If "Yes", specify in comments.  
• Medication prescribed by a M.D. for medical conditions; **not psychiatric medicines**. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems.
- M5. Do you receive a pension for a physical disability? ☐ 1-Yes ☐ 0-No  
• If "Yes", specify in comments.  
• Include Worker's Compensation, exclude psychiatric disability.
- M6. How many days have you experienced medical problems in the past 30 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 patient were abstinent (e.g., cirrhosis of the liver, abscesses from needles, etc.).
- For questions M7 & M8, please ask patient to use the Patient's Rating Scale.
- M7. How troubled or bothered have you been by these medical problems in the past 30 days? ☐ ☐ ☐ ☐ ☐  
• Restrict response to problem days of question M6.
- M8. How important to you now is treatment for these medical problems? ☐ ☐ ☐ ☐ ☐  
• Refers to the need for **new** or **additional** medical treatment by the patient.

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

- M10. Patient's misrepresentation? ☐ 1-Yes ☐ 0-No
- M11. Patient's inability to understand? ☐ 1-Yes ☐ 0-No

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

Comments:

THIS DATA NOT ENTERED

QSORRESU='DAY'

QSEVLNT=-P30D

QSEVLNT=-P30D

30629

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Serial Number:

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment: <b>QSDTC</b> (MM/DD/YYYY)	Site:
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**\* E1.** **QSTEST** Education completed   
• GED = 12 years, note in comments A-Yrs. B-Mos.  
• Include formal education only. **QSORRESU='MONTH'**  
**QSORRESU='YEAR'**

**\* E2.** Training or technical education completed   
• Formal/organized training only. Mos.  
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? ☐ 1-Yes ☐ 0-No  
• Valid license; not suspended/revoked.

**E5.** Do you have an automobile available for use? ☐ 1-Yes ☐ 0-No  
• 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?   
• Full time=35+ hours weekly; does not necessarily mean most recent job. A-Yrs. B-Mos. **QSORRESU='MONTH'**  
**QSORRESU='YEAR'**

**\* E7.** Usual (or last) occupation 

1 2 3 4 5 6 7 8 9 0

  
See Hollingshead categories on page 16  
(Specify in detail-30 characters)

**E9.** Does someone contribute the majority of your support? ☐ 1-Yes ☐ 0-No

**E10.** Usual employment pattern, past three years:  
☐ 1-Full time (35+ hours) ☐ 5-Military Service  
☐ 2-Part time (reg. hrs) ☐ 6-Retired/disability  
☐ 3-Part time (irreg. hrs) ☐ 7-Unemployed  
☐ 4-Student ☐ 8-In controlled environment

• 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?   
• Include "under the table" work, paid sick days, and vacations.

Comments:

THIS DATA NOT ENTERED

QSEVLINT=-P3Y

QSORRESU='DAY'

QSEVLNT=-P30D

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Serial Number:

30629

ASI003-02/18/2003-Final V.1

# EMPLOYMENT/SUPPORT STATUS (continued)

Page 5 of 16

DOMAIN: QS

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment: <b>QSDTC</b> (MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>

**QSTEST** **QSORRES**  
For questions E12-17: How much money did you receive from the following sources in the past 30 days?

- E12. Employment: \$   
• **Net** or "take home" pay, include any "under the table" money.
- E13. Unemployment compensation: \$
- E14. Welfare: \$   
• Include food stamps, transportation money provided by an agency to go to and from treatment.
- E15. Pensions, benefits, or social security: \$   
• Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.
- E16. Mate, family or friends: \$   
• 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. Illegal **Cash** obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. \$   
**Do not** attempt to convert drugs exchanged to a dollar value.
- E18. How many people depend on you for the majority of their food, shelter, etc.?   
• Must be regularly depending on patient, do include alimony/child support, do not include the patient or self-supporting spouse, etc.
- E19. How many days have you experienced employment problems in the past 30?   
• Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

For question E20-21, please ask patient to use the Patient's Rating Scale.

- E20. How troubled or bothered have you been by these employment problems in the past 30 days? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5  
• If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems.
- E21. How important to you *now* is counseling for these employment problems? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5  
• The patient's rating in question E20-21 refer to question E19.  
• Stress help in finding or preparing for a job, not giving them a job.

## CONFIDENCE RATINGS

Is the above information significantly distorted by:

- E23. Patient's misrepresentation? ☐ 1-Yes ☐ 0-No
- E24. Patient's inability to understand? ☐ 1-Yes ☐ 0-No

Comments:

THIS DATA NOT ENTERED

QSEVLNT=-P30D

QSORRESU='DOLLAR'

QSEVLNT=-P30D

QSORRESU='DAY'

QSEVLNT=-P30D

QSEVLNT=-P30D

30629

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Serial Number:

ASI003-02/18/2003-Final V.1

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment:	<b>QSDTC</b> (MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

QSTEST	QSEVLNT=P30D	QSORRES		Route of administration: 1-Oral 2-Nasal 3-Smoking 4-Non IV injection 5-IV injection 98-NA  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.
		Past 30 A-Days	Lifetime use B-Years	
D1. Alcohol - (any use at all)		<input type="text"/>	<input type="text"/>	
D2. Alcohol - (to intoxication)		<input type="text"/>	<input type="text"/>	
D3. Heroin		<input type="text"/>	<input type="text"/>	
D4. Methadone		<input type="text"/>	<input type="text"/>	
D5. Other opiates/ analgesics		<input type="text"/>	<input type="text"/>	
D6. Barbiturates		<input type="text"/>	<input type="text"/>	
D7. Other sed/ hyp/tranq.		<input type="text"/>	<input type="text"/>	
D8. Cocaine		<input type="text"/>	<input type="text"/>	
D9. Amphetamines		<input type="text"/>	<input type="text"/>	
D10. Cannabis		<input type="text"/>	<input type="text"/>	
D11. Hallucinogens		<input type="text"/>	<input type="text"/>	
D12. Inhalants		<input type="text"/>	<input type="text"/>	
D13. More than one substance per day (including alcohol).		<input type="text"/>	<input type="text"/>	

Comments:

**THIS DATA NOT ENTERED**

30629

**THIS DATA NOT ENTERED**

Serial Number:

ASI003-02/18/2003-Final V.1



# ALCOHOL/DRUGS (continued)

Page 7 of 16

DOMAIN: QS

USUBJID	Name Code:	Date of Assessment:	QSDTC (MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

**QSTEST** **QSORRES**

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

Comments:

THIS DATA NOT ENTERED

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

\* D19. Alcohol abuse

\* D20. Drug abuse  
Include detoxification, halfway houses, in/outpatient counseling and AA or NA (if 3+ meetings within one month period)

How many of these were detox only:

D21. Alcohol?

D22. Drugs?

• If D19="00", then question D21 is "NN"

If D20="00", then question D22 is "NN"

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

D23. Alcohol

\$

D24. Drugs

• Only count actual money spent. What is the \$

\$

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

■ Include AA/NA

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

For questions D28-31, please ask patient to use the Patient's Rating Scale. The patient is rating the need for additional substance abuse treatment.

D28. How troubled or bothered have you been the past 30 days by these alcohol problems? 0 1 2 3 4

D30. How important to you now is treatment for these alcohol problems? 0 1 2 3 4

D27. How many days in the past 30 have you experienced drug problems?

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

D29. How troubled or bothered have you been in the past 30 days by these drug problems? 0 1 2 3 4

D31. How important to you now is treatment for these drug problems? 0 1 2 3 4

## CONFIDENCE RATINGS

Is the above information significantly distorted by:

D34. Patient's misrepresentation? 0 1-Yes 0 0-No

D35. Patient's inability to understand? 0 1-Yes 0 0-No

QSEVLNT=-P30D QSORRESU='DOLLAR'

QSEVLNT=-P30D QSORRESU='DOLLAR'

QSEVLNT=-P30D QSORRESU='DAY'

QSEVLNT=-P30D QSORRESU='DAY'

QSEVLNT=-P30D

QSEVLNT=-P30D QSORRESU='DAY'

QSEVLNT=-P30D

THIS DATA NOT ENTERED

Serial Number:

ASI003-02/18/2003-Final V.1

30629

ID #: **USUBJID**

Name Code:

Date of Assessment: **QSDTC** (MM/DD/YYYY)

Site:

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- QSTEST**  
L1. Was this admission prompted or suggested by the criminal justice system?  
☐ 1-Yes ☐ 0-No  
• judge, probation/parole officer, etc.

- QSORRES**  
L2. Are you on probation or parole?  
☐ 1-Yes ☐ 0-No  
• Note duration and level in comments.

How many times in your life \* have you been arrested and charged with the following:

- \* L3. Shoplifting/vandalism 

--	--
- \* L4. Parole/probation violations 

--	--
- \* L5. Drug charges 

--	--
- \* L6. Forgery 

--	--
- \* L7. Weapons offense 

--	--
- \* L8. Burglary/larceny/B&E 

--	--
- \* L9. Robbery 

--	--
- \* L10. Assault 

--	--
- \* L11. Arson 

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Include total number of counts, not just convictions. Do not include juvenile (pre-age 18) crimes, unless they were charged as an adult.

Include formal charges only.

Comments:

**THIS DATA NOT ENTERED**

30629

**THIS DATA NOT ENTERED**

Serial Number:

ASI003-02/18/2003-Final V.1

**LEGAL STATUS**  
(continued)

Page 9 of 16

DOMAIN: QS

ID #: USUBJID

Name Code:

Date of Assessment: QSDTC (MM/DD/YYYY)

Site:

**QSTEST**

**QSORRES**

\* (L12)

Rape

\* (L13)

Homicide/manslaughter

\* (L14)

Prostitution

\* (L15)

Contempt of court

\* (L16)

Other: \_\_\_\_\_

\* (L17)

How many of these charges resulted in convictions?

- If L3-16="00", then question L17="NN".
- Do not include misdemeanor offenses from questions L18-20 below.
- Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas.

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

\* (L18)

Disorderly conduct, vagrancy, public intoxication

\* (L19)

Driving while intoxicated

\* (L20)

Major driving violations

- Moving violations: speeding, reckless driving, no license, etc.

\* (L21)

How many months were you incarcerated in your life?

Mos.

- If incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated.

Comments:

THIS DATA NOT ENTERED

QSORRESU='MONTH'

30629

THIS DATA NOT ENTERED

Serial Number:

ASI003-02/18/2003-Final V.1

**LEGAL STATUS**  
(continued)

Page 10 of 16

DOMAIN: QS

ID #: USUBJID

Name Code:

Date of Assessment: QSDTC (MM/DD/YYYY)

Site:

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**QSTEST**

**QSORRES**

- L24. Are you presently awaiting charges, trial or sentence? ☐ 1-Yes ☐ 0-No
- L25. What for? (If multiple charges, use most severe.)
- Refers to question L24. If more than one, choose most severe.
  - Don't include civil cases, unless a criminal offense is involved.
- ☐ 03-Shoplift ☐ 08-Burglary ☐ 13-Homicide ☐ 19-DWI
- ☐ 04-Prob. viol. ☐ 09-Robbery ☐ 14-Prostitution ☐ 20-Major driving violation
- ☐ 05-Drug ☐ 10-Assault ☐ 15-Contempt
- ☐ 06-Forgery ☐ 11-Arson ☐ 16-Other ☒ -98-NA
- ☐ 07-Weapons ☐ 12-Rape ☐ 18-Disorderly conduct

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

--	--
- Include being arrested and released on the same day.

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

--	--
- 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 patient to use the Patient's Rating Scale

- L28. How serious do you feel your present legal problems are? ☐ ☐ ☐ ☐ ☐
- Exclude civil problems.
- L29. How important to you *now* is counseling or referral for these legal problems? ☐ ☐ ☐ ☐ ☐
- Patient 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. Patient's misrepresentation? ☐ 1-Yes ☐ 0-No
- L32. Patient's inability to understand? ☐ 1-Yes ☐ 0-No

Comments: THIS DATA NOT ENTERED

QSORRESU='DAY'

QSEVLINT=-P30D

QSORRESU='DAY'

QSEVLINT=-P30D

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

THIS DATA NOT ENTERED

Serial Number:

ASI003-02/18/2003-Final V.1

ID #: **USUBJID**

Name Code:

Date of Assessment: **QSDTC** (MM/DD/YYYY)

Site:

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**QSTEST****QSORRES****F1.**Marital  
Status:

- ☐ 1-Married    ☐ 4-Separated  
☐ 2-Remarried    ☐ 5-Divorced  
☐ 3-Widowed    ☐ 6-Never Married

Common-law marriage=1. Specify in comments.

**F3.**

Are you satisfied with this situation?

Satisfied=generally liking the situation. Refers to question F1.

- ☐ 2-Yes    ☐ 0-No    ☐ 1-Indifferent

\*

**F4.**

Usual living arrangements (past 3 yrs.):

- ☐ 1-With sexual partner and children    ☐ 6-With friends  
☐ 2-With sexual partner alone    ☐ 7-Alone  
☐ 3-With children alone    ☐ 8-Controlled environment  
☐ 4-With parents    ☐ 9-No stable arrangements  
☐ 5-With family

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.**

Are you satisfied with these living arrangements?

- ☐ 2-Yes    ☐ 0-No    ☐ 1-Indifferent

Do you live with anyone who:

**F7.**Has a current alcohol problem? ☐ 1-Yes    ☐ 0-No**F8.**Uses non-prescribed drugs? ☐ 1-Yes    ☐ 0-No**F9.**

With whom do you spend most of your free time?  
If a girlfriend/boyfriend is considered as family by  
patient, then they must refer to them as family  
throughout this section, not as a friend.

- ☐ 1-Family    ☐ 2-Friends    ☐ 3-Alone

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

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

- ☐ 2-Yes    ☐ 0-No    ☐ 1-Indifferent

Comments:

**THIS DATA NOT ENTERED****QSEVLINT=-P3Y**

Only one answer per question, please.

**THIS DATA NOT ENTERED**

Serial Number:

ASI003-02/18/2003-Final V.1

# **FAMILY/SOCIAL RELATIONS** (continued)

Page 12 of 16

**DOMAIN: QS**

ID #: **USUBJID**

Name Code:

Date of Assessment: **QSDTC** (MM/DD/YYYY)

Site:

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

**QSORRES**

**QSTEST**

A. Past 30 days

B. In your life

- (F18.) Mother ☐ 1-Yes ☐ 0-No ☐ NA
- (F19.) Father ☐ 1-Yes ☐ 0-No ☐ NA
- (F20.) Brothers/sisters ☐ 1-Yes ☐ 0-No ☐ NA
- (F21.) Sexual partner/spouse ☐ 1-Yes ☐ 0-No ☐ NA
- (F22.) Children ☐ 1-Yes ☐ 0-No ☐ NA
- (F23.) Other significant family:    
 (specify)
- (F24.) Close friends ☐ 1-Yes ☐ 0-No ☐ NA
- (F25.) Neighbors ☐ 1-Yes ☐ 0-No ☐ NA
- (F26.) Co-workers ☐ 1-Yes ☐ 0-No ☐ NA

"Serious problems" mean those that endangered the relationship.

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

- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA
- ☐ 1-Yes ☐ 0-No ☐ NA

**QSEVLINT=-P30D**

Did anyone abuse you:

A. Past 30 days

B. In your life

- F28. Physically (cause you physical harm)? ☐ 1-Yes ☐ 0-No ☐ 1-Yes ☐ 0-No
- F29. Sexually (force sexual advances/acts)? ☐ 1-Yes ☐ 0-No ☐ 1-Yes ☐ 0-No

Comments:

**THIS DATA NOT ENTERED**

30629

**THIS DATA NOT ENTERED**

Serial Number:

Serial number of this page should match page 1

ASI003-02/18/2003-Final V.1

# **FAMILY/SOCIAL RELATIONS** (continued)

Page 13 of 16

DOMAIN: QS

ID #: USUBJID

Name Code:

Date of Assessment: QSDTC (MM/DD/YYYY)

Site:

QSTEST

QSORRES

- (F30) How many days in the past 30 have you had serious conflicts with your family?

For questions F32-34, please ask patient to use the Patient's Rating Scale

- (F32) How troubled or bothered have you been in the past 30 days by these family problems? (1-5)

- (F34) How important to you *now* is treatment or counseling for these family problems? (1-5)

Patient is rating his/her need for counseling for family problems, not whether they would be willing to attend.

- (F31) How many days in the past 30 have you had serious conflicts with other people (excluding family)?

For questions F33-35, ask the patient to use the patient's rating scale

- (F33) How troubled or bothered have you been in the past 30 days by social problems? (1-5)

- (F35) How important to you *now* is treatment or counseling for these social problems? (1-5)

- Include patient's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems.

## CONFIDENCE RATINGS

Is the above information significantly distorted by:

- (F37) Patient's misrepresentation? (1-Yes 0-No)  
(F38) Patient's inability to understand? (1-Yes 0-No)

Comments:

THIS DATA NOT ENTERED

QSEVLINT=-P30D

QSEVLINT=-P30D  
QSORRESU='DAY'

QSEVLINT=-P30D

30629

THIS DATA NOT ENTERED

Serial Number:

ASI003-02/18/2003-Final V.1

ID #: **USUBJID**

Name Code:

Date of Assessment: **QSDTC** (MM/DD/YYYY)

Site:

**QSTEST****QSORRES**

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

\* **P1.** In a hospital or inpatient setting?
 
\* **P2.** As an outpatient or private patient?
 
**P3.** Do you receive a pension for a psychiatric disability? ☐ 1-Yes ☐ 0-No

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.

Have you had a significant period of time, (that was not a **QSEVLINT=-P30D** direct result of drug/alcohol use), in which you have:**A. Past 30 days****B. In your life****P4.** Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No**P5.** Experienced serious anxiety/tension-upright, unreasonably worried, inability to feel relaxed?☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No**P6.** Experienced hallucinations-saw things or heard voices that were not there?☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No**P7.** Experienced trouble understanding, concentrating, or remembering?☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No**P8.** Experienced trouble controlling violent behavior including episodes of rage, or violence?☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No**P9.** Experienced serious thoughts of suicide?  
• Patient seriously considered a plan for taking his/her life.☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No**P10.** Attempted suicide?

- Include actual suicidal gestures or attempts

☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No**P11.** Been prescribed medication for any psychological/emotional problem?

- Prescribed for the patient by MD.

Record "Yes" if a medication was prescribed *even if* the patient is not taking it.☐ 1-Yes ☐ 0-No☐ 1-Yes ☐ 0-No

For questions P8-10, patient could have been under the influence of alcohol/drugs.

Comments:

**THIS DATA NOT ENTERED**

30629

**THIS DATA NOT ENTERED**

Serial Number:



**PSYCHIATRIC STATUS**  
(continued)

Page 15 of 16

DOMAIN: QS

ID #: USUBJID

Name Code:

Date of Assessment: QSDTC (MM/DD/YYYY)

Site:

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QSTEST

QSORRES

(P12)

How many days in the past 30 have you experienced these psychological or emotional problems?

--	--

QSEVLINT=-P30D

QSORRESU='DAY'

- This refers to problems noted in question P4-10

For questions P13 & 14, please ask patient to use the Patient's Rating Scale

(P13)

How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? 0 1 2 3 4 5

QSEVLINT=-P30D

- Patient should be rating the problem days from question P12

(P14)

How important to you *now* is treatment for these psychological or emotional problems? 0 1 2 3 4 5

**CONFIDENCE RATINGS**

Is the above information significantly distorted by:

(P22)

Patient's misrepresentation? 1-Yes 0-No

(P23)

Patient's inability to understand? 1-Yes 0-No

Comments:

THIS DATA NOT ENTERED

30629

THIS DATA NOT ENTERED



Serial Number:

ASI003-02/18/2003-Final V.1

ID #:	Name Code:	Date of Assessment:	(MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/>	<input type="text"/>	<input type="text"/>

Patient Rating Scale	Comments (include question number)
0-Not at all 1-Slightly 2-Moderately 3-Considerably 4-Extremely	THIS DATA NOT ENTERED
<b>Hollingshead Categories</b>	
1. Higher executive, major professional, owner of large business.  2. Business manager of medium sized business, lesser professionals, i.e., nurses, opticians, pharmacists, social workers, teachers.  3. Administrative personnel, manager, minor professionals, owner/proprietor of small business, i.e., bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent. 4. Clerical and sales, technicians, small businesses (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary).  5. Skilled manual-usually having had training (barber, brakeman, chef, electrician, fireman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police, 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 helper, unspecified labor, porter, include unemployed).  8. Homemaker.  9. Student, disabled, no occupation.	

30629

THIS DATA NOT ENTERED

Serial Number:

## Form 333—Dose Log Bup Protocol 0003

StudyNumber:

STUDYID

Node:

Site:

Evaluator#:

ID#:

USUBJID

Name Code:

Week #:

Study Day:

Date of Assessment:

EXDTC (MM/DD/YYYY)

Treatment phase:  
(Mark one only)☐

Screening

☐

Induction/stabilization

☐

Early termination

VISITNUM

☐

Taper

☐

End of taper

☐

Post taper

☐

1 Month post taper

☐

3 Months post randomization

☐

3 Months post taper

Start with the date of the last clinic visit and document each day of participation (do not include today).  
Today's dose will be recorded on NEXT WEEK'S log.

A. Date of dose (MM/DD/YY):	B. Dose taken, as reported:	C. Location	D. Dose frequency: mark one; specify 'other' below
EXSTDTC	EXDOSE EXDOSU	Clinic Home Both	EXDOSFRQ Once daily BID TID QID Other
1. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
2. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
3. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
4. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
5. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
6. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
7. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>
8. <input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/>	<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>

9. Is the patient's final dose recorded above? ☐ Yes ☐ No (dose continuing)

Comments (200 characters):

DOMAIN: CO  
COVAL  
RDOMAIN=EX  
IDVAR=VISITNUM

QNAM=EXFINAL  
QLABEL=IS PATIENT FINAL  
DOSE RECORDED  
IDVAR=VISITNUM

QNAM=EXLOCALE  
QLABEL=LOCATION DOSED  
IDVAR=VISITNUM

THIS DATA NOT ENTERED



Page

of

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Serial Number:

54978



# Form 223—Concomitant Medication

Page 1 of 1

DOMAIN: CM

StudyNumber: STUDYID

Node:

Site:

Evaluator#:

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ID #: USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment: (MM/DD/YYYY)																								
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		/			/																							
Treatment phase: (Mark one only)	<input type="radio"/> Screening <input type="radio"/> Induction/stabilization <input type="radio"/> Post Study	VISITNUM	<input type="radio"/> Taper <input type="radio"/> End of taper <input type="radio"/> Post taper	CMDTC <input type="radio"/> 1 Month post taper <input type="radio"/> 3 Months post randomization <input type="radio"/> 3 Months post taper																								
EPOCH																												

CMCAT=CONCOMITANT

1. Medication number  
(Start with 001 and continue through the end of the study):

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8. Start date: CMSTDTC

		/			/				
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2. Medication (200 characters):

CMTRT
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START:



MD signature and date:

THIS DATA NOT ENTERED

3. Linked to AE # (if not linked, code "000"):

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CMGRPID

4. If not linked to an AE, indication:

CMINDC
--------

9. End date:

CMENDTC

		/			/				
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5. Amount:

						.		
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CMDOSE

6. Units (Select ONE unit that describes in the greatest detail the amount of medication taken by the subject)

- |                                 |                                  |                                     |   |
|---------------------------------|----------------------------------|-------------------------------------|---|
| <input type="radio"/> capsule   | <input type="radio"/> microliter | <input type="radio"/> puff          | <input type="radio"/> teaspoon              |
| <input type="radio"/> drop      | <input type="radio"/> milligram  | <input type="radio"/> spray/squirt  | <input type="radio"/> unknown               |
| <input type="radio"/> grain     | <input type="radio"/> milliliter | <input type="radio"/> suppository   | <input type="radio"/> other (specify below) |
| <input type="radio"/> gram      | <input type="radio"/> ounce      | <input type="radio"/> tablespoon    |   |
| <input type="radio"/> microgram | <input type="radio"/> patch      | <input type="radio"/> tablet/caplet |   |

CMDOSU

--

7. Frequency: CMDOSFRQ

- |                                  |                           |   |
|----------------------------------|---------------------------|---|
| <input type="radio"/> Once daily | <input type="radio"/> TID | <input type="radio"/> PRN                   |
| <input type="radio"/> BID        | <input type="radio"/> QID | <input type="radio"/> Other (specify below) |

--

END:



MD signature and date:

THIS DATA NOT ENTERED

THIS DATA NOT ENTERED

49742



Serial Number:

CMD003-08/02/04-Final v.2

# Form 281—Clinical Opiate Withdrawal Scale

Page 1 of 2 **DOMAIN: QS, VS**

StudyNumber: **STUDYID** Node: Site: Evaluator#: **QSEVAL**

ID #: **USUBJID** Name Code: Week #: Study Day: Date of Assessment: (MM/DD/YYYY)

Treatment phase: (Mark one only) **EPOCH** ☐ Screening **VISITNUM** ☐ Taper **QSDTC/VSDTC** ☐ 1 Month post taper  
☐ Induction/stabilization ☐ End of taper ☐ 3 Months post randomization  
☐ Early termination ☐ Post taper ☐ 3 Months post taper

For each item, mark the choice that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

## QSTEST

### QSORRES

1. Resting pulse rate: *measured after patient is sitting or lying for one minute*

- ☐ 0 - pulse rate 80 or below  
☐ 1 - pulse rate 81-100  
☐ 2 - pulse rate 101-120  
☐ 4 - pulse rate greater than 120

Beats/minute

  

**VS.VSTEST=PULSE RATE**

**VS.VSORRES**

**VS.VSORRESU**

2. GI upset: *over last 1/2 hour*

- ☐ 0 - no GI symptoms  
☐ 1 - stomach cramps  
☐ 2 - nausea or loose stool  
☐ 3 - vomiting or diarrhea  
☐ 5 - multiple episodes of diarrhea or vomiting

**QSEVLINT=-PT30M**

3. Sweating: *over past 1/2 hour not accounted for by room temperature or patient activity*

- ☐ 0 - no report of chills or flushing  
☐ 1 - subjective report of chills or flushing  
☐ 2 - flushed or observable moistness on face  
☐ 3 - beads of sweat on brow or face  
☐ 4 - sweat streaming off face

**QSEVLINT=-PT30M**

4. Tremor: *observation of outstretched hands*

- ☐ 0 - no tremor  
☐ 1 - tremor can be felt, but not observed  
☐ 2 - slight tremor observable  
☐ 4 - gross tremor or muscle twitching

5. Restlessness: *observation during assessment*

- ☐ 0 - able to sit still  
☐ 1 - reports difficulty sitting still, but is able to do so  
☐ 3 - frequent shifting or extraneous movements of legs/arms  
☐ 5 - unable to sit still for more than a few seconds

         

**THIS DATA NOT ENTERED**

Serial Number:

COWS003-02/18/2003-Final V.1

64638

**COWS**  
(continued)

Page 2 of 2 **DOMAIN: QS**

ID #:	Name Code:	Date of Assessment:	(MM/DD/YYYY)	Site:
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**QSTEST**      **QSORRES**

**6. Yawning: observation during assessment**

- ☐ 0 - no yawning
- ☐ 1 - yawning once or twice during assessment
- ☐ 2 - yawning three or more times during assessment
- ☐ 4 - yawning several times/minute

**7. Pupil size:**

- ☐ 0 - pupils pinned or normal size for room light
- ☐ 1 - pupils possibly larger than normal for room light
- ☐ 2 - pupils moderately dilated
- ☐ 5 - pupils so dilated that only the rim of the iris is visible

**8. Anxiety or irritability:**

- ☐ 0 - none
- ☐ 1 - patient reports increasing irritability or anxiousness
- ☐ 2 - patient obviously irritable or anxious
- ☐ 4 - patient so irritable or anxious that participation in the assessment is difficult

**9. Bone or joint aches: if patient was having pain previously, only the additional component attributed to opiate withdrawal is scored**

- ☐ 0 - not present
- ☐ 1 - mild diffuse discomfort
- ☐ 2 - patient reports severe diffuse aching of joints/muscle
- ☐ 4 - patient is rubbing joints or muscles and is unable to sit still because of discomfort

**10. Gooseflesh skin:**

- ☐ 0 - skin is smooth
- ☐ 3 - piloerection of skin can be felt or hairs standing up on arms
- ☐ 5 - prominent piloerection

**11. Runny nose or tearing: not accounted for by cold symptoms or allergies**

- ☐ 0 - not present
- ☐ 1 - nasal stuffiness or unusually moist eyes
- ☐ 4 - nose constantly running or tears streaming down cheeks

Total score:	<div style="border: 1px solid black; width: 20px; height: 20px;"></div>	The total score is the sum of all 11 items. Leave blank if a question was not answered.	Initials of evaluator and date scored:
Score: 5-12=mild; 13-24=moderate; 25-36=moderately severe; more than 36=severe withdrawal			

Please mark bubbles FULLY:

THIS DATA NOT ENTERED

Serial Number:

COWS003-02/18/2003-Final V.1

64638



# Clinic Visit Form (continued)

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment:	<b>EXDTC/CODTC/QSDTC</b> (MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Prescription information (complete at every data visit; complete at non-data visits if a new prescription is given):				# of Tablets:	
				2 mg	8 mg
14. # tablets on hand:				<input type="text"/>	<input type="text"/>
<input type="radio"/> Actual count <input type="radio"/> Self report <input type="radio"/> NA <input type="radio"/> Unk					
15. Dose taken at clinic: <b>EX.DOSE</b>				<input type="text"/>	<input type="text"/>
Total: <input type="text"/> mg Bup				<input type="text"/>	<input type="text"/>
16. Number of days prescribed for: <b>DATEST</b>				<input type="text"/>	
<b>DAORRES</b>				<b>DATEST/DAORRES</b>	<b>DATEST/DAORRES</b>
A. Date of dose (mm/dd/yy)		B. Total dose prescribed:		C/D. Number of tablets:	
<b>DADTC</b>					
17. <input type="text"/>		<input type="text"/>		<input type="text"/>	
18. <input type="text"/>		<input type="text"/>		<input type="text"/>	
19. <input type="text"/>		<input type="text"/>		<input type="text"/>	
20. <input type="text"/>		<input type="text"/>		<input type="text"/>	
21. <input type="text"/>		<input type="text"/>		<input type="text"/>	
22. <input type="text"/>		<input type="text"/>		<input type="text"/>	
23. <input type="text"/>		<input type="text"/>		<input type="text"/>	
24. <input type="text"/>		<input type="text"/>		<input type="text"/>	
25. Total number of tablets prescribed for take-home:				<input type="text"/>	<input type="text"/>
<b>Psychosocial counseling (complete every data visit):</b> <b>QSCAT=PSYCHOSOCIAL COUNSELING</b>					
26. Since the last data visit, has the subject attended psychosocial counseling?					
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA (first data visit)					
26A. If Yes, how many times since the last data visit?					
Individual in-house:		Group in-house		12-step	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
				Other (specify)	
				<input type="text"/>	
<b>Comments (200 characters MAX):</b> <b>DOMAIN: CO</b> <b>COVAL</b> <b>RDOMAIN=DA</b> <b>IDVAR=DASPID</b>					
<b>Comments (30 characters MAX):</b> <b>DOMAIN: CO</b> <b>COVAL</b> <b>RDOMAIN=QS</b> <b>IDVAR=QSSEQ</b>					

MD signature and date:

THIS DATA NOT ENTERED

THIS DATA NOT ENTERED

Serial Number:

CVF003-08/02/04-Final v.2

12156



# Form 251—Demographics Form

Page 1 of 2

DOMAIN: DM, SC

Study Number: **STUDYID**

--	--	--	--	--	--	--	--	--	--

Node:

--	--

Site:

--	--	--	--

Evaluator #:

--	--	--	--

ID #: **USUBJID**

--	--	--	--

Name Code:

--	--	--	--

Week #:

--	--

Study Day:

--	--	--	--

Date of Assessment:

--	--	--	--	--	--	--	--

(MM/DD/YYYY)

Treatment phase:  
(Mark one only)

**EPOCH**

- ☐ Screening  
☐ Induction/stabilization  
☐ Early termination

**VISITNUM**

- ☐ Taper  
☐ End of taper  
☐ Post taper

**DMDTC/SCDTC**

- ☐ 1 Month post taper  
☐ 3 Months post randomization  
☐ 3 Months post taper

1. Sex: **DM.SEX**

- ☐ Male ☐ Female

2. Date of birth: **DM.BRTHDTC**

--	--	--	--	--	--	--	--

(mm/dd/yyyy)

3. Ethnicity/Race: **DM.RACE** (if multiple, then 'MULTIPLE')

For each of the following, answer "Yes" to all that apply to you, and "No" to those that do not.

- ☐ Yes ☐ No White  
☐ Yes ☐ No Black or African American  
☐ Yes ☐ No American Indian or Alaskan Native  
☐ Yes ☐ No Spanish, Hispanic, or Latino

**SCTEST**

**SCORRES**

QNAM=SOTHERS  
QLABEL=SPANISH, HISPANIC,  
OR LATINO: OTHER TEXT  
IDVAR=SCSEQ

- ☐ Yes ☐ No

- (mark all that apply)  
Mexican, Mexican-American, or Chicano  
Puerto Rican  
Cuban  
Other (specify)

- ☐ Yes ☐ No

Asian

(mark all that apply)

Asian-Indian

Chinese

Filipino

Japanese

Korean

Vietnamese

Other (specify)

- ☐ Yes ☐ No

Native Hawaiian or Pacific Islander

(mark all that apply)

Native Hawaiian

Guamanian or Chamorro

Samoan

Other (specify)

- ☐ Yes ☐ No

Other (specify)

- ☐ Participant chooses not to answer

QNAM=OOTHERS  
QLABEL=ETHNICITY/RACE:  
OTHER TEXT  
IDVAR=SCSEQ

4. Education completed:  
(GED=12 years)

**SCTEST**

**SCORRES**

Years:

--	--

**SCORRESU**

5. Usual employment pattern:

a. Past 3 years: **SCTEST**

- ☐ Full time (35+ hrs/wk) ☐ Service  
☐ Part time (regular hours) ☐ Retired/Disability  
☐ Part time (irreg., day-work) ☐ Homemaker  
☐ Student ☐ Unemployed  
☐ In controlled environment

**SCORRES**

b. Past 30 days: **SCTEST**

- ☐ Full time (35+ hrs/wk) ☐ Service  
☐ Part time (regular hours) ☐ Retired/Disability  
☐ Part time (irreg., daywork) ☐ Homemaker  
☐ Student ☐ Unemployed  
☐ In controlled environment

**SCORRES**

6. Marital status: **SCTEST**

- ☐ Legally married  
☐ Living with partner/Cohabiting  
☐ Widowed  
☐ Separated  
☐ Divorced  
☐ Never married

**SCORRES**

QNAM=NOTHERS  
QLABEL=NATIVE HAWAIIAN  
OR PACIFIC ISLANDER:  
OTHER TEXT  
IDVAR=SCSEQ

23859

Serial Number:



1	2	3	4	5	6	7	8	9	0
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THIS DATA NOT ENTERED

DEM003-02/18/2003-Final V.1

# Demographics Form (continued)

Page 2 of 2

DOMAIN: SU

ID #:	Name Code:	Date of Assessment:	SUDTC	Site:
USUEJID				

7. Drug/Alcohol Use: **SUCAT=DRUG/ALCOHOL USE**  
 For the following, please record use information for the past 30 days (days of use), lifetime (years of regular use), and route of administration. For lifetime use, the use of a substance 3 or more times per week is considered regular use. The usual route of administration should be coded. If more than 1 route is frequently used, then choose the most serious. The routes are listed from least severe to most severe. If Past 30 Days and Lifetime Use are zero, route should be coded as "N/A." If substance use is less than 6 months, code Lifetime use as 00 years (6-12 months of use is coded as 1 year) and make a note on the form.

SUBSTANCE:	Past 30:		Lifetime Use:		Most frequent route of administration:					Comments:
	Days	Years	Oral	Nasal	Smoking	Injection (IV or non-IV)	N/A			
Alcohol (any use at all)			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	THIS DATA NOT ENTERED	
Alcohol (to intoxication)			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Heroin			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Methadone/LAAM (prescribed)			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Methadone/LAAM (illicit)			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Other Opiates/Analgesics			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Barbiturates			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Other Sedatives/Hypnotics /Tranquilizers including Benzodiazepines			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Cocaine			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Amphetamines/ Methamphetamine			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Cannabis			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Hallucinogens			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Inhalants			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
More than 1 substance per day (including alcohol)										
Nicotine (tobacco products)			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>		

8. According to the interviewer, which substance is the major problem? Interviewer should determine the major drug of abuse. Code as above. Ask patient when not clear.

- |  |  |   |   |
|--|--|---|---|
| <input type="radio"/> No problem             | <input type="radio"/> Methadone/LAAM (illicit) | <input type="radio"/> Amphetamines/Meth | <input type="radio"/> Alcohol and drug (dual addiction) |
| <input type="radio"/> Alcohol (any)          | <input type="radio"/> Opiates/Analgesics       | <input type="radio"/> Cannabis          | <input type="radio"/> Polydrug                          |
| <input type="radio"/> Alcohol (intox.)       | <input type="radio"/> Barbiturates             | <input type="radio"/> Hallucinogens     |   |
| <input type="radio"/> Heroin                 | <input type="radio"/> Sed/Hyp/Tranq/Benz       | <input type="radio"/> Inhalants         |   |
| <input type="radio"/> Methadone/LAAM (presc) | <input type="radio"/> Cocaine                  | <input type="radio"/> Nicotine          |   |

**SUCAT=MAJOR DRUG PROBLEM**

SUTRT

Serial Number:

23859

THIS DATA NOT ENTERED

# Form 256—DSM IV Criteria Substance Related Disorders

StudyNumber: STUDYID

Node:

Site:

Evaluator#:

QSEVAL

ID #: USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment: QSDTC (MM/DD/YYYY)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Treatment phase: (Mark one only)	<input type="radio"/> Screening <input type="radio"/> Induction/stabilization <input type="radio"/> Early termination	VISITNUM	<input type="radio"/> Taper <input type="radio"/> End of taper <input type="radio"/> Post taper	<input type="radio"/> 1 Month post taper <input type="radio"/> 3 Months post randomization <input type="radio"/> 3 Months post taper
EPOCH				

QSEVLINT=-P12M

QSTEST

Opiates  
Benzodiazepines  
Alcohol  
Amphetamines  
Cannabis  
Cocaine  
Hallucinogens  
Inhalants  
Sedatives

1. Have you used \_\_\_\_\_ in the past 12 months?  
*Continue the assessment only for drugs used within the past 12 months.*

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Yes
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	No

QSORRES

- A1. Have you found that you needed to use a lot more (drug) in order to get high than you did when you first started using it? IF YES, how much more? IF NO, what about finding that when you used the same amount, it had much less effect than before?

Tolerance, as defined by either a need for markedly increased amounts of the substance in order to achieve intoxication or desired effect, or markedly diminished effect with continued use of the same amount of substance

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

- A2. Have you ever had withdrawal symptoms, that is felt sick when you cut down or stopped using (drug)? IF YES, what symptoms did you have? [Need to refer to withdrawal symptoms associated with each drug:] Have you used (drug) to keep yourself from getting sick with (specific withdrawal symptom[s])?

Withdrawal, as manifested by either the characteristic withdrawal syndrome for the substance (see special criteria sets for withdrawal in p. 185 of DSM-IV manual) or the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

- A3. Have you often found that when you started using (drug), you ended up using more of it than you were planning to? IF NO, what about using it over a much longer period of time than you were planning to?

Substance often taken in larger amounts or over a longer period than subject intended

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

63478

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Serial Number:

## DSM IV Criteria (continued)

## Dependence

ID #:	Name Code:	Date of Assessment:	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

QSEVLINT=-P12M

QSTEST

Opiates  
Benzodiazepines  
Alcohol  
Amphetamines  
Cannabis  
Cocaine  
Hallucinogens  
Inhalants  
Sedatives

A4. Have you tried to cut down or stop using (drug)? IF YES, have you ever actually stopped using (drug) altogether? (How many times did you try to cut down or stop altogether?) IF UNCLEAR, did you want to stop or cut down? IF NO, is this something you kept worrying about?

QSORRES

Persistent desire or one or more unsuccessful efforts to cut down or control substance use.

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

A5. Have you spent a lot of time using (drug) or doing whatever you had to do to get it? Did it take you a long time to get back to normal? (How much time?)

A great deal of time spent in activities necessary to get the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain smoking) or recover from its effects.

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

A6. Have you had times when you would use (drug) so often that you used (drug) instead of working or spending time in hobbies with your family or friends?

Important social, occupational, or recreational activities given up or reduced because of substance abuse.

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

A7. IF NOT ALREADY KNOWN, has (drug) caused psychological problems, like making you depressed? IF NOT ALREADY KNOWN, has (drug) ever caused physical problems or made a physical problem worse? IF YES TO EITHER OF THE ABOVE, did you keep on using (drug) anyway?

Continued substance use despite knowledge of having persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the use of the substance (e.g., continued drinking despite worsening ulcer).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

Number of "Present" responses for each column. Dependence is indicated by a total of 3 or more.

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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63478

THIS DATA NOT ENTERED

Serial Number:

# DSM IV Criteria (continued)

Page 3 of 4

DOMAIN: QS

## Substance Abuse

Complete this page only if participant does not meet substance dependence criteria on pages 1 & 2.

ID #:	Name Code:	Date of Assessment:	(MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Now I'd like to ask you a few more questions about your use of (drug not coded as meeting criteria for dependence).

QSEVLINT=-P12M

A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following occurring within a 12-month period.

QSTEST

Opiates  
Benzodiazepines  
Alcohol  
Amphetamines  
Cannabis  
Cocaine  
Hallucinogens  
Inhalants  
Sedatives

B1. Have you often been intoxicated or high while very hungover with (drug) while you were doing something important like being at school or work, or taking care of children? IF NO, what about missing something important, like staying away from school or work or missing an appointment because you were intoxicated, high, or very hungover? IF YES AND UNKNOWN, how often? (Over what period of time?)

Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school, neglect of children or household).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

QSORRES

B2. Have you ever used (drug) in a situation in which it might have been dangerous to use (drug) at all? (Have you ever driven while you were really too high to drive?) IF YES AND UNKNOWN, how often? (Over what period of time?)

Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

B3. Has your use of (drug) ever gotten you into trouble with the law? IF YES AND UNKNOWN, how often? (Over what period of time?)

Recurrent substance-related legal problems (e.g., arrests for substance-related disorderly conduct).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

B4. Has your use of (drug) caused problems with other people, such as with family members, friends, or people at work? (Did you ever get into physical fights or bad arguments about your drug use?) IF YES, did you keep on using (drug) anyway? (Over what period of time?)

Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

Number of "Present" responses for each column. Abuse is indicated by a total of 1 or more.

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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63478

THIS DATA NOT ENTERED

Serial Number:

# DSM IV Criteria (continued)

Page 4 of 4

DOMAIN: QS

## Summary

ID #:	USUBJID	Name Code:	Date of Assessment:	QSDTC	(MM/DD/YYYY)	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

### QSTEST

### QSORRES

1. Is participant currently opioid dependent? ☐ Yes ☐ No
2. Is participant currently dependent on any other substance (e.g., alcohol, benzodiazapines) which requires medical attention? ☐ Yes ☐ No
3. Is participant currently in need of medical assistance for opioid withdrawal? ☐ Yes ☐ No

Comments:

THIS DATA NOT ENTERED



Signature and date:

THIS DATA NOT ENTERED

63478

THIS DATA NOT ENTERED

Serial Number:



# Form 306—Inclusion Exclusion Bup Protocol 0003

Page 1 of 1

DOMAIN: IE

Study Number: STUDYID

Node:

Site:

Evaluator #:

ID #: USUBJID Name Code: Week #: Study Day: Date of Assessment: IEDTC (MM/DD/YYYY)

Treatment phase:  
(Mark one only)

EPOCH

- ☐ Screening  
☐ Induction/stabilization  
☐ Early termination

VISITNUM

- ☐ Taper  
☐ End of taper  
☐ Post taper

- ☐ 1 Month post taper  
☐ 3 Months post randomization  
☐ 3 Months post taper

## IECAT A. INCLUSION CRITERIA

IETEST

- ☐ Yes ☐ No 1. Is the participant 15 years or older?
- ☐ Yes ☐ No 2. Does the participant meet DSM-IV criteria for opiate dependence?
- ☐ Yes ☐ No 3. Is the participant in good general health or, in case of a medical/psychiatric condition needing ongoing treatment, under the care of a physician willing to continue participant's medical management and cooperate with the study physicians? Must be documented in progress note and release of information obtained for physician prior to enrollment.
- ☐ Yes ☐ No 4. Is the participant agreeable to and capable of signing the informed consent approved by the IRB and, if under the age of 18 (excluding emancipated minors), providing assent and concurrent consent from a parent or legal guardian?
- ☐ Yes ☐ No 5. If female of childbearing potential, does the participant agree to use of one of the following acceptable methods of birth control:
- ☐ NA
- a. oral contraceptives/patch  
b. barrier (diaphragm, cervical cap with spermicide, etc.) or condom  
c. intrauterine progesterone contraceptive system  
d. levonorgestrel implant  
e. medroxyprogesterone acetate contraceptive injection  
f. complete abstinence?
- ☐ Yes ☐ No 6. Has the participant provided a methadone and benzodiazepine negative urine test result immediately preceding BUP/NX induction?

IEORRES

NOTE: Only exceptions to IE are in the database. That includes "No" responses for inclusion and "yes" responses for exclusion criteria.

## IECAT B. EXCLUSION CRITERIA

- ☐ Yes ☐ No 1. Does the participant have a medical condition that would, in the opinion of the study physician, make participation medically hazardous (e.g., acute hepatitis, unstable cardiovascular, liver or renal disease)?
- ☐ Yes ☐ No 2. Does the participant have a known allergy or sensitivity to buprenorphine or naloxone?
- ☐ Yes ☐ No 3. Does the participant have an acute severe psychiatric condition requiring immediate treatment, or posing an imminent suicide risk?
- ☐ Yes ☐ No 4. Is the participant dependent on alcohol, other depressants, or stimulants, requiring immediate medical attention?
- ☐ Yes ☐ No 5. Does the participant have a current pattern of benzodiazepine use, as assessed by the study physician, which would preclude safe participation in the study?
- ☐ Yes ☐ No 6. Has the participant participated in an investigational drug study, including buprenorphine, within the past 30 days prior to screening?
- ☐ Yes ☐ No 7. Has the participant had methadone or LAAM maintenance or detoxification within 30 days of enrollment?
- ☐ Yes ☐ No 8. Does the participant have pending legal action that could prohibit or interfere with participation?
- ☐ Yes ☐ No 9. Is the participant unable to remain in area for the duration of treatment?
- ☐ Yes ☐ No 10. If female, is the participant pregnant, lactating, or planning to become pregnant?
- ☐ NA
- ☐ Yes ☐ No 11. Is the participant seeking long-term (greater than 2 months) opiate maintenance treatment?

Draft

ALL ITEMS MUST BE COMPLETED  
FOR ENROLLED PARTICIPANTS

THIS DATA NOT ENTERED

Serial Number:

INC003-03/03/03-Final v.1

# Form 307—Induction

Page 1 of 1

DOMAIN: DM, SC, DS

StudyNumber: STUDYID

Node:

Site:

Evaluator#:

ID #: USUBJID	Name Code:	Week #: VISITNUM	Study Day:	Date of Assessment: DMDTC/SCDTC/DSDTC
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Treatment phase: (Mark one only)	<input type="radio"/> Screening <input type="radio"/> Induction/stabilization <input type="radio"/> Early termination	<input type="radio"/> Taper <input type="radio"/> End of taper <input type="radio"/> Post taper	<input type="radio"/> 1 Month post taper <input type="radio"/> 3 Months post randomization <input type="radio"/> 3 Months post taper	
EPOCH				

SC.SCTEST

SC.SCORRES

1. Are the answers to all inclusion criteria "Yes" and all exclusion criteria "No"?

☐ Yes ☐ No

DS.DSTERM

DS.DSOCCUR

2. Has participant been induced in the study?

☐ Yes (complete question #3) ☐ No (complete question #4)

3. If **inducted** into the study:

A. DS.DSTERM

DS.DSSTDTC

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	---	----------------------	---	----------------------	----------------------	----------------------	----------------------

B. Date of first dose of medication/induction:

DM.RFSTDTC

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	---	----------------------	---	----------------------	----------------------	----------------------	----------------------

(mm/dd/yyyy)

- OR -

4. If **NOT inducted**, reason(s) why:

DS.DSTERM

DS.DSOCCUR

- A. Failed to return to clinic
- B. Changed mind regarding participation
- C. Incarceration (current or pending)
- D. Death (complete SAE form)
- E. More than 14 days elapsed since consent
- F. Did not meet inclusion/exclusion criteria
- G. Other (specify below)

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

H. Specify (200 characters):

QNAM=DSOTHER  
QLABEL=NOT INDUCTED OTHER SPECIFY  
IDVAR=VISITNUM

23998

THIS DATA NOT ENTERED

Serial Number:

IND003-03/03/03-Final v.1



# Form 331—Hepatitis and Liver Tests

Page 1 of 1

DOMAIN: LB, CO

StudyNumber: STUDYID

Node:

Site:

Evaluator#:

ID #: USUBJID

Name Code:

Week #:

Study Day:

Date of Assessment: LBDTC (MM/DD/YYYY)

Treatment phase:  
(Mark one only)

EPOCH

- ☐ Screening  
☐ Induction/stabilization  
☐ Early termination

VISITNUM

- ☐ Taper  
☐ End of taper  
☐ Post taper

- ☐ 1 Month post taper  
☐ 3 Months post randomization  
☐ 3 Months post taper

## LBCAT=HEPATITIS SEROLOGY

Hepatitis Serology: screening only; repeat testing not required.

LBORRES

LBORRES

LBORRES

1. Hepatitis B surface antigen (HBs Ag) LBTEST	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Indeterminate	2. Hepatitis B core IGM antibody (Anti-HBc) LBTEST	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Indeterminate	3. Hepatitis C virus antibody (HCV Ab) LBTEST	<input type="radio"/> Positive <input type="radio"/> Negative <input type="radio"/> Indeterminate
---	---	---	---	--	---

Liver Functions: to be assessed at screening, study day 0, and study day 28 for all participants. Additional LFT monitoring requirements are outlined in the protocol version 7.

## LBCAT=LIVER FUNCTION

Test result:

Comments-specify question number (200 characters max):

LBTEST

4. Total protein

g/dL

LBORRESU

5. SGOT / AST

U/L

6. SGPT / ALT

U/L

7. GGTP / GGT

U/L

8. Total bilirubin

mg/dL

9. LDH

U/L

10. Alkaline phosphatase

U/L

DOMAIN: CO  
COVAL  
RDOMAIN=LB  
IDVAR=VISITNUM

11. Is additional monitoring required under protocol guidelines?

- ☐ Yes  
☐ No

QNAM=LBMONIT  
QLABEL=ADDITIONAL MONITORING REQUIRED  
IDVAR=LBDTC

MD signature and date:

THIS DATA NOT ENTERED

THIS DATA NOT ENTERED

Serial Number:

6127

# Form 271—Medical History

Page 1 of 1

DOMAIN: MH

Study Number: STUDYID

Node:

Site:

Evaluator#:

ID #: USUBJID

Name Code:

Week #:

Study Day:

Date of Assessment: MHDTC (MM/DD/YYYY)

Treatment phase:  
(Mark one only)

EPOCH

☐ Screening

☐ Induction/stabilization

☐ Early termination

VISITNUM

☐ Taper

☐ End of taper

☐ Post taper

☐ 1 Month post taper

☐ 3 Months post randomization

☐ 3 Months post taper

MHTERM

MHOCCUR

MHOCCUR

MHSPID

MEDICAL CONDITION	PAST HISTORY	ACTIVE
1. Cardiovascular	<input type="radio"/> Y <input type="radio"/> N	<input type="radio"/> Y <input type="radio"/> N
2. Hepatic	<input type="radio"/> Y <input type="radio"/> N	<input type="radio"/> Y <input type="radio"/> N
3. Renal	<input type="radio"/> Y <input type="radio"/> N	<input type="radio"/> Y <input type="radio"/> N
4. Psychiatric	<input type="radio"/> Y <input type="radio"/> N	<input type="radio"/> Y <input type="radio"/> N
5. Respiratory	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
6. Gastrointestinal	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
7. Genitourinary	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
8. Endocrine	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
9. Seizure	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
10. Dermatological	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
11. Eyes, ears, nose, and throat	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
12. Skin test positive for TB	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
13. X-ray positive for TB	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
14. Symptoms of TB	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
15. Musculoskeletal	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
16. Neurological	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
17. Allergies	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA
18. Other (specify below)	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> NA

18C. Specify (30 characters)

DOMAIN: CO

COVAL

RDOMAIN=MH

IDVAR=VISITNUM

Notes (200 characters max):

MD signature and date:

THIS DATA NOT ENTERED

THIS DATA NOT ENTERED

Serial Number:

MHX003-02/18/2003-Final V.1

60952

# Form 266—Physical Exam

Page 1 of 1 **DOMAIN: PE, VS**

StudyNumber: **STUDYID**

Node:

Site:

Evaluator#:

ID #: **USUBJID**

Name Code:

Week #:

Study Day:

Date of Assessment:

**PEDTC/VSDTC**

Treatment phase:  
(Mark one only)

**EPOCH**

☐ Screening

☐ Induction/stabilization

☐ Early termination

**VISITNUM**

☐ Taper

☐ End of taper

☐ Post taper

☐ 1 Month post taper

☐ 3 Months post randomization

☐ 3 Months post taper

A. Height (inches)

**VS.VSTEST VSORRES VSORRESU**

B. Weight (pounds)

**VS.VSTEST VSORRES VSORRESU**

**PEORRES**

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

Circled items represent  
recommended minimum  
physical exam

**PESPID**

**PETEST**

1. Skin, Hair, and Nails
2. Head and Neck
3. Ears, Eyes, Nose, and Throat
4. Heart
5. Chest
6. Lungs
7. Abdomen
8. Extremities
9. Lymph Nodes
10. Neurological
11. Rectal
12. Genitalia
13. Prostate
14. Breasts
15. Pelvic
16. Musculoskeletal
17. Other:

Normal	Abnormal, not clinically significant	Abnormal, clinically significant	Not assessed
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments (if abnormal, please comment-50 characters):

**DOMAIN: CO**  
**COVAL**  
**RDOMAIN=PE**  
**IDVAR=PESPID**

18. Was an EKG performed? ☐ Yes ☐ No

(Perform EKG if participant is >40 years old or has a history of cardiovascular disease)

18A. If yes, results: ☐ Normal  
☐ Abnormal, not clinically significant  
☐ Abnormal, clinically significant

MD signature and date:

**THIS DATA NOT ENTERED**

**THIS DATA NOT ENTERED**

Serial Number:

22632

CMCAT=PRIOR

Page 1 of 1

DOMAIN: CM

## Form 222—Prior Medications

Study Number: STUDYID

Node:

Site:

Evaluator #:

ID #:	USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment:	CMDTC
Treatment phase: (Mark one only)		<input checked="" type="radio"/> Screening <input type="radio"/> Induction/stabilization <input type="radio"/> Early termination		<input type="radio"/> Taper <input type="radio"/> End of taper <input type="radio"/> Post taper		<input type="checkbox"/> 1 Month post taper <input type="checkbox"/> 3 Months post randomization <input type="checkbox"/> 3 Months post taper
EPOCH		VISITNUM				

Has the participant taken any medications in the past 2 weeks?

☐ Y☐ N

THIS DATA NOT RETAINED

A. Medication Generic name of medication (30 characters)	B. Indication (30 characters)	C. Amount	D. UNITS: (Select ONE unit that describes in the greatest detail the amount of medication taken by the subject A-capsule G-milligram M-suppository B-drop H-milliliter N-tablet/spoon C-grain I-ounce O-tablet/caplet D-gram J-patch P-teaspoon E-microgram K-puff Q-unknown F-microliter L-spray/squirt R-other	E. FREQ.: 1-once daily 2-BID 3-TID 4-QID 5-PRN 6-other	F. Start date Medication start date (MMDDYY)	G. End date If ended, enter last date medication taken (MMDDYY)	H. Continuing Mark 'Y' if continuing, 'N' if not	
CMSPID				CMDOSE	CMSTDT	CMENDTC	CMSTRF	
1. Item #	A. Medication	B. Indication	C. Amount	D. Unit	E. Freq.	F. Start date:	G. End date:	H. Cont.
	CMTRT	CMINDC						<input type="radio"/> Y <input type="radio"/> N
								<input type="radio"/> Y <input type="radio"/> N
								<input type="radio"/> Y <input type="radio"/> N
								<input type="radio"/> Y <input type="radio"/> N
								<input type="radio"/> Y <input type="radio"/> N
								<input type="radio"/> Y <input type="radio"/> N
								<input type="radio"/> Y <input type="radio"/> N

Page

of

MD signature and date:

THIS DATA NOT ENTERED

THIS DATA NOT ENTERED

Serial Number:

PMD003-03/03/03-Final v.1

44072



# Form 334—Randomization

Page 1 of 1

StudyNumber: **STUDYID**

Node:

Site:

Evaluator #: **DOMAIN: SC, DM**

ID #: **USUBJID**

Name Code:

Week #:

Study Day:

Date of Assessment:

**DMDTC/SCDTC**

**VISITNUM**

**SC.SCTEST**

1. Date randomized:  
(MM/DD/YYYY)

**SC.SCORRES**

		/			/				
--	--	---	--	--	---	--	--	--	--

**SC.SCTEST**

2. Bup/Nx dose at start of randomization  
(expressed as mg bup):

**SC.SCORRES**

- ☐ 8 mg      ☐ 16 mg      ☐ 24 mg

**DM.ARM**

3. Taper group:

- ☐ 7-day taper      ☐ 28-day taper

**SC.SCTEST**

4. Card number:

**SC.SCORRES**

--	--	--

**Fax IMMEDIATELY to Pacific Node  
CTN 003 Coordinating Center**

**Fax #: (310) 445-5606**

38149

**THIS DATA NOT ENTERED**

Serial Number:

RAN003-03/03/03-Final v.1

QSCAT=RISK BEHAVIORS SURVEY  
Form 318—Risk Behaviors Survey

Page 1 of 6

DOMAIN: QS

StudyNumber: STUDYID

Node:

Site:

Evaluator#:

QSEVAL

ID #: USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment: QSDTC
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Treatment phase: (Mark one only)	<input type="radio"/> Screening <input type="radio"/> Induction/stabilization <input type="radio"/> Early termination	VISITNUM	<input type="radio"/> Taper <input type="radio"/> End of taper <input type="radio"/> Post taper	<input type="radio"/> 1 Month post taper <input type="radio"/> 3 Months post randomization <input type="radio"/> 3 Months post taper
EPOCH				

**INTERVIEWER: The RBS contains sensitive information on drug use and sexual behavior.  
Please ensure that you have developed rapport with the participant before asking these questions.**

A. DRUG USE QSSCAT=DRUG

I'm going to ask you some questions about your drug use. I'll ask what types of drugs you've used and how often you use them.

A	B	C	D	E	F
Have you ever used__? (if no use, skip to the next drug)	How many days did you use __ in the last 30 days? (if 00, do not ask parts C-F, & skip to the next drug)	How many days did you inject __ in the last 30 days? (If 00, skip to part E)	How many times a day did you inject __? (Average # of injections/day)	How many days did you use __ without injecting (smoking, snorting, swallowing) in the last 30 days? (If 00, then skip to the next drug class)	How many times a day did you use __ without injecting?
QSTEST					
1. Cocaine by itself (injected or snorted)? QSORRES <input type="radio"/> Y <input type="radio"/> Unknown <input type="radio"/> N <input type="radio"/> Refused	QSORRESU=DAY <input type="text"/>	<input type="text"/>	<input type="text"/>	QSORRESU=DAY <input type="text"/>	<input type="text"/>
2. Heroin (by itself)? <input type="radio"/> Y <input type="radio"/> Unknown <input type="radio"/> N <input type="radio"/> Refused	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3. Heroin and cocaine mixed together (speedball)? <input type="radio"/> Y <input type="radio"/> Unknown <input type="radio"/> N <input type="radio"/> Refused	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
4. Other opiates (Demerol, codeine, dilaudid)? <input type="radio"/> Y <input type="radio"/> Unknown <input type="radio"/> N <input type="radio"/> Refused	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
5. Amphetamines (methamphetamine, speed, crank)? <input type="radio"/> Y <input type="radio"/> Unknown <input type="radio"/> N <input type="radio"/> Refused	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

26142

1 2 3 4 5 6 7 8 9 0

THIS DATA NOT ENTERED

Serial Number:

RBS003-03/03/03-Final v.1

QSCAT=RISK BEHAVIOR SURVEY

ID #:	USUBJID	Name Code:	Date of Assessment:	(MM/DD/YYYY)	Site:	QSDTC
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

QSEVLINT=-P30D

QSTEST

QSSCAT=DRUG INJECTION

B. DRUG INJECTION (If no injection use in the past 30 days, skip to section C.)

QSORRES

1. In the last 30 days, how many times (# of injections) did you inject using works (needles/syringes) that YOU KNOW had been used by someone else? (If 00, then skip to B3)
2. Of the times you injected after someone, how many times did you clean the works with full-strength bleach? (Number cannot exceed total number of times used after a friend (qB1)).
3. How many times in the last 30 days did you use a cooker/cotton/rinse water that had been used by another injector?
4. How many times in the last 30 days did you fix drugs with another person, then split the drug solution (through use of the same cooker/spoon or through front or back loading)?

<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

C. SEXUAL ACTIVITY

QSSCAT=SEXUAL ACTIVITY

Now I'm going to ask you some questions about sex. I'm referring here to anybody you've had sex with in the last 30 days.

1. During the last 30 days, with how many people did you have vaginal, oral, or anal sex?

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

(If none, enter "000" and the questionnaire is completed)

2. How many of your partners were female?  
(Number cannot exceed total number of people (qC1)).
3. How many of your partners were male?  
(Number cannot exceed total number of people (qC1)).

<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

4. Interviewer: Code gender of respondent

☐ 1-Male ☐ 2-Female ☐ 9-Don't know

If 'Male', complete sections D, E, F, G, & I.

If 'Female', complete sections D, G, H, & I.

If 'Don't know', ask ALL sex/gender specific questions and allow client to answer as they like.

Please mark bubbles FULLY:

Correct

Incorrect



26142

THIS DATA NOT ENTERED

Serial Number:

RBS003-03/03/03-Final v.1

QSCAT=RISK BEHAVIOR SURVEY

ID #:	USUBJID	Name Code:	Date of Assessment:	(MM/DD/YYYY)	Site:	QSDTC
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

QSEVLINT=-P30D

QSSCAT=SEXUAL ACTIVITY – CLIENT WITH FEMALE PARTNER

D. Ask male/female clients who had female partners

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

- 1A. How many women performed oral sex ("went down") on you?  
(If 000, then skip to question 2A.  
Number cannot exceed total number of female partners (qC2)).

QSTEST

QSORRES

- 1B. How often did your partner(s) perform oral sex ("go down") on you?

- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |

- 1C. How often did you use condoms/dental dams when your partner(s) performed oral sex ("went down") on you?

- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

- 2A. How many women did you perform oral sex ("go down") on?  
(If 000, then skip to the next section appropriate for the sex of this client.  
Number cannot exceed total number of female partners (qC2)).

- 2B. How often did you perform oral sex ("go down") on your partners?

- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |

- 2C. How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)?

- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

THIS DATA NOT ENTERED

Serial Number:

RBS003-03/03/03-Final v.1

26142



QSCAT=RISK BEHAVIOR SURVEY

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment: (MM/DD/YYYY)	Site: <b>QSDTC</b>
<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>

QSEVLINT=-P30D

QSSCAT=SEXUAL ACTIVITY – MALE CLIENT WITH FEMALE PARTNER

E. Ask male clients who had female partners

1A. How many women did you have vaginal sex with?  
(If 000, then skip to question 2A.)

Number cannot exceed total number of female partners (qC2).

QSTEST

QSORRES

1B. How often did you have vaginal sex?

- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |

1C. How often did you use a condom?

- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

2A. How many women did you have (insertive) anal sex with?  
(If 000, then skip to the next section appropriate for the sex of this client.)  
Number cannot exceed total number of female partners (qC2))

2B. How often did you have (insertive) anal sex?

- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |

2C. How often did you use a condom?

- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

QSSCAT=SEXUAL ACTIVITY – MALE CLIENT WITH MALE PARTNER

F. Ask male clients who have had male partners

1A. How many men did you have (insertive) anal sex with?  
(If 000, then skip to the next section appropriate for the sex of this client.)  
Number cannot exceed total number of male partners (qC3)).

1B. How often did you have (insertive) anal sex?

- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |

1C. How often did you use a condom?

- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

Please fill bubbles completely: ☐ ☒ ☐ ☐

26142

THIS DATA NOT ENTERED

Serial Number:

RBS003-03/03/03-Final v.1

DOMAIN: QS

QSCAT=RISK BEHAVIOR SURVEY

ID #: USUBJID	Name Code:	Date of Assessment: (MM/DD/YYYY)	Site: QSDTC
<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>

QSEVLINT=-P30D

QSSCAT=SEXUAL ACTIVITY – CLIENT WITH MALE PARTNER

G. Ask male/female clients who had male partners

1A. How many men performed oral sex ("went down") on you?

(If 000, then skip to question 2A.

Number cannot exceed total number of male partners (qC3)).

QSTEST

QSORRES

1B. How often did your partner(s) perform oral sex ("go down") on you?

- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |

1C. How often did you use condoms/dental dams when your partner(s) performed oral sex ("went down") on you?

- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

2A. How many men did you perform oral sex ("go down") on?

(If 000, then skip to the next section appropriate for the sex of this client.

Number cannot exceed total number of male partners (qC3)).

2B. How often did you perform oral sex ("go down") on your partners?

- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |

2C. How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)?

- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

Please print within the boxes.

Correct

9

Incorrect

9

26142

THIS DATA NOT ENTERED

Serial Number:

RBS003-03/03/03-Final v.1

DOMAIN: QS

QSCAT=RISK BEHAVIOR SURVEY

USUBJID		Name Code:		Date of Assessment:		(MM/DD/YYYY)		QSDTC	
ID #								Site:	

QSEVLINT=-P30D

QSSCAT=SEXUAL ACTIVITY – FEMALE CLIENT WITH MALE PARTNER

H. Ask female clients who had male partners

--	--	--

QSORRES

QSTEST

- 1A. How many men did you have vaginal sex with?  
(If 000, then skip to the next section appropriate for the sex of this client.  
Number cannot exceed total number of male partners (qC3)).
- 1B. How often did you have vaginal sex?
- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |
- 1C. How often did you use a condom?
- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

QSSCAT=SEXUAL ACTIVITY – CLIENT WITH MALE PARTNER

I. Ask male/female clients who had male partners

--	--	--

- 1A. How many men did you have (receptive) anal sex with?  
(If 000, end questionnaire.  
Number cannot exceed total number of male partners (qC3)).
- 1B. How often did you have (receptive) anal sex?
- |   |  |   |
|---|--|---|
| <input type="radio"/> Once or irregularly   | <input type="radio"/> 2-6 times a week | <input type="radio"/> 4 or more times a day |
| <input type="radio"/> Less than once a week | <input type="radio"/> About once a day | <input type="radio"/> Don't know/unsure     |
| <input type="radio"/> About once a week     | <input type="radio"/> 2-3 times a day  | <input type="radio"/> Refused               |
- 1C. How often did you use a condom?
- |   |   |   |
|---|---|---|
| <input type="radio"/> Never                   | <input type="radio"/> More than half the time | <input type="radio"/> Don't know/unsure |
| <input type="radio"/> Less than half the time | <input type="radio"/> Always                  | <input type="radio"/> Refused           |
| <input type="radio"/> About half the time     |   |   |

1	2	3	4	5	6	7	8	9	0
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THIS DATA NOT ENTERED									
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Serial Number:

RBS003-03/03/03-Final v.1

26142

**DOMAIN: AE**

AESEER=Y

## 1. Omitted

QNAM=AESEX  
QLABEL=SEX (SAE PAGE)  
IDVAR=AESEQ

3. Date of birth:

--	--

 / 

--	--

 / 

--	--	--	--

QNAM=AEDOB  
QLABEL=DATE OF BIRTH (SAE PAGE)  
IDVAR=AESEQ

4. Race/Ethnicity:

☐ White, not of Hispanic origin
 ☐ Asian or Pacific Islander  
☐ Hispanic or Latino
 ☐ Native American or Native Alaskan  
☐ African American or Black, not of Hispanic origin
 ☐ Unknown  
☐ Other

QNAME=AEETHOT  
QLABEL=RACE/E

QNAM=AEETHNIC  
QLABEL=RACE/ETHNICITY (SAE PAGE)  
IDVAR=AESEQ

QNAM=AEETHOTH  
QLABEL=RACE/ETHNICITY OTHER, SPECIFY  
IDVAR=AESEQ

5. Height:



(inches)

QNAM=AEHGT  
QLABEL=HEIGHT (SAE PAGE)  
IDVAR=AESEQ

6. Weight:

(pounds)

QNAM=AEWGT  
QLABEL=WEIGHT (SAE PAGE)  
IDVAR=AFSEQ

**SERIOUS ADVERSE EVENT**7. Serious adverse event description (90 char max per line)

	AETERM

8. Onset date:

--	--

 / 

--	--

 / 

--	--	--	--

AESTDTC

9. Severity grade: ☐ Severe ☐ Life-threatening ☐ Lethal

AESEV

10. Was SAE related to Investigational Agent?

AEREL

☐ Definitely   ☐ Probably   ☐ Possibly   ☐ Remotely   ☐ Definitely not   ☐ Unknown

**Please use the final page of the form for additional notes.**

THIS DATA NOT ENTERED
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Serial Number:

SAE003-08/02/04-Final v.2



SAE  
(continued)

Page 2 of 4

DOMAIN: AE

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment:	(MM/DD/YYYY) <b>AEDTC</b>	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/>	<input type="text"/>

11. Action taken regarding Investigational Agent: **AEACN**
- ☐ None ☐ Reduced dose  
☐ Discontinued permanently ☐ Increased dose  
☐ Discontinued temporarily ☐ Delayed dose

12. Other action(s) taken: **AEACNOTH**  
(mark all that apply)
- ☐ None  
☐ Remedial therapy - pharmacologic  
☐ Remedial therapy - nonpharmacologic  
☐ Hospitalization (new or prolonged)

13. Outcome: **AEOUT** **AESDEATH** **AESDISAB**  
**AESLIFE** **AESCONG**  
**AESHOSP** **AESMIE**
- ☐ Death ☐ Disability  
☐ Life-threatening event ☐ Congenital anomaly  
☐ Hospitalization ☐ Other

QNAM=RELTEST1-RELTEST3

QLABEL=SAE - RELEVANT TESTS/LAB DATA, LINE 1 (2,3)

IDVAR=AESEQ

14. Relevant tests/laboratory data, including dates (90 char max per line):


specify:  
(30 char max)

QNAM=AESOUTOT

QLABEL=OUTCOME - OTHER, SPECIFY

IDVAR=AESEQ

15. Relevant history, including pre-existing medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.-90 char max per line):


16. SAE resolution date:

**AEENDTC**  /  /

(mm/dd/yyyy)

- ☐ Continuing If continuing then  
**AEENRF=DURING/AFTER**

QNAM=RELHIST1-RELHIST3

QLABEL=RELEVANT HISTORY, PRE-EXIST COND, LINE 1 (2,3)

IDVAR=AESEQ

Please mark bubbles FULLY:

Correct



Incorrect



Draft

THIS DATA NOT ENTERED

Serial Number:

SAE003-08/02/04-Final v.2

ID #: <b>USUBJID</b>	Name Code:	Date of Assessment: (MM/DD/YYYY)	AEDTC	Site:
<div style="border: 1px solid black; width: 40px; height: 20px;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px;"></div> / <div style="border: 1px solid black; width: 40px; height: 20px;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px;"></div>	<div style="border: 1px solid black; width: 40px; height: 20px;"></div>

  

17. Omitted

18. Investigational Agent name:

19. Lot number:

20. Expiration date: Month:  Year:

21. Route of administration:

<input type="radio"/> auricular	<input type="radio"/> intravenous	<input type="radio"/> sublingual
<input type="radio"/> inhaled	<input type="radio"/> nasal	<input type="radio"/> transdermal
<input type="radio"/> intra-articular	<input type="radio"/> oral	<input type="radio"/> vaginal
<input type="radio"/> intramuscular	<input type="radio"/> rectal	<input type="radio"/> unknown
<input type="radio"/> intraocular	<input type="radio"/> subcutaneous	<input type="radio"/> other

22. Frequency:

<input type="radio"/> single dose	<input type="radio"/> twice daily	<input type="radio"/> as needed
<input type="radio"/> every other day	<input type="radio"/> three times a day	<input type="radio"/> other
<input type="radio"/> once daily	<input type="radio"/> four times a day	

23. Quantity:

24. Unit code: (Select ONE unit that describes in the greatest detail the amount of medication taken by the subject)

<input type="radio"/> capsule	<input type="radio"/> microliter	<input type="radio"/> puff	<input type="radio"/> teaspoon
<input type="radio"/> drop	<input type="radio"/> milligram	<input type="radio"/> spray/squirt	<input type="radio"/> unknown
<input type="radio"/> grain	<input type="radio"/> milliliter	<input type="radio"/> suppository	<input type="radio"/> other
<input type="radio"/> gram	<input type="radio"/> ounce	<input type="radio"/> tablespoon	
<input type="radio"/> microgram	<input type="radio"/> patch	<input type="radio"/> tablet	

specify: (30 char max)

specify: (30 char max)

specify: (30 char max)

specify: (30 char max)

  

25. Start date:  /  /

26. Stop date:  /  /

27. Name of investigator:

Investigator's signature: THIS DATA NOT ENTERED

Date signed:  /  /

28. Name of physician:

Physician's signature: THIS DATA NOT ENTERED

Date signed:  /  /

Serial Number:

SAE003-08/02/04-Final v.2

[illegible]

SAE003-08/02/04-Final v.2

QSCAT=SATISFACTION QUESTIONNAIRE  
Form 242—Satisfaction Questionnaire

Page 1 of 2

DOMAIN: QS

Study Number: STUDYID

Node:

Site:

Evaluator #:

QSEVAL

ID #: USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment:	QSDTC (YYYY)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Treatment phase: (Mark one only) EPOCH	<input type="checkbox"/> Screening <input type="checkbox"/> Induction/stabilization <input type="checkbox"/> Early termination	VISITNUM	<input type="checkbox"/> Taper <input type="checkbox"/> End of taper <input type="checkbox"/> Post taper	<input type="checkbox"/> 1 Month post taper <input type="checkbox"/> 3 Months post randomization <input type="checkbox"/> 3 Months post taper	

Please tell us about your experience as a participant in this study.  
Your honesty is appreciated!

QSTEST

1. How easy was it for you to get to the clinic?

QSORRES

Very difficult ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Very easy

2. How easy was it for you to become a participant in this study?

Very difficult ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Very easy

3. During the first month, how much did Suboxone help you to stop using opiates?

Not at all ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Extremely helpful

4. During the first month, how much did Suboxone help you with your withdrawal symptoms?

Not at all ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Totally eliminated

- 5A. How easy was it to get off Suboxone?

Very hard ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Very easy

- 5B. If you had the option, how long would you have liked to take Suboxone before being tapered off?

☐ This was just right  
☐ 2 months
 ☐ 3 months  
☐ 6 months
 ☐ 9 months  
☐ 1 year
 ☐ More than 1 year

- 5C. If you had the choice, how long do you think the taper should be?

☐ 1 week  
☐ 2 weeks
 ☐ 3 weeks  
☐ 4 weeks
 ☐ 2 months  
☐ 3 months
 ☐ Longer than 3 months

Please mark ONE answer per question.

THIS DATA NOT ENTERED

Serial Number:

SAT003-03/03/03-Final v.1



# Satisfaction Questionnaire (continued)

Page 2 of 2

DOMAIN: QS

ID #: USUBJID	Name Code:	Date of Assessment: QSDTC	Site:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

## QSTEST

6. Overall, how satisfied were you with the treatment you received? QSORRES

*Not satisfied* ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 *Very satisfied*

7. How effective do you think Suboxone is in treating opiate dependence?

*Not at all effective* ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 *Very effective*

8. If you had it to do over again, would you still choose to participate?

☐ Definitely not ☐ Probably not ☐ Possibly ☐ Probably ☐ Definitely

9. What would you change about the study, if anything?  
(200 characters)

DOMAIN: CO  
COVAL  
RDOMAIN=QS  
IDVAR=VISITNUM

THIS DATA NOT ENTERED

Serial Number:

SAT003-03/03/03-Final v.1

# Form 216—Study Termination Form

Page 1 of 1

DOMAIN: DS, DM, SC

StudyNumber: STUDYID

Node:

Site:

Evaluator#:

ID #: USUBJID

Name Code:

Week #:

Study Day:

Date of Assessment: DSDTC (MM/DD/YYYY)

Treatment phase:  
(Mark one only)

EPOCH

- ☐ Screening  
☐ Induction/stabilization  
☐ Early termination

VISITNUM

- ☐ Taper  
☐ End of taper  
☐ Post taper

- ☐ 1 Month post taper  
☐ 3 Months post randomization  
☐ 3 Months post taper

DM.RFENDTC

1. Date of last visit to the clinic:

SC.SCTEST

SC.SCORRES

2. Study day corresponding to date of last visit:

DSTERM

3. Withdrawn by investigator

☐ Y ☐ N

DSOCCUR

- ☐ Y ☐ N A. More than 14 days from consent  
☐ Y ☐ N B. Missed 1 week of medication  
☐ Y ☐ N C. More than 3 days window at randomization  
☐ Y ☐ N D. Missed 3 consecutive data collection visits (1 month)  
☐ Y ☐ N E. Pregnancy/birth control change  
☐ Y ☐ N F. Medical/psychiatric status change  
☐ Y ☐ N G. Sensitivity or allergy to study medication  
☐ Y ☐ N H. Other administrative (specify) \_\_\_\_\_

4. Withdrawn by participant

☐ Y ☐ N

- ☐ Y ☐ N A. Withdrew consent  
☐ Y ☐ N B. Transferred to another treatment program - indicate type(s)  
☐ Methadone ☐ Naltrexone  
☐ LAAM ☐ Inpatient detox or treatment  
☐ Drug free ☐ Other (specify) \_\_\_\_\_  
☐ Therapeutic community  
☐ Y ☐ N C. Participant has moved from the area  
☐ Y ☐ N D. Participant is in a controlled environment/incarcerated  
☐ Y ☐ N E. Participant can/will no longer attend clinic  
☐ Y ☐ N F. Death  
☐ Y ☐ N G. Other (specify) \_\_\_\_\_

Comments (200 characters)

QNAM=DSWITHD  
QLABEL=OTHER REASON  
FOR WITHDRAWAL  
IDVAR=VISITNUM

THIS DATA NOT ENTERED

Serial Number:

24163

QSCAT=VISUAL ANALOG SCALE

Form 261—Visual Analog Scale

Page 1 of 1

DOMAIN: QS

Study Number: STUDYID

Node:

Site:

Evaluator #:

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QSEVAL

ID #: USUBJID	Name Code:	Week #:	Study Day:	Date of Assessment:	(MM/DD/YYYY)																										
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EPOCH Treatment phase: (Mark one only)		VISITNUM		QSDTC																											
<input type="radio"/> Screening		<input type="radio"/> Taper		<input type="radio"/> 1 Month post taper																											
<input type="radio"/> Induction/stabilization		<input type="radio"/> End of taper		<input type="radio"/> 3 Months post randomization																											
<input type="radio"/> Early termination		<input type="radio"/> Post taper		<input type="radio"/> 3 Months post taper																											

Indicate how you feel  
RIGHT NOW  
by drawing a vertical black line.

QSTEST

1. How much do you currently crave opiates?

Not at all

Extremely

QSORRES

QSORRESU=0-100 POINT ANALOG SCALE

2. How would you rate your current opiate withdrawal symptoms?

None

Severe

3. How much does the study medication help you to not use other opiates?

☐ NA

Not at all

Extremely

Please mark scale with a BOLD BLACK pen ( | )

THIS DATA NOT ENTERED

Serial Number:

VAS003-02/18/2003-Final V.1