NIDA

Annotated Design For Trial: CTN0029

Protocol: CTN29

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SDTM 1.1/IG 3.1.1
ANNOTATION FOR CTN0029

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

DOMAIN: DM, SC

CTN0029 : 2901 - Demographics (DEM)

Patient Information

***WARNING: ANY CHANGES MADE TO THESE FIELDS BELOW (Patient Number and Node) WILL CHANGE THE IDENTIFICATION OF THIS SUBJECT - Changes that make these fields empty will not be acted upon and the prior values will remain for the purpose of identification. ***

1.	Patient Number	A15 siteno-NODE-Participant ID — USUBJID
2.	Node	A3 — SC.SCTEST=NODE
3.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) — DM.DMDTC/SC.SCDTC
4.	Visit Number	[99] xxx [98] 98 NA — VISIT / VISITNUM
Demographics		
5.	1. Sex	[1] 1 Male [2] 2 Female [98] 98 NA — DM.SEX
6.*	2. Date of Birth	NReq / NReq / NReq (1945-1992) — DM.BRTHDTC
7.	3. Ethnicity	3a. [2] 2 Not of Spanish origin, Hispanic or Latino; [1] 1 Spanish origin, Hispanic or Latino — DM.ETHNIC 3b.1. Mexican, Mexican-American, Chicano [0] 0 No [1] 1 Yes [98] 98 NA 3b.2. Puerto Rican [0] 0 No [1] 1 Yes [98] 98 NA 3b.3. Cuban [0] 0 No [1] 1 Yes [98] 98 NA 3b.4. Hispanic or Latino, other (specify) [0] 0 No [1] 1 Yes (specify) A50 [98] 98 NA [98] 98 NA
Race	DM.RACE (if multiple, then = 'MULTIPLE')	
8.	4.a American Indian or Alaskan Native	[0] 0 No [1] 1 Yes [98] 98 NA — SC.SCTEST / SC.SCORRES
9.	4.b Asian	[0] 0 No [1] 1 Yes (If Yes) [98] 98 NA — SC.SCTEST / SC.SCORRES 4.b.1 Asian-Indian [0] 0 No [1] 1 Yes [98] 98 NA 4.b.2 Chinese [0] 0 No [1] 1 Yes [98] 98 NA 4.b.3 Filipino [0] 0 No [1] 1 Yes [98] 98 NA 4.b.4 Japanese [0] 0 No [1] 1 Yes [98] 98 NA 4.b.5 Korean [0] 0 No [1] 1 Yes [98] 98 NA 4.b.6 Vietnamese [0] 0 No [1] 1 Yes [98] 98 NA 4.b.7 Asian, other [0] 0 No [1] 1 Yes (specify) A50 [98] 98 NA QNAM=AOTHERS QLABEL=ASIAN: OTHER TEXT IDVAR=SCSEQ
10.	4.c Black or African American	[0] 0 No [1] 1 Yes [98] 98 NA — SC.SCTEST / SC.SCORRES
11.	4.d Native Hawaiian or Pacific Islander	[0] 0 No [1] 1 Yes (If Yes) [98] 98 NA 4.d.1 Native Hawaiian [0] 0 No [1] 1 Yes [98] 98 NA 4.d.2 Guamanian or Chamarro [0] 0 No [1] 1 Yes [98] 98 NA 4.d.3 Samoan [0] 0 No [1] 1 Yes [98] 98 NA 4.d.4 Native Hawaiian or Pacific Islander, other [0] 0 No [1] 1 Yes (specify) A50 [98] 98 NA QNAM=NOTHERS QLABEL=NATIVE HAWAIIAN OR PACIFIC ISLANDER: OTHER TEXT IDVAR=SCSEQ
12.	4.eWhite	[0] 0 No [1] 1 Yes [98] 98 NA — SC.SCTEST / SC.SCORRES
13.	4.f Race: Other	[0] 0 No [1] 1 Yes Other (specify) A50 [98] 98 NA — SC.SCTEST / SC.SCORRES QNAM=OOTHERS QLABEL=RACE OTHER: OTHER TEXT IDVAR=SCSEQ
14.	4.g Race: Participant chooses not to answer	[1] 1 Yes [98] 98 NA — THIS DATA NOT STORED

15.	4.h Race: Unknown	THIS DATA NOT STORED	[1] ○ 1 Yes [98] ○ 98 NA **DOMAIN: SC, CO**
Education			
16.	5.Education completed (GED=12)	SC.SCTEST / SC.SCORRES	[99] ○ xx (0 < n <= 99) (Years) [98] ○ 98 NA SC.SCORRESU=YEARS
Employment			
17.	6a.Usual Employment Pattern - Past 3 years		Pulldown List 1 SC.SCTEST / SC.SCORRES SCEVLINT=-P3Y
18.	6b.Usual Employment Pattern - Past 30 days		Pulldown List 2 SC.SCTEST / SC.SCORRES SCEVLINT = -P30D
Marital Status			
19.	7. Marital Status		Pulldown List 3 SC.SCTEST / SC.SCORRES
20.*	8. Comments		A200 CO.COVAL IDVAR=USUBJID

* Item is not required

QSCAT=THOUGHTS ABOUT ABSTINENCE (TTA)

DOMAIN: QS

CTN0029 : 2902 - Thoughts About Abstinence (TAA)		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
Section I		
This section asks about how you feel about st QSTEST tte smoking at this time in your life. On the scales below, circle the number that best represents how you feel about st QSORRES ful you will be, and how you will do after you quit.		
3.	1. Using the scale below, how would you describe your desire to quit smoking cigarettes at this time in your life?	Pulldown List 1 (0 = No desire, 9 = Greatest desire)
4.	2. Using the scale below, how would you describe your how successful you expect to be in quitting?	Pulldown List 2 (0 = Very low chance, 9 = Very high chance)
5.	3. Using the scale below, how would you describe how difficult it will be to keep from smoking cigarettes at this time in your life?	Pulldown List 3 (0 = Very easy, 9 = Very difficult)
Section II		
6.	4. What is the GOAL you have chosen for yourself about smoking cigarettes at this time?	Pulldown List 4 A200 (Specify your own goal)

DOMAIN: QS

CTN0	QSCAT= Smoking History Survey (SHS1)	
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
This assessment is t	QSTEST by a Research Assistant	QSORRES
3.	1. How old were you when you first smoked a cigarette?	[99] xx (1 =< n <= 55) [98] 98 NA
4.	2. How old were you when you first started regular daily cigarette smoking?	[99] xx (1 =< n <= 55) [98] 98 NA
5.	3. On average, how many cigarettes are you currently smoking per day?	[99] xx (0 =< n <= 99) [98] 98 NA
6.	4. Over the past year how many cigarettes did you smoke per day?	[99] xx (0 =< n <= 99) [98] 98 NA
7.	5. How many years have you been smoking?	[99] xx (0 =< n <= 55) [98] 98 NA
8.	6.a What brand of cigarettes or tobacco do you smoke most?	[99] SPECIFY BRAND A50 [98] 98 NA
9.	6.b Length	[1] 1 Regular [2] 2 100's [3] 3 Other 6.c (Specify other length): A50 [98] 98 NA
10.	6.d Pack style	[1] 1 Hard pack [2] 2 Soft pack [98] 98 NA
11.	6.e Mentholated	[1] 1 Non-mentholated [2] 2 Mentholated [98] 98 NA
12.	7. Among your close friends and family, what percentage would you say smoke?	Pulldown List 1
13.	8.a Are there any other cigarette smokers in your household/living arrangements?	[0] 0 No [1] 1 Yes 8.b If YES, How many? xx (1 =< n <= 99) [98] 98 NA
14.	9.How much do the people closest to you want you to stop smoking?	Pulldown List 2

DOMAIN: QS

CTN0 QSCAT= Smoking History Survey (Contd) (SHS2)		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
Smoking History (10 QSTEST		QSORRES
3.	10. If you were to stop, how helpful would the people closest to you be?	Pulldown List 1
4.	11.a Have you ever used non-cigarette tobacco products?	[0] 0 No [1] 1 Yes, (If Yes, answer below) **11.b Cigars** [1] 1 Yes [0] 0 No **11.c Pipes** [1] 1 Yes [0] 0 No **11.d Bidis** [1] 1 Yes [0] 0 No **11.e Smokeless tobacco** [1] 1 Yes [0] 0 No [98] 98 NA
5.	12. How many times have you attempted to quit smoking?	[1] xxx (0 =< n <= 999) [98] 98 NA ***(IF ZERO times, answer questions 13 & 14.)***
6.	13. Since you started smoking regularly, what is the longest time that you have gone without smoking any cigarettes?	Pulldown List 2
7.	14.a Have you ever experienced uncomfortable symptoms when you stopped smoking?	[0] 0 Does not apply - I have never stopped smoking [1] 1 I have stopped smoking in the past but never experienced uncomfortable symptoms [2] I have stopped smoking in the past and have experienced uncomfortable symptoms If yes, what symptoms did you experience: **14.b Craving** [1] 1 Yes [0] 0 No **14.c Decreased heart rate** [1] 1 Yes [0] 0 No **14.d Irritability** [1] 1 Yes [0] 0 No **14.e Anxiety** [1] 1 Yes [0] 0 No **14.f Increased eating** [1] 1 Yes [0] 0 No **14.g Restlessness** [1] 1 Yes [0] 0 No **14.h Difficulty concentrating** [1] 1 Yes [0] 0 No **14.i Other** [1] 1 Yes **(If Yes), Other SPECIFY** [0] 0 No A200 [98] 98 NA
Enter the number of times you have tried the following method to stop smoking:		
8.	15.a Self-help material (for example American Lung Association material, materials from doctor, etc...)	[99] xxx (0 =< n <= 999) [98] 98 NA
9.	15.b A formal cessation program (for example with classes, group discussions, etc...)	[99] xxx (0 =< n <= 999) [98] 98 NA
10.	15.c A private consultation with your doctor or mental health physician	[99] xxx (0 =< n <= 999) [98] 98 NA
11.	15.d Hypnosis/Acupuncture	[99] xxx (0 =< n <= 999) [98] 98 NA
12.	15.e Nicotine medicated gum	[99] xxx (0 =< n <= 999) [98] 98 NA
13.	15.f Zyban	[99] xxx (0 =< n <= 999) [98] 98 NA

DOMAIN: QS

CTN0	QSCAT= Smoking History Survey (Contd) (SHS3)	
1.	**Assessment Date** QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	**Visit Number** VISITNUM	[99] xxx [98] 98 NA
Smoking History (15.g-18)		
Enter the number of times you have tried th	QSTEST : to stop smoking:	QSORRES
3.	**15.g On your own (cold turkey)**	[99] xxx (0 =< n <= 999) [98] 98 NA
4.*	**15.h Other**	[1] xxx (0 =< n <= 999) **15.i Other please describe:** A50 [98] 98 NA
5.	**16.a Have you ever used nicotine skin patches?**	[0] 0 No [98] 98 NA [1] 1 Yes (If Yes, complete the following:) **16.b If you have used nicotine skin patches, how many times?** xxx (0 =< n <= 999) **16.c If you have used nicotine skin patches, did you have any problems with the patch?** [0] 0 No [98] 98 NA [1] 1 Yes If **16.c was yes, please describe:** A200
6.	**17.a When was your last attempt to stop/quit smoking?**	(If Never attempted,STOP) [0] 0 Never attempted [98] 98 NA [1] Pulldown List 1 [99] **17.b When was the date of the last attempt to quit smoking?** Req / NReq / Req (1948-2009) [98] 98 NA **17.c Did you use a smoking cessation counseling program or medication to help you quit smoking?** [1] 1 Yes [0] 0 No [98] 98 NA **17.d For how long did you go without smoking at that time?** [0] 0 Never stopped [1] 1 Hours [2] 2 Days [3] 3 Weeks [4] 4 Months [5] 5 Years [98] 98 NA [99] **17.e How did you stop? Please describe:** [98] 98 NA A200 [99] **17.f Why did you start again? Please describe:** [98] 98 NA A200
7.	**18. What is the longest period of time you have gone without smoking?**	Pulldown List 2

* Item is not required

QSCAT=

DOMAIN: QS

	CTN0029 : 2904 - PRISM Suicidal and Homicidal Intent (PSM)		
1.	**Assessment Date**	QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	**Visit Number**	VISITNUM	[99] xxx [98] 98 NA
3.	**1. Recurrent Thoughts of Death**	QSTEST	**A. Rating Scale:** [-9] -9 Not Answered [1] 1 Absent [2] 2 Subthreshold [3] 3 Present **B. Most Recent Occurrence:** [1] 1 Prior to the past 6 months [2] 2 In the past 6 months [98] 98 NA — QSORRES
4.	**2. Recurrent Suicidal Ideation**		**A. Rating Scale:** [-9] -9 Not Answered [1] 1 Absent [2] 2 Subthreshold [3] 3 Present **B. Most Recent Occurrence:** [1] 1 Prior to the past 6 months [2] 2 In the past 6 months [98] 98 NA
5.	**3. Specific Suicide Plan**		**A. Rating Scale:** [-9] -9 Not Answered [1] 1 Absent [2] 2 Subthreshold [3] 3 Present **B. Most Recent Occurrence:** [1] 1 Prior to the past 6 months [2] 2 In the past 6 months [98] 98 NA
6.	**4. Suicide Gesture**		**A. Rating Scale:** [-9] -9 Not Answered [1] 1 Absent [2] 2 Subthreshold [3] 3 Present **B. Most Recent Occurrence:** [1] 1 Prior to the past 6 months [2] 2 In the past 6 months [98] 98 NA
7.	**5. Suicide Attempt**		**A. Rating Scale:** [-9] -9 Not Answered [1] 1 Absent [3] 3 Present **B. Most Recent Occurrence:** [1] 1 Prior to the past 6 months [2] 2 In the past 6 months [98] 98 NA
8.	**6. Recurrent Homicidal Ideation**		**A. Rating Scale:** [-9] -9 Not Answered [1] 1 Absent [2] 2 Subthreshold [3] 3 Present **B. Most Recent Occurrence:** [1] 1 Prior to the past 6 months [2] 2 In the past 6 months [98] 98 NA
9.*	**7. Specific Homicidal Plan**		**A. Rating Scale:** [1] 1 Absent [3] 3 Present [-9] -9 Not Answered

* Item is not required

DOMAIN: LB, CO

CTN0029 : 2905 - Urine Drug Screen (UDS) LBCAT=DRUG SCREEN		
1.	Assessment Date LBDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISIT / VISITNUM	[99] xxx [98] 98 NA
Section I: Urine Collection		
3.	1. Was a urine sample obtained? LBSTAT / LBREASND	(If Yes, skip to question 2) [0] 0 No 1.a Why was a urine sample not obtained? [1] 1 Participant reported being unable to provide sample [2] 2 Participant refused to provide sample [3] 3 Study Staff Error [4] Other (SPECIFY): A200 [1] 1 Yes [98] 98 NA
4.	2. Was urine collection observed?	[0] 0 No [1] 1 Yes [98] 98 NA
5.	3. Urine temperature within expected range (between 90 and 99 degrees Fahrenheit)?	[0] 0 No [1] 1 Yes [98] 98 NA
Section II: Urine Drug Screen Results		
6.	4. Benzodiazepines LBTEST / LBTESTCD	[1] 1 Negative [2] 2 Positive [3] 3 Unknown [98] 98 NA LBORRES
7.	5. Cocaine	[1] 1 Negative [2] 2 Positive [3] 3 Unknown [98] 98 NA
8.	6. Methamphetamine	[1] 1 Negative [2] 2 Positive [3] 3 Unknown [98] 98 NA
9.	7. Morphine (opiates)	[1] 1 Negative [2] 2 Positive [3] 3 Unknown [98] 98 NA
10.	8. THC (marijuana)	[1] 1 Negative [2] 2 Positive [3] 3 Unknown [98] 98 NA
11.*	9. Comments	A200 CO.COVAL IDVAR=LBSEQ
* Item is not required		

QNAM=LBSUPER
QLABEL=URINE COLLECTION SUPERVISED
IDVAR=LBSEQ

QNAM=LBTEMP
QLABEL=URINE TEMP WITHIN EXPECTED RANGE
IDVAR=LBSEQ

QSCAT=

DOMAIN: QS

CTN0029 : 2906 - Adult Self Report Scale (ASR)			
1.	Assessment Date	QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	QSTEST VISITNUM	[99] xxx [98] 98 NA QSORRES
Please check the box that best describes how you have felt and conducted yourself over the past 6 months.			
3.	1. How often do you have trouble wrapping up the final details of a project once the challenging parts have been done?		Pulldown List 1
4.	2. How often do you have difficulty getting things in order when you have to do a task that requires organization?		Pulldown List 1
5.	3. How often do you have problems remembering appointments or obligations?		Pulldown List 1
6.	4. When you have a task that requires a lot of thought, how often do you avoid or delay getting started?		Pulldown List 1
7.	5. How often do you fidget or squirm with your hands or your feet when you have to sit for a long time?		Pulldown List 1
8.	6. How often do you feel overly active and compelled to do things, like you were driven by a motor?		Pulldown List 1

DOMAIN: VS, CO

CTN0029 : 2915 - Vital Signs (VSF)		
1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) VSDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT/VISITNUM
Reading 1	VSCAT=READING 1	
3.	Pulse (beats per minute)	[99] A. xxx (35 =< n <= 150) [98] 98 NA VSORRES
4.	Blood Pressure	[99] B. Systolic xxx (45 =< n <= 180) [98] 98 NA
5.	Blood Pressure	[99] C. Diastolic xxx (35 =< n <= 120) [98] 98 NA
6.	Weight (Scrn, wks 6, 11)	[99] D. xxx (80 =< n <= 400) lbs [98] 98 NA
7.	Height (Scrn)	[99] E. xxx in [98] 98 NA
Reading 2	VSCAT=READING 2	
If the systolic blood pressure for the first reading is: 1. >130 (for pts 40-55) or >135 (for pts <40) or 2. <90 OR the diastolic blood pressure for the first reading is 1. >90 (for pts 40-55) or >95 (for pts <40) or 2. <60 then wait for five minutes and then repeat the assessment.		
8.	Blood Pressure	[99] B. Systolic xxx (45 =< n <= 180) [98] 98 NA
9.	Blood Pressure	[99] C. Diastolic xxx (35 =< n <= 120) [98] 98 NA
Reading 3	VSCAT=READING 3	
If two blood pressure readings were completed then average the systolic readings and average the diastolic readings and record the averages in the appropriate fields below.		
10.	Systolic average of 1 and 2	[99] B. Systolic xxx (45 =< n <= 180) [98] 98 NA
11.	Diastolic average of 1 and 2	[99] C. Diastolic xxx (35 =< n <= 120) [98] 98 NA
12.*	Comments	F. A200 CO.COVAL
* Item is not required		IDVAR=USUBJID

QSCAT=

DOMAIN: QS

CTN0029 : 2918 - DSM-IV ADHD CHECKLIST (DSM)			
1.	Assessment Date	QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	VISITNUM	[99] xxx [98] 98 NA
3.	1. Carelessness	QSTEST	QSORRES Pulldown List 1
4.	2. Difficulty sustaining attention in activities		Pulldown List 1
5.	3. Doesn't listen		Pulldown List 1
6.	4. No follow through		Pulldown List 1
7.	5. Can't organize		Pulldown List 1
8.	6. Avoids/dislikes tasks requiring sustained mental effort		Pulldown List 1
9.	7. Loses important items		Pulldown List 1
10.	8. Easily distractible		Pulldown List 1
11.	9. Forgetful in daily activities		Pulldown List 1
12.	10. Squirms and fidgets		Pulldown List 1
13.	11. Can't stay seated		Pulldown List 1
14.	12. Runs/climbs excessively		Pulldown List 1
15.	13. Can't play/work quietly		Pulldown List 1
16.	14. On the go, driven by a motor		Pulldown List 1
17.	15. Talks excessively		Pulldown List 1
18.	16. Blurts out answers		Pulldown List 1
19.	17. Can't wait for turn		Pulldown List 1
20.	18. Intrudes/interrupts others		Pulldown List 1
21.	Total Score (Screening/Baseline Only)		[99] xx (2922-Study Eligibility Q-4) [98] 98 NA

QSCAT=

DOMAIN: QS

CTN0029 : 2919 - CGI For ADHD (CGI)		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
Global Severity of ADHD QSTEST		QSORRES
3.	1. How severe were the participant's ADHD symptoms during the past two (2) weeks (for screening/baseline) or since the previous visit (for active study)?	Pulldown List 1

SUCAT=TOBACCO USE – PRE ACTIVE STUDY

DOMAIN: SU

CTN0029 : 2921 - Tobacco Use - Pre-Study (TUP1)

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) SUDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM
3.	Day 1 SUGRPID=PRE STUDY FILE 1 SUSPID	[99] Date Req / Req / Req (2005-2009) SUSTDTC; Cigarettes Smoked? [1] 1 Yes SUOCCUR; Number of Cigarettes Smoked? xxx (0 =< n <= 999) SUTRT = CIGARETTE; [0] 0 No SUDOSE / SUDOSU; [98] 98 NA
4.	Day 2	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
5.	Day 3	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
6.	Day 4	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
7.	Day 5	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
8.	Day 6	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
9.	Day 7	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
10.	Day 8	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
11.	Day 9	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
12.	Day 10	[99] Date Req / Req / Req (2005-2009); Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No; [98] 98 NA
13.	Day 11	[99] Date / / Cigarettes Smoked?

DOMAIN: SU

SUGRPID

SUSPID

SUSTDTC

SUOCCUR

SUDOSE / SUDOSU

SUTRT = CIGARETTE

		[99] ○ Req / Req / Req (2005-2009) [98] ○ 98 NA [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No
14.	Day 12	[99] ○ Date Req / Req / Req (2005-2009) [98] ○ 98 NA Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No
15.	Day 13	[99] ○ Date Req / Req / Req (2005-2009) [98] ○ 98 NA Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No
16.	Day 14	[99] ○ Date Req / Req / Req (2005-2009) [98] ○ 98 NA Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No
17.	Day 15	[99] ○ Date Req / Req / Req (2005-2009) [98] ○ 98 NA Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No
18.	Day 16	[99] ○ Date Req / Req / Req (2005-2009) [98] ○ 98 NA Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No
19.	Day 17	[99] ○ Date Req / Req / Req (2005-2009) [98] ○ 98 NA Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No
20.	Day 18	[99] ○ Date Req / Req / Req (2005-2009) [98] ○ 98 NA Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No

SUCAT=TOBACCO USE – PRE ACTIVE STUDY

DOMAIN: SU

CTN0029 : 2921 - Tobacco Use - Pre-Study Contd (TUP2)

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) SUDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM
Assessment Contd		SUGRPID=PRE STUDY FILE 2
3.	Day 19	[99] Date Req / Req / Req (2005-2009) SUSTDTC Cigarettes Smoked? [1] 1 Yes SUOCCUR Number of Cigarettes Smoked? [0] SUDOSE / SUDOSU [98] 98 NA
4.	Day 20	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
5.	Day 21	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
6.	Day 22	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
7.	Day 23	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
8.	Day 24	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
9.	Day 25	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
10.	Day 26	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
11.	Day 27	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
12.	Day 28	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA

SUSPID

SUTRT = CIGARETTE

DOMAIN: SU, LB, QS, CO

13.	Carbon Monoxide Reading 29a. Current time:	[99] ○ Req : Req 24-hour clock [98] ○ 98 NA
14.	29b. Trial #1 CO	[99] ○ xxx ppm [98] ○ 98 NA
15.	29c. Trial #2 CO	[99] ○ xxx ppm [98] ○ 98 NA
16.	30a. Have you smoked anything else besides tobacco products in the past 7 days (for example, herbal cigarettes, marijuana joints, etc)?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
17.	30b. Do you work, or have you been, in an area where there is quite a bit of car exhaust(for example, garage, etc)?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 N
18.	30c. Do you know if you have a defective furnace at home that could be giving out a higher-than-normal reading of CO?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
19.	31a. Have you used any non-cigarette tobacco products in the past 28 days (during the time-frame assessed for cigarette use)?	[0] ○ 0 No [1] ○ 1 Yes - If Yes: 31b. Chews: xxx (0 =< n <= 999) 31c. Dips: xxx (0 =< n <= 999) 31d. Pipefuls: xxx (0 =< n <= 999) 31e. Cigars: xxx (0 =< n <= 999) [98] ○ 98 NA
20.	32. Were any of these products used in the past week?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
21.*	33. Comments	A50

* Item is not required

LB.LBDTC LBCAT = TOBACCO USE – ACTIVE STUDY

LB.LBTEST/LBTESTCD/LBORRES/LBORRESU LBCAT=TOBACCO USE – PRE ACTIVE STUDY

LB.LBTEST/LBTESTCD/LBORRES/LBORRESU LBCAT = TOBACCO USE – PRE ACTIVE STUDY

SU.SUOCCUR SU.SUEVLINT=-P7D

SU.SUTRT=SMOKED ANYTHING ELSE BESIDES TOBACCO IN PAST 7 DAYS

SU.SUTRT=NON CIGARETTE TOBACCO PRODUCT

SU.SUOCCUR

SUDOSE / SUDOSU SU.SUEVLINT=-P28D

SU.SUOCCUR SU.SUEVLINT=-P7D

CO.COVAL

IDVAR=SUSEQ

QS.QSTEST = WORK WHERE THERE IS CARE EXHAUST?

QSTESTCD= RCNOYE1

QSORRES

QS.QSTEST = DEFECTIVE FURNACE AT HOME

QSTESTCD= RCNOYE2

QSORRES

DOMAIN: MH

CTN0029 : 2907 - Medical History Addendum (MHA)

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) MHDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM
I. Cardiovascular History A. Personal History		MHCAT=CARDIOVASCULAR HISTORY MHSCAT=PERSONAL HISTORY
3.	1. Participant's age?	[99] xxx (0 =< n <= 130) [98] 98 NA
4.	2. Hypertension MHTERM MHOCCUR	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
5.	3. Coronary artery disease	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
6.	4. Chest pain	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
7.	5. Palpitations	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
8.	6. Shortness of Breath	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
9.	7. Dizziness	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
10.	8.1 Syncope	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
11.	8.2 History of CHF	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
12.	8.3 History of MI	[0] 0 No [1] 1 Yes Specify

QNAM=MHAGE
QLABEL=MEDICAL HISTORY AGE
IDVAR=MHGRPID

QNAM=MHSPEC
QLABEL=MEDICAL HISTORY SPECIFY
IDVAR=MHSEQ

QNAM=MHPRES
QLABEL=CONDITION PRESENT CURRENTLY
IDVAR=MHSEQ

DOMAIN: MH, CO

		A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
B. Family History	MHCAT=CARDIOVASCULAR HISTORY	MHSCAT=FAMILY HISTORY
13.	9. History of Early MI MHTERM	MHOCCUR [0] 0 No [1] 1 Yes [9] 9 Unknown [98] 98 NA Specify A200
14.	10. History of sudden cardiac death	[0] 0 No [1] 1 Yes [9] 9 Unknown [98] 98 NA Specify A200
15.	11. History of significant arrhythmias?	[0] 0 No [1] 1 Yes [9] 9 Unknown [98] 98 NA Specify A200
16.	12. History of congenital heart disease (particularly cardiomyopathy?	[0] 0 No [1] 1 Yes [9] 9 Unknown [98] 98 NA Specify A200
17.*	13. Comments:	A200 CO.COVAL IDVAR=MHGRPID
II. Assessment of Other Study Eligibility Criteria:	MHCAT=ASSESSMENT OF OTHER STUDY ELIGIBILITY CRITERIA = MHSCAT	
18.	14. Is the participant currently taking any medication to treat ADHD or Smoking? MHTERM	[1] 1 Yes [0] 0 No [98] 98 NA MHOCCUR
19.	15. Has the participant been treated for ADHD in the past 90 days with any psychostimulant medications?	[1] 1 Yes [0] 0 No [98] 98 NA
20.	15a. Methylphenidate (Ritalin)	[1] 1 Yes [0] 0 No [98] 98 NA
21.	15b. OROS-Methylphenidate	[1] 1 Yes [0] 0 No [98] 98 NA
22.	15c. Adderall	[1] 1 Yes [0] 0 No [98] 98 NA
23.	15d. Metadate	[1] 1 Yes [0] 0 No [98] 98 NA
24.	15e. Methylin	[1] 1 Yes [0] 0 No [98] 98 NA
25.	15f. Other	[1] 1 Yes (If yes, specify 'other' psychostimulant medication in 15g) **15g.** Specify Other: A50 [0] 0 No [98] 98 NA
26.	16a. Has the participant ever been treated with Methylphenidate (e.g., Ritalin, OROS-MPH)?	[1] 1 Yes [0] 0 No [98] 98 NA
27.	16b. If treated with methylphenidate, did the participant fail to evidence a decrease in ADHD symptoms despite having received an adequate trial of Methylphenidate?	[1] 1 Yes [0] 0 No [98] 98 NA
28.	17. Have you had an adverse or allergic reaction to OROS-MPH?	[1] 1 Yes [0] 0 No [98] 98 NA
29.	18. Does the participant have a history of narrow angle glaucoma?	[1] 1 Yes [0] 0 No [98] 98 NA
30.	19. Does the participant or anyone in his/her family have tics or Tourette's Syndrome?	[1] 1 Yes [0] 0 No [98] 98 NA
31.*	20. Comments:	A200 CO.COVAL IDVAR=MHGRPID

* Item is not required

QNAM=MHSPEC
QLABEL=MEDICAL HISTORY SPECIFY
IDVAR=MHSEQ

DOMAIN: MH

CTN0029 : 2911 - Medical History (MDH)

1.	Assessment Date	MHDTC — Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	VISIT / VISITNUM — [99] xxx [98] 98 NA
Medical History		MHCAT=MEDICAL HISTORY = MHSCAT
3.	1. Asthma	MHTERM — MHOCCUR — [0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA; Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA; [9] 9 Unknown; [98] 98 NA
4.	2. Cardiovascular	[0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA; Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA; [9] 9 Unknown; [98] 98 NA
5.	3. Dermatologic	[0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA; Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA; [9] 9 Unknown; [98] 98 NA
6.	4. Drug Allergies	[0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA; Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA; [9] 9 Unknown; [98] 98 NA
7.	5. Endocrine	[0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA; Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA; [9] 9 Unknown; [98] 98 NA
8.	6. Gastrointestinal	[0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA; Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA; [9] 9 Unknown; [98] 98 NA
9.	7. Genitourinary	[0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA; Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA; [9] 9 Unknown; [98] 98 NA
10.	8. Head Injury	[0] 0 No [1] 1 Yes; Specify A200; Condition Present Currently? 0 No 1 Yes 98 NA

QNAM=MHPRES
QLABEL=CONDITION PRESENT CURRENTLY
IDVAR=MHSEQ

QNAM=MHEXCL
QLABEL=CONDITION EXCLUDES PARTICIPANT
IDVAR=MHSEQ

QNAM=MHSPEC
QLABEL=MEDICAL HISTORY SPECIFY
IDVAR=MHSEQ

DOMAIN: MH

			[0] ○ [1] ○ [98] ○ Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA
11.	9. HEENT MHTERM	QNAM=MHPRES QLABEL=CONDITION PRESENT CURRENTLY IDVAR=MHSEQ	MHOCCUR [0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA QNAM=MHSPEC QLABEL=MEDICAL HISTORY SPECIFY IDVAR=MHSEQ
12.	10. Hematologic	QNAM=MHEXCL QLABEL=CONDITION EXCLUDES PARTICIPANT IDVAR=MHSEQ	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA
13.	11. Hepatic		[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA
14.	12. Infectious Disease		[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA
15.	13. Metabolic		[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA
16.	14. Musculoskeletal		[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA
17.	15. Other Allergies		[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA [9] ○ 9 Unknown [98] ○ 98 NA
18.	16. Pulmonary		[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA

DOMAIN: MH

		Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
19.	17. Renal MHTERM QNAM=MHPRES QLABEL=CONDITION PRESENT CURRENTLY IDVAR=MHSEQ	MHOCCUR [0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA QNAM=MHSPEC QLABEL=MEDICAL HISTORY SPECIFY IDVAR=MHSEQ
20.	18. Reproductive system QNAM=MHEXCL QLABEL=CONDITION EXCLUDES PARTICIPANT IDVAR=MHSEQ	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
Psychiatric/Neurological History	MHCAT=MEDICAL HISTORY MHSCAT=PSYCHIATRIC/NEUROLOGICAL HISTORY	
21.	19. Anxiety or Panic Disorder	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
22.	20. Attention Deficit Hyperactivity Disorder	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
23.	21. Bipolar Disorder	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
24.	22. Clinically Significant Neurological Damage	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
25.	23. Epilepsy or Seizure Disorder	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
26.	24. Major Depressive Disorder	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA

DOMAIN: MH

		Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
27.	25. Schizophrenia MHTERM QNAM=MHPRES QLABEL=CONDITION PRESENT CURRENTLY IDVAR=MHSEQ	MHOCCUR [0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA QNAM=MHSPEC QLABEL=MEDICAL HISTORY SPECIFY IDVAR=MHSEQ
28.	26. Tourette's Syndrome QNAM=MHEXCL QLABEL=CONDITION EXCLUDES PARTICIPANT IDVAR=MHSEQ	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
29.	27. Suicidal Ideation	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
30.	28. Suicidal Behavior	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
31.	29. Homicidal Ideation	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
32.	30. Homicidal Behavior	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
33.	31. Violent Behavior	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA [9] 9 Unknown [98] 98 NA
34.	32. Psychotic Episodes	[0] 0 No [1] 1 Yes Specify A200 Condition Present Currently? [0] 0 No [1] 1 Yes [98] 98 NA Condition Excludes Participant? [0] 0 No [1] 1 Yes [98] 98 NA 9 Unknown

DOMAIN: MH

MHCAT=MEDICAL HISTORY

MHSCAT=OTHER RELEVANT MEDICAL HISTORY

MHOCCUR

MHTERM

QNAM=MHPRES
QLABEL=CONDITION PRESENT CURRENTLY
IDVAR=MHSEQ

QNAM=MHSPEC
QLABEL=MEDICAL HISTORY SPECIFY
IDVAR=MHSEQ

QNAM=MHEXCL
QLABEL=CONDITION EXCLUDES PARTICIPANT
IDVAR=MHSEQ

		[9] ○ [98] ○ 98 NA
Indicate other relevant medical history		
35.	33. Other 1	[99] ○ Specify A200 [98] ○ 98 NA Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
36.	34. Other 2	[99] ○ Specify A200 [98] ○ 98 NA Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
37.	35. Other 3	[99] ○ Specify A200 [98] ○ 98 NA Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
Surgical History		
38.	36. Has the subject had any major surgery?	[0] ○ 0 No [1] ○ 1 Yes [9] ○ 9 Unknown [98] ○ 98 NA
	Type of Surgery	Surgery Date
39.		

MHTERM

Procedures and Dates Entry		
39.a	Type of Surgery	A255
39.b	Surgery Date	[99] ○ NReq / NReq / NReq (1950-2009) [0] ○ Unknown

MHSTDTC

MHCAT=MEDICAL HISTORY

MHSCAT=SURGERY

RPCAT=PREGNANCY AND BIRTH CONTROL ASSESSMENT

DOMAIN: RP, CO

CTN0029 : 2912 - Pregnancy and Birth Control Assessment (PBC)		
1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) RPDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM
Pregnancy Test		
3.	1. Was a pregnancy test performed? RPTEST/RPTESTCD	[0] 0 No [1] 1 Yes [98] 98 NA RPORRES
4.	2. Date of pregnancy test:	[99] Req / Req / Req (2005-2009) [98] 98 NA
5.	3. Pregnancy test result:	[1] 1 Negative [2] 2 Positive [98] 98 NA
Breastfeeding - Complete only during Baseline/Screening		
6.	4. Is the participant breastfeeding?	[0] 0 No [1] 1 Yes [98] 98 NA
Birth Control Method - Complete on during Baseline/Screening		
7.	5a. Does the participant agree to use an acceptable method of birth control?	[0] 0 No [1] 1 Yes (If Yes, Indicate all methods of birth control the participant agrees to use:) [0] 0 No [1] 1 Yes [98] 98 NA **5b. Abstinence** [0] 0 No [1] 1 Yes [98] 98 NA **5c. Barrier** [0] 0 No [1] 1 Yes [98] 98 NA **5d. IUD** [0] 0 No [1] 1 Yes [98] 98 NA **5e. Levonorgestrel Implant** [0] 0 No [1] 1 Yes [98] 98 NA **5f. Medroxyprogesterone Acetate Injection** [0] 0 No [1] 1 Yes [98] 98 NA **5g. Oral Contraceptives** [0] 0 No [1] 1 Yes [98] 98 NA **5h. Patch** [0] 0 No [1] 1 Yes [98] 98 NA **5i. Surgical Sterilization** [0] 0 No [1] 1 Yes **5j. Other:** [98] 98 NA **5k. Specify** A100 [98] 98 NA
8.*	6. Comments	A200 CO.COVAL
* Item is not required		IDVAR=RPSEQ

QSCAT=

DOMAIN: QS

CTN0029 : 2916 - Summary of CIDI and ASPD Screen (CID)		
1.	Assessment Date	QSDTC — Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	VISITNUM — [99] xxx [98] 98 NA
A. Substance Abuse/Dependence Disorders		
3.	1. Does the participant meet DSM-IV criteria for any current substance abuse or dependence disorders?	[0] 0 No [1] 1 Yes [98] 98 NA
	DSM-IV Code	DSM-IV Diagnosis
4.		
2. If Yes, list the substance abuse/dependence disorder(s) for which the participant currently meets criteria Entry		
4.a	Substance Abuse/Dependence Disorders DSM IV Code1 — QSTEST	xxxxxxx.
4.b	Substance Abuse/Dependence Disorders DSM IV Diagnosis 1 — QSTEST	A200
5.	3. Does the participant meet DSM-IV criteria for a lifetime diagnosis for any substance abuse/dependence disorder for which he or she does not meet current criteria?	[0] 0 No [1] 1 Yes [98] 98 NA
	DSM-IV Code	DSM-IV Diagnosis
6.		
4. If Yes, list the disorder(s) for which the participant meets lifetime criteria Entry		
6.a	Lifetime DSM IV Code 1 — QSTEST	xxxxxxx. — QSORRES
6.b	Lifetime DSM IV Diagnosis 1 — QSTEST	A200 — QSORRES
B. Axis I, Non-Substance Abuse/Dependence Disorders		
7.	5. Does the participant currently meet DSM-IV criteria for any non-substance abuse/dependence disorders?	[0] 0 No [1] 1 Yes [98] 98 NA
	DSM-IV Code	DSM-IV Diagnosis
8.		
6. If Yes, list the disorder(s) for which the participant currently meets criteria Entry		
8.a	Non-substance abuse/dependence DSM-IV Code 1 — QSTEST	xxxxxxx. — QSORRES
8.b	Non-substance abuse/dependence DSM-IV Diagnosis 1 — QSTEST	A200 — QSORRES
9.	7. Does the participant meet DSM-IV criteria for a lifetime diagnosis for any non-substance abuse/dependence disorder for which he or she does not meet current criteria?	[0] 0 No [1] 1 Yes [98] 98 NA
	DSM-IV Code	DSM-IV Diagnosis
10.		
8. If Yes, list the disorder(s) for which the participant meets lifetime criteria Entry		
10.a	Lifetime Non substance abuse/dependence DSM-IV Code 1 — QSTEST	xxxxxxx. — QSORRES
10.b	Lifetime Non substance abuse/dependence DSM-IV Diagnosis 1 — QSTEST	A200 — QSORRES
II. Summary of DSM-IV Screen for Antisocial Personality Disorder		
11.	9. Does the participant meet criteria for antisocial personality disorder?	[0] 0 No [1] 1 Yes [98] 98 NA — QSORRES

DOMAIN: EG

CTN0029 : 2940 - Electrocardiogram (ECG)

1.	**Assessment Date**	Req / Req / Req (2005-2009) (mm/dd/yyyy) EGDTC
2.	**Visit Number**	[99] ○ xxx [98] ○ 98 NA VISIT / VISITNUM
A. ECG Overall Results		
3.	**ECG overall results**	[0] ○ 0 Normal [1] ○ 1 Abnormal [98] ○ 98 NA

EGTEST/EGTESTCD

EGORRES

2. Increased QRS Voltage
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
3. QTc Prolongation
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
4. Left Atrial Hypertrophy
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
5. Right Atrial Hypertrophy
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
6. Left Ventricular Hypertrophy
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
7. Right Ventricular Hypertrophy
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
8. Acute Infarction
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
9. Subacute Infarction
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
10. Old Infarction
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
11. Myocardial Ischemia
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
12. Digitalis Effect
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
13. Symmetrical T-wave Inversions
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
14. Poor R-Wave Progression
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
15. Other Nonspecific ST/T
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
16. Sinus Tachycardia
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
17.Sinus Bradycardia
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
18. Superventricular Premature Beat
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
19.Ventricular Premature Beat
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
20. Supraventricular Tachycardia
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
21. Ventricular Tachycardia
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
22. Atrial Fibrillation
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
23. Atrial Flutter
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
24. Other Rhythm Abnormalities
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
25. Implanted Pacemaker
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
26. 1st Degree A-V Block
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
27. 2nd Degree A-V Block
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
28. 3rd Degree A-V Block
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
29. LBB Block
[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA
30. RBB Block

DOMAIN: EG

EGTEST/EGTESTCD

EGORRES

		[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA 31. Pre-excitation Syndrome [1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA 32. Other Intraventricular Condition Block [1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ 98 NA 33. Other Abnormality [99] ○ specify: | A200 | [98] ○ 98 NA
4.	34. Ventricular rate (bpm):	34. Ventricular rate (bpm): [99] ○ | xxx | [98] ○ 98 NA
5.	35. QRS (ms):	35. QRS (ms): [99] ○ | xxx | [98] ○ 98 NA
6.	36. PR (ms):	36. PR (ms): [99] ○ | xxx | [98] ○ 98 NA
7.	37. QTc (ms):	37. QTc (ms): [99] ○ | xxx | [98] ○ 98 NA

DOMAIN: QS

CTN0029 : 2920 - Adult ADHD Clinical Diagnostic Scale (ACDS1) =QSCAT		
1.	**Assessment Date**	Req / Req / Req (2005-2009) (mm/dd/yyyy) QSDTC
2.	**Visit Number**	[99] xxx [98] VISITNUM
ADHD CHILDHOOD HISTORY		
3.	**1. Makes a Lot of Careless Mistakes** QSTEST	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate QSORRES [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
4.	**2. Difficulty Sustaining Attention on Tasks/Play Activities**	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
5.	**3. Doesn't Listen**	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
6.	**4. Difficulty Following Instructions**	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
7.	**5. Difficulty Organizing Tasks**	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
8.	**6. Dislikes/Avoids Tasks Requiring Attention**	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
9.	**7. Loses Things**	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
10.	**8. Easily Distracted**	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe 6 Absent or false due to therapeutic medication

DOMAIN: QS

		[6] ○ [8] ○ 8 Present or true due to medical condition [9] ○ 9 Inadequate information [98] ○ 98 NA
11.	**9. Forgetful in Daily Activities**	[1] ○ 1 Not present **[99]** ○ [2] ○ 2 Mild Age: | xx | Grade: | xx | [3] ○ 3 Moderate [4] ○ 4 Severe [6] ○ 6 Absent or false due to therapeutic medication [8] ○ 8 Present or true due to medical condition [9] ○ 9 Inadequate information [98] ○ 98 NA
12.	**10. Fidget**	[1] ○ 1 Not present **[99]** ○ [2] ○ 2 Mild Age: | xx | Grade: | xx | [3] ○ 3 Moderate [4] ○ 4 Severe [6] ○ 6 Absent or false due to therapeutic medication [8] ○ 8 Present or true due to medical condition [9] ○ 9 Inadequate information [98] ○ 98 NA
13.	**11. Difficulty Remaining Seated**	[1] ○ 1 Not present **[99]** ○ [2] ○ 2 Mild Age: | xx | Grade: | xx | [3] ○ 3 Moderate [4] ○ 4 Severe [6] ○ 6 Absent or false due to therapeutic medication [8] ○ 8 Present or true due to medical condition [9] ○ 9 Inadequate information [98] ○ 98 NA

DOMAIN: QS

CTN0029 : 2920 - Adult ADHD Clinical Diagnostic Scale Contd (ACDS-CHIST2) =QSCAT		
1.	Assessment Date	Req QSDTC (2005-2009) (mm/dd/yyyy)
2.	Visit Number	[99] [xxx] [98] VISITNUM
ADHD CHILDHOOD HISTORY Contd		
3.	12. Runs or Climbs Excessively QSTEST	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate QSORRES [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
4.	13. Difficulty Playing Quietly	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
5.	14. On the Go/Acts Like Driven by Motor	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
6.	15. Talks Excessively	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
7.	16. Blurts Out Answers	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
8.	17. Difficulty Waiting Turn	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
9.	18. Interrupts or Intrudes	[1] 1 Not present [99] [2] 2 Mild Age: xx Grade: xx [3] 3 Moderate [4] 4 Severe [6] 6 Absent or false due to therapeutic medication [8] 8 Present or true due to medical condition [9] 9 Inadequate information [98] 98 NA
10.	19. Duration of childhood symptoms	[1] 1 Not present [99] [2] 2 Symptoms persisted less than 6 months Age: xx Grade: xx [3] 3 Symptoms persisted at least 6 months [9] 9 Inadequate information 98 NA

DOMAIN: QS

		[98] ○
11.	**20. Age of Onset**	*[1]* ○ 1 Not present **[99]** ○ *[2]* ○ 2 Onset of symptoms since 7 years of age *[3]* ○ 3 Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 **20a. Specify age:** xx *[9]* ○ 9 Inadequate information *[98]* ○ 98 NA
12.	**21. Some Impairment in 2 or More Settings (Childhood)**	Pulldown List 1
13.	**22. Assess Clinically Significant Impairment**	Pulldown List 1

DOMAIN: QS

CTN0029 : 2920 - Adult ADHD Clinical Diagnostic Scale Contd (ACDS-CSYMP1)	=QSCAT		
1.	**Assessment Date**	QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	**Visit Number**	VISITNUM	[99] xxx [98] 98 NA
Childhood ADHD Symptoms Summary			
Check yes or no to symptoms that respondent has indicated he/she experienced in childhood			
I. INATTENTION	=QSSCAT	QSTEST	QSORRES
3.	23. Careless/Sloppy		[1] 1 Yes [2] 2 No [98] 98 NA
4.	24. Difficulty Sustaining Attention		[1] 1 Yes [2] 2 No [98] 98 NA
5.	25. Doesn't Listen		[1] 1 Yes [2] 2 No [98] 98 NA
6.	26. Difficulty Following Instructions (Finishing)		[1] 1 Yes [2] 2 No [98] 98 NA
7.	27. Difficulty Organizing Tasks/Activities		[1] 1 Yes [2] 2 No [98] 98 NA
8.	28. Avoidance of Tasks with Sustained Mental Effort		[1] 1 Yes [2] 2 No [98] 98 NA
9.	29. Loses Things		[1] 1 Yes [2] 2 No [98] 98 NA
10.	30. Easily Distracted		[1] 1 Yes [2] 2 No [98] 98 NA
11.	31. Forgetful in Daily Activities		[1] 1 Yes [2] 2 No [98] 98 NA
II. HYPERACTIVITY/IMPULSIVITY	=QSSCAT		
12.	32. Fidgets/Squirms		[1] 1 Yes [2] 2 No [98] 98 NA
13.	33. Difficulty Remaining Seated		[1] 1 Yes [2] 2 No [98] 98 NA
14.	34. Runs/Climbs Excessively/Inappropriately		[1] 1 Yes [2] 2 No [98] 98 NA
15.	35. Difficulty Playing Quietly		[1] 1 Yes [2] 2 No [98] 98 NA
16.	36. On the go/Driven by a motor		[1] 1 Yes [2] 2 No [98] 98 NA
17.	37. Talks Excessively		[1] 1 Yes [2] 2 No [98] 98 NA
18.	38. Blurts Out Answers		[1] 1 Yes [2] 2 No [98] 98 NA
19.	39. Difficulty Waiting Turn		[1] 1 Yes [2] 2 No [98] 98 NA
20.	40. Interrupts or Intrudes		[1] 1 Yes [2] 2 No [98] 98 NA
21.	41. Did respondent report ADHD symptoms prior to age 7?		[1] 1 Yes [2] 2 No [98] 98 NA

DOMAIN: QS

CTN0029 : 2920 - Adult ADHD Clinical Diagnostic Scale - Contd (ACDS-AHIST1)		=QSCAT	
1.	Assessment Date	QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	VISITNUM	[99] xxx [98] 98 NA
ADHD ADULT HISTORY			
Think about only the past twelve months, that is, since(month, year). In the past 12 months...		QSTEST	QSORRES
3.	42. Makes a Lot of Careless Mistakes		Pulldown List 1
4.	43. Difficulty Sustaining Attention on Tasks/Play Activities?		Pulldown List 1
5.	44. Does not Listen		Pulldown List 1
6.	45. Difficulty Following Instructions		Pulldown List 1
7.	46. Difficulty Organizing Tasks		Pulldown List 1
8.	47. Dislikes/Avoids Tasks Requiring Attention		Pulldown List 1
9.	48. Loses Things		Pulldown List 1
10.	49. Easily Distracted		Pulldown List 1
11.	50. Forgetful in Daily Activities		Pulldown List 1
12.	51. Fidget		Pulldown List 1
13.	52. Difficulty Remaining Seated		Pulldown List 1

DOMAIN: QS

CTN0029 : 2920 - Adult ADHD Clinical Diagnostic Scale - Contd (ACDS-AHIST2)		=QSCAT
1.	Assessment Date	QSDTC — Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	VISITNUM — [99] ○ xxx [98] ○ 98 NA
ADHD ADULT HISTORY Contd		QSTEST — QSORRES
3.	53. Restlessness (Runs or Climbs Excessively)	Pulldown List 1
4.	54. Difficulty Playing Quietly	Pulldown List 1
5.	55. On the Go/Acts Like Driven by Motor	Pulldown List 1
6.	56. Talks Excessively	Pulldown List 1
7.	57. Blurts Out Answers	Pulldown List 1
8.	58. Difficulty Waiting Turn	Pulldown List 1
9.	59. Interrupts or Intrudes	Pulldown List 1
10.	60. Duration of adult symptoms	Pulldown List 2
11.	61. Some impairment in 2 or more settings	Pulldown List 1
12.	62. Assess clinically significant impairment	Pulldown List 1

DOMAIN: QS

CTN0029 : 2920 - Adult ADHD Clinical Diagnostic Scale Contd (ACDS-ASYMP) =QSCAT		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
Adult ADHD Symptoms Summary		
Check yes or no to symptoms that respondent has indicated he/she experienced in		
I. INATTENTION =QSSCAT	QSTEST	QSORRES
3.	63. Careless/Sloppy	[1] 1 Yes [2] 2 No [98] 98 NA
4.	64. Difficulty sustaining attention	[1] 1 Yes [2] 2 No [98] 98 NA
5.	65. Doesn't listen	[1] 1 Yes [2] 2 No [98] 98 NA
6.	66. Difficulty following instructions (finishing)	[1] 1 Yes [2] 2 No [98] 98 NA
7.	67. Difficulty organizing tasks/activities	[1] 1 Yes [2] 2 No [98] 98 NA
8.	68. Avoidance of tasks with sustained mental effort	[1] 1 Yes [2] 2 No [98] 98 NA
9.	69. Loses things	[1] 1 Yes [2] 2 No [98] 98 NA
10.	70. Easily distracted	[1] 1 Yes [2] 2 No [98] 98 NA
11.	71. Forgetful in daily activities	[1] 1 Yes [2] 2 No [98] 98 NA
II. HYPERACTIVITY/IMPULSIVITY =QSSCAT		
12.	72. Fidgets/Squirms	[1] 1 Yes [2] 2 No [98] 98 NA
13.	73. Difficulty remaining seated	[1] 1 Yes [2] 2 No [98] 98 NA
14.	74. Runs/Climbs excessively/Inappropriately	[1] 1 Yes [2] 2 No [98] 98 NA
15.	75. Difficulty playing quietly	[1] 1 Yes [2] 2 No [98] 98 NA
16.	76. On the go/Driven by a motor	[1] 1 Yes [2] 2 No [98] 98 NA
17.	77. Talks excessively	[1] 1 Yes [2] 2 No [98] 98 NA
18.	78. Blurts out answers	[1] 1 Yes [2] 2 No [98] 98 NA
19.	79. Difficulty waiting turn	[1] 1 Yes [2] 2 No [98] 98 NA
20.	80. Interrupts or Intrudes	[1] 1 Yes [2] 2 No [98] 98 NA
21.	81. Childhood onset of ADHD (prior to age 7)?	[1] 1 Yes [2] 2 No [98] 98 NA
22.	82. Significant and sufficient current ADHD symptoms?	[1] 1 Yes [2] 2 No [98] 98 NA
23.	83. Significant impairment in two or more settings?	[1] 1 Yes [2] 2 No [98] 98 NA
24.	84. -Are symptoms primarily due to ADHD and not another mental health disorder?	[1] 1 Yes [2] 2 No [98] 98 NA
25.	85. Subtyping	[1] 1 ADHD, Inattentive subtype [2] 2 ADHD, Hyperactive-Impulsive Subtype [3] 3 ADHD, Combined Subtype [98] 98 NA

DOMAIN: QS

	CTN0029 : 2908 - Withdrawal Scale For Tobacco (WST) =QSCAT	
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
	Please rate the following items based on how you have felt or what you have noticed over the last 24 hours. QSTEST	QSORRES
3.	1. Desire to Smoke	Pulldown List 1
4.	2. Anger, Irritability, Frustration	Pulldown List 1
5.	3. Anxiety, Nervousness	Pulldown List 1
6.	4. Difficulty Concentrating	Pulldown List 1
7.	5. Impatience, Restlessness	Pulldown List 1
8.	6. Hunger	Pulldown List 1
9.	7. Awakening at Night	Pulldown List 1
10.	8. Depression	Pulldown List 1

DOMAIN: QS

=QSCAT

CTN0029 : 2909 - Beck Depression Inventory - II (BDI)		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	99] xxx [98] 98 NA
3.	1. Sadness QSTEST	Pulldown List 1 QSORRES
4.	2. Pessimism	Pulldown List 2
5.	3. Past Failure	Pulldown List 3
6.	4. Loss of Pleasure	Pulldown List 4
7.	5. Guilty Feelings	Pulldown List 5
8.	6. Punishment Feelings	Pulldown List 6
9.	7. Self-Dislike	Pulldown List 7
10.	8. Self-Criticalness	Pulldown List 8
11.	9. Suicidal Thoughts or Wishes	Pulldown List 9
12.	10. Crying	Pulldown List 10
13.	11. Agitation	Pulldown List 11
14.	12. Loss of Interest	Pulldown List 12
15.	13. Indecisiveness	Pulldown List 13
16.	14. Worthlessness	Pulldown List 14
17.	15. Loss of Energy	Pulldown List 15
18.	16. Changes in Sleeping Pattern	Pulldown List 16
19.	17. Irritability	Pulldown List 17
20.	18. Changes in Appetite	Pulldown List 18
21.	19. Concentration Difficulty	Pulldown List 19
22.	20. Tiredness or Fatigue	Pulldown List 20
23.	21. Loss of Interest in Sex	Pulldown List 21

DOMAIN: QS

CTN0029 : 2913 - Fagerstrom Test For Nicotine Dependence (FTND) =QSCAT		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
Please read each question. Choose the letter of the alphabet corresponding to the answer choice which best describe the response:		
3.	1. How soon after you wake up do you smoke your first cigarette? QSTEST	[3] 3 (a) Within 5 minutes [2] 2 (b) Within 6-30 minutes [1] 1 (c) Within 31-60 minutes [0] 0 (d) After 60 minutes [98] 98 NA QSORRES
4.	2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library, at the movies, etc.?	[1] 1 (a) Yes [0] 0 (b) No [98] 98 NA
5.	3. Which cigarette would you hate most to give up?	[1] 1 (a) The first one in the morning [0] 0 (b) Any of the others [98] 98 NA
6.	4. How many cigarettes per day do you smoke?	[0] 0 (a) 10 or less [1] 1 (b) 11-20 [2] 2 (c) 21-30 [3] 3 (d) 31 or more [98] 98 NA
7.	5. Do you smoke more frequently during the first hours after waking than during the rest of the day?	[1] 1 (a) Yes [0] 0 (b) No [98] 98 NA
8.	6. Do you smoke if you are so ill that you are in bed most of the day?	[1] 1 (a) Yes [0] 0 (b) No [98] 98 NA

DOMAIN: IE, SC

CTN0029 : 2922 - Study Eligibility (STE)		
1.	Assessment Date	IEDTC — Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	VISIT / VISITNUM — [99] xxx [98] 98 NA
Inclusion Criteria		IECAT
3.	1. An adult aged 18-55	IETEST — [1] 1 Yes [0] 0 No [-5] -5 Not Assessed — IEORRES
4.	2. Able to understand and provide written informed consent in English? (Signed consent form)	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
5.	3. Diagnosed with a DSM IV diagnosis of ADHD, as determined by the Adult Clinical Diagnostic Scale (ACDS) v 1.2	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
6.	4. Measured by the ADHD DSM IV Checklist with an ADHD Symptom Score >22	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
7.	5. Confirmed as having smoked cigarettes for at least 3 months, currently smoking at least 10 cigarettes/day and having a measured exhaled CO level >= 8 ppm	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
8.	6. Interested in quitting smoking and willingness to comply with all study procedures and medication instructions (based on the judgment of the study investigator, inherent in Consent Form)	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
9.	7. Confirmed, if female and of childbearing age, has agreed to use one of the specified methods of birth control during the study	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
10.	8. Negative, as confirmed by urine screen for cocaine, methamphetamine, opiates, benzodiazepines and marijuana	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
Exclusion Criteria		
11.	9. Meet DSM IV criteria for current abuse of any psychoactive substance other than nicotine?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
12.	10. Meet DSM IV criteria for lifetime diagnosis of psychosis or bipolar disorder?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
13.	11. Meet DSM IV criteria for current major depression or any anxiety disorder except specific phobias?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
14.	12.Currently have or have had a medical condition, which in the judgment of the medical clinician, would make study participation unsafe or which would make treatment compliance difficult or put the study staff at undue risk	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
15.	13. Report having been treated for ADHD in the last 30 days with psychomotor stimulants?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
16.	14. Use other smoking cessation counseling program(s) or medication treatment(s) currently or in the last 30 days	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
17.	15. Have a history of narrow angle glaucoma?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
18.	16. Have a history of seizure disorder?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
19.	17. Have tics or Tourette's syndrome, or a family history of Tourette's syndrome?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
20.	18. Have an allergy to OROS-MPH?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
21.	19. If female, have a positive pregnancy test or report being pregnant or breastfeeding?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
22.	20. Have an ECG with significant arrhythmias or abnormal conduction which, in the opinion of the study physician, precludes participation in the study?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
23.	21. Take a monoamine oxidase (MAO) inhibitor or has taken one within two weeks of randomization?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
24.	22. Take any medication used for treating either ADHD or smoking?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
25.	23. Take any medication which, in the judgment of the medical clinician, may produce interactions with OROS-MPH that are sufficiently dangerous so as to exclude the patient from participating in the study?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
26.	24. In the judgment of the investigator, seem unlikely to complete the study protocol?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
27.	25. Report having used tobacco products, other than cigarettes, in the past week?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
28.	26. If 40 to 55 years of age, have blood pressure readings greater than 130/80 and/or a heart rate of more than 88 beats per minute on two clinic visits; if less than 40 years old have blood pressure readings greater than 135/85 and/or heart rate more than 90 beats per minute on two clinic visits?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
29.	27. Meets the DSM IV criteria for Antisocial Personality Disorder?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
30.	28. Previously received reasonable treatment with methyphenidate (as judged by medical clinician) and failed to evidence a reduction in ADHD symptoms in response to this treatment?	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
31.	29. Represent a significant suicidal/homicidal risk	[1] 1 Yes [0] 0 No [-5] -5 Not Assessed
32.	30. Eligible for the study	[1] 1 Yes [0] 0 No — SC.SCTEST / SC.SCORRES

NOTE: Only exceptions to IE are in the database. That includes “No” responses for Inclusion and “YES” responses for exclusion criteria.

DOMAIN: LB, CO

	CTN0029 : 2926 - Urine Cotinine Collection (UCC)	LBCAT=URINE COTININE COLLECTION
1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	[99] xxx [98] 98 NA
Section 1: Urine Collection		
3.	1. Was a urine sample obtained?	[0] 0 No [1] 1 Participant reported being unable to provide sample [2] 2 Participant refused to provide sample [3] 3 Study Staff Error [4] 4 Other: Specify: A200 [1] 1 Yes [98] 98 NA
4.	2. Was urine collection observed?	[0] 0 No [1] 1 Yes [98] 98 NA
5.	3. Urine temperature within expected range (between 90 and 99 degrees Fahrenheit)?	[0] 0 No [1] 1 Yes [98] 98 NA
Section II: Urine Shipping		
6.	4a. Was the urine sample shipped?	[0] 0 No 4b. If sample not shipped, why? [1] 1 Sample invalid [2] 2 Sample lost [3] 3 Too little urine collected [4] 4 Other: Specify: A200 [1] 1 Yes 4c. Date sample was shipped? Req / Req / Req (2005-2009) [98] 98 NA
7.*	5. Comments	A100

* Item is not required

LBDTC

VISIT / VISITNUM

LBSTAT / LBREASND

QNAM=LBSUPER
QLABEL=URINE COLLECTION SUPERVISED
IDVAR=LBSEQ

QNAM=LBTEMP
QLABEL=URINE TEMP WITHIN EXPECTED RANGE
IDVAR=LBSEQ

QNAM=LBSHIP
QLABEL=URINE SAMPLE SHIPPED
IDVAR=LBSEQ

QNAM=LBSHIPDT
QLABEL=DATE SAMPLE SHIPPED
IDVAR=LBSEQ

CO.COVAL
IDVAR=LBSEQ

Note: Urine Cotinine results will also be in the LB file where LBTEST='COTININE'

DOMAIN: DM, SC

CTN0029 : 2923 - Randomization (RND)		
1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) SC.SCDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM
SECTION 1 Must be completed prior to randomizing the study candidate.		
3.	1. Has it been determined that the individual is eligible for the study, as defined by the inclusion/exclusion criteria?	[0] 0 No [1] 1 Yes [98] 98 NA SC.SCTEST / SC.SCORRES
SECTION 2 Complete Randomization Procedure		
4.	2. Medication Kit Number assigned to participant?	[99] A20 [98] 98 NA SUPPRESSED DUE TO DUP./ERRANT KIT NUMBERS
5.	3. Date of Randomization?	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA DM.RFSTDTC
6.	4. If participant was eligible, but not randomized, please mark reason:	[1] 1 No longer interested in participating in the study [2] 2 Left prior to randomization and failed to return [3] 3 Other, Specify: A50 [98] 98 NA SC.SCTEST / SC.SCORRES

QNAM=NRNOTHER
QLABEL=NOT RANDOMIZED: OTHER TEXT
IDVAR=SCSEQ

DOMAIN: QS

CTN0029 : 2927 - Treatment Compliance - Counseling (TCC) =QSCAT		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
3.	1. Study Week for which compliance is being assessed: QSTEST	[99] xx [98] 98 NA QSORRES
4.	2. How many sessions were scheduled during the study week?	[99] xx [98] 98 NA
5.	3. How many sessions were attended during the study week?	[99] xx [98] 98 NA
6.	4. How many scheduled sessions did the participant miss?	[99] xx [98] 98 NA
7.	5. How many sessions did you cancel?	[99] xx [98] 98 NA
8.	6. Based on the participant's session participation and completion of homework assignments, how compliant was the participant:	Pulldown List 1
9.*	7. Comments:	A200

* Item is not required

DOMAIN: SU

CTN0029 : 2933 - Tobacco Use - Active Study (TUA) - Repeating Form

SUCAT=TOBACCO USE – ACTIVE STUDY

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) SUDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM
3.	Sequence Number	[99] xx [98] 98 NA SUGRPID = ACTIVE STUDY FILE 1
4.	Day 1 SUSPID	[99] Date Req / Req / Req (2005-2009) SUSTDTC Cigarettes Smoked? SUOCCUR SUTRT = CIGARETTE [1] 1 Yes Number of Cigarettes Smoked? SUDOSE / SUDOSU xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
5.	Day 2	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
6.	Day 3	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
7.	Day 4	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
8.	Day 5	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
9.	Day 6	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA
10.	Day 7	[99] Date Req / Req / Req (2005-2009) Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No [98] 98 NA

DOMAIN: SU, LB, QS, CO

11.	Carbon Monoxide Reading: 8a. Current time: (24-hour clock)	[99] ○ NReq : NReq *24-hour clock* [98] ○ 98 NA LB.LBDTC LBCAT = TOBACCO USE – ACTIVE STUDY
12.	8b. Trial #1 CO	[99] ○ xxx ppm [98] ○ 98 NA LB.LBTEST/LBTESTCD/LBORRES/LBORRESU LBCAT=TOBACCO USE – ACTIVE STUDY
13.	8c. Trial #2 CO	[99] ○ xxx ppm [98] ○ 98 NA LB.LBTEST/LBTESTCD/LBORRES/LBORRESU LBCAT = TOBACCO USE – ACTIVE STUDY
14.	9a. Have you smoked anything else besides tobacco products in the past 7 days (for example, herbal cigarettes, marijuana joints, etc)?	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ 98 NA SU.SUOCCUR SU.SUTRT=SMOKED ANYTHING ELSE BESIDES TOBACCO IN PAST 7 DAYS SU.SUEVLINT=-P7D
15.	9b. Do you work, or have you been, in an area where there is quite a bit of car exhaust (for example, garage, etc)?	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ 98 NA
16.	9c. Do you know if you have a defective furnace at home that could be giving out a higher-than-normal reading of CO?	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ 98 NA
17.	10a. Have you used any non-cigarette tobacco products in the past 7 days (during the time-frame assessed for cigarette use)?	*[0]* ○ 0 No SU.SUOCCUR **[1]** ○ 1 Yes (If no, then stop) - If Yes: **10b. chews:** xxx (0 =< n <= 999) SUDOSE / SUDOSU SU.SUEVLINT=-P7D **10c. dips:** xxx (0 =< n <= 999) **10d. pipefuls:** xxx (0 =< n <= 999) SU.SUTRT=NON CIGARETTE TOBACCO PRODUCT **10e. cigars:** xxx (0 =< n <= 999) *[98]* ○ 98 NA
18.*	11. Comments	A200 CO.COVAL IDVAR=SUSEQ

* Item is not required

QS.QSTEST = WORK WHERE THERE IS CARE EXHAUST?

QSTESTCD= RCNOYE1

QSORRES

QS.QSTEST = DEFECTIVE FURNACE AT HOME

QSTESTCD= RCNOYE2

QSORRES

DOMAIN: EX, CO

CTN0029 : 2928 - Treatment Compliance - Medication - Participant Report (TCM) - Repeating Form

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	[99] xxx [98] 98 NA
3.	Sequence Number	[99] xx [98] 98 NA
Medication - Participant Report		
4.	1. Study Week being assessed:	[99] xx [98] 98 NA
5.	Day 1	[99] A. Date Req / Req / Req (2005-2009) B. # pills presc x C. # pills taken xx D. patch strength xx E. # patch taken x F. Comments A200 [98] 98 NA
6.	Day 2	[99] Req / Req / Req (2005-2009) x xx xx x A200 [98] 98 NA
7.	Day 3	[99] Req / Req / Req (2005-2009) x xx xx x A200 [98] 98 NA
8.	Day 4	[99] Req / Req / Req (2005-2009) x xx xx x A200 [98] 98 NA
9.	Day 5	[99] Req / Req / Req (2005-2009) x xx xx x A200 [98] 98 NA
10.	Day 6	[99] Req / Req / Req (2005-2009) x xx xx x A200 [98] 98 NA
11.	Day 7	[99] Req / Req / Req (2005-2009) x xx xx x A200 [98] 98 NA

EXDTC

VISIT / VISITNUM

EXSPID

EXTRT=OROS-MPH EXTRT=NICOTINE

EXDOSFRM=PILL EXDOSFRM=PATCH

EXGRPID

EXTPT

EXSTDTC

EXDOSTXT

EXDOSE

EXDOSU

EXDOSE

CO.COVAL

IDVAR=EXSEQ

DOMAIN: DA

CTN0029 : 2938 - Treatment Compliance - Pill Count (TCP) - Repeating Form

Section I: Scheduled OROS-MPH/Placebo	DACAT=SCHEDULED OROS-MPH/PLACEBO	
1.	Assessment Date — DADTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number — VISIT / VISITNUM	[99] xxx [98] 98 NA
3.	Sequence Number — DASPID	[99] xx [98] 98 NA
4.	1. Study week for which compliance is being assessed: — DAGRPID	[99] xx [98] 98 NA
5.	2. Date bottle dispensed: — DATEST/DATESTCD	[99] Req / Req / Req (2005-2007) (mm/dd/yyyy) [98] 98 NA — DAORRES
6.	3. Number of pills returned-expected:	[99] xx [98] 98 NA
7.	4. Number of pills returned - actual:	[99] xx [98] 98 NA
8.	5. Number of pills reported lost:	[99] xx [98] 98 NA
9.	6. Date bottle returned:	[99] Req / Req / Req (2005-2007) (mm/dd/yyyy) [98] 98 NA
10.	7. Was replacement medication dispensed?	[0] 0 No [1] 1 Yes [98] 98 NA
11.	8. Are there any inconsistencies between pill count and self-reported administration of pills?	[0] 0 No [1] 1 Yes [98] 98 NA
Section II: Replacement OROS-MPH/Placebo	DACAT=REPLACEMENT OROS-MPH/PLACEBO	
12.	9. Date replacement bottle dispensed:	[99] Req / Req / Req (2005-2007) (mm/dd/yyyy) [98] 98 NA
13.	10. Number of pills dispensed:	[99] xx [98] 98 NA
14.	11. Number of pills returned-expected:	[99] xx [98] 98 NA
15.	12. Number of pills returned - actual:	[99] xx [98] 98 NA
16.	13. Number of pills reported lost:	[99] xx [98] 98 NA
17.	14. Date replacement bottle returned:	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA

DOMAIN: QS

CTN0029 : 2930 - Drug Rating Questionnaire (DRQ) =QSCAT		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
For each question, please fill in the circle below the number that best represents how you feel		
3.	1. Do you feel that your medication has been effective in treating your ADD/ADHD symptoms? QSTEST	Pulldown List 1 not at all = 1 somewhat = range 5-6 very much = 10 QSORRES
4.	2. Do you like the way your medication makes you feel?	Pulldown List 1 not at all = 1 somewhat = range 5-6 very much = 10
5.	3. When you take your medication, how high/ euphoric feeling do you get?	Pulldown List 2 not at all = 1 sometimes high/euphoric feeling = range 5-6 very high/euphoric feeling = 10
6.	4. When you take your medication, how depressed/ down feeling do you get?	Pulldown List 3 not at all = 1 sometimes depressed feeling = range 5-6 very depressed/down feeling = 10
7.	5. Do you ever crave your medication?	Pulldown List 4 not at all = 1 sometimes = range 5-6 very frequently = 10
8.	6. When you take your medication, do you ever crave cigarettes, alcohol, or other non-prescribed drugs?	Pulldown List 4 not at all = 1 sometimes = range 5-6 very frequently = 10

DOMAIN: DA

CTN0029 : 2939 - Treatment Compliance - Patch Count (TPC) - Repeating Form

Section I: Original Nicotine Patches	DACAT=ORIGINAL NICOTINE PATCHES		
1.	**Assessment Date**	DADTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	**Visit Number**	VISIT / VISITNUM	[99] xxx [98] 98 NA
3.	**Sequence Number**	DASPID	[99] xx [98] 98 NA
4.	**1. Study weeks being assessed:**	DAGRPID	Pulldown List 1
5.	**2. Date patches dispensed:**	DATEST/DATESTCD	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA DAORRES
6.	**3. Strength of patches dispensed:**		[99] xx [98] 98 NA
7.	**4. Number of patches returned-expected:**		[99] xx [98] 98 NA
8.	**5. Number of patches returned-actual:**		[99] xx [98] 98 NA
9.	**6. Number of patches reported lost:**		[99] xx [98] 98 NA
10.	**7. Date patches returned:**		[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
11.	**8. Were replacement patches dispensed?**		[0] 0 No [1] 1 Yes [98] 98 NA
12.	**9. Are there any inconsistencies between patch count and self-reported administration of patches?**		[0] 0 No [1] 1 Yes [98] 98 NA
Section II: Replacement Nicotine Patches	DACAT=REPLACEMENT NICOTINE PATCHES		
13.	**10. Date replacement patches dispensed:**		[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
14.	**11. Strength of patches dispensed:**		[99] xx [98] 98 NA
15.	**12. Number of patches dispensed:**		[99] xx [98] 98 NA
16.	**13. Number of patches returned-expected:**		[99] xx [98] 98 NA
17.	**14. Number of patches returned-actual:**		[99] xx [98] 98 NA
18.	**15. Number of patches reported lost:**		[99] xx [98] 98 NA
19.	**16. Date replacement patches returned:**		[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA

DOMAIN: QS

	CTN0029 : 2929 - Study Questionnaire (STQ) =QSCAT	
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
	Please rate the degree to which you agree with each statement. QSTEST	QSORRES
3.	1. My attention is just as good in the afternoon as it is in the morning.	Pulldown List 1
4.	2. My attention is just as good in the evening as it is in the morning.	Pulldown List 1
5.	3. My attention is equally good throughout the day.	Pulldown List 1
6.	4. My urge to smoke is highest in the morning.	Pulldown List 1
7.	5. My urge to smoke is highest in the afternoon.	Pulldown List 1
8.	6. My urge to smoke is highest in the evening.	Pulldown List 1
9.	7. My urge to smoke is the same throughout the day.	Pulldown List 1
10.	8. I am better able to concentrate and complete tasks now that during past quit attempts.	Pulldown List 1
11.	9. The study medication has made quitting smoking easier than in the past.	Pulldown List 1
12.	10. If you think that the study medication is helping you to stop smoking, please provide a brief description of how the medication is helping you:	[99] A200 [98] 98 NA
	With respect to the weekly clinic visits, staff, and other reseach participants, please answer the following questions: QSSCAT=RATING STAFF, OTHER PARTICIPANTS AND VISITS	
13.	11. I have trouble coming to these visits because they interfere with my other activities.	Pulldown List 1
14.	12. Due to transportation problems, it is complicated to come to these clinic visits.	Pulldown List 1
15.	13. I feel that the health care providers in this clinic are genuinely trying to help me with my problems.	Pulldown List 1
16.	14. I feel that my smoking problem is more important to overcome than my attention deficit hyperactivity problem.	Pulldown List 1
17.	15. The other research participants I see in the clinic seem to be friendly and pleasant, and I can picture becoming friends with some of them.	Pulldown List 1
18.	16. If I fail to complete the treatments of this study, there is no one to blame but myself.	Pulldown List 1
19.	17. The clinic environment feels safe, pleasant, and friendly.	Pulldown List 1
20.	18. I fully expect to complete this study.	Pulldown List 1
21.	19. Smoking helps my attention.	Pulldown List 1
22.	20. I want to continue with the study medication.	Pulldown List 1

DOMAIN: QS

CTN0029 : 2931 - Medication Blind Assessment - Participant (MBP) =QSCAT		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
3.	1. As a participant in this study, you have been taking either OROS-MPH or Placebo (sugar) pills. Which kind of pill do you think you have been taking? QSTEST	[1] 1 OROS-MPH [2] 2 Placebo (sugar) [98] 98 NA QSORRES
4.	2. How confident are you that your selection for question 1 is actually the type of pills that you have been taking?	Pulldown List 1

DOMAIN: QS

CTN0029 : 2932 - Medication Blind Assessment - RA (MBR) =QSCAT		
1.	Assessment Date QSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number VISITNUM	[99] xxx [98] 98 NA
3.	1. This participant has been taking either OROS-MPH or Placebo (sugar) pills. Which kind of pills do you think this participant has been taking? QSTEST	[1] 1 OROS-MPH [2] 2 Placebo (sugar) [98] 98 NA QSORRES
4.	2. How confident are you that your selection for question 1 is actually the type of pills that the participant has been taking?	[1] 1 Not at all confident [2] 2 Mildly confident [3] 3 Moderately confident [4] 4 Quite confident [5] 5 Very confident 3. If you selected "Very Confident" in response to question 2, what is the basis for your confidence? [1] 1 My observation of the participant's response to the medication [2] 2 Information about the patient's treatment assignment (e.g., accidentally saw paperwork, blind broken for medical purposes, etc.) [3] 3 Other (specify): A50 [98] 98 NA [98] 98 NA

DS.DSCAT :END OF ACTIVE STUDY PHASE

DOMAIN: DS, DM

CTN0029 : 2935 - Participant Status At The End Of The Active Study Phase (PSE)		
1.	Assessment Date DS.DSDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number DS.VISIT	[99] xxx [98] 98 NA
3.	1. Date last research visit attended DS.DSSTRDTC DM.RFENDTC	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
4.	2. Please indicate the participant's status at the end of his or her participation in the active study phase (select only one response):	Pulldown List 1 DS.DSTERM/DSDECOD
5.*	2a. Specify (for Administrative Discharge or Other)	[99] A200 [98] 98 NA
6.	3a. Does the participant plan to seek treatment for his or her ADHD?	[0] 0 No [1] 1 Yes If yes, what type of treatment is he or she planning to seek? 3.a.1 Medication [0] 0 No [1] 1 Yes [98] 98 NA 3.a.2 Psychosocial [0] 0 No [1] 1 Yes [98] 98 NA [98] 98 NA
7.	4a. Does the participant plan to seek smoking cessation treatment?	[0] 0 No [1] 1 Yes If yes, what type of treatment is he or she planning to seek? 4.a.1 Medication [0] 0 No [1] 1 Yes [98] 98 NA 4.a.2 Psychosocial [0] 0 No [1] 1 Yes [98] 98 NA [98] 98 NA
* Item is not required		

QNAM=TRTADHD
QLABEL=TYPE OF TREATMENT FOR ADHD SOUGHT
IDVAR=DSSEQ

QNAM=ADMSPEC
QLABEL=ADMINISTRATION DISCHARGE OR OTHER: SPECIFY
IDVAR=SCSEQ

QNAM=TRTSMOKE
QLABEL=TYPE OF TREATMENT FOR SMOKING CESSATION SOUGHT
IDVAR=DSSEQ

DOMAIN: SU

SUCAT=TOBACCO USE – POST ACTIVE STUDY

CTN0029 : 2934 - Tobacco Use - Post Active Study (TUR1)

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) SUDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM

Study Week 11 SUGRPID = POST STUDY FILE 1

3.	Day 1	[99] Date Req / Req / Req (2005-2009) SUSTDTC; [98] 98 NA	Cigarettes Smoked? [1] 1 Yes SUOCCUR; Number of Cigarettes Smoked? xxx (0 =< n <= 999) SUDOSE / SUDOSU; [0] 0 No
4.	Day 2	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No
5.	Day 3	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No
6.	Day 4	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No
7.	Day 5	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No
8.	Day 6	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No
9.	Day 7	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No

SUTRT = CIGARETTE

SUSPID

Study Week 12

10.	Day 8	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No
11.	Day 9	[99] Date Req / Req / Req (2005-2009); [98] 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No
12.	Day 10	[99] Date Req / Req / Req (2005-2009); 98 NA	Cigarettes Smoked? [1] 1 Yes; Number of Cigarettes Smoked? xxx (0 =< n <= 999); [0] 0 No

DOMAIN: SU

		[98]
13.	Day 11	[99] Date Req / Req / Req (2005-2009) [98] 98 NA Cigarettes Smoked? [1] 1 Yes [0] 0 No Number of Cigarettes Smoked? xxx (0 =< n <= 999)
14.	Day 12	[99] Date Req / Req / Req (2005-2009) [98] 98 NA Cigarettes Smoked? [1] 1 Yes [0] 0 No Number of Cigarettes Smoked? xxx (0 =< n <= 999)
15.	Day 13	[99] Date Req / Req / Req (2005-2009) [98] 98 NA Cigarettes Smoked? [1] 1 Yes [0] 0 No Number of Cigarettes Smoked? xxx (0 =< n <= 999)
16.	Day 14	[99] Date Req / Req / Req (2005-2009) [98] 98 NA Cigarettes Smoked? [1] 1 Yes [0] 0 No Number of Cigarettes Smoked? xxx (0 =< n <= 999)

SUSPID

SUSTDTC

SUOCCUR

SUTRT = CIGARETTE

SUDOSE / SUDOSU

DOMAIN: SU

SUCAT=TOBACCO USE – POST ACTIVE STUDY

CTN0029 : 2934 - Tobacco Use - Post Active Study Contd (TUR2)

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) SUDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT / VISITNUM

Study Week 13 SUGRPID = POST STUDY FILE 2

3.	Day 15	[99] Date Req / Req / Req (2005-2009) SUSTDTC [98] 98 NA	Cigarettes Smoked? SUOCCUR [1] 1 Yes Number of Cigarettes Smoked? SUDOSE / SUDOSU xxx (0 =< n <= 999) [0] 0 No
4.	Day 16	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No
5.	Day 17	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No
6.	Day 18	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No
7.	Day 19	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No
8.	Day 20	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No
9.	Day 21	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No

Study Week 14

10.	Day 22	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No
11.	Day 23	[99] Date Req / Req / Req (2005-2009) [98] 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No
12.	Day 24	[99] Date Req / Req / Req (2005-2009) 98 NA	Cigarettes Smoked? [1] 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] 0 No

SUSPID

SUTRT = CIGARETTE

DOMAIN: SU, LB, QS, CO

		[98] ○
13.	Day 25	[99] ○ Date: Req / Req / Req (2005-2009) Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No [98] ○ 98 NA
14.	Day 26	[99] ○ Date: Req / Req / Req (2005-2009) Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No [98] ○ 98 NA
15.	Day 27	[99] ○ Date: Req / Req / Req (2005-2009) Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No [98] ○ 98 NA
16.	Day 28	[99] ○ Date: Req / Req / Req (2005-2009) Cigarettes Smoked? [1] ○ 1 Yes Number of Cigarettes Smoked? xxx (0 =< n <= 999) [0] ○ 0 No [98] ○ 98 NA
17.	29. Has the participant smoked within the past 7 days?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
18.	Carbon Monoxide Reading: 30.a Current time:	[99] ○ Req : Req 24-hour clock (24-hour clock) [98] ○ 98 NA
19.	30.b Trial #1 CO	[1] ○ xxx ppm [98] ○ 98 NA
20.	30.c Trial #2 CO	[1] ○ xxx ppm [98] ○ 98 NA
21.	31.a Have you smoked anything else besides tobacco products in the past 7 days (for example, herbal cigarettes, marijuana joints, etc)?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
22.	31.b Do you work, or have you been, in an area where there is quite a bit of car exhaust (for example, garage, etc)?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
23.	31.c Do you know if you have a defective furnace at home that could be giving out a higher-than-normal reading of CO?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ 98 NA
24.	32.a Have you used any non-cigarette tobacco products during study weeks 11 through 14 (during the time-frame assessed for cigarette use)?	[0] ○ 0 No [1] ○ 1 Yes 32b. chews: xxx (0 =< n <= 999) 32c. dips: xxx (0 =< n <= 999) 32d. pipefuls: xxx (0 =< n <= 999) 32e. cigars: xxx (0 =< n <= 999) [98] ○ 98 NA
25.*	33. Comments	A200

* Item is not required

SUSPID

SUSTDTC

SUOCCUR

SUTRT = CIGARETTE

SUDOSE / SUDOSU

SUOCCUR SUTRT = SMOKED WITHIN THE PAST 7 DAYS SUEVLINT=-P7D

LB.LBDTC LBCAT=TOBACCO USE – POST ACTIVE STUDY

SU.SUOCCUR SU.SUEVLINT=-P7D

SU.SUTRT=SMOKED ANYTHING ELSE BESIDES TOBACCO IN PAST 7 DAYS

SU.SUOCCUR SU.SUTRT=NON CIGARETTE TOBACCO PRODUCT

SUDOSE / SUDOSU

SU.SUEVLINT=-P28D

CO.COVAL

IDVAR=SUSEQ

QS.QSTEST = WORK WHERE THERE IS CARE EXHAUST?

QSTESTCD= RCNOYE2

QSORRES

LB.LBTEST/LBTESTCD/LBORRES/LBORRESU
LBCAT=TOBACCO USE – POST ACTIVE STUDY

LB.LBTEST/LBTESTCD/LBORRES/LBORRESU
LBCAT=TOBACCO USE – POST ACTIVE STUDY

QS.QSTEST = DEFECTIVE FURNACE AT HOME

QSTESTCD= RCNOYE3

QSORRES

DOMAIN: CM

CTN0029 : 2914 - Prior And Concomitant Medications (PCM) - Repeating Form

1.	Assessment Date CMDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number Data not valid: no visit info	[99] xxx [98] 98 NA
3.	Sequence Number	[99] xx [98] 98 NA
4.	1. Has the participant taken any additional medications or changed dose/frequency of a medication since the last visit (or if this the baseline/screening visit, has the participant taken any medications in the past 30 days)?	[1] 1 Yes [0] 0 No [98] 98 NA USE ONLY IF THIS = 1
5.	2. Medication Name *(Generic name if possible; otherwise brand name)* CMTRT	[99] A200 [98] 98 NA
6.	3. Purpose/Indication: CMINDC	[99] A200 [98] 98 NA
7.	4. Is the drug being given for the treatment of an AE?	[1] 1 Yes [0] 0 No [98] 98 NA
8.	5. Quantity per administration CMDOSE	[99] xxxxxxxxxxxxxx. [98] 98 NA
9.	6. Dosage Units *(If other, specify in 6.b)*. CMDOSU (6A) CMDOSTXT (6B)	a. Pulldown List 1 b. A50
10.	7. Dosage Form *(If other, specify in 7.b)*. CMDOSFRM	a. Pulldown List 2 b. A50
11.	8. Route of Administration *(If other, specify in 8.b)*. CMROUTE	a. Pulldown List 3 b. A50
12.	9. Frequency If Other Frequency, then specify. CMDOSFRQ	a. Pulldown List 4 b. A50
13.	10. Date added or dosage changed (Enter date medication was first taken or date when dosage or frequency was modified)	[99] NReq / NReq / NReq (1920-2009) (mm/dd/yyyy) [98] 98 NA CMSTDTC
14.	11. If a medication is continuing at the same dose and frequency and the visit on which it is assessed is prior to the final visit of the study (visit 12 which occurs in week 15) then circle the visit on which it was assessed (following initial visit on which it was reported) and initial next to the visit number to indicate that the medication was assessed.	[99] Visit(s) [98] 98 NA EITHER 99 OR 98 NO USEFUL DATA [1] 01 [2] 02 [12] 12
15.	12. Date discontinued/changed/date of final study visit *(If the dosage or frequency was modified, enter date of termination and re-enter as a new medication with the new dosage and/or frequency).*	[99] NReq / NReq / NReq (1920-2009) (mm/dd/yyyy) [98] 98 NA CMENDTC
16.	13. Visit on which Date discontinued/changed/date of final study visit field (see 12) completed.	Pulldown List 5

QNAM=ADDFORM
QLABEL=ADDITION INFO ON FORM TYPE
IDVAR=CMSEQ

QNAM=ADDRTE
QLABEL=ADDITIONAL ROUTE INFORMATION
IDVAR=CMSEQ

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

QNAM=VISITNO
QLABEL=VISIT THAT DRUG WAS DISCONTINUED OR CHANGED
IDVAR=CMSEQ

QNAM=ADDFREQ
QLABEL=ADDITIONAL FREQUENCY INFORMATION
IDVAR=CMSEQ

RPCAT=PREGNANCY AND OUTCOME

DOMAIN: RP

CTN0029 : 2917 - Pregnancy and Outcome (POC)			
1.	**Assessment Date**	RPDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	**Visit Number**	VISIT / VISITNUM	[99] xxx [98] 98 NA
Section I: Information about Pregnancy			
3.	**1. Who discovered the pregnancy?**	RPTEST/RPTESTCD	[1] 1 Study Participant [2] 2 Study Staff [98] 98 NA
4.	**2. How was the pregnancy verified?**		[99] **(Select all that apply)** [1] Urine Pregnancy Test [1] Serum Pregnancy Test [1] Ultrasound [98] 98 NA
5.	**3. Date on which the pregnancy was verified:**		[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
6.	**4. Date on which study staff was aware of pregnancy:**		[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
7.	**5. Date on which study medication was discontinued:**		[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
8.	**6. Approximate due date:**		[99] Req / NReq / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
Section II: Outcome of Pregnancy			
9.	**7. Outcome of Pregnancy:**		[1] 1 Normal [2] 2 Abnormal **7.a** If Abnormal Outcome, specify abnormality: A100 [3] 3 Miscarriage [4] 4 Terminated [5] 5 Other **7.b** If Other, Outcome, specify other: A100 [98] 98 NA
10.	**8. Date of Delivery:**		[99] NReq / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA
11.	**9. Number of live births - *this pregnancy*?**		[0] 0 **9.a** If 0 live births, indicate reason: [1] 1 [2] 2 [3] 3 [98] 98 NA A100
12.	**10. Type of Delivery**		[1] 1 Vaginal [2] 2 Cesarean Section [98] 98 NA

RPORRES

RPCAT=PREGNANCY AND OUTCOME

DOMAIN: RP

CTN0029 : 2917 - Pregnancy and Outcome Contd (POC NB)

1.	Assessment Date	RPDTC	Req / Req / Req (2005-2009) (mm/dd/yyyy)													
2.	Visit Number	VISIT / VISITNUM	[99] xxx [98] 98 NA													
	Gender		Weeks	Days	Lbs	Ozs	Length	Circumference	APGAR Score: 1 min	APGAR Score: 5 min	APGAR Score: 24 hrs	Normal	Specify	Contributing factors		
3.																

Newborn Information Entry

RPTEST/RPTESTCD

RPORRES

3.a	Gender	[1] 1 Male [2] 2 Female [98] 98 NA
3.b	Gestational age at delivery: Weeks	[99] xx Weeks [98] 98 NA
3.c	Gestional age at delivery: Days	[99] x Days [98] 98 NA
3.d	Weight: lbs	[99] xx lbs [98] 98 NA
3.e	Weight: ozs	[99] xx ozs [98] 98 NA
3.f	Length	[99] xx cm [98] 98 NA
3.g	Head circumference	[99] xx cm [98] 98 NA
3.h	APGAR Score: 1 min	[99] xx 1 min [98] 98 NA
3.i	APGAR Score: 5 min	[99] xx 5 min [98] 98 NA
3.j	APGAR Score: 24 hrs	[99] xx 24 hrs [98] 98 NA
3.k	Normal infant?	[0] 0 No [1] 1 Yes [98] 98 NA
3.l	If No, specify abnormality:	[99] A200 [98] 98 NA
3.m	Contributing factors to abnormality	[99] A200 [98] 98 NA

4.*	14. If more than 3 babies, record physical characteristics and any abnormality and contributing factors in comments.	[99] A200 [98] 98 NA

* Item is not required

DOMAIN: AE

CTN0029 : 2924 - Adverse Events (AE) - Repeating Form

1.	Assessment Date	Req / Req / Req (2005-2009) (mm/dd/yyyy) AEDTC
2.	Visit Number	[99] xxx [98] 98 NA VISIT/VISITNUM/EPOCH
3.	Sequence Number	[99] xx [98] 98 NA
4.	1. Did the participant have any new adverse events or severity changes in previously reported AEs... If No or NA, Please leave the rest of the questions on the form blank.	[1] 1 Yes [0] 0 No [98] 98 NA
5.*	2. Adverse Event Name/Description:	[99] A100 [98] 98 NA AETERM
6.*	3a.Type of Report:	[1] 1 New Adverse Event [2] 2 Change in severity of an existing Adverse Event SUPPAE: RCAEF003A [98] 98 NA
7.*	If there is a change in severity report, then record the Visit# and Sequence# of the prior AE	[99] 3.b Visit #: xxx [98] 98 NA SUPPAE: AEF003B
8.*	Sequence #:	[99] 3.c xx [98] 98 NA SUPPAE: AEF003C
9.*	4. Date of onset (or change) of event (mm/dd/yyy)	[99] Req / Req / Req (2005-2009) [98] 98 NA AESTDTC
10.*	5. Study Related	Pulldown List 1 AEREL
11.*	6.Severity	Pulldown List 2 AESEV
12.*	7. Action Taken Regarding OROS-MPH/Placebo	Pulldown List 3 AEACN
13.*	8. Action Taken Regarding Nicotine Patch	Pulldown List 4 SUPPAE: AEF008
14.*	9a.1 Other Action Taken?	Pulldown List 5 AEACNOTH
15.*	9a.2 Other Action Taken?	Pulldown List 5 SUPPAE: AEF0091
16.*	9a.3 Other Action Taken?	Pulldown List 5 SUPPAE: AEF0092
17.*	9b. Description of other actions or comments:	[99] A200 [98] 98 NA SUPPAE: AEF009B
18.*	10. Was the Adverse Event Serious? (If Yes, you must complete an SAE form and report it correctly)	[1] 1 Yes [0] 0 No [98] 98 NA AESER
19.*	11. Outcome	Pulldown List 6 AEOUT
20.*	12.1 Visit on which AE assessed	[1] 01 [98] 98 NA SUPPAE: AEF0121
21.*	12.2 Visit on which AE Assessed	[2] 02 [98] 98 NA SUPPAE: AEF0122
22.*	12.3 Visit on which AE Assessed	[3] 03 [98] 98 NA SUPPAE: AEF0123
23.*	12.4 Visit on which AE Assessed	[5] 05 [98] 98 NA SUPPAE: AEF0124
24.*	12.5 Visit on which AE Assessed	[7] 07 [98] 98 NA SUPPAE: AEF0125
25.*	12.6 Visit on which AE Assessed	[9] 09 [98] 98 NA SUPPAE: AEF0126
26.*	12.7 Visit on which AE Assessed	[11] 11 [98] 98 NA SUPPAE: AEF0127
27.*	12.8 Visit on which AE Assessed	[12] 12 [98] 98 NA SUPPAE: AEF0128
28.*	13. Visit on which Outcome recorded	[99] xxx [98] 98 NA SUPPAE: TCAEF013
29.*	14. Date of resolution or change in severity?	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA AEENDTC

* Item is not required

DOMAIN: AE

CTN0029 : 2925 - Serious Adverse Events (SAE1) - Repeating Form

An AE form must be submitted for this event		
1.	**Assessment Date**	Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	**Visit Number**	[99] xxx [98] 98 NA
3.	**Sequence Number**	xx
4.	**AE Visit #**	xxx
5.	**AE Sequence Number**	xx
6.	**1. SAE Report Status**	Pulldown List 1
7.	**2. SAE Name (name of event)**	[99] A200 [98] 98 NA SUPPAE: SAE002
8.	**3. SAE Description**	[99] A200 [98] 98 NA SUPPAE: SAE003
9.	**4. SAE Onset Date**	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA SUPPAE: SAE004_DT
10.	**5. SAE Resolution Date**	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA SUPPAE: SAE005_DT
11.	**6.a SAE Categorization: Death** AESDTH	[1] 1 Yes [0] 0 No [98] 98 NA
12.	**6.b SAE Categorization: Life Threatening** AESLIFE	[1] 1 Yes [0] 0 No [98] 98 NA
13.	**6.c SAE Categorization: Hospitalization (initial or prolonged)** AESHOSP	[1] 1 Yes [0] 0 No [98] 98 NA
14.	**6.d SAE Categorization: Disability** AESDISAB	[1] 1 Yes [0] 0 No [98] 98 NA
15.	**6.e SAE Categorization: Congenital Anomaly** AESCONG	[1] 1 Yes Pulldown List 2 [0] 0 No [98] 98 NA
16.	**6.f SAE Categorization: Required Intervention to Prevent One of the Above Outcomes**	[1] 1 Yes [0] 0 No [98] 98 NA SUPPAE: SAE006F
17.	**7. Severity of SAE**	Pulldown List 3 SUPPAE: PCSAE007
18.	**8. Relationship to Study Agent** AEREL	[1] 1 Definitely [2] 2 Probably [3] 3 Possibly [4] 4 Unrelated [98] 98 NA
19.	**9. SAE Action Taken**	Pulldown List 4 SUPPAE: SAE009
20.	**10. SAE Outcome**	[1] 1 Recovered/resolved [2] 2 Recovered or resolved with sequelae [3] 3 Not recovered/not resolved [4] 4 Fatal [98] 98 NA SUPPAE: SAE010
21.	**11. Date of Death**	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA SUPPAE: NO Death dates in file
Please complete the investigational data fields below (Note: 12a should be answered NA if blind still intact)		
22.	**12. Is the investigational agent information known?**	[1] 1 Yes [0] 0 No [98] 98 NA SUPPAE: SAE012
23.	**12a. Investigational Agent Name (if known)**	[99] A50 [98] 98 NA SUPPAE: NO Agent names in file
24.	**12b. Investigational Agent Lot Number**	[99] A22 [98] 98 NA SUPPAE: SAE012b
25.	**12c. Investigational Agent Expiration Date**	[99] Req / Req (2005-2007) [98] 98 NA SUPPAE: NO Investigational dates in file month / year
26.	**12d. Quantity of Investigational Agent Administered**	[99] xxx [98] 98 NA SUPPAE: SAE012d
27.	**12e. Start Date**	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA SUPPAE: SAE012e_dt
28.	**12f. Date Last Administered**	[99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA SUPPAE: SAE012f_dt
29.	**12g. Investigational Agent Dosage**	Pulldown List 5 SUPPAE: SAE012g

DOMAIN: AE

30.	12h. Dosage Form	Pulldown List 6		SUPPAE: SAE012h
31.	12i. Administration Frequency	Pulldown List 7		SUPPAE: SAE012I
32.	12j.Route of Administration	Pulldown List 8		SUPPAE: SAE012J
33.	13. Relevant tests/laboratory data, including dates	[99] A200	[98] 98 NA	SUPPAE: NO data in file

DOMAIN: AE

CTN0029 : 2925 - Serious Adverse Events Concomitant Drug (SAE2) - Repeating Form

Concomitant Drug Therapy Entry			
1.a	Visit Number	[99] ○ xxx [98] ○ 98 NA	
1.b	Sequence Number	xx	
1.c	AE Visit #	xxx	
1.d	AE Sequence Number	xx	
1.e	14a. Drug (include generic name)	A50	SUPPAE: SAE014A
1.f	14b. Quantity per Administration	[99] ○ xx [98] ○ 98 NA	SUPPAE: SAE014B
1.g	14c. Dosage Units	Pulldown List 1	SUPPAE: SAE014C
1.h	14d. Dosage Form	Pulldown List 2	SUPPAE: SAE014D
1.i	14e. Route of Administration	Pulldown List 3	SUPPAE: SAE014E
1.j	14f. Administration Frequency	Pulldown List 4	SUPPAE: SAE014F

DOMAIN: AE

CTN0029 : 2925 - Serious Adverse Events Contd (SAE2B) - Repeating Form

SAE Contd		
1.	Visit Number	[99] ○ xxx [98] ○ 98 NA
2.	Sequence Number	xx
3.	AE Visit #	xxx
4.	AE Sequence Number	xx
5.	15. Relevant history, including date of consent and pre-existing medical conditons (e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)	A200 SUPPAE: SAE015
6.*	16. Additonal Comments	A200 SUPPAE: SAE016
17. Address SAE question to the following Clinical Staff:		
7.	17a. Name (print)	A50 SUPPAE: SAE017A
8.	17b. Phone Number	A20 SUPPAE: SAE017B
9.	17c.Email	A50 SUPPAE: SAE017C
10.	17d. SAE Reporters Name (please print)	A50 SUPPAE: SAE017D
11.	17e. Site M.D. Name	A50 SUPPAE: SAE017E
12.	17g. Study Medical Monitor Name	A50 SUPPAE: SAE017G

* Item is not required

DOMAIN: QS

CTN0029 : 2937 - Initial Quit (IQD)		=QSCAT
1.	Assessment Date	QSDTC: Req / Req / Req (2005-2009) (mm/dd/yyyy)
2.	Visit Number	VISITNUM: [99] xxx [98] 98 NA
Achieving an inital quit		
3.	1. Date of the participant's quit day:	QSTEST: [99] Req / Req / Req (2005-2009) (mm/dd/yyyy) [98] 98 NA — QSORRES
Study Week 5 Assessment		
4.	2a. Since your quit date on (see question 1) have you had a period of 24 hours or more in which you did not smoke at all?	[0] 0 No [1] 1 Yes — 2b. If yes, on what date did this abstinence period begin? Req / Req / Req (2005-2009) [98] 98 NA
If no, assess success of initial quit again during week 6		
Study Week 6 Assessment		
5.	2c. Since your quit date on (see question 1) have you had a period of 24 hours or more in which you did not smoke at all?	[0] 0 No [1] 1 Yes — 2d. If yes, on what date did this abstinence period begin? Req / Req / Req (2005-2009) [98] 98 NA
If no, assess success of initial quit again during week 7		
Study Week 7 Assessment		
6.	2e. Between your quit date on (see question 1) and (end date for inital quit time-frame from the Smoking Assessment Time-Frames Worksheet) did you have a period of 24 hours or more in which you did not smoke at all?	[0] 0 No [1] 1 Yes — 2f. If yes, on what date did this abstinence period begin? Req / Req / Req (2005-2009) [98] 98 NA

QSSCAT

DOMAIN: QS

CTN0029 : Protocol Violation Log (PVL) - Repeating Form =QSCAT

QSTEST

QSORRES

1.	Node ID / Name	Pulldown List 1
2.	Site ID / Name	Pulldown List 2
3.	Node Principal Investigator	A50
4.	Site Principal Investigator	A50
5.	Site PI of Record	A50
General Information on protocol violation:		
6.	1. SitePV	xxx
7.	2. Violation Date QSDTC	Req / Req / Req (2005-2009)
8.	3. Part ID	xxxx
9.	4. Violation Type	Pulldown List 3 If Other, Specify: A50
10.	5. Reported by	A10
11.	6. Reported Date	Req / Req / Req (2005-2009)
12.	7. Date Site	Req / Req / Req (2005-2009)
13.	8. Date Log	Req / Req / Req (2005-2009)
14.	9. QA Monitor	A20
15.	10. Date QA	NReq / Req / Req (2005-2009)
16.	11. Initials of QA	A3
17.	Description	A200
18.	Current Status	A200
19.	Resolution	A200