

**[Unspecified]**

**Annotated Design For Trial: pmctn30L2**

**Protocol: StudyVersion1**

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**March 11, 2009 9:52AM**

| <b>Time and Events Schedule For Study: pmctn30L2</b>                                                                                                                       |                        |            |                                    |                                    |                                    |                                |                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------|------------------------------------|------------------------------------|------------------------------------|--------------------------------|----------------------------------------------|
|                                                                                                                                                                            | <b>Assessment</b>      | <b>CRF</b> | <b>18MOS<br/>(18MOS)<br/>[ S ]</b> | <b>30MOS<br/>(30MOS)<br/>[ S ]</b> | <b>42MOS<br/>(42MOS)<br/>[ S ]</b> | <b>CAS<br/>(CAS)<br/>[ S ]</b> | <b>Conflict<br/>(Conflict)<br/>[ U/R/D ]</b> |
| 1                                                                                                                                                                          | PATIENT INFORMATION    | PI         | 1                                  |                                    |                                    |                                |                                              |
| 2                                                                                                                                                                          | PARTICIPANT STATUS     | PTSTAT     | 2                                  | 1                                  | 1                                  |                                |                                              |
| 3                                                                                                                                                                          | Form Completion Status | FORMCOMP   | 3                                  | 2                                  | 2                                  |                                |                                              |
| 4                                                                                                                                                                          | CTN-ASI Lite Follow Up | ASF1       | 4-DF                               | 3-DF                               | 3-DF                               |                                |                                              |
| 5                                                                                                                                                                          | CTN-ASI Lite Follow Up | ASF2       | 5-DF                               | 4-DF                               | 4-DF                               |                                |                                              |
| 6                                                                                                                                                                          | CTN-ASI Lite Follow Up | ASF3       | 6-DF                               | 5-DF                               | 5-DF                               |                                |                                              |
| 7                                                                                                                                                                          | CTN-ASI Lite Follow Up | ASF4       | 7-DF                               | 6-DF                               | 6-DF                               |                                |                                              |
| 8                                                                                                                                                                          | CTN-ASI Lite Follow Up | ASF5       | 8-DF                               | 7-DF                               | 7-DF                               |                                |                                              |
| 9                                                                                                                                                                          | CTN-ASI Lite Follow Up | ASF6       | 9-DF                               | 8-DF                               | 8-DF                               |                                |                                              |
| 10                                                                                                                                                                         | CTN-ASI Lite Follow Up | ASF7       | 10-DF                              | 9-DF                               | 9-DF                               |                                |                                              |
| 11                                                                                                                                                                         | CTN-ASI Lite Follow Up | ASF8       | 11-DF                              | 10-DF                              | 10-DF                              |                                |                                              |
| 12                                                                                                                                                                         | Protocol Violation Log | PVL        |                                    |                                    |                                    | 1-RF                           |                                              |
| 13                                                                                                                                                                         | Study Termination      | STF        |                                    |                                    |                                    | 2                              |                                              |
| Key: [S] = Scheduled Visit [O] = Optional Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit<br>C = Common Form DF = Dynamic Form RF = Repeating Form |                        |            |                                    |                                    |                                    |                                |                                              |

| pmctn30L2 : SCREENING (SCR) |                                           |                                                                                                                                                                                                                                                                                                                |
|-----------------------------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Screening                   |                                           |                                                                                                                                                                                                                                                                                                                |
| 1.                          | NODE                                      | A2 (pmctn30A3cdd:frSCR.NODE / NODE)                                                                                                                                                                                                                                                                            |
| 2.                          | CTP Site                                  | A4 (pmctn30A3cdd:frSCR.CTPSITE / SITE)                                                                                                                                                                                                                                                                         |
| 3.                          | Participant ID (4 digits must be entered) | A4 (pmctn30A3cdd:frSCR.PIID / PARTICIPANT ID)                                                                                                                                                                                                                                                                  |
| 4.                          | Gender (verbal question)                  | (pmctn30A3cdd:frSCR.DEM002 / GENDER)<br>[1] <input type="radio"/> Male<br>[2] <input type="radio"/> Female                                                                                                                                                                                                     |
| 5.                          | Date of Birth                             | Req [v] / Req [v] / Req [v] (1929-1991) (pmctn30A3cdd:frSCR.DEM001_DT / DATE OF BIRTH)                                                                                                                                                                                                                         |
| 6.                          | Date of randomization in CTN0030          | Req [v] / Req [v] / Req [v] (2006-2008) (pmctn30A3cdd:frSCR.DEM003_DT / RANDOMIZATION DATE)                                                                                                                                                                                                                    |
| 7.                          | Was consent obtained by local site        | (pmctn30A3cdd:frSCR.DEM004 / CONSENT AT SITE)<br>[1] <input type="radio"/> Yes<br>[0] <input type="radio"/> No (if no ask next question)<br>Reason Consent Not Obtained<br>Pulldown List 1 [v] (pmctn30A3cdd:frSCR.DEM004A / REASON NO CONSENT)<br>A50 (pmctn30A3cdd:frSCR.DEM04S / REASON NO CONSENT SPECIFY) |

| Pulldown List 1: |                                    |       |             |
|------------------|------------------------------------|-------|-------------|
| RefName          | Display Text                       | Value | Design Note |
| ieCONSENT1       | 1 Contact could not be established | 1     |             |
| ieCONSENT2       | 2 Participant-Initiated (refused)  | 2     |             |
| ieCONSENT3       | 3 Investigator-initiated           | 3     |             |
| ieCONSENT4       | 4 Death                            | 4     |             |
| ieCONSENT5       | 5 Jail                             | 5     |             |
| ieCONSENT6       | 6 Other (specify)                  | 6     |             |

| CDD: pmctn30A3cdd Table: frSCR Key Type: PATIENTVISIT |                                |             |
|-------------------------------------------------------|--------------------------------|-------------|
| Column Name                                           | Column Data Type               | Design Note |
| NODE                                                  | STRING(2) - A2                 |             |
| CTPSITE                                               | STRING(4) - A4                 |             |
| PIID                                                  | STRING(4) - A4                 |             |
| DEM002                                                | NUMERIC                        |             |
| DEM001_DT                                             | DATE - DDMONYYYY               |             |
| DEM003_DT                                             | DATE - DDMONYYYY               |             |
| DEM004                                                | NUMERIC                        |             |
| DEM004A                                               | STRING(255) - 1, 2, 3, 4, 5, 6 |             |
| DEM04S                                                | STRING(50) - A50               |             |

**pmctn30L2 : ENROLLMENT (ENR)**

|                        |                |                                                 |
|------------------------|----------------|-------------------------------------------------|
| *                      |                |                                                 |
| 1.*                    | Participant ID | (pmctn30A3cdd:frENR.PINUM / PARTICIPANT NUMBER) |
| * Item is not required |                |                                                 |

**CDD: pmctn30A3cdd Table: frENR Key Type: PATIENTVISIT**

| Column Name | Column Data Type | Design Note |
|-------------|------------------|-------------|
| PINUM       | STRING(25) - A25 |             |

**pmctn30L2 : PATIENT INFORMATION (PI)****Patient Information**

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

|    |                |                                   |                                                |
|----|----------------|-----------------------------------|------------------------------------------------|
| 1. | Participant ID | A25<br>siteno-NODE-Participant ID | (pmctn30A3cdd:frPI.PINUM / PARTICIPANT NUMBER) |
|----|----------------|-----------------------------------|------------------------------------------------|

**Item Design Notes:**

| Item No. | Design Note                            |
|----------|----------------------------------------|
| 1.       | mapped from Enrollment form to PI form |

**CDD: pmctn30A3cdd Table: frPI Key Type: PATIENTVISIT**

| Column Name | Column Data Type | Design Note |
|-------------|------------------|-------------|
| PINUM       | STRING(25) - A25 |             |

| pmctn30L2 : PARTICIPANT STATUS (PTSTAT) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. VISIT                                | Pulldown List 1 <input type="button" value="v"/> (pmctn30A3cdd:frPTSTAT.PIVISIT / PISTAT VISIT)                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2. Did participant attend visit?        | (pmctn30A3cdd:frPTSTAT.PIATTEND / PISTAT VERBAL)<br>[1] <input type="radio"/> Yes, agreement to participate confirmed verbally<br>[0] <input type="radio"/> No (participant no longer interested in participating)<br>[2] <input type="radio"/> No (other; see next question)<br>Reason not attended<br>Pulldown List 2 <input type="button" value="v"/> (pmctn30A3cdd:frPTSTAT.PIREASON / PISTAT REASON NO VISIT)<br>A50 <input type="button" value="v"/> (pmctn30A3cdd:frPTSTAT.PIREASSP / PISTAT REASON NOVIS SPECIFY) |

| Pulldown List 1: |              |       |             |
|------------------|--------------|-------|-------------|
| RefName          | Display Text | Value | Design Note |
| ieVISIT1         | 18 month     | 1     |             |
| ieVISIT2         | 30 month     | 2     |             |
| ieVISIT3         | 42 month     | 3     |             |

| Pulldown List 2: |                                    |       |             |
|------------------|------------------------------------|-------|-------------|
| RefName          | Display Text                       | Value | Design Note |
| ieCONSENT1       | 1 Contact could not be established | 1     |             |
| ieCONSENT2       | 2 Participant-Initiated (refused)  | 2     |             |
| ieCONSENT3       | 3 Investigator-initiated           | 3     |             |
| ieCONSENT4       | 4 Death                            | 4     |             |
| ieCONSENT5       | 5 Jail                             | 5     |             |
| ieCONSENT6       | 6 Other (specify)                  | 6     |             |

| CDD: pmctn30A3cdd Table: frPTSTAT Key Type: PATIENTVISIT |                                |             |
|----------------------------------------------------------|--------------------------------|-------------|
| Column Name                                              | Column Data Type               | Design Note |
| PIVISIT                                                  | STRING(255) - 1, 2, 3          |             |
| PIATTEND                                                 | NUMERIC                        |             |
| PIREASON                                                 | STRING(255) - 1, 2, 3, 4, 5, 6 |             |
| PIREASSP                                                 | STRING(50) - A50               |             |

| pmctn30L2 : Form Completion Status (FORMCOMP) |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.                                            | Form Completion Status | (pmctn30A3cdd:frFORMCOMP.FORMSTAT / FORMCOMP STATUS)<br>[0] <input type="radio"/> Form Initiated<br>[1] <input type="radio"/> Patient Unable/Unwilling to Answer<br>[2] <input type="radio"/> Call Disrupted<br>[3] <input type="radio"/> Data Collection Error (specify) (pmctn30A3cdd:frFORMCOMP.FORMSTA1 / DE ERROR SPECIFY)<br>  A50  <br>[4] <input type="radio"/> Not Applicable/Other (specify) (pmctn30A3cdd:frFORMCOMP.FORMSTA2 / NA OTHER SPECIFY)<br>  A50       |
| 2.                                            | Outcome                | (pmctn30A3cdd:frFORMCOMP.FORMOUT / FORMCOMP OUTCOME)<br>[1] <input type="radio"/> Completed<br>[2] <input type="radio"/> Partial completion-no additional data will be collected (specify): (pmctn30A3cdd:frFORMCOMP.FORMOUT2 / FORMCOMP PARTIAL SPECIFY)<br>  A50  <br>[3] <input type="radio"/> Partial completion-additional data will be collected<br>[4] <input type="radio"/> Other (specify): (pmctn30A3cdd:frFORMCOMP.FORMOUT1 / FORMCOMP OUTCOME SPECIFY)<br>  A50 |

| CDD: pmctn30A3cdd Table: frFORMCOMP Key Type: PATIENTVISIT |                  |             |
|------------------------------------------------------------|------------------|-------------|
| Column Name                                                | Column Data Type | Design Note |
| FORMSTAT                                                   | NUMERIC          |             |
| FORMSTA1                                                   | STRING(50) - A50 |             |
| FORMSTA2                                                   | STRING(50) - A50 |             |
| FORMOUT                                                    | NUMERIC          |             |
| FORMOUT2                                                   | STRING(50) - A50 |             |
| FORMOUT1                                                   | STRING(50) - A50 |             |

| pmctn30L2 : CTN-ASI Lite Follow Up (ASF1)                                                                       |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SECTION 1: CTN-ASI Lite Follow Up v. 1: General Information                                                     |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 1.                                                                                                              | Assessment Date:                                                                                                                                                                                                                                                                                                                         | Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2014) (pmctn30A3cdd:frASF1.VISITDT / VISIT DATE)                                                                                                                                                                                                                                                                |
| 2.                                                                                                              | G19. Have you been in a controlled environment in the past 30 days? (A place, theoretically, without access to drugs/alcohol)                                                                                                                                                                                                            | (pmctn30A3cdd:frASF1.G19 / ASF1 G19)<br>[1] <input type="radio"/> No<br>[2] <input type="radio"/> Jail<br>[3] <input type="radio"/> Alcohol Or Drug Treatment<br>[4] <input type="radio"/> Medical Treatment<br>[5] <input type="radio"/> Psychiatric Treatment<br>[6] <input type="radio"/> Other (specify):<br>A50<br>[97] <input type="radio"/> Not answered<br>(pmctn30A3cdd:frASF1.G19A / ASF1 G19 SPECIFY) |
| 3.                                                                                                              | G20. How many days? (Refers to total number of days detained in the past 30 days)                                                                                                                                                                                                                                                        | (pmctn30A3cdd:frASF1.RCG20 / ASF1 G20 RADIO)<br>[1] <input type="radio"/> xx (0 =< n <= 30) days (pmctn30A3cdd:frASF1.G20 / ASF1 G20)<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable                                                                                                                                                                                    |
| 4.*                                                                                                             | General Comments:                                                                                                                                                                                                                                                                                                                        | A200 (pmctn30A3cdd:frASF1.GCOM / ASF1 G20 COMMENT)                                                                                                                                                                                                                                                                                                                                                               |
| SECTION 2: CTN-ASI LITE v. 1: Medical Status                                                                    |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 5.                                                                                                              | M6. How many days have you experienced medical problems in the past 30 days? (Do not include ailments directly caused by drugs/alcohol) (Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the participant were abstinent) (e.g. cirrhosis of liver, abscesses from needles, etc) | (pmctn30A3cdd:frASF1.RCM6 / ASF1 M6 RADIO)<br>[1] <input type="radio"/> xx (0 =< n <= 30) days (pmctn30A3cdd:frASF1.M6 / ASF1 M6)<br>[97] <input type="radio"/> Not answered                                                                                                                                                                                                                                     |
| For questions M7 & M8, ask participant specifying not at all, slightly, moderately, considerably, or extremely. |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 6.                                                                                                              | M7. How troubled or bothered have you been by these medical problems in the past 30 days? (Restrict response to problem days of question M6)                                                                                                                                                                                             | Pulldown List 1 <input type="checkbox"/> (pmctn30A3cdd:frASF1.M7 / ASF1 M7)                                                                                                                                                                                                                                                                                                                                      |
| 7.                                                                                                              | M8. How important to you now is treatment for these medical problems?<br>Refers to the need for new or additional medical treatment by the participant.                                                                                                                                                                                  | Pulldown List 2 <input type="checkbox"/> (pmctn30A3cdd:frASF1.M8 / ASF1 M8)                                                                                                                                                                                                                                                                                                                                      |
| Confidence Ratings: Is the above information significantly distorted by:                                        |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 8.                                                                                                              | M10. Participant's misrepresentation?                                                                                                                                                                                                                                                                                                    | (pmctn30A3cdd:frASF1.M10 / ASF1 M10)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                                                                                                            |
| 9.                                                                                                              | M11. Participant's inability to understand?                                                                                                                                                                                                                                                                                              | (pmctn30A3cdd:frASF1.M11 / ASF1 M11)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                                                                                                            |
| 10.*                                                                                                            | Medical Comments:                                                                                                                                                                                                                                                                                                                        | A200 (pmctn30A3cdd:frASF1.MCOM / ASF1 COMMENT)                                                                                                                                                                                                                                                                                                                                                                   |
| * Item is not required                                                                                          |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                  |

| Pulldown List 1: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieXTRMSCL0       | 0 Not At All    | 0     |             |
| ieXTRMSCL1       | 1 Slightly      | 1     |             |
| ieXTRMSCL2       | 2 Moderately    | 2     |             |
| ieXTRMSCL3       | 3 Considerably  | 3     |             |
| ieXTRMSCL4       | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |



| Pulldown List 2: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieXTRMSCL0       | 0 Not At All    | 0     |             |
| ieXTRMSCL1       | 1 Slightly      | 1     |             |
| ieXTRMSCL2       | 2 Moderately    | 2     |             |
| ieXTRMSCL3       | 3 Considerably  | 3     |             |
| ieXTRMSCL4       | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| CDD: pmctn30A3cdd Table: frASF1 Key Type: PATIENTVISIT |                                 |             |
|--------------------------------------------------------|---------------------------------|-------------|
| Column Name                                            | Column Data Type                | Design Note |
| VISITDT                                                | DATE - DDMONYYYY                |             |
| G19                                                    | NUMERIC                         |             |
| G19A                                                   | STRING(50) - A50                |             |
| RCG20                                                  | NUMERIC                         |             |
| G20                                                    | NUMERIC - N2                    |             |
| GCOM                                                   | STRING(200) - A200              |             |
| RCM6                                                   | NUMERIC                         |             |
| M6                                                     | NUMERIC - N2                    |             |
| M7                                                     | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| M8                                                     | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| M10                                                    | NUMERIC                         |             |
| M11                                                    | NUMERIC                         |             |
| MCOM                                                   | STRING(200) - A200              |             |

| pmctn30L2 : CTN-ASI Lite Follow Up (ASF2)                                     |                                                                                                                                                                                                                                                            |                                                                                                                                                                                            |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SECTION 3: CTN-ASI LITE v. 1: Employment/Support Status                       |                                                                                                                                                                                                                                                            |                                                                                                                                                                                            |
| 1.                                                                            | Assessment Date:                                                                                                                                                                                                                                           | Req <input type="button" value="v"/> /   Req <input type="button" value="v"/> /   Req <input type="button" value="v"/> (2009-2014) (pmctn30A3cdd:frASF2.VISITDT / VISIT DATE)              |
| 2.                                                                            | E10. Usual employment pattern, past year? (Answer should represent the majority of the last 1 year, not just the most recent selection. If there are equal times for more than one category, select that which best represents the most current situation) | Pulldown List 1 <input type="button" value="v"/> (pmctn30A3cdd:frASF2.E10 / ASF2 E10)                                                                                                      |
| 3.                                                                            | E11. How many days were you paid for working in the past 30 days?<br>Include under the table work, paid sick days, and vacation.                                                                                                                           | (pmctn30A3cdd:frASF2.rcE11 / ASF2 E11 RADIO)<br>[1] <input type="radio"/> xx ( 0 =< n <= 30 )   days (pmctn30A3cdd:frASF2.E11 / ASF2 E11)<br>[97] <input type="radio"/> Not answered       |
| How much money did you receive from the following source in the past 30 days? |                                                                                                                                                                                                                                                            |                                                                                                                                                                                            |
| 4.                                                                            | E17. Illegal:<br>Cash obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc.<br>Do not attempt to convert drugs exchanged to a dollar value.                                                                             | (pmctn30A3cdd:frASF2.rcE17 / ASF2 E17 RADIO)<br>[1] <input type="radio"/> \$   xxxxx ( 0 =< n <= 99999 )   (pmctn30A3cdd:frASF2.E17 / ASF2 E17)<br>[97] <input type="radio"/> Not answered |

| Item Design Notes: |             |
|--------------------|-------------|
| Item No.           | Design Note |
| 3.                 | 1           |

| Pulldown List 1: |                                  |       |             |
|------------------|----------------------------------|-------|-------------|
| RefName          | Display Text                     | Value | Design Note |
| ieFullTm         | 1 Full Time (35+ hours/week)     | 1     |             |
| iePaTmRe         | 2 Part Time (Regular Hours)      | 2     |             |
| iePaTmIr         | 3 Part Time (Irregular day work) | 3     |             |
| ie4Stude         | 4 Student                        | 4     |             |
| ieMilSer         | 5 Military Service               | 5     |             |
| ieRetDis         | 6 Retired/Disability             | 6     |             |
| ieUnempl         | 7 Unemployed                     | 7     |             |
| ieConEnv         | 8 In Controlled Environment      | 8     |             |
| ieNotAns         | 97 Not answered                  | 97    |             |

| CDD: pmctn30A3cdd Table: frASF2 Key Type: PATIENTVISIT |                                          |             |
|--------------------------------------------------------|------------------------------------------|-------------|
| Column Name                                            | Column Data Type                         | Design Note |
| VISITDT                                                | DATE - DDMONYYYY                         |             |
| E10                                                    | STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 97 |             |
| rcE11                                                  | NUMERIC                                  |             |
| E11                                                    | NUMERIC - N2                             |             |
| rcE17                                                  | NUMERIC                                  |             |
| E17                                                    | NUMERIC - N5                             |             |

| pmctn30L2 : CTN-ASI Lite Follow Up (ASF3)                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SECTION 4: CTN-ASI LITE V. 1: Drug/Alcohol Use                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                      |
| Route of Administration:<br>1 = Oral 2 = Nasal 3 = Smoking 4 = Non-IV injection 5 = IV Injection<br>Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe. If Past 30 Days is zero, route should be Not Applicable. |                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                      |
| 1.                                                                                                                                                                                                                                                                                                         | Assessment Date:                                                                                                                                                                                                                                                                                                                                                                      | Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2014) (pmctn30A3cdd:frASF3.VISITDT / VISIT DATE)                                                    |
| 2.                                                                                                                                                                                                                                                                                                         | D1. Alcohol (any use at all)                                                                                                                                                                                                                                                                                                                                                          | A Past 30 (Days) (pmctn30A3cdd:frASF3.D1a / ASF3 D1A)<br>xx ( 0 =< n <= 30 )                                                                                                                         |
| 3.                                                                                                                                                                                                                                                                                                         | D2. Alcohol (to intoxication)                                                                                                                                                                                                                                                                                                                                                         | A Past 30 (Days) (pmctn30A3cdd:frASF3.D2a / ASF3 D2A)<br>xx ( 0 =< n <= 30 )                                                                                                                         |
| 4.                                                                                                                                                                                                                                                                                                         | D3. Heroin                                                                                                                                                                                                                                                                                                                                                                            | A Past 30 (Days) (pmctn30A3cdd:frASF3.D3a / ASF3 D3A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 1 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D3c / ASF3 D3C)                 |
| 5.                                                                                                                                                                                                                                                                                                         | D4. Methadone/LAAM (prescribed)                                                                                                                                                                                                                                                                                                                                                       | A Past 30 (Days) (pmctn30A3cdd:frASF3.D4a / ASF3 D4A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 2 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D4c / ASF3 D4C)                 |
| 6.                                                                                                                                                                                                                                                                                                         | D4a. Methadone/LAAM (illicit)                                                                                                                                                                                                                                                                                                                                                         | A Past 30 (Days) (pmctn30A3cdd:frASF3.D4a1 / ASF3 D4A1) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 3 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D4a1c / ASF3 D4A1C)           |
| 7.                                                                                                                                                                                                                                                                                                         | D5. Other opiates/analgesics:                                                                                                                                                                                                                                                                                                                                                         | A Past 30 (Days) (pmctn30A3cdd:frASF3.D5a / ASF3 D5A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 4 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D5c / ASF3 D5C)                 |
| 8.                                                                                                                                                                                                                                                                                                         | D6. Barbiturates:                                                                                                                                                                                                                                                                                                                                                                     | A Past 30 (Days) (pmctn30A3cdd:frASF3.D6a / ASF3 D6A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 5 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D6c / ASF3 D6C)                 |
| 9.                                                                                                                                                                                                                                                                                                         | D7. Other sedatives/hypnotics/tranquilizers:                                                                                                                                                                                                                                                                                                                                          | A Past 30 (Days) (pmctn30A3cdd:frASF3.D7a / ASF3 D7A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 6 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D7c / ASF3 D7C)                 |
| 10.                                                                                                                                                                                                                                                                                                        | D8. Cocaine:                                                                                                                                                                                                                                                                                                                                                                          | A Past 30 (Days) (pmctn30A3cdd:frASF3.D8a / ASF3 D8A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 7 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D8c / ASF3 D8C)                 |
| 11.                                                                                                                                                                                                                                                                                                        | D9. Amphetamines:                                                                                                                                                                                                                                                                                                                                                                     | A Past 30 (Days) (pmctn30A3cdd:frASF3.D9a / ASF3 D9A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 8 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D9c / ASF3 D9C)                 |
| 12.                                                                                                                                                                                                                                                                                                        | D10. Cannabis:                                                                                                                                                                                                                                                                                                                                                                        | A Past 30 (Days) (pmctn30A3cdd:frASF3.D10a / ASF3 D10A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 9 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D10c / ASF3 D10C)             |
| 13.                                                                                                                                                                                                                                                                                                        | D11. Hallucinogens:                                                                                                                                                                                                                                                                                                                                                                   | A Past 30 (Days) (pmctn30A3cdd:frASF3.D11a / ASF3 D11A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 10 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D11c / ASF3 D11C)            |
| 14.                                                                                                                                                                                                                                                                                                        | D12. Inhalants:                                                                                                                                                                                                                                                                                                                                                                       | A Past 30 (Days) (pmctn30A3cdd:frASF3.D12a / ASF3 D12A) C Route of Administration<br>xx ( 0 =< n <= 30 ) Pulldown List 11 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D12c / ASF3 D12C)            |
| 15.                                                                                                                                                                                                                                                                                                        | D36. Nicotine (tobacco products)                                                                                                                                                                                                                                                                                                                                                      | A Past 30 (Days) (pmctn30A3cdd:frASF3.D36a / ASF3 D36A)<br>xx ( 0 =< n <= 30 )                                                                                                                       |
| 16.                                                                                                                                                                                                                                                                                                        | D13. More than 1 substance per day (including alcohol, excluding nicotine):                                                                                                                                                                                                                                                                                                           | A Past 30 (Days) (pmctn30A3cdd:frASF3.D13a / ASF3 D13A)<br>xx ( 0 =< n <= 30 )                                                                                                                       |
| 17.                                                                                                                                                                                                                                                                                                        | D14. According to the interviewer, which substance(s) is/are the major problem?<br>Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). Code the number next to the drug in questions D1-12 (code prescribed or illicit methadone as 04). 00 = no problem, 15 = alcohol and one or more drugs; 16 = more than one drug but no alcohol. Ask patient | (pmctn30A3cdd:frASF3.rcD14 / ASF3 D14 RADIO)<br>[1] <input type="radio"/> Pulldown List 12 <input type="checkbox"/> (pmctn30A3cdd:frASF3.D14 / ASF3 D14 )<br>[97] <input type="radio"/> Not answered |

when not clear.

| Pulldown List 1: |                    |       |             |
|------------------|--------------------|-------|-------------|
| RefName          | Display Text       | Value | Design Note |
| ieOral           | 1 Oral             | 1     |             |
| ieNasal          | 2 Nasal            | 2     |             |
| ieSmokin         | 3 Smoking          | 3     |             |
| ieNonIVI         | 4 Non IV injection | 4     |             |
| ieIVinje         | 5 IV injection     | 5     |             |
| ieNotAns         | 97 Not answered    | 97    |             |
| ieNotApp         | 96 Not applicable  | 96    |             |

| Pulldown List 2: |                    |       |             |
|------------------|--------------------|-------|-------------|
| RefName          | Display Text       | Value | Design Note |
| ieOral           | 1 Oral             | 1     |             |
| ieNasal          | 2 Nasal            | 2     |             |
| ieSmokin         | 3 Smoking          | 3     |             |
| ieNonIVI         | 4 Non IV injection | 4     |             |
| ieIVinje         | 5 IV injection     | 5     |             |
| ieNotAns         | 97 Not answered    | 97    |             |
| ieNotApp         | 96 Not applicable  | 96    |             |

| Pulldown List 3: |                    |       |             |
|------------------|--------------------|-------|-------------|
| RefName          | Display Text       | Value | Design Note |
| ieOral           | 1 Oral             | 1     |             |
| ieNasal          | 2 Nasal            | 2     |             |
| ieSmokin         | 3 Smoking          | 3     |             |
| ieNonIVI         | 4 Non IV injection | 4     |             |
| ieIVinje         | 5 IV injection     | 5     |             |
| ieNotAns         | 97 Not answered    | 97    |             |
| ieNotApp         | 96 Not applicable  | 96    |             |

| Pulldown List 4: |                    |       |             |
|------------------|--------------------|-------|-------------|
| RefName          | Display Text       | Value | Design Note |
| ieOral           | 1 Oral             | 1     |             |
| ieNasal          | 2 Nasal            | 2     |             |
| ieSmokin         | 3 Smoking          | 3     |             |
| ieNonIVI         | 4 Non IV injection | 4     |             |
| ieIVinje         | 5 IV injection     | 5     |             |
| ieNotAns         | 97 Not answered    | 97    |             |
| ieNotApp         | 96 Not applicable  | 96    |             |

| Pulldown List 5: |  |  |  |
|------------------|--|--|--|
|                  |  |  |  |

| RefName  | Display Text       | Value | Design Note |
|----------|--------------------|-------|-------------|
| ieOral   | 1 Oral             | 1     |             |
| ieNasal  | 2 Nasal            | 2     |             |
| ieSmokin | 3 Smoking          | 3     |             |
| ieNonIVI | 4 Non IV injection | 4     |             |
| ieIVinje | 5 IV injection     | 5     |             |
| ieNotAns | 97 Not answered    | 97    |             |
| ieNotApp | 96 Not applicable  | 96    |             |

| Pulldown List 6: |                    |       |             |
|------------------|--------------------|-------|-------------|
| RefName          | Display Text       | Value | Design Note |
| ieOral           | 1 Oral             | 1     |             |
| ieNasal          | 2 Nasal            | 2     |             |
| ieSmokin         | 3 Smoking          | 3     |             |
| ieNonIVI         | 4 Non IV injection | 4     |             |
| ieIVinje         | 5 IV injection     | 5     |             |
| ieNotAns         | 97 Not answered    | 97    |             |
| ieNotApp         | 96 Not applicable  | 96    |             |

| Pulldown List 7: |                    |       |             |
|------------------|--------------------|-------|-------------|
| RefName          | Display Text       | Value | Design Note |
| ieOral           | 1 Oral             | 1     |             |
| ieNasal          | 2 Nasal            | 2     |             |
| ieSmokin         | 3 Smoking          | 3     |             |
| ieNonIVI         | 4 Non IV injection | 4     |             |
| ieIVinje         | 5 IV injection     | 5     |             |
| ieNotAns         | 97 Not answered    | 97    |             |
| ieNotApp         | 96 Not applicable  | 96    |             |

| Pulldown List 8: |                    |       |             |
|------------------|--------------------|-------|-------------|
| RefName          | Display Text       | Value | Design Note |
| ieOral           | 1 Oral             | 1     |             |
| ieNasal          | 2 Nasal            | 2     |             |
| ieSmokin         | 3 Smoking          | 3     |             |
| ieNonIVI         | 4 Non IV injection | 4     |             |
| ieIVinje         | 5 IV injection     | 5     |             |
| ieNotAns         | 97 Not answered    | 97    |             |
| ieNotApp         | 96 Not applicable  | 96    |             |

| Pulldown List 9: |              |       |             |
|------------------|--------------|-------|-------------|
| RefName          | Display Text | Value | Design Note |
| ieOral           | 1 Oral       | 1     |             |
| ieNasal          | 2 Nasal      | 2     |             |
|                  |              |       |             |

|          |                    |    |  |
|----------|--------------------|----|--|
| ieSmokin | 3 Smoking          | 3  |  |
| ieNonIVI | 4 Non IV injection | 4  |  |
| ieIVinje | 5 IV injection     | 5  |  |
| ieNotAns | 97 Not answered    | 97 |  |
| ieNotApp | 96 Not applicable  | 96 |  |

**Pulldown List 10:**

| RefName  | Display Text       | Value | Design Note |
|----------|--------------------|-------|-------------|
| ieOral   | 1 Oral             | 1     |             |
| ieNasal  | 2 Nasal            | 2     |             |
| ieSmokin | 3 Smoking          | 3     |             |
| ieNonIVI | 4 Non IV injection | 4     |             |
| ieIVinje | 5 IV injection     | 5     |             |
| ieNotAns | 97 Not answered    | 97    |             |
| ieNotApp | 96 Not applicable  | 96    |             |

**Pulldown List 11:**

| RefName  | Display Text      | Value | Design Note |
|----------|-------------------|-------|-------------|
| ieNasal  | 2 Nasal           | 2     |             |
| ieNotAns | 97 Not answered   | 97    |             |
| ieNotApp | 96 Not applicable | 96    |             |

**Pulldown List 12:**

| RefName     | Display Text                                | Value | Design Note |
|-------------|---------------------------------------------|-------|-------------|
| ieNoProb    | 00 No Problem                               | 0     |             |
| ieAlcAny    | 01 Alcohol (any use at all)                 | 1     |             |
| ieAlcToI    | 02 Alcohol (to intoxicification)            | 2     |             |
| ieHeroin    | 03 Heroin                                   | 3     |             |
| ieMethad    | 04 Methadone                                | 4     |             |
| ieOthOpi    | 05 Other Opiates/Analgesics                 | 5     |             |
| ieBarbit    | 06 Barbiturates                             | 6     |             |
| ieOthSed    | 07 Other Sedatives/Hypnotics/Tranquillizers | 7     |             |
| ieCocain    | 08 Cocaine                                  | 8     |             |
| ieAmphet    | 09 Amphetamines                             | 9     |             |
| ieCannab    | 10 Cannabis                                 | 9     |             |
| ieHalluc    | 11 Hallucinogens                            | 11    |             |
| ieInhalants | 12 Inhalants                                | 12    |             |
| ieAlcDru    | 15 Alcohol and one or more drugs            | 15    |             |
| ieDrNoAl    | 16 More than one drug but no alcohol        | 16    |             |

**CDD: pmctn30A3cdd Table: frASF3 Key Type: PATIENTVISIT**

| Column Name | Column Data Type | Design Note |
|-------------|------------------|-------------|
| VISITDT     | DATE - DDMONYYYY |             |

|       |                                                               |  |
|-------|---------------------------------------------------------------|--|
| D1a   | NUMERIC - N2                                                  |  |
| D2a   | NUMERIC - N2                                                  |  |
| D3a   | NUMERIC - N2                                                  |  |
| D3c   | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D4a   | NUMERIC - N2                                                  |  |
| D4c   | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D4a1  | NUMERIC - N2                                                  |  |
| D4a1c | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D5a   | NUMERIC - N2                                                  |  |
| D5c   | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D6a   | NUMERIC - N2                                                  |  |
| D6c   | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D7a   | NUMERIC - N2                                                  |  |
| D7c   | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D8a   | NUMERIC - N2                                                  |  |
| D8c   | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D9a   | NUMERIC - N2                                                  |  |
| D9c   | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D10a  | NUMERIC - N2                                                  |  |
| D10c  | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D11a  | NUMERIC - N2                                                  |  |
| D11c  | STRING(255) - 1, 2, 3, 4, 5, 97, 96                           |  |
| D12a  | NUMERIC - N2                                                  |  |
| D12c  | STRING(255) - 2, 97, 96                                       |  |
| D36a  | NUMERIC - N2                                                  |  |
| D13a  | NUMERIC - N2                                                  |  |
| rcD14 | NUMERIC                                                       |  |
| D14   | STRING(255) - 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 9, 11, 12, 15, 16 |  |

| pmctn30L2 : CTN-ASI Lite Follow Up (ASF4)                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SECTION 4: CTN-ASI LITE V. 1: Drug/Alcohol Use                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                              |
| How much money would you say you spent during the past 30 days on:<br>Max. = \$99999                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                              |
| 1.                                                                                                                                                                                                                                                                      | Assessment Date:<br>Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2009-2014) (pmctn30A3cdd:frASF4.VISITDT / VISIT DATE)                                                                                                                                                        |
| 2.                                                                                                                                                                                                                                                                      | D23. Alcohol:<br>Only count actual money spent. What is the financial burden caused by alcohol?<br>[1] <input type="radio"/> \$   xxxxx (0 = < n <= 99999)   (pmctn30A3cdd:frASF4.D23 / ASF4 D23)<br>[97] <input type="radio"/> Not answered                                                                                 |
| 3.                                                                                                                                                                                                                                                                      | D24. Drugs:<br>Only count actual money spent. What is the financial burden caused by drugs?<br>[1] <input type="radio"/> \$   xxxxx (0 = < n <= 99999)   (pmctn30A3cdd:frASF4.D24 / ASF4 D24)<br>[97] <input type="radio"/> Not answered                                                                                     |
| 4.                                                                                                                                                                                                                                                                      | D26. How many days in the past 30 have you experienced alcohol problems?<br>Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.<br>[1] <input type="radio"/> xx (0 = < n <= 30)   days (pmctn30A3cdd:frASF4.D26 / ASF4 D26)<br>[97] <input type="radio"/> Not answered |
| For questions D28-D31, please ask participant to use the Participant Rating Scale, specifying 0 for not at all, 1 for slightly, 2 for moderately, 3 for considerably, and 4 for extremely. The participant is rating the need for additional substance abuse treatment. |                                                                                                                                                                                                                                                                                                                              |
| 5.                                                                                                                                                                                                                                                                      | D28. How troubled or bothered have you been in the past 30 days by Alcohol Problems?<br>Pulldown List 1 <input type="checkbox"/> (pmctn30A3cdd:frASF4.D28 / ASF4 D28)                                                                                                                                                        |
| 6.                                                                                                                                                                                                                                                                      | D30. How important to you now is treatment for Alcohol problems?<br>Pulldown List 2 <input type="checkbox"/> (pmctn30A3cdd:frASF4.D30 / ASF4 D30)                                                                                                                                                                            |
| 7.                                                                                                                                                                                                                                                                      | D27. How many days in the past 30 have you experienced drug problems?<br>Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.<br>[1] <input type="radio"/> xx (0 = < n <= 30)   days (pmctn30A3cdd:frASF4.D27 / ASF4 D27)<br>[97] <input type="radio"/> Not answered    |
| 8.                                                                                                                                                                                                                                                                      | D29. How troubled or bothered have you been in the past 30 days by Drug Problems?<br>Pulldown List 3 <input type="checkbox"/> (pmctn30A3cdd:frASF4.D29 / ASF4 D29)                                                                                                                                                           |
| 9.                                                                                                                                                                                                                                                                      | D31. How important to you now is treatment for drug problems?<br>Pulldown List 4 <input type="checkbox"/> (pmctn30A3cdd:frASF4.D31 / ASF4 D31)                                                                                                                                                                               |
| Confidence Ratings: Is the above information significantly distorted by:                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                              |
| 10.                                                                                                                                                                                                                                                                     | D34. Participant's misrepresentation?<br>(pmctn30A3cdd:frASF4.D34 / ASF4 D34)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                               |
| 11.                                                                                                                                                                                                                                                                     | D35. Participant's inability to understand?<br>(pmctn30A3cdd:frASF4.D35 / ASF4 D35)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                         |
| 12.*                                                                                                                                                                                                                                                                    | Drug & Alcohol Comments:<br>A200 (pmctn30A3cdd:frASF4.DCOM / ASF4 COMMENT)                                                                                                                                                                                                                                                   |
| * Item is not required                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                              |

| Pulldown List 1: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAl         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |



| Pulldown List 2: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAI         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| Pulldown List 3: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAI         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| Pulldown List 4: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAI         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| CDD: pmctn30A3cdd Table: frASF4 Key Type: PATIENTVISIT |                                 |             |
|--------------------------------------------------------|---------------------------------|-------------|
| Column Name                                            | Column Data Type                | Design Note |
| VISITDT                                                | DATE - DDMONYYYY                |             |
| rcD23                                                  | NUMERIC                         |             |
| D23                                                    | NUMERIC - N5                    |             |
| rcD24                                                  | NUMERIC                         |             |
| D24                                                    | NUMERIC - N5                    |             |
| rcD26                                                  | NUMERIC                         |             |
| D26                                                    | NUMERIC - N2                    |             |
| D28                                                    | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| D30                                                    | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| rcD27                                                  | NUMERIC                         |             |
| D27                                                    | NUMERIC - N2                    |             |
| D29                                                    | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| D31                                                    | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| D34                                                    | NUMERIC                         |             |

|      |                    |  |
|------|--------------------|--|
| D35  | NUMERIC            |  |
| DCOM | STRING(200) - A200 |  |

| pmctn30L2 : CTN-ASI Lite Follow Up (ASF5)                                                                      |                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SECTION 5: CTN-ASI LITE V. 1: Legal Status                                                                     |                                                                                                                                                                                                                                                                                                                                                                            |
| 1.                                                                                                             | Assessment Date:  Req <input type="button" value="v"/> /  Req <input type="button" value="v"/> /  Req <input type="button" value="v"/> (2009-2014) (pmctn30A3cdd:frASF5.VISITDT / VISIT DATE)                                                                                                                                                                              |
| 2.                                                                                                             | L24. Are you presently awaiting charges, trial or sentence?<br>(pmctn30A3cdd:frASF5.L24 / ASF5 L24)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered                                                                                                                                                            |
| 3.                                                                                                             | L27. How many days in the past 30, have you engaged in illegal activities for profit? Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc.<br>(pmctn30A3cdd:frASF5.rcL27 / ASF5 L27 RADIO)<br>[1] <input type="radio"/> xx (0 =< n <= 30)   days (pmctn30A3cdd:frASF5.L27 / ASF5 L27)<br>[97] <input type="radio"/> Not answered |
| For questions L28-29: Ask participant specifying not at all, slightly, moderately, considerably, or extremely. |                                                                                                                                                                                                                                                                                                                                                                            |
| 4.                                                                                                             | L28. How serious do you feel your present legal problems are? Exclude civil problems.  Pulldown List 1 <input type="button" value="v"/> (pmctn30A3cdd:frASF5.L28 / ASF5 L28)                                                                                                                                                                                               |
| 5.                                                                                                             | L29. How important to you now is counseling or referral for these legal problems? Participant is rating a need for additional referral to legal counsel for defense against criminal charges.  Pulldown List 2 <input type="button" value="v"/> (pmctn30A3cdd:frASF5.L29 / ASF5 L29)                                                                                       |
| Confidence Ratings: Is the above information significantly distorted by:                                       |                                                                                                                                                                                                                                                                                                                                                                            |
| 6.                                                                                                             | L31. Participant's misrepresentation?<br>(pmctn30A3cdd:frASF5.L31 / ASF5 L31)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                             |
| 7.                                                                                                             | L32. Participant's inability to understand?<br>(pmctn30A3cdd:frASF5.L32 / ASF5 L32)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                       |
| 8.*                                                                                                            | Legal Comments: <input type="text" value="A200"/> (pmctn30A3cdd:frASF5.LCOM / ASF5 COMMENT)                                                                                                                                                                                                                                                                                |
| * Item is not required                                                                                         |                                                                                                                                                                                                                                                                                                                                                                            |

| Pulldown List 1: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAl         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| Pulldown List 2: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAl         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| CDD: pmctn30A3cdd Table: frASF5 Key Type: PATIENTVISIT |                                 |             |
|--------------------------------------------------------|---------------------------------|-------------|
| Column Name                                            | Column Data Type                | Design Note |
| VISITDT                                                | DATE - DDMONYYYY                |             |
| L24                                                    | NUMERIC                         |             |
| rcL27                                                  | NUMERIC                         |             |
| L27                                                    | NUMERIC - N2                    |             |
| L28                                                    | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| L29                                                    | STRING(255) - 0, 1, 2, 3, 4, 97 |             |
| L31                                                    | NUMERIC                         |             |
| L32                                                    | NUMERIC                         |             |
| LCOM                                                   | STRING(200) - A200              |             |

| pmctn30L2 : CTN-ASI Lite Follow Up (ASF6)                                                                                                |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SECTION 6: CTN-ASI LITE V. 1: Family/Social Relationships                                                                                |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                   |
| 1.                                                                                                                                       | Assessment Date:                                                                                                 | Req <input type="button" value="v"/> /   Req <input type="button" value="v"/> /   Req <input type="button" value="v"/> (2009-2014) (pmctn30A3cdd:frASF6.VISITDT / VISIT DATE)                                                                                                                                                     |
| 2.                                                                                                                                       | F1. Marital status:<br>Common-law marriage = 1;                                                                  | Pulldown List 1 <input type="button" value="v"/> (pmctn30A3cdd:frASF6.F1 / ASF6 F1)                                                                                                                                                                                                                                               |
| 3.                                                                                                                                       | F3. Are you satisfied with this situation?<br>Satisfied = Generally liking the situation. Refers to question F1. | (pmctn30A3cdd:frASF6.F3 / ASF6 F3)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[2] <input type="radio"/> Indifferent<br>[97] <input type="radio"/> Not answered                                                                                                                                           |
| <b>Have you had significant periods in which you have experienced serious problems getting along with:</b>                               |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                   |
| Serious problems mean those that endangered the relationship. A problem requires contact of some sort, either by telephone or in person. |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                   |
| 4.                                                                                                                                       | F18. Mother:                                                                                                     | (pmctn30A3cdd:frASF6.F18a / ASF6 F18A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable                                                                                                                   |
| 5.                                                                                                                                       | F19. Father:                                                                                                     | (pmctn30A3cdd:frASF6.F19a / ASF6 F19A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable                                                                                                                   |
| 6.                                                                                                                                       | F20. Brother/sisters:                                                                                            | (pmctn30A3cdd:frASF6.F20a / ASF6 F20A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable                                                                                                                   |
| 7.                                                                                                                                       | F21. Sexual partner/spouse:                                                                                      | (pmctn30A3cdd:frASF6.F21a / ASF6 F21A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable                                                                                                                   |
| 8.                                                                                                                                       | F22. Children:                                                                                                   | (pmctn30A3cdd:frASF6.F22a / ASF6 F22A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable                                                                                                                   |
| 9.                                                                                                                                       | F23. Other significant family (specify):                                                                         | (pmctn30A3cdd:frASF6.rcF23 / ASF6 F23 RADIO)<br>[1] <input type="radio"/> A50   (pmctn30A3cdd:frASF6.F23c / ASF6 F23 SPECIFY) [98] <input type="radio"/> NA<br>(pmctn30A3cdd:frASF6.F23a / ASF6 F23A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered |

|     |                     |                                                                                                                                                                                                                 |
|-----|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                     | [96] <input type="radio"/> Not applicable                                                                                                                                                                       |
| 10. | F24. Close friends: | (pmctn30A3cdd:frASF6.F24a / ASF6 F24A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable |
| 11. | F25. Neighbors      | (pmctn30A3cdd:frASF6.F25a / ASF6 F25A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable |
| 12. | F26. Co-workers:    | (pmctn30A3cdd:frASF6.F26a / ASF6 F26A)<br>Past 30 Days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered<br>[96] <input type="radio"/> Not applicable |

| Pulldown List 1: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieMarrie         | 1 Married       | 1     |             |
| ieRemarr         | 2 Remarried     | 2     |             |
| ieWidowe         | 3 Widowed       | 3     |             |
| ieSepara         | 4 Separated     | 4     |             |
| ieDivorc         | 5 Divorced      | 5     |             |
| ieNevMar         | 6 Never married | 6     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| CDD: pmctn30A3cdd Table: frASF6 Key Type: PATIENTVISIT |                                    |             |
|--------------------------------------------------------|------------------------------------|-------------|
| Column Name                                            | Column Data Type                   | Design Note |
| VISITDT                                                | DATE - DDMONYYYY                   |             |
| F1                                                     | STRING(255) - 1, 2, 3, 4, 5, 6, 97 |             |
| F3                                                     | NUMERIC                            |             |
| F18a                                                   | NUMERIC                            |             |
| F19a                                                   | NUMERIC                            |             |
| F20a                                                   | NUMERIC                            |             |
| F21a                                                   | NUMERIC                            |             |
| F22a                                                   | NUMERIC                            |             |
| rcF23                                                  | NUMERIC                            |             |
| F23c                                                   | STRING(50) - A50                   |             |
| F23a                                                   | NUMERIC                            |             |
| F24a                                                   | NUMERIC                            |             |
| F25a                                                   | NUMERIC                            |             |

|      |         |  |
|------|---------|--|
| F26a | NUMERIC |  |
|------|---------|--|

| pmctn30L2 : CTN-ASI Lite Follow Up (ASF7)                                                                           |                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SECTION 7: CTN-ASI Lite Follow Up v. 1: Family/Social Relationships                                                 |                                                                                                                                                                                                                                                                                               |
| 1.                                                                                                                  | Assessment Date: <input type="text"/>   Req <input type="text"/> /   Req <input type="text"/> /   Req <input type="text"/> (2009-2014) (pmctn30A3cdd:frASF7.VISITDT / VISIT DATE)                                                                                                             |
| 2.                                                                                                                  | F30. How many days in the past 30 have you had serious conflicts with your family?<br>(pmctn30A3cdd:frASF7.rcF30 / ASF7 F30 RADIO)<br>[1] <input type="radio"/> xx ( 0 = < n <= 30 )   days (pmctn30A3cdd:frASF7.F30 / ASF7 F30)<br>[97] <input type="radio"/> Not answered                   |
| For questions F32 and F34, ask participant specifying not at all, slightly, moderately, considerably, or extremely. |                                                                                                                                                                                                                                                                                               |
| 3.                                                                                                                  | F32. How troubled or bothered have you been in the past 30 days by these family problems?<br>Pulldown List 1 <input type="text"/> (pmctn30A3cdd:frASF7.F32 / ASF7 F32)                                                                                                                        |
| 4.                                                                                                                  | F34. How important to you now is treatment or counseling for these family problems?<br>Participant is rating his/her need for counseling for family problems, not whether the family would be willing to attend.<br>Pulldown List 2 <input type="text"/> (pmctn30A3cdd:frASF7.F34 / ASF7 F34) |
| Confidence Ratings: Is the above information significantly distorted by:                                            |                                                                                                                                                                                                                                                                                               |
| 5.                                                                                                                  | F37. Participant's misrepresentation?<br>(pmctn30A3cdd:frASF7.F37 / ASF7 F37)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                |
| 6.                                                                                                                  | F38. Participant's inability to understand?<br>(pmctn30A3cdd:frASF7.F38 / ASF7 F38)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                          |
| 7.*                                                                                                                 | Family Comments:<br><input type="text" value="A200"/> (pmctn30A3cdd:frASF7.FCOM / ASF7 COMMENT)                                                                                                                                                                                               |
| * Item is not required                                                                                              |                                                                                                                                                                                                                                                                                               |

| Pulldown List 1: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAl         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| Pulldown List 2: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAl         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| CDD: pmctn30A3cdd Table: frASF7 Key Type: PATIENTVISIT |                  |             |
|--------------------------------------------------------|------------------|-------------|
| Column Name                                            | Column Data Type | Design Note |
| VISITDT                                                | DATE - DDMONYYYY |             |
|                                                        |                  |             |



|       |                                 |  |
|-------|---------------------------------|--|
| rcF30 | NUMERIC                         |  |
| F30   | NUMERIC - N2                    |  |
| F32   | STRING(255) - 0, 1, 2, 3, 4, 97 |  |
| F34   | STRING(255) - 0, 1, 2, 3, 4, 97 |  |
| F37   | NUMERIC                         |  |
| F38   | NUMERIC                         |  |
| FCOM  | STRING(200) - A200              |  |

| <b>pmctn30L2 : CTN-ASI Lite Follow Up (ASF8)</b>                                                                                                                                              |                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Have you had a significant period of time (that was not a direct result of drug/alcohol use) in which you have:                                                                               |                                                                                                                                                                             |
| 1. Assessment Date:                                                                                                                                                                           | Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2009-2014) (pmctn30A3cdd:frASF8.VISITDT / VISIT DATE)                                       |
| 2. P4. Experienced serious depression - sadness, hopelessness, loss of interest, difficulty with daily function?                                                                              | (pmctn30A3cdd:frASF8.P4a / ASF8 P4A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered            |
| 3. P5. Experienced serious anxiety/tension - uptight, unreasonably worried, inability to feel relaxed?                                                                                        | (pmctn30A3cdd:frASF8.P5a / ASF8 P5A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered            |
| 4. P6. Experienced hallucinations - saw things or heard voices that other people did not hear or see?                                                                                         | (pmctn30A3cdd:frASF8.P6a / ASF8 P6A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered            |
| 5. P7. Experienced trouble understanding, concentrating, or remembering?                                                                                                                      | (pmctn30A3cdd:frASF8.P7a / ASF8 P7A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered            |
| For questions P8-P10, participant could have been under the influence of alcohol/drugs                                                                                                        |                                                                                                                                                                             |
| 6. P8. Experienced trouble controlling violent behavior including episodes of rage, or violence?                                                                                              | (pmctn30A3cdd:frASF8.P8a / ASF8 P8A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered            |
| 7. P9. Experienced serious thoughts of suicide? Patient seriously considered a plan for taking his/her life.                                                                                  | (pmctn30A3cdd:frASF8.P9a / ASF8 P9A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered            |
| 8. P10. Attempted suicide? Include actual suicidal gestures or attempts.                                                                                                                      | (pmctn30A3cdd:frASF8.P10a / ASF8 P10A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered          |
| 9. P11. Been prescribed medication for any psychological/emotional problem? Prescribed for the patient by MD. Record Yes if a medication was prescribed even if the patient is not taking it. | (pmctn30A3cdd:frASF8.P11a / ASF8 P11A)<br>Past 30 days<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>[97] <input type="radio"/> Not answered          |
| 10. P12. How many days in the past 30 have you experienced these psychological or emotional problems? This refers to problems noted in questions P4-P10.                                      | (pmctn30A3cdd:frASF8.rcP12 / ASF8 P12 RADIO)<br>[1] <input type="radio"/> xx (0 =< n <= 30) (pmctn30A3cdd:frASF8.P12 / ASF8 P12)<br>[97] <input type="radio"/> Not answered |

For questions P13-P14, ask participant specifying not at all, slightly, moderately, considerably, or extremely.

|                                                                          |                                                                                                                    |                                                                                                    |
|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| 11.                                                                      | P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? | Pulldown List 1 <input type="button" value="v"/> (pmctn30A3cdd:frASF8.P13 / ASF8 P13)              |
| 12.                                                                      | P14. How important to you now is treatment for these psychological or emotional problems?                          | Pulldown List 2 <input type="button" value="v"/> (pmctn30A3cdd:frASF8.P14 / ASF8 P14)              |
| Confidence Ratings: Is the above information significantly distorted by: |                                                                                                                    |                                                                                                    |
| 13.                                                                      | P22. Participant's misrepresentation?                                                                              | (pmctn30A3cdd:frASF8.P22 / ASF8 P22)<br>[0] <input type="radio"/> No [1] <input type="radio"/> Yes |
| 14.                                                                      | P23. Participant's inability to understand?                                                                        | (pmctn30A3cdd:frASF8.P23 / ASF8 P23)<br>[0] <input type="radio"/> No [1] <input type="radio"/> Yes |
| 15.*                                                                     | Psychiatric Comments:                                                                                              | <input type="text" value="A200"/> (pmctn30A3cdd:frASF8.PCOM / ASF8 COMMENT)                        |

\* Item is not required

| Pulldown List 1: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAI         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| Pulldown List 2: |                 |       |             |
|------------------|-----------------|-------|-------------|
| RefName          | Display Text    | Value | Design Note |
| ieNoAtAI         | 0 Not at all    | 0     |             |
| ieSlight         | 1 Slightly      | 1     |             |
| ieModrtly        | 2 Moderately    | 2     |             |
| ieConsid         | 3 Considerably  | 3     |             |
| ieExtrem         | 4 Extremely     | 4     |             |
| ieNotAns         | 97 Not answered | 97    |             |

| CDD: pmctn30A3cdd Table: frASF8 Key Type: PATIENTVISIT |                  |             |
|--------------------------------------------------------|------------------|-------------|
| Column Name                                            | Column Data Type | Design Note |
| VISITDT                                                | DATE - DDMONYYYY |             |
| P4a                                                    | NUMERIC          |             |
| P5a                                                    | NUMERIC          |             |
| P6a                                                    | NUMERIC          |             |
| P7a                                                    | NUMERIC          |             |
| P8a                                                    | NUMERIC          |             |
| P9a                                                    | NUMERIC          |             |
| P10a                                                   | NUMERIC          |             |
| P11a                                                   | NUMERIC          |             |
| rcP12                                                  | NUMERIC          |             |

|      |                                 |  |
|------|---------------------------------|--|
| P12  | NUMERIC - N2                    |  |
| P13  | STRING(255) - 0, 1, 2, 3, 4, 97 |  |
| P14  | STRING(255) - 0, 1, 2, 3, 4, 97 |  |
| P22  | NUMERIC                         |  |
| P23  | NUMERIC                         |  |
| PCOM | STRING(200) - A200              |  |

| pmctn30L2 : Protocol Violation Log (PVL) - Repeating Form |                                            |                                                                                                                                                                                                                                                                           |                     |                   |              |          |  |  |
|-----------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------|--------------|----------|--|--|
| #                                                         | Assessment Date:                           | PV Date                                                                                                                                                                                                                                                                   | 4<br>Violation Type | Description of PV | PV Resolved? | Comments |  |  |
| 1                                                         |                                            |                                                                                                                                                                                                                                                                           |                     |                   |              |          |  |  |
| 1.                                                        | Assessment Date:                           | Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2014) (pmctn30A3cdd:frPVL.VISITDT / VISIT DATE)                                                                                                  |                     |                   |              |          |  |  |
| 2.                                                        | Date of violation:                         | Req <input type="button" value="v"/> / Req <input type="button" value="v"/> / Req <input type="button" value="v"/> (2009-2014) (pmctn30A3cdd:frPVL.PVL001 / PVL VIOLATION DATE)                                                                                           |                     |                   |              |          |  |  |
| 3.                                                        | Violation Type:                            | Pulldown List 1 <input type="button" value="v"/> (pmctn30A3cdd:frPVL.PVL002 / PVL VIOLATION CODE)<br>If Other is indicated, please provide the specification: (pmctn30A3cdd:frPVL.PVL002S / PVL SPECIFY IF OTHER CODE)<br><input type="text" value="A100"/>               |                     |                   |              |          |  |  |
| 4.                                                        | Description of violation:                  | <input type="text" value="A200"/> (pmctn30A3cdd:frPVL.PVL003 / PVL DESCRIPTION)                                                                                                                                                                                           |                     |                   |              |          |  |  |
| 5.                                                        | Has this Protocol Violation been resolved? | (pmctn30A3cdd:frPVL.PVL004 / PVL RESOLVED RADIO)<br><input checked="" type="radio"/> Yes - If Yes: Indicate resolution /corrective action taken (pmctn30A3cdd:frPVL.PVL005 / PVL RESOLUTION TEXT)<br><input type="text" value="A200"/><br><input type="radio"/> No<br>[0] |                     |                   |              |          |  |  |
| 6.*                                                       | Comments:                                  | <input type="text" value="A200"/> (pmctn30A3cdd:frPVL.PVL006 / PVL COMMENT)                                                                                                                                                                                               |                     |                   |              |          |  |  |
| * Item is not required                                    |                                            |                                                                                                                                                                                                                                                                           |                     |                   |              |          |  |  |

| Pulldown List 1: |              |       |             |
|------------------|--------------|-------|-------------|
| RefName          | Display Text | Value | Design Note |
| iePVL_01         | 01           | 1     |             |
| iePVL_01A        | 01A          | 2     |             |
| iePVL_01B        | 01B          | 3     |             |
| iePVL_01C        | 01C          | 4     |             |
| iePVL_01E        | 01E          | 5     |             |
| iePVL_02         | 02           | 6     |             |
| iePVL_05         | 05           | 7     |             |
| iePVL_05A        | 05A          | 8     |             |
| iePVL_05B        | 05B          | 9     |             |
| iePVL_05C        | 05C          | 10    |             |
| iePVL_07C        | 07C          | 11    |             |
| iePVL_07D        | 07D          | 12    |             |
| iePVL_99         | 99           | 13    |             |
| iePVL_99A        | 99A          | 14    |             |
| iePVL_99B        | 99B          | 15    |             |
| iePVL_99D        | 99D          | 16    |             |

| CDD: pmctn30A3cdd Table: frPVL Key Type: PATIENTVISIT |                                                                     |             |
|-------------------------------------------------------|---------------------------------------------------------------------|-------------|
| Column Name                                           | Column Data Type                                                    | Design Note |
| VISITDT                                               | DATE - DDMONYYYY                                                    |             |
| PVL001                                                | DATE - DDMONYYYY                                                    |             |
| PVL002                                                | STRING(255) - 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 |             |
| PVL002S                                               | STRING(100) - A100                                                  |             |
| PVL003                                                | STRING(200) - A200                                                  |             |
| PVL004                                                | NUMERIC                                                             |             |
| PVL005                                                | STRING(200) - A200                                                  |             |
| PVL006                                                | STRING(200) - A200                                                  |             |

| pmctn30L2 : Study Termination (STF)                                                                   |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Do not answer Reason for early termination questions if the participant completed the follow-up phase |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1.                                                                                                    | Date of study completion or termination:                      | Req <input type="checkbox"/> /  Req <input type="checkbox"/> /  Req <input type="checkbox"/> (2009-2014) (pmctn30A3cdd:frSTF.STF001DT / STF COMPLETE OR TERM DATE)                                                                                                                                                                                                                                                                                  |
| 2.                                                                                                    | Is follow-up phase completed (end of 42mo follow-up window)?  | (pmctn30A3cdd:frSTF.STF004 / STF FUP PH COMPLETE)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes<br>Completed visits (check all completed)<br>(pmctn30A3cdd:frSTF.STF003A / STF 18 MONTH COMPLETE)<br>[1] <input type="checkbox"/> 18mo<br>(pmctn30A3cdd:frSTF.STF003B / STF 30 MONTH COMPLETE)<br>[1] <input type="checkbox"/> 30mo<br>(pmctn30A3cdd:frSTF.STF003C / STF 42 MONTH COMPLETE)<br>[1] <input type="checkbox"/> 42mo |
| Reason for early termination (do not answer if participant completed the follow-up phase):            |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3.*                                                                                                   | Investigator-initiated termination/administrative withdrawal? | (pmctn30A3cdd:frSTF.STF005 / STF INV TERMINATION)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                                                                                                                                  |
| 4.*                                                                                                   | Participant-initiated termination?                            | (pmctn30A3cdd:frSTF.STF006 / STF PART TERMINATION)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                                                                                                                                 |
| 5.*                                                                                                   | Death?                                                        | (pmctn30A3cdd:frSTF.STF007 / STF DEATH)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                                                                                                                                            |
| 6.*                                                                                                   | Some other reason?                                            | (pmctn30A3cdd:frSTF.STF008 / STF OTHER REASON)<br>[0] <input type="radio"/> No<br>[1] <input type="radio"/> Yes                                                                                                                                                                                                                                                                                                                                     |
| 7.*                                                                                                   | If Yes, to any early termination reason: Specify details      | <input type="text" value="A200"/> (pmctn30A3cdd:frSTF.STF009 / STF EARLY TERM SPECIFY)                                                                                                                                                                                                                                                                                                                                                              |
| 8.*                                                                                                   | Comments:                                                     | <input type="text" value="A200"/> (pmctn30A3cdd:frSTF.STFCOM / STF COMMENT)                                                                                                                                                                                                                                                                                                                                                                         |
| * Item is not required                                                                                |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

| Column Name | Column Data Type   | Design Note |
|-------------|--------------------|-------------|
| STF001DT    | DATE - DDMYYYYY    |             |
| STF004      | NUMERIC            |             |
| STF003A     | STRING(255)        |             |
| STF003B     | STRING(255)        |             |
| STF003C     | STRING(255)        |             |
| STF005      | NUMERIC            |             |
| STF006      | NUMERIC            |             |
| STF007      | NUMERIC            |             |
| STF008      | NUMERIC            |             |
| STF009      | STRING(200) - A200 |             |
| STFCOM      | STRING(200) - A200 |             |

**CRB Electronic Signature Affidavit**

By my dated signature below, I, **[First Name] [Last Name]**, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this patient.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.

**CRF Electronic Signature Affidavit**

By my dated signature below, I, **[First Name] [Last Name]**, verify that this case report form accurately displays the results of the examinations, tests, evaluations and treatments noted within.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.