## *C O N F I D E N T I A L*

## Data Dictionary Report

Sponsor: cscc          Study: dexamethasone          Printed: 11.07.2007 at 10:43 AM EST

## Datastream : ACF1

## Associated Forms : Follow-up I - ACS Assessment

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed<br>->Other<br>->Serious Adverse Event<br>->Subject is still an in-patient at the hospital<br>->Subject or parent/guardian decision | text | $40. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| ASSDA | Date of Assessment (Day) | number | 2. | no | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | no | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | no | none | | |
| ASSDT | Date of Assessment | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| ASSHR | Time of Assessment (Hour) | number | 2. | no | none | | |
| ASSMI | Time of Assessment (Minute) | number | 2. | no | none | | |
| ASSTM | Time of Assessment | time | TIME5. | no | range | 00:00 | 23:59 |
| RESPRAT | Respiratory rate | number | 2. | no | range | 16 | 40 |
| SPO2VAL | SpO2 current value | number | 3. | no | range | 80 | 100 |
| SPO2NA | SpO2 not done | number | 1. | no | range | 1 | 1 |
| RETRAC | Retractions<br>->No<br>->Yes | text | $3. | no | value | | |
| NASAL | Nasal flaring<br>->No<br>->Yes | text | $3. | no | value | | |
| MUSC | Use of accessory muscles<br>->No<br>->Yes | text | $3. | no | value | | |
| THORAC | Current thoracic pain scale | number | 2. | no | range | 0 | 10 |
| OVERALL | Overall body pain | number | 2. | no | range | 0 | 10 |
| SCALE | Pain scale<br>->Numeric rating scale<br>->Oucher scale | text | $20. | no | value | | |
| PAIN1 | Lower back | number | 1. | no | range | 1 | 1 |
| PAIN2 | Upper extremities | number | 1. | no | range | 1 | 1 |
| PAIN3 | Head and neck | number | 1. | no | range | 1 | 1 |
| PAIN4 | Abdomen | number | 1. | no | range | 1 | 1 |
| PAIN5 | Lower extremities | number | 1. | no | range | 1 | 1 |
| SUPO2 | Supplemental O2<br>->No | text | $3. | no | value | | |

| | | | | | |
|---|---|---|---|---|---|
| | ->Yes | | | | |
| VENTSUP | Invasive or noninvasive ventilatory support | text | $3. | no | value |
| | ->No | | | | |
| | ->Yes | | | | |
| COMMENT | Comments for page | text | $200. | no | none |

### Edit Checks

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| | |
|---|---|
| ACF1-0001 | Since "Was the assessment completed" is equal to "No", a reason must be checked. |
| | --->implies(COMPLET == 'No', REASON != null) |
| ACF1-0001rev | Since a reason has been checked, "Was the assessment completed" should be equal to "No". |
| | --->revimplies(COMPLET == 'No', REASON != null) |
| ACF1-0002 | Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed. |
| | --->implies(REASON == 'Other', OTHSP != null) |
| ACF1-0002rev | Since "Specify" is completed, the reason that the assessment was not completed should be classified as "Other". |
| | --->revimplies(REASON == 'Other', OTHSP != null) |
| ACF1-0101 | Since "Was the assessment completed" is equal to "No", the rest of the form must be BLANK. |
| | --->implies(COMPLET == 'No', ASSDT == null && ASSTM == null && RESPRAT == null && SPO2VAL == null && SPO2NA == null && RETRAC == null && NASAL == null && MUSC == null && THORAC == null && OVERALL == null && SCALE == null && PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null && SUPO2 == null && VENTSUP == null) |
| ACF1-0004 | Since "Was the assessment completed" is "Yes", "Date of Assessment" must be completed. |
| | --->implies(COMPLET == 'Yes', ASSDT != null) |
| ACF1-0005 | Since "Was the assessment completed" is "Yes", "Time of Assessment" must be completed. |
| | --->implies(COMPLET == 'Yes', ASSTM != null) |
| ACF1-0006 | Since "Was the assessment completed" is "Yes", "Respiratory Rate" must be completed. |
| | --->implies(COMPLET == 'Yes', RESPRAT != null) |
| ACF1-0007 | Since "Was the assessment completed" is "Yes", "SpO2 off O21-Current Value" must be completed, % OR N/A, but NOT Both. |
| | --->implies(COMPLET == 'Yes', xor(SPO2VAL != null, SPO2NA != null)) |
| ACF1-0008 | Since "Was the assessment completed" is "Yes", "Work of breathing - Retractions" must be completed. |
| | --->implies(COMPLET == 'Yes', RETRAC != null) |
| ACF1-0009 | Since "Was the assessment completed" is "Yes", "Work of breathing - Nasal flaring" must be completed. |
| | --->implies(COMPLET == 'Yes', NASAL != null) |
| ACF1-0010 | Since "Was the assessment completed" is "Yes", "Work of breathing - Use of accessory muscles" must be completed. |
| | --->implies(COMPLET == 'Yes', MUSC != null) |
| ACF1-0011 | Since "Was the assessment completed" is "Yes", "Current thoracic pain scale" must be completed. |
| | --->implies(COMPLET == 'Yes', THORAC != null) |
| ACF1-0012 | Since "Was the assessment completed" is "Yes", "Overall body pain" must be completed. |
| | --->implies(COMPLET == 'Yes', OVERALL != null) |
| ACF1-0013 | Since "Was the assessment completed" is "Yes", "Pain scale" must be completed. |
| | --->implies(COMPLET == 'Yes', SCALE != null) |
| ACF1-0113 | Since "Non-thoracic body pain" is equal to 0, "Location of pain" must be blank. |

           --->implies(OVERALL == 0 || OVERALL == null, PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null)

ACF1-0113rev   Since "Location of pain" is blank, "Non-thoracic body pain" must equal to 0.

           --->revimplies(OVERALL == 0 || OVERALL == null, PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null)

ACF1-0015   Since "Was the assessment completed" is "Yes", "Supplemental O2" must be completed.

           --->implies(COMPLET == 'Yes', SUPO2 != null)

ACF1-0016   Since "Was the assessment completed" is "Yes", "Invasive/Noninvasive ventilatory support" must be completed.

           --->implies(COMPLET == 'Yes', VENTSUP != null)

## Datastream : ACF2

## Associated Forms : Follow-up II - ACS Assessment

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed<br>->Lost to follow-up<br>->Other<br>->Serious Adverse Event<br>->Subject or parent/guardian decision<br>->Subject was readmitted to the hospital | text | $40. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| ASSDA | Date of Assessment (Day) | number | 2. | no | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | no | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | no | none | | |
| ASSDT | Date of Assessment | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| ASSHR | Time of Assessment (Hour) | number | 2. | no | none | | |
| ASSMI | Time of Assessment (Minute) | number | 2. | no | none | | |
| ASSTM | Time of Assessment | time | TIME5. | no | range | 00:00 | 23:59 |
| RESPRAT | Respiratory rate | number | 2. | no | range | 16 | 40 |
| SPO2VAL | SpO2 current value | number | 3. | no | range | 80 | 100 |
| SPO2ND | SpO2 not done | number | 1. | no | range | 1 | 1 |
| RETRAC | Retractions<br>->No<br>->Yes | text | $3. | no | value | | |
| NASAL | Nasal flaring<br>->No<br>->Yes | text | $3. | no | value | | |
| MUSC | Use of accessory muscles<br>->No<br>->Yes | text | $3. | no | value | | |
| THORAC | Current thoracic pain scale | number | 2. | no | range | 0 | 10 |
| OVERALL | Overall body pain | number | 2. | no | range | 0 | 10 |
| SCALE | Pain scale<br>->Numeric rating scale<br>->Oucher scale | text | $20. | no | value | | |
| PAIN1 | Lower back | number | 1. | no | range | 1 | 1 |
| PAIN2 | Upper extremities | number | 1. | no | range | 1 | 1 |
| PAIN3 | Head and neck | number | 1. | no | range | 1 | 1 |
| PAIN4 | Abdomen | number | 1. | no | range | 1 | 1 |
| PAIN5 | Lower extremities | number | 1. | no | range | 1 | 1 |
| SUPO2 | Supplemental O2<br>->No<br>->Yes | text | $3. | no | value | | |
| VENTSUP | Invasive or noninvasive ventilatory support<br>->No<br>->Yes | text | $3. | no | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

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| | |
|---|---|
| ACF2-0001 | Since "Was the assessment completed" is equal to "No", a reason must be checked.<br>--->implies(COMPLET == 'No', REASON != null) |
| ACF2-0001rev | Since a reason has been completed, "Was the assessment completed" should be equal to "No"<br>--->revimplies(COMPLET == 'No', REASON != null) |
| ACF2-0002 | Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed.<br>--->implies(REASON == 'Other', OTHSP != null) |
| ACF2-0002rev | Since "Specify" is completed, the reason that the assessment was not completed should be classified as "Other".<br>--->revimplies(REASON == 'Other', OTHSP != null) |
| ACF2-0101 | Since "Was the assessment completed" is equal to "No", the rest of the form must be BLANK.<br>--->implies(COMPLET == 'No', ASSDT == null && ASSTM == null && RESPRAT == null && SPO2VAL == null && SPO2ND == null && RETRAC == null && NASAL == null && MUSC == null && THORAC == null && OVERALL == null && SCALE == null && PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null && SUPO2 == null && VENTSUP == null) |
| ACF2-0004 | Since "Was the assessment completed" is "Yes", "Date of Assessment" must be completed.<br>--->implies(COMPLET == 'Yes', ASSDT != null) |
| ACF2-0005 | Since "Was the assessment completed" is "Yes", "Time of Assessment" must be completed.<br>--->implies(COMPLET == 'Yes', ASSTM != null) |
| ACF2-0006 | Since "Was the assessment completed" is "Yes", "Respiratory Rate" must be completed.<br>--->implies(COMPLET == 'Yes', RESPRAT != null) |
| ACF2-0007 | Since "Was the assessment completed" is "Yes", "SpO2 off O21-Current Value" must be completed, % OR N/A, but NOT Both.<br>--->implies(COMPLET == 'Yes', xor(SPO2VAL != null, SPO2ND != null)) |
| ACF2-0008 | Since "Was the assessment completed" is "Yes", "Work of breathing - Retractions" must be completed.<br>--->implies(COMPLET == 'Yes', RETRAC != null) |
| ACF2-0009 | Since "Was the assessment completed" is "Yes", "Work of breathing - Nasal flaring" must be completed.<br>--->implies(COMPLET == 'Yes', NASAL != null) |
| ACF2-0010 | Since "Was the assessment completed" is "Yes", "Work of breathing - Use of accessory muscles" must be completed.<br>--->implies(COMPLET == 'Yes', MUSC != null) |
| ACF2-0011 | Since "Was the assessment completed" is "Yes", "Current thoracic pain scale" must be completed.<br>--->implies(COMPLET == 'Yes', THORAC != null) |
| ACF2-0012 | Since "Was the assessment completed" is "Yes", "Overall body pain" must be completed.<br>--->implies(COMPLET == 'Yes', OVERALL != null) |
| ACF2-0013 | Since "Was the assessment completed" is "Yes", "Pain scale" must be completed.<br>--->implies(COMPLET == 'Yes', SCALE != null) |
| ACF2-0113 | Since "Non-thoracic body pain" is equal to 0, "Location of pain" must be blank.<br>--->implies(OVERALL == 0 \|\| OVERALL == null, PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null) |
| ACF2-0113rev | Since "Location of pain" is blank, "Non-thoracic body pain" must be 0,.<br><br>--->revimplies(OVERALL == 0 \|\| OVERALL == null, PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null) |

ACF2-0015   Since "Was the assessment completed" is "Yes", "Supplemental O2" must be completed.
            --->implies(COMPLET == 'Yes', SUPO2 != null)

ACF2-0016   Since "Was the assessment completed" is "Yes", "Invasive/Noninvasive ventilatory support"
            must be completed.
            --->implies(COMPLET == 'Yes', VENTSUP != null)

## Datastream : ACSA

## Associated Forms : Study Enrollment - ACS Assessment

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| ASSDA | Date of Assessment (Day) | number | 2. | yes | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | yes | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | yes | none | | |
| ASSDT | Date of Assessment | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| ASSHR | Time of Assessment (Hour) | number | 2. | yes | none | | |
| ASSMI | Time of Assessment (Minute) | number | 2. | yes | none | | |
| ASSTM | Time of Assessment | time | TIME5. | yes | range | 00:00 | 23:59 |
| RESPRAT | Respiratory rate | number | 2. | yes | range | 16 | 40 |
| SPO2VAL | SpO2 current value | number | 3. | no | range | 80 | 100 |
| SPO2NA | SpO2 not available | number | 1. | no | range | 1 | 1 |
| RETRAC | Retractions<br>->No<br>->Yes | text | $3. | yes | value | | |
| NASAL | Nasal flaring<br>->No<br>->Yes | text | $3. | yes | value | | |
| MUSC | Use of accessory muscles<br>->No<br>->Yes | text | $3. | yes | value | | |
| THORAC | Current thoracic pain scale | number | 2. | yes | range | 0 | 10 |
| OVERALL | Overall body pain | number | 2. | yes | range | 0 | 10 |
| SCALE | Pain scale<br>->Numeric rating scale<br>->Oucher scale | text | $20. | yes | value | | |
| PAIN1 | Lower back | number | 1. | no | range | 1 | 1 |
| PAIN2 | Upper extremities | number | 1. | no | range | 1 | 1 |
| PAIN3 | Head and neck | number | 1. | no | range | 1 | 1 |
| PAIN4 | Abdomen | number | 1. | no | range | 1 | 1 |
| PAIN5 | Lower extremities | number | 1. | no | range | 1 | 1 |
| SUPO2 | Supplemental O2<br>->No<br>->Yes | text | $3. | yes | value | | |
| VENTSUP | Invasive or noninvasive ventilatory support<br>->No<br>->Yes | text | $3. | yes | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

ACSA-0001    For "SpO2 off O2¹ (off oxygen > 1 minute)", either "Value" or "N/A" must be checked.
--->xor(SPO2VAL != null, SPO2NA != null)

ACSA-0002    Since "Non-thoracic body pain" is equal to 0, "Location of pain" must be blank.
--->implies(OVERALL == 0, PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null)

ACSA-0003    Since Non-thoracic pain is NOT ZERO, at least one value must be checked for "Location of pain".

--->implies(OVERALL > 0 && OVERALL != null, PAIN1 != null || PAIN2 != null || PAIN3 != null ||

PAIN4 != null || PAIN5 != null)

## Datastream : ACSD

## Associated Forms : Day {DAYNUM}, {HOUR} on {ASSDT}

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| DAYNUM | Hospitalization day number | number | 2. | yes | none | | |
| HOUR | Assessment hour | text | $35. | yes | value | | |
| | ->(1) 4-hour | | | | | | |
| | ->(2) 8-hour | | | | | | |
| | ->(3) 12-hour | | | | | | |
| | ->(4) 16-hour | | | | | | |
| | ->(5) 20-hour | | | | | | |
| | ->(6) 24-hour | | | | | | |
| | ->(7) Discharge (if applicable) | | | | | | |
| ASSDA | Date of Assessment (Day) | number | 2. | yes | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | yes | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | yes | none | | |
| ASSDT | Date of Assessment | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| ASSHR | Time of Assessment (Hour) | number | 2. | yes | none | | |
| ASSMI | Time of Assessment (Minute) | number | 2. | yes | none | | |
| ASSTM | Time of Assessment | time | TIME5. | yes | range | 00:00 | 23:59 |
| COMPLET | If and when an assessment was completed | text | $17. | yes | value | | |
| | ->>30 minutes early | | | | | | |
| | ->>30 minutes late | | | | | | |
| | ->Assessment missed | | | | | | |
| | ->on schedule | | | | | | |
| RESPRAT | Respiratory rate | number | 2. | no | range | 16 | 40 |
| SPO2VAL | SpO2 current value | number | 3. | no | range | 80 | 100 |
| SPO2NA | Spo2 not available | number | 1. | no | range | 1 | 1 |
| RETRAC | Retractions | text | $3. | no | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| NASAL | Nasal flaring | text | $3. | no | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| MUSC | Use of accessory muscles | text | $3. | no | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| THORAC | Current thoracic pain scale | number | 2. | no | range | 0 | 10 |
| OVERALL | Overall body pain | number | 2. | no | range | 0 | 10 |
| SCALE | Pain scale | text | $20. | no | value | | |
| | ->Numeric rating scale | | | | | | |
| | ->Oucher scale | | | | | | |
| PAIN1 | Lower back | number | 1. | no | range | 1 | 1 |
| PAIN2 | Upper extremities | number | 1. | no | range | 1 | 1 |
| PAIN3 | Head and neck | number | 1. | no | range | 1 | 1 |
| PAIN4 | Abdomen | number | 1. | no | range | 1 | 1 |
| PAIN5 | Lower extremities | number | 1. | no | range | 1 | 1 |
| SUPO2 | Supplemental O2 | text | $3. | no | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| VENTSUP | Invasive or noninvasive ventilatory | text | $3. | no | value | | |

    support
     ->No
     ->Yes

| | | | | | |
|---|---|---|---|---|---|
| COMMENT | Comments for page | | text | $200. | no | none |

### Edit Checks

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**ACSD-0001**  Since Assessment Completed was MISSED, Rest of the Form should be BLANK

--->implies(COMPLET == 'Assessment missed', RESPRAT == null && SPO2VAL == null && SPO2NA == null && RETRAC == null && NASAL == null && MUSC == null && THORAC == null && OVERALL == null && PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null && SCALE == null && SUPO2 == null && VENTSUP == null)

**ACSD-0101**  Since Assessment Completed was NOT MISSED, Rest of the Form should be COMPLETED

--->implies(COMPLET != 'Assessment missed', RESPRAT != null && (SPO2VAL != null || SPO2NA != null) && RETRAC != null && NASAL != null && MUSC != null && THORAC != null && OVERALL != null && SCALE != null && SUPO2 != null && VENTSUP != null)

**ACSD-0002**  For "SpO2 off O2$^1$ (off oxygen > 1 minute)", either "Value" or "N/A" must be checked.

--->implies(COMPLET != 'Assessment missed', xor(SPO2VAL != null, SPO2NA != null))

**ACSD-0003**  Since Non-thoracic pain is equal to 0, "Location of pain" must be blank.

--->implies(COMPLET != 'Assessment missed' && OVERALL == 0 || OVERALL == null, PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null)

**ACSD-0003rev**  Since "Location of pain" is blank, Non-thoracic pain must be 0.

--->revimplies(COMPLET != 'Assessment missed' && OVERALL == 0 || OVERALL == null, PAIN1 == null && PAIN2 == null && PAIN3 == null && PAIN4 == null && PAIN5 == null)

## Datastream : AEXP

## Associated Forms : Adverse Experiences

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| SAE | Serious Adverse Event | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| ADVEXP | Adverse Event Text | text | $200. | yes | none | | |
| SICKLE | Sickle Cell Related | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| ONSETDA | Onset Date (Day) | number | 2. | yes | none | | |
| ONSETMO | Onset Date (Month) | number | 2. | yes | none | | |
| ONSETYR | Onset Date (Year) | number | 4. | yes | none | | |
| ONSETDT | Onset Date | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| STOPDA | Stop Date (Day) | number | 2. | no | none | | |
| STOPMO | Stop Date (Month) | number | 2. | no | none | | |
| STOPYR | Stop Date (Year) | number | 4. | no | none | | |
| STOPDT | Stop Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| OUTCOME | Outcome | text | $43. | yes | value | | |
| | ->Death | | | | | | |
| | ->Medically Stable | | | | | | |
| | ->Ongoing | | | | | | |
| | ->Present at death, not contributing to death | | | | | | |
| | ->Resolved with sequelae | | | | | | |
| | ->Resolved without sequalae | | | | | | |
| SEVERE | Severity | text | $16. | yes | value | | |
| | ->Death | | | | | | |
| | ->Life threatening | | | | | | |
| | ->Mild | | | | | | |
| | ->Moderate | | | | | | |
| | ->Severe | | | | | | |
| RELAT | Related to Study Drug | text | $19. | yes | value | | |
| | ->Definitely related | | | | | | |
| | ->Possibly related | | | | | | |
| | ->Probably not/remote | | | | | | |
| | ->Probably related | | | | | | |
| | ->Unrelated | | | | | | |
| ACTION1 | None | number | 1. | no | range | 1 | 1 |
| ACTION2 | Study treatment interrupted/modified | number | 1. | no | range | 1 | 1 |
| ACTION3 | Study treatment discontinued | number | 1. | no | range | 1 | 1 |
| ACTION4 | Comcomitant medication given/changed | number | 1. | no | range | 1 | 1 |
| ACTION5 | Hospitalization | number | 1. | no | range | 1 | 1 |
| ACTION6 | ER/Day hospital | number | 1. | no | range | 1 | 1 |
| ACTION7 | Other | number | 1. | no | range | 1 | 1 |
| ACT7SP | Other, specify | text | $200. | no | none | | |

### Edit Checks

AEXP-0001    If "Serious" is "Yes", "Severity" must be "Severe, Life threatening or Death".

|  | --->implies(SAE == 'Yes', (SEVERE == 'Severe' \|\| SEVERE == 'Life threatening' \|\| SEVERE == 'Death')) |
|---|---|
| AEXP-0001rev | If "Severity" is "Severe, Life threatening or Death", "Serious" must be "Yes". |
|  | --->revimplies(SAE == 'Yes', (SEVERE == 'Severe' \|\| SEVERE == 'Life threatening' \|\| SEVERE == 'Death')) |
| AEXP-0002 | If "Outcome" is "Ongoing", "Stop Date" should be blank. <br> --->implies(OUTCOME == 'Ongoing', STOPDT == null) |
| AEXP-0002rev | If "Stop Date" is blank, "Outcome" must be "Ongoing". |
|  | --->revimplies(OUTCOME == 'Ongoing', STOPDT == null) |
| AEXP-0003 | If "Action Taken" is "None", Other Actions Taken must be blank. <br> --->implies(ACTION1 != null, (ACTION2 == null && ACTION3 == null && ACTION4 == null && ACTION5 == null && ACTION6 == null && ACTION7 == null)) |
| AEXP-0004 | If "Action Taken - None" is blank, At least one Actions Taken must be checked. <br> --->implies(ACTION1 == null, (ACTION2 != null \|\| ACTION3 != null \|\| ACTION4 != null \|\| ACTION5 != null \|\| ACTION6 != null \|\| ACTION7 != null)) |
| AEXP-0005 | If "Action Taken" is "Hospitalization", "Serious" must be "Yes". <br> --->implies(ACTION5 != null, SAE == 'Yes') |
| AEXP-0006 | If "Action Taken" is "Other", "Specify" must be completed. <br> --->implies(ACTION7 != null, ACT7SP != null) |
| AEXP-0006rev | If "Specify" is completed, "Action Taken" must be "Other". |
|  | --->revimplies(ACTION7 != null, ACT7SP != null) |

## Datastream : AEYN

## Associated Forms : Adverse Experiences

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| AEYN | Did the subject experience any AEs<br>->No<br>->Yes | text | $3. | yes | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

*No Edit Checks*

## Datastream : BCUL

## Associated Forms : Blood Culture

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| BCND | Blood culture not done | number | 1. | no | range | 1 | 1 |
| BACDA | Date of Assessment (Day) | number | 2. | no | none | | |
| BACMO | Date of Assessment (Month) | number | 2. | no | none | | |
| BACYR | Date of Assessment (Year) | number | 4. | no | none | | |
| BACDT | Date of Assessment | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| RESULT | Culture result  ->Negative  ->Positive | text | $8. | no | value | | |
| CONTAM | Presumed contaminant  ->No  ->Yes | text | $3. | no | value | | |
| ORG1 | Streptococcus pneumoniae | number | 1. | no | range | 1 | 1 |
| ORG2 | Chlamydia pneumonia | number | 1. | no | range | 1 | 1 |
| ORG3 | Mycoplasma pneumoniae | number | 1. | no | range | 1 | 1 |
| ORG4 | Mycoplasma hominis | number | 1. | no | range | 1 | 1 |
| ORG5 | Staphylococcus aureus | number | 1. | no | range | 1 | 1 |
| ORG6 | Other staphylococcus species | number | 1. | no | range | 1 | 1 |
| ORG7 | E. coli | number | 1. | no | range | 1 | 1 |
| ORG8 | Salmonella species | number | 1. | no | range | 1 | 1 |
| ORG9 | Other | number | 1. | no | range | 1 | 1 |
| ORGSP | Other, specify | text | $40. | no | none | | |
| THERAPY | Antimicrobial therapy initiated  ->No  ->Yes | text | $3. | no | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

BCUL-0001 Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Date Obtained" cannot be completed.
--->implies(BCND != null, BACDT == null)

BCUL-0002 Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Culture Results" cannot be checked.
--->implies(BCND != null, RESULT == null)

BCUL-0003 Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Presumed Contaminant" cannot be checked.
--->implies(BCND != null, CONTAM == null)

BCUL-0004 Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Specify" cannot be completed.
--->implies(BCND != null, ORGSP == null)

BCUL-0005 Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Other" cannot be checked.
--->implies(BCND != null, ORG9 == null)

BCUL-0006 Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Salmonella species" cannot be checked.
--->implies(BCND != null, ORG8 == null)

BCUL-0007 Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "E. coli" cannot be checked.

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    --->implies(BCND != null, ORG7 == null)

**BCUL-0008** Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Other Staphylococcus species" cannot be checked.
    --->implies(BCND != null, ORG6 == null)

**BCUL-0009** Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Staphylococcus aureus" cannot be checked.
    --->implies(BCND != null, ORG5 == null)

**BCUL-0010** Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Mycoplasma hominis" cannot be checked.
    --->implies(BCND != null, ORG4 == null)

**BCUL-0011** Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Mycoplasma pneumoniae" cannot be checked.
    --->implies(BCND != null, ORG3 == null)

**BCUL-0012** Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Chlamydia pneumoniae" cannot be checked.
    --->implies(BCND != null, ORG2 == null)

**BCUL-0013** Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Streptococcus pneumoniae" cannot be checked.
    --->implies(BCND != null, ORG1 == null)

**BCUL-0014** Since "Subject does not have a fever, baseline blood culture was not performed" is checked, "Antimicrobial therapy initiated" cannot be checked.
    --->implies(BCND != null, THERAPY == null)

**BCUL-0101** Since "Subject does not have a fever, baseline blood culture was not performed" is NOT checked, "Date Obtained" must be completed.
    --->implies(BCND == null, BACDT != null)

**BCUL-0102** Since "Subject does not have a fever, baseline blood culture was not performed" is NOT checked, "Culture Results" must be checked.
    --->implies(BCND == null, RESULT != null)

**BCUL-0103** Since "Subject does not have a fever, baseline blood culture was not performed" is NOT checked, "Presumed Contaminant" must be checked.
    --->implies(BCND == null, CONTAM != null)

**BCUL-0114** Since "Subject does not have a fever, baseline blood culture was not performed" is NOT checked, "Antimicrobial therapy initiated" must be checked.
    --->implies(BCND == null, THERAPY != null)

**BCUL-0015** Since "Culture Results" is "Negative", "Specify" cannot be completed.
    --->implies(RESULT == 'Negative', ORGSP == null)

**BCUL-0016** Since "Culture Results" is "Negative", "Other" cannot be completed.
    --->implies(RESULT == 'Negative', ORG9 == null)

**BCUL-0017** Since "Culture Results" is "Negative", "Salmonella species" cannot be completed.
    --->implies(RESULT == 'Negative', ORG8 == null)

**BCUL-0018** Since "Culture Results" is "Negative", "E. coli" cannot be completed.
    --->implies(RESULT == 'Negative', ORG7 == null)

**BCUL-0019** Since "Culture Results" is "Negative", "Other Staphylococcus species" cannot be completed.
    --->implies(RESULT == 'Negative', ORG6 == null)

**BCUL-0020** Since "Culture Results" is "Negative", "Staphylococcus aureus" cannot be completed.
    --->implies(RESULT == 'Negative', ORG5 == null)

**BCUL-0021** Since "Culture Results" is "Negative", "Mycoplasma hominis" cannot be completed.
    --->implies(RESULT == 'Negative', ORG4 == null)

**BCUL-0022** Since "Culture Results" is "Negative", "Mycoplasma pneumoniae" cannot be completed.
    --->implies(RESULT == 'Negative', ORG3 == null)

**BCUL-0023** Since "Culture Results" is "Negative", "Chlamydia pneumoniae" cannot be completed.

         --->implies(RESULT == 'Negative', ORG2 == null)

BCUL-0024    Since "Culture Results" is "Negative", "Streptococcus pneumoniae" cannot be completed.

         --->implies(RESULT == 'Negative', ORG1 == null)

BCUL-0025    Since the organism has been classified as "Other", "Specify" must be completed.

         --->implies(ORG9 != null, ORGSP != null)

BCUL-0025rev    Since "Specify" is completed, the organism must be classified as "Other".

         --->revimplies(ORG9 != null, ORGSP != null)

BCUL-0026    Since "Culture Results" is "Positive", at least one Organism must be checked.

         --->implies(RESULT == 'Positive', (ORG1 != null || ORG2 != null || ORG3 != null || ORG4 != null || ORG5 != null || ORG6 != null || ORG7 != null || ORG8 != null || ORG9 != null))

## Datastream : CIBC

## Associated Forms : Blood Culture

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| CBACDA | Date of Assessment (Day) | number | 2. | yes | none | | |
| CBACMO | Date of Assessment (Month) | number | 2. | yes | none | | |
| CBACYR | Date of Assessment (Year) | number | 4. | yes | none | | |
| CBACDT | Date of Assessment | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| CRESULT | Culture result<br>->Negative<br>->Positive | text | $8. | yes | value | | |
| CCONTAM | Presumed contaminant<br>->No<br>->Yes | text | $3. | yes | value | | |
| CORG1 | Streptococcus pneumoniae | number | 1. | no | range | 1 | 1 |
| CORG2 | Chlamydia pneumoniae | number | 1. | no | range | 1 | 1 |
| CORG3 | Mycoplasma pneumoniae | number | 1. | no | range | 1 | 1 |
| CORG4 | Mycoplasma hominis | number | 1. | no | range | 1 | 1 |
| CORG5 | Staphylococcus aureus | number | 1. | no | range | 1 | 1 |
| CORG6 | Other staphylococcus species | number | 1. | no | range | 1 | 1 |
| CORG7 | E. coli | number | 1. | no | range | 1 | 1 |
| CORG8 | Salmonella species | number | 1. | no | range | 1 | 1 |
| CORG9 | Other | number | 1. | no | range | 1 | 1 |
| CORGSP | Other, specify | text | $40. | no | none | | |
| CTHERAP | Antimicrobial therapy initiated<br>->No<br>->Yes | text | $3. | yes | value | | |

### Edit Checks

CIBC-0015   Since "Culture Results" is "Negative", "Specify" cannot be completed.
--->implies(CRESULT == 'Negative', CORGSP == null)

CIBC-0016   Since "Culture Results" is "Negative", "Other" cannot be completed.
--->implies(CRESULT == 'Negative', CORG9 == null)

CIBC-0017   Since "Culture Results" is "Negative", "Salmonella species" cannot be completed.
--->implies(CRESULT == 'Negative', CORG8 == null)

CIBC-0018   Since "Culture Results" is "Negative", "E. coli" cannot be completed.
--->implies(CRESULT == 'Negative', CORG7 == null)

CIBC-0019   Since "Culture Results" is "Negative", "Other Staphylococcus species" cannot be completed.
--->implies(CRESULT == 'Negative', CORG6 == null)

CIBC-0020   Since "Culture Results" is "Negative", "Staphylococcus aureus" cannot be completed.
--->implies(CRESULT == 'Negative', CORG5 == null)

CIBC-0021   Since "Culture Results" is "Negative", "Mycoplasma hominis" cannot be completed.
--->implies(CRESULT == 'Negative', CORG4 == null)

CIBC-0022   Since "Culture Results" is "Negative", "Mycoplasma pneumoniae" cannot be completed.
--->implies(CRESULT == 'Negative', CORG3 == null)

CIBC-0023   Since "Culture Results" is "Negative", "Chlamydia pneumoniae" cannot be completed.
--->implies(CRESULT == 'Negative', CORG2 == null)

CIBC-0024   Since "Culture Results" is "Negative", "Streptococcus pneumoniae" cannot be completed.
--->implies(CRESULT == 'Negative', CORG1 == null)

CIBC-0025   Since the organism has been classified as "Other", "Specify" must be completed.

--->implies(CORG9 != null, CORGSP != null)

CIBC-0026    Since "Culture Results" is "Positive", at least one Organism must be checked.

--->implies(CRESULT == 'Positive', (CORG1 != null || CORG2 != null || CORG3 != null || CORG4 != null || CORG5 != null || CORG6 != null || CORG7 != null || CORG8 != null || CORG9 != null))

## Datastream : CIXR

## Associated Forms : Chest Radiograph

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| CRAYDA | Date of X-Ray (Day) | number | 2. | yes | none | | |
| CRAYMO | Date of X-Ray (Month) | number | 2. | yes | none | | |
| CRAYYR | Date of X-Ray (Year) | number | 4. | yes | none | | |
| CRAYDT | Date of X-Ray | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| CRAYHR | Time of X-Ray (Hour) | number | 2. | yes | none | | |
| CRAYMI | Time of X-Ray (Minute) | number | 2. | yes | none | | |
| CRAYTM | Time of X-Ray | time | TIME5. | yes | range | 00:00 | 23:59 |
| CPULYN | Pulminary infiltrate<br>->No<br>->Yes | text | $3. | yes | value | | |
| CIFYES | Pulminary infiltrate present<br>->Existing<br>->New | text | $8. | no | value | | |
| CCOMM | Comments | text | $200. | no | none | | |

### Edit Checks

| CIXR-0001 | Since "Pulmonary Infiltrate" is equal to "Yes", "New" or "Existing" must be completed.<br>--->implies(CPULYN == 'Yes', CIFYES != null) |
|---|---|
| CIXR-0001rev | Since "New" or "Existing" is completed, "Pulmonary Infiltrate" must be "Yes".<br><br>--->revimplies(CPULYN == 'Yes', CIFYES != null) |
| CIXR-0002 | Since "Pulmonary Infiltrate" is equal to "Yes", "Comments" cannot be BLANK.<br>--->implies(CPULYN == 'Yes', CCOMM != null) |

## Datastream : CMED

## Associated Forms : Concomitant Medications

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| MEDICAT | Medication | text | $200. | yes | none | | |
| INDICAT | Indication | text | $200. | yes | none | | |
| DOSE | Dose | text | $20. | no | none | | |
| UNIT | Unit | text | $20. | yes | value | | |
| | ->CAP | | | | | | |
| | ->Exchange Transfusion | | | | | | |
| | ->G | | | | | | |
| | ->GTT | | | | | | |
| | ->MCG | | | | | | |
| | ->MG | | | | | | |
| | ->ML | | | | | | |
| | ->OTHER | | | | | | |
| | ->Simple Transfusion | | | | | | |
| | ->TAB | | | | | | |
| UNITSP | Unit specify | text | $20. | no | none | | |
| STRANSP | Simple transfusion specify | number | 2. | no | none | | |
| ROUTE | Route | text | $5. | yes | value | | |
| | ->IA | | | | | | |
| | ->IM | | | | | | |
| | ->INH | | | | | | |
| | ->INTRA | | | | | | |
| | ->IS | | | | | | |
| | ->IV | | | | | | |
| | ->OTHER | | | | | | |
| | ->PO | | | | | | |
| | ->PR | | | | | | |
| | ->SC | | | | | | |
| | ->SQ | | | | | | |
| | ->TOP | | | | | | |
| ROUTSP | Route specify | text | $20. | no | none | | |
| PREXIST | Preexisting | number | 1. | no | range | 1 | 1 |
| STARTDA | Start Date (Day) | number | 2. | no | none | | |
| STARTMO | Start Date (Month) | number | 2. | no | none | | |
| STARTYR | Start Date (Year) | number | 4. | no | none | | |
| STARTDT | Start Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| STARTHR | Start Time (Hour) | number | 2. | no | none | | |
| STARTMI | Start Time (Minute) | number | 2. | no | none | | |
| STARTTM | Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| STOPDA | Stop Date (Day) | number | 2. | no | none | | |
| STOPMO | Stop Date (Month) | number | 2. | no | none | | |
| STOPYR | Stop Date (Year) | number | 4. | no | none | | |
| STOPDT | Stop Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| STOPHR | Stop Time (Hour) | number | 2. | no | none | | |
| STOPMI | Stop Time (Minute) | number | 2. | no | none | | |
| STOPTM | Stop Time | time | TIME5. | no | range | 00:00 | 23:59 |
| ONGOING | Preexisting | number | 1. | no | range | 1 | 1 |

### Edit Checks

| CMED-0001 | If "Unit" is categorized as "Other", "Other Specify" must be completed. |
| | --->implies(UNIT == 'OTHER', UNITSP != null) |
| CMED-0001rev | If "Other Specify" is completed", Unit" must be categorized as "Other". |
| | --->revimplies(UNIT == 'OTHER', UNITSP != null) |
| CMED-0008 | If "Unit" is categorized as "Simple Transfusion", "Simple Transfusion Specify" must be completed. |
| | --->implies(UNIT == 'SIMPLE', STRANSP != null) |
| CMED-0008rev | If "Simple Transfusion Specify" is completed", Unit" must be categorized as "Simple Transfusion". |
| | --->revimplies(UNIT == 'SIMPLE', STRANSP != null) |
| CMED-0009 | If "Unit" is categorized as "Simple Transfusion or Exchange Transfusion", "Dose" should be blank. |
| | --->implies(UNIT == 'SIMPLE' || UNIT == 'EXCHANGE', DOSE == null) |
| CMED-0009rev | If "Dose" is blank, "Unit" should be categorized as "Simple Transfusion or Exchange Transfusion". |
| | --->revimplies(UNIT == 'SIMPLE' || UNIT == 'EXCHANGE', DOSE == null) |
| CMED-0002 | If "Route" is categorized as "Other", "Specify" must be completed. |
| | --->implies(ROUTE == 'OTHER', ROUTSP != null) |
| CMED-0002rev | If "Specify" is completed", "Route" must be categorized as "Other". |
| | --->revimplies(ROUTE == 'OTHER', ROUTSP != null) |
| CMED-0003 | If "Start Date" is blank, "Preexisting" must be checked. |
| | --->implies(STARTDT == null, PREXIST != null) |
| CMED-0004 | If "Ongoing" is checked, "Stop Date" must be blank. |
| | --->implies(ONGOING != null, STOPDT == null) |
| CMED-0005 | If "Ongoing" is NOT checked, "Stop Date" must be completed. |
| | --->implies(ONGOING == null, STOPDT != null) |
| CMED-0006 | If "Ongoing" is checked, "Stop Time" must be blank. |
| | --->implies(ONGOING != null, STOPTM == null) |

## <u>Datastream</u> : CMYN

## <u>Associated Forms</u> : Concomitant Medications

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

*No Edit Checks*

## Datastream : COMP

## Associated Forms : Study Completion

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| CMPYN | Did the subject complete the study | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| LASTDA | Date of last contact (Day) | number | 2. | no | none | | |
| LASTMO | Date of last contact (Month) | number | 2. | no | none | | |
| LASTYR | Date of last contact (Year) | number | 4. | no | none | | |
| LASTDT | Date of last contact | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| REASON | Primary reason for withdrawal | text | $63. | no | value | | |
| | ->Death | | | | | | |
| | ->Discontinuation | | | | | | |
| | ->Failed to satisfy enrollment criteria | | | | | | |
| | ->Lost to follow-up | | | | | | |
| | ->Other | | | | | | |
| | ->Other adverse event | | | | | | |
| | ->Screen failure | | | | | | |
| | ->Subject/guardian choice | | | | | | |
| DISCON1 | Discontinuation: New hypertension | number | 1. | no | range | 1 | 1 |
| DISCON2 | Discontinuation: Stroke | number | 1. | no | range | 1 | 1 |
| DISCON3 | Discontinuation: Gastrointestinal hemorrhage | number | 1. | no | range | 1 | 1 |
| DISCON4 | Discontinuation: Pregnancy | number | 1. | no | range | 1 | 1 |
| DISCON5 | Discontinuation: Doctors opinion | number | 1. | no | range | 1 | 1 |
| SP1 | Enrollment Criteria, Specify | text | $100. | no | none | | |
| SP3 | Subject/Guardian choice, Specify | text | $100. | no | none | | |
| SP4 | Other Adverse Event, Specify | text | $100. | no | none | | |
| SP5 | Other, Specify | text | $100. | no | none | | |
| INVEST | Investigators opinion into which arm this subject was randomized | text | $12. | yes | value | | |
| | ->Dexamethasone | | | | | | |
| | ->No opinion | | | | | | |
| | ->Placebo | | | | | | |
| SCOORD | Study coordinators opinion into which arm this subject was randomized | text | $12. | yes | value | | |
| | ->Dexamethasone | | | | | | |
| | ->No opinion | | | | | | |
| | ->Placebo | | | | | | |
| SUBJ | Subjects opinion into which arm they were randomized | text | $12. | yes | value | | |
| | ->Dexamethasone | | | | | | |
| | ->No opinion | | | | | | |
| | ->Placebo | | | | | | |
| PISIG | PI signature | number | 1. | yes | range | 1 | 1 |
| SIGDA | Completion Date (Day) | number | 2. | yes | none | | |
| SIGMO | Completion Date (Month) | number | 2. | yes | none | | |
| SIGYR | Completion Date (Year) | number | 4. | yes | none | | |
| SIGDT | Completion Date | date | DATE9. | yes | range | 2006-10-01 | 2012-12-31 |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

| COMP-0003 | Since "Did subject complete the study" is equal to "Yes", "Date of Last Contact" cannot be completed. |
| | --->implies(CMPYN == 'Yes', LASTDT == null) |
| COMP-0001 | Since "Did subject complete the study" is equal to "Yes", "REASON" cannot be completed. |
| | --->implies(CMPYN == 'Yes', REASON == null) |
| COMP-0002 | Since "Did subject complete the study" is equal to "Yes", "Other, Specify" cannot be completed. |
| | --->implies(CMPYN == 'Yes', SP5 == null) |
| COMP-0005 | Since "Did subject complete the study" is equal to "Yes", "Other adverse event, Specify" cannot be completed. |
| | --->implies(CMPYN == 'Yes', SP4 == null) |
| COMP-0006 | Since "Did subject complete the study" is equal to "Yes", "In the doctor's opinion the subject's health, safety and/or well-being was threatened by continued participation in the study" cannot be checked. |
| | --->implies(CMPYN == 'Yes', DISCON5 == null) |
| COMP-0007 | Since "Did subject complete the study" is equal to "Yes", "Pregnancy" cannot be checked. |
| | --->implies(CMPYN == 'Yes', DISCON4 == null) |
| COMP-0008 | Since "Did subject complete the study" is equal to "Yes", "Gastrointestinal hemorrhage" cannot be checked. |
| | --->implies(CMPYN == 'Yes', DISCON3 == null) |
| COMP-0009 | Since "Did subject complete the study" is equal to "Yes", "Stroke" cannot be checked. |
| | --->implies(CMPYN == 'Yes', DISCON2 == null) |
| COMP-0010 | Since "Did subject complete the study" is equal to "Yes", "New hypertension (not preexisting) that requires treatment with anti-hypertensive medications" cannot be checked. |
| | --->implies(CMPYN == 'Yes', DISCON1 == null) |
| COMP-0012 | Since "Did subject complete the study" is equal to "Yes", "Legal representative, Specify" cannot be completed. |
| | --->implies(CMPYN == 'Yes', SP3 == null) |
| COMP-0017 | Since "Did subject complete the study" is equal to "Yes", "Enrollment criteria, Specify" cannot be completed. |
| | --->implies(CMPYN == 'Yes', SP1 == null) |
| COMP-0018 | Since "Did subject complete the study" is equal to "No", "REASON" must be checked. |
| | --->implies(CMPYN == 'No', REASON != null) |
| COMP-0019 | Since "Did subject complete the study" is equal to "No", "Date of Last Contact" must be completed. |
| | --->implies(CMPYN == 'No', LASTDT != null) |
| COMP-0020 | Since "Discontinuation" is checked, at least one condition must be checked. |
| | --->implies(REASON == 'Discontinuation', (DISCON1 != null \|\| DISCON2 != null \|\| DISCON3 != null \|\| DISCON4 != null \|\| DISCON5 != null)) |
| COMP-0020rev | Since at least one condition is checked, "Discontinuation" must be checked. |
| | --->revimplies(REASON == 'Discontinuation', (DISCON1 != null \|\| DISCON2 != null \|\| DISCON3 != null \|\| DISCON4 != null \|\| DISCON5 != null)) |
| COMP-0021 | Since "Subject failed to satisfy enrollment criteria" is checked, "Specify" must be completed. |
| | --->implies(REASON == 'Failed to satisfy enrollment criteria', SP1 != null) |
| COMP-0021rev | Since "Specify" is completed, "Subject failed to satisfy enrollment criteria" must be checked. |
| | --->revimplies(REASON == 'Failed to satisfy enrollment criteria', SP1 != null) |
| COMP-0023 | Since "Subject or subject's legal representative requested to withdraw" is checked, "Specify" must be completed. |

--->implies(REASON == 'Subject/guardian choice', SP3 != null)

COMP-0023rev   Since "Specify" is completed, "Subject or subject's legal representative requested to withdraw" must be checked.

--->revimplies(REASON == 'Subject/guardian choice', SP3 != null)

COMP-0024   Since "Other adverse event" is checked, "Specify" must be completed.

--->implies(REASON == 'Other adverse event', SP4 != null)

COMP-0024rev   Since "Specify" is completed, "Other adverse event" must be checked.

--->revimplies(REASON == 'Other adverse event', SP4 != null)

COMP-0025   Since "Other" is checked, "Specify" must be completed.

--->implies(REASON == 'Other', SP5 != null)

COMP-0025rev   Since "Specify" is completed, "Other" must be checked.

--->revimplies(REASON == 'Other', SP5 != null)

## Datastream : DASS

## Associated Forms : Day {DAYNUM} on {ASSDT}

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| DAYNUM | Hospitalization day number | number | 2. | yes | none | | |
| ASSDA | Date of Assessment (Day) | number | 2. | yes | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | yes | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | yes | none | | |
| ASSDT | Date of Assessment | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| TEMP | Maximum temperature | number | 4.1 | yes | range | 36.0 | 39.5 |
| RATE | Heart rate | number | 3. | yes | range | 40 | 150 |
| RESP | Respiratory rate | number | 2. | yes | range | 16 | 40 |
| SYS1 | Maximum systolic | number | 3. | yes | range | 50 | 250 |
| DIA1 | Corresponding diastolic | number | 3. | yes | range | 20 | 150 |
| SYS2 | Corresponding systolic | number | 3. | yes | range | 50 | 250 |
| DIA2 | Maximum diastolic | number | 3. | yes | range | 20 | 150 |
| O2SAT | Minimum O2 saturation | number | 3. | yes | range | 80 | 100 |
| HYPER | New onset hypertension<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Suspected reason<br>->Crying or irritated<br>->Fluid overload<br>->Other<br>->Severe pain<br>->Unknown | text | $19. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| TREAT | Required treatment<br>->No<br>->Yes | text | $3. | no | value | | |
| FLUID | Fluid overload<br>->No<br>->Yes | text | $3. | yes | value | | |
| TRAN | Any blood transfusion<br>->No<br>->Yes | text | $3. | yes | value | | |
| TRANTYP | Transfusion type<br>->Exchange<br>->Simple | text | $8. | no | value | | |
| NUMSIMP | Number of simple transfusions | number | 2. | no | none | | |
| SUPO2 | Subject using supplemental O2<br>->No<br>->Yes | text | $3. | yes | value | | |
| SUPO2HR | O2 Start Time (Hour) | number | 2. | no | none | | |
| SUPO2MI | O2 Start Time (Minute) | number | 2. | no | none | | |
| SUPO2TM | O2 Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| FEVER | Subject have fever > or = 38.5<br>->No<br>->Yes | text | $3. | yes | value | | |
| FEVERHR | Fever Start Time (Hour) | number | 2. | no | none | | |
| FEVERMI | Fever Start Time (Minute) | number | 2. | no | none | | |
| FEVERTM | Fever Start Time | time | TIME5. | no | range | 00:00 | 23:59 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| HYPOX | Is subject hypoxemic | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| HYPOXHR | Hypoxemic Start Time (Hour) | number | 2. | no | none | | |
| HYPOXMI | Hypoxemic Start Time (Minute) | number | 2. | no | none | | |
| HYPOXTM | Hypoxemic Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

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| | |
|---|---|
| DASS-0001 | Since "Did the subject receive any blood transfusions in the 24 hour period" is equal to "Yes", either "Simple" or "Exchange" must be checked.<br>--->implies(TRAN == 'Yes', TRANTYP != null) |
| DASS-0001rev | Since either "Simple" or "Exchange" is checked, "Did the subject receive any blood transfusions in the 24 hour period" must be "Yes".<br>--->revimplies(TRAN == 'Yes', TRANTYP != null) |
| DASS-0003 | Since "Simple" is checked, "How many transfusions" must be completed.<br>--->implies(TRANTYP == 'Simple', NUMSIMP != null) |
| DASS-0003rev | Since "How many transfusions" is completed, "Simple" must be checked.<br><br>--->revimplies(TRANTYP == 'Simple', NUMSIMP != null) |
| DASS-0004 | Since "Did the subject start using supplemental O2 in this 24 hour period" is equal to "Yes", "Time started" must be completed.<br>--->implies(SUPO2 == 'Yes', SUPO2TM != null) |
| DASS-0004rev | Since "Time started" is completed, "Did the subject start using supplemental O2 in this 24 hour period" must be "Yes".<br>--->revimplies(SUPO2 == 'Yes', SUPO2TM != null) |
| DASS-0005 | Since "Did the subject start a fever >= 38.5°C in this 24 hour period" is equal to "Yes", "Time Started" must be completed.<br>--->implies(FEVER == 'Yes', FEVERTM != null) |
| DASS-0005rev | Since "Time Started" is completed, "Did the subject start a fever >= 38.5°C in this 24 hour period" must be "Yes".<br>--->revimplies(FEVER == 'Yes', FEVERTM != null) |
| DASS-0006 | Since "Did the subject become hypoxemic in this 24 hour period" is equal to "Yes", "Time Started" must be completed.<br>--->implies(HYPOX == 'Yes', HYPOXTM != null) |
| DASS-0006rev | Since "Time Started" is completed, "Did the subject become hypoxemic in this 24 hour period" must be "Yes".<br>--->revimplies(HYPOX == 'Yes', HYPOXTM != null) |
| DASS-0200 | Since "Does the subject have new onset hypertension (per protocol)" is equal to "Yes", "What is the suspected reason" must be completed.<br>--->implies(HYPER == 'Yes', REASON != null) |
| DASS-0200rev | Since "What is the suspected reason" is completed, "Does the subject have new onset hypertension (per protocol)" must be "Yes".<br>--->revimplies(HYPER == 'Yes', REASON != null) |
| DASS-0201 | Since "What is the suspected reason" is "Other", "Other, Specify" must be completed.<br>--->implies(REASON == 'Other', OTHSP != null) |
| DASS-0201rev | Since "Other, Specify" is completed, "What is the suspected reason" must be "Other"<br><br>--->revimplies(REASON == 'Other', OTHSP != null) |
| DASS-0202 | Since "Does the subject have new onset hypertension (per protocol)" is equal to "Yes", "Did this require treatment" must be completed. |

    --->implies(HYPER == 'Yes', TREAT != null)

DASS-
0202rev

Since "Did this require treatment" is completed, "Does the subject have new onset hypertension (per protocol)" must be "Yes".

    --->revimplies(HYPER == 'Yes', TREAT != null)

DASS-0203

If "What is the suspected reason" is "Fluid overload", "Does the subject have fluid overload" must be "Yes".

    --->implies(REASON == 'Fluid overload', FLUID == 'Yes')

## <u>Datastream</u> : DEMO

## <u>Associated Forms</u> : Demographics/Study Entry Health History

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| ASSDA | Date of Assessment (Day) | number | 2. | yes | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | yes | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | yes | none | | |
| ASSDT | Date of Assessment | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| DOBDA | Date of Birth (Day) | number | 2. | yes | none | | |
| DOBMO | Date of Birth (Month) | number | 2. | yes | none | | |
| DOBYR | Date of Birth (Year) | number | 4. | yes | none | | |
| DOBDT | Date of Birth | date | DATE9. | yes | range | 1936-10-01 | 2001-10-01 |
| GENDER | Gender <br> ->Female <br> ->Male | text | $6. | yes | value | | |
| ETHNIC | Ethnicity <br> ->Hispanic or Latino <br> ->Not Hispanic or Latino | text | $22. | yes | value | | |
| RACE1 | American Indian/Alaska Native | number | 1. | no | range | 1 | 1 |
| RACE2 | Asian | number | 1. | no | range | 1 | 1 |
| RACE3 | Black or African-American | number | 1. | no | range | 1 | 1 |
| RACE4 | Native Hawaiian or other Pacific Islander | number | 1. | no | range | 1 | 1 |
| RACE5 | White | number | 1. | no | range | 1 | 1 |
| RACE6 | Other | number | 1. | no | range | 1 | 1 |
| OTHSP | Other, specify | text | $40. | no | none | | |
| GENOTYP | Genotype <br> ->SB0 <br> ->SS | text | $3. | yes | value | | |
| ENROLDA | Date of Study Enrollment (Day) | number | 2. | yes | none | | |
| ENROLMO | Date of Study Enrollment (Month) | number | 2. | yes | none | | |
| ENROLYR | Date of Study Enrollment (Year) | number | 4. | yes | none | | |
| ENROLDT | Date of Study Enrollment | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| ENROLHR | Time of Study Enrollment (Hour) | number | 2. | yes | none | | |
| ENROLMI | Time of Study Enrollment (Minute) | number | 2. | yes | none | | |
| ENROLTM | Time of Study Enrollment | time | TIME5. | yes | range | 00:00 | 23:59 |
| SEVERE | Severity of ACS <br> ->Mild-moderate <br> ->Severe | text | $13. | yes | value | | |
| CHESTYN | Chest radiograph taken <br> ->No <br> ->Yes | text | $3. | yes | value | | |
| RANDNUM | Randomization number | number | 4. | yes | none | | |
| RANDDA | Date of Randomization (Day) | number | 2. | yes | none | | |
| RANDMO | Date of Randomization (Month) | number | 2. | yes | none | | |
| RANDYR | Date of Randomization (Year) | number | 4. | yes | none | | |
| RANDDT | Date of Randomization | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| RANDHR | Time of Randomization (Hour) | number | 2. | yes | none | | |
| RANDMI | Time of Randomization (Minute) | number | 2. | yes | none | | |
| RANDTM | Time of Randomization | time | TIME5. | yes | range | 00:00 | 23:59 |
| WEIGHT | Weight | number | 5.1 | yes | range | 22 | 120 |
| SYS | Systolic blood pressure | number | 3. | yes | range | 50 | 250 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| DIA | Diastolic blood pressure | number | 3. | yes | range | 20 | 150 |
| ACS | Lifetime episodes of ACS | number | 3. | no | none | | |
| ACSUK | ACS episodes unknown | number | 1. | no | range | 1 | 1 |
| ASTHMA | Ever diagnosed with asthma | text | $7. | yes | value | | |
| | ->No | | | | | | |
| | ->Unknown | | | | | | |
| | ->Yes | | | | | | |
| SUPO2 | Subject using supplemental O2 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| SUPO2DA | O2 Start Date (Day) | number | 2. | no | none | | |
| SUPO2MO | O2 Start Date (Month) | number | 2. | no | none | | |
| SUPO2YR | O2 Start Date (Year) | number | 4. | no | none | | |
| SUPO2DT | O2 Start Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| SUPO2HR | O2 Start Time (Hour) | number | 2. | no | none | | |
| SUPO2MI | O2 Start Time (Minute) | number | 2. | no | none | | |
| SUPO2TM | O2 Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| YESO2 | O2 saturation | number | 3. | no | range | 80 | 100 |
| FEVER | Subject has fever > or = 38.5 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| FEVERDA | Fever Start Date (Day) | number | 2. | no | none | | |
| FEVERMO | Fever Start Date (Month) | number | 2. | no | none | | |
| FEVERYR | Fever Start Date (Year) | number | 4. | no | none | | |
| FEVERDT | Fever Start Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| FEVERHR | Fever Start Time (Hour) | number | 2. | no | none | | |
| FEVERMI | Fever Start Time (Minute) | number | 2. | no | none | | |
| FEVERTM | Fever Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| TEMP | Temperature | number | 4.1 | no | range | 36.0 | 39.5 |
| HYPOX | Is subject hypoxemic | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| HYPOXDA | Hypoxemic Start Date (Day) | number | 2. | no | none | | |
| HYPOXMO | Hypoxemic Start Date (Month) | number | 2. | no | none | | |
| HYPOXYR | Hypoxemic Start Date (Year) | number | 4. | no | none | | |
| HYPOXDT | Hypoxemic Start Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| HYPOXHR | Hypoxemic Start Time (Hour) | number | 2. | no | none | | |
| HYPOXMI | Hypoxemic Start Time (Minute) | number | 2. | no | none | | |
| HYPOXTM | Hypoxemic Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| NOVALUE | Steady state value | number | 3. | yes | range | 80 | 100 |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

DEMO-0001   "Date of Assessment" must be after "Date of Birth".
    --->ASSDT > DOBDT

DEMO-0002   At least one value for race must be checked
    --->RACE1 != null || RACE2 != null || RACE3 != null || RACE4 != null || RACE5 != null || RACE6 != null

DEMO-0003   Since race has been classified as "Other", "Specify" must be completed.
    --->implies(RACE6 != null, OTHSP != null)

DEMO-   Since "Specify" is completed, "Other, specify" must be checked.

0003rev

|  |  |
|---|---|
| | --->revimplies(RACE6 != null, OTHSP != null) |
| DEMO-0004 | Either "How many lifetime episodes of ACS" OR "Unknown" must be completed. If neither value can be completed, provide an override reason. |
| | --->xor(ACS != null, ACSUK != null) |
| DEMO-0005 | Since "Is the subject using supplemental O2 at study enrollment" is equal to "Yes", "Date Started" must be completed. |
| | --->implies(SUPO2 == 'Yes', SUPO2DT != null) |
| DEMO-0005rev | Since "Date Started" is completed, "Is the subject using supplemental O2; at study enrollment" must be "Yes". |
| | --->revimplies(SUPO2 == 'Yes', SUPO2DT != null) |
| DEMO-0006 | Since "Is the subject using supplemental O2 at study enrollment" is equal to "Yes", "Tiime Started" must be completed. |
| | --->implies(SUPO2 == 'Yes', SUPO2TM != null) |
| DEMO-0006rev | Since "Tiime Started" is completed, "Is the subject using supplemental O2 at study enrollment" must be "Yes",. |
| | --->revimplies(SUPO2 == 'Yes', SUPO2TM != null) |
| DEMO-0007 | Since "Is the subject using supplemental O2 at study enrollment" is equal to "Yes", "O2 saturation" must be completed. |
| | --->implies(SUPO2 == 'Yes', YESO2 != null) |
| DEMO-0007rev | Since "O2 saturation" is completed, "Is the subject using supplemental O2 at study enrollment" must be "Yes". |
| | --->revimplies(SUPO2 == 'Yes', YESO2 != null) |
| DEMO-0008 | Since "Did the subject have a fever >= 38.5°C at study enrollment" is equal to "Yes", "Date Started" must be completed. |
| | --->implies(FEVER == 'Yes', FEVERDT != null) |
| DEMO-0008rev | Since "Date Started" is completed, "Did the subject have a fever >= 38.5°C at study enrollment" must be "Yes". |
| | --->revimplies(FEVER == 'Yes', FEVERDT != null) |
| DEMO-0009 | Since "Did the subject have a fever >= 38.5°C at study enrollment" is equal to "Yes", "Time Started" must be completed. |
| | --->implies(FEVER == 'Yes', FEVERTM != null) |
| DEMO-0009rev | Since "Time Started" is completed, "Did the subject have a fever >= 38.5°C at study enrollment" must be "Yes". |
| | --->revimplies(FEVER == 'Yes', FEVERTM != null) |
| DEMO-0010 | Since "Did the subject have a fever >= 38.5°C at study enrollment" is equal to "Yes", "Temperature at study enrollment" must be completed. |
| | --->implies(FEVER == 'Yes', TEMP != null) |
| DEMO-0010rev | Since "Temperature at study enrollment" is completed, "Did the subject have a fever >= 38.5°C at study enrollment" must be "Yes". |
| | --->revimplies(FEVER == 'Yes', TEMP != null) |
| DEMO-0011 | Since "Is the subject hypoxemic at study enrollment" is equal to "Yes", "Date Started" must be completed. |
| | --->implies(HYPOX == 'Yes', HYPOXDT != null) |
| DEMO-0011rev | Since "Date Started" is completed, "Is the subject hypoxemic at study enrollment" must be "Yes". |
| | --->revimplies(HYPOX == 'Yes', HYPOXDT != null) |
| DEMO-0012 | Since "Is the subject hypoxemic at study enrollment" is equal to "Yes", "Time Started" must be completed. |
| | --->implies(HYPOX == 'Yes', HYPOXTM != null) |
| DEMO-0012rev | Since "Time Started" is completed, "Is the subject hypoxemic at study enrollment" must be "Yes". |

--->revimplies(HYPOX == 'Yes', HYPOXTM != null)

DEMO-0200    Date of Randomization must be on or after the Date of Enrollment

--->RANDDT >= ENROLDT

DEMO-0201    If Date of Randomization and Date of Enrollment are the same, then Time of Randomization must be at or after the Time of Enrollment

--->implies(RANDDT == ENROLDT, RANDTM >= ENROLTM)

## Datastream : DEVI

## Associated Forms : Deviation on {DEVIDT}

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| COMPDA | Date Form Completed (Day) | number | 2. | yes | none | | |
| COMPMO | Date Form Completed (Month) | number | 2. | yes | none | | |
| COMPYR | Date Form Completed (Year) | number | 4. | yes | none | | |
| COMPDT | Date Form Completed | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| COMPINT | Form completed by | text | $3. | yes | none | | |
| DEVIDA | Date of protocol deviation (Day) | number | 2. | yes | none | | |
| DEVIMO | Date of protocol deviation (Month) | number | 2. | yes | none | | |
| DEVIYR | Date of protocol deviation (Year) | number | 4. | yes | none | | |
| DEVIDT | Date of protocol deviation | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| RANDOMZ | Was the subject randomized<br>->No<br>->Yes | text | $3. | yes | value | | |
| DEVITYP | Type of deviation<br>->Dosing Error<br>->Exclusion Criteria Not Met<br>->Inclusion Criteria Not Met<br>->Informed Consent<br>->Missed Procedure or Laboratory Measure<br>->Missed Visit<br>->Mistimed Visit<br>->Other<br>->Randomization or Masking Error | text | $30. | yes | value | | |
| RANDSP | Randomization or Masking Error, specify | text | $80. | no | none | | |
| DOSERSP | Dosing Error, specify | text | $80. | no | none | | |
| OVERDOS | Did this lead to an overdose<br>->No<br>->Yes | text | $3. | no | value | | |
| MISSVIS | Which visit was missed<br>->Day<br>->Discharge<br>->Follow-up I<br>->Follow-up II<br>->Screening<br>->Study Enrollment | text | $20. | no | value | | |
| DAYMISS | Day number for the missed visit | number | 2. | no | none | | |
| MISTIME | Which visit was mistimed<br>->Day<br>->Discharge<br>->Follow-up I<br>->Follow-up II<br>->Screening<br>->Study Enrollment | text | $20. | no | value | | |
| DAYTIME | Day number for the mistimed visit | number | 2. | no | none | | |
| OUTWIND | How far outside window, mistimed<br>->1 Day<br>->2-3 Days | text | $10. | no | value | | |

| | | | | | |
|---|---|---|---|---|---|
| | ->3+ Days | | | | |
| MISPROC | Which visit, assessment missed | text | $20. | no | value |
| | ->Day | | | | |
| | ->Discharge | | | | |
| | ->Follow-up I | | | | |
| | ->Follow-up II | | | | |
| | ->Screening | | | | |
| | ->Study Enrollment | | | | |
| DAYPROC | Day number for the missed procedure | number | 2. | no | none |
| PARTALL | Was the entire assessment missed | text | $3. | no | value |
| | ->No | | | | |
| | ->Yes | | | | |
| MISPART | Which part of the assessment was missed | text | $80. | no | none |
| MISSALL | Which assessment was missed | text | $20. | no | value |
| | ->ACS Assessment | | | | |
| | ->Daily Assessment | | | | |
| | ->Follow-up I Assessment | | | | |
| | ->Follow-up II Assessment | | | | |
| | ->Hematology Lab | | | | |
| | ->Hospital Discharge | | | | |
| | ->Interval Health History | | | | |
| | ->Other, specify | | | | |
| | ->Respiratory Assessments | | | | |
| OTHASMT | Other Assessment, specify | text | $40. | no | none |
| INCL1 | Inclusion number, 1 | text | $15. | no | value |
| | ->Inclusion 1 | | | | |
| | ->Inclusion 2 | | | | |
| | ->Inclusion 3 | | | | |
| | ->Inclusion 4 | | | | |
| | ->Inclusion 5 | | | | |
| | ->Inclusion 6 | | | | |
| INCL2 | Inclusion number, 2 | text | $15. | no | value |
| | ->Inclusion 1 | | | | |
| | ->Inclusion 2 | | | | |
| | ->Inclusion 3 | | | | |
| | ->Inclusion 4 | | | | |
| | ->Inclusion 5 | | | | |
| | ->Inclusion 6 | | | | |
| INCL3 | Inclusion number, 3 | text | $15. | no | value |
| | ->Inclusion 1 | | | | |
| | ->Inclusion 2 | | | | |
| | ->Inclusion 3 | | | | |
| | ->Inclusion 4 | | | | |
| | ->Inclusion 5 | | | | |
| | ->Inclusion 6 | | | | |
| EXCL1 | Exclusion number, 1 | text | $15. | no | value |
| | ->Exclusion 1 | | | | |
| | ->Exclusion 10 | | | | |
| | ->Exclusion 2 | | | | |
| | ->Exclusion 3 | | | | |
| | ->Exclusion 4 | | | | |
| | ->Exclusion 5 | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | ->Exclusion 6 | | | | | | |
| | ->Exclusion 7 | | | | | | |
| | ->Exclusion 8 | | | | | | |
| | ->Exclusion 9 | | | | | | |
| EXCL2 | Exclusion number, 2 | text | $15. | no | value | | |
| | ->Exclusion 1 | | | | | | |
| | ->Exclusion 10 | | | | | | |
| | ->Exclusion 2 | | | | | | |
| | ->Exclusion 3 | | | | | | |
| | ->Exclusion 4 | | | | | | |
| | ->Exclusion 5 | | | | | | |
| | ->Exclusion 6 | | | | | | |
| | ->Exclusion 7 | | | | | | |
| | ->Exclusion 8 | | | | | | |
| | ->Exclusion 9 | | | | | | |
| EXCL3 | Exclusion number, 3 | text | $15. | no | value | | |
| | ->Exclusion 1 | | | | | | |
| | ->Exclusion 10 | | | | | | |
| | ->Exclusion 2 | | | | | | |
| | ->Exclusion 3 | | | | | | |
| | ->Exclusion 4 | | | | | | |
| | ->Exclusion 5 | | | | | | |
| | ->Exclusion 6 | | | | | | |
| | ->Exclusion 7 | | | | | | |
| | ->Exclusion 8 | | | | | | |
| | ->Exclusion 9 | | | | | | |
| INFORSP | Informed consent, specify | text | $80. | no | none | | |
| OTHERSP | Other, specify | text | $80. | no | none | | |
| DEVIRES | Reason for deviation | text | $80. | yes | none | | |
| DEVIPRV | Steps taken to resolve and prevent recurrence | text | $80. | yes | none | | |
| DEVIAE | Devisation result in adverse event | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| DEVISAE | Devisation result in serious adverse event | text | $3. | no | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| CONTINU | Subject continue with the study | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| DEVIIRB | Is report to IRB required | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| REPODA | Date IRB reported (Day) | number | 2. | no | none | | |
| REPOMO | Date IRB reported (Month) | number | 2. | no | none | | |
| REPOYR | Date IRB reported (Year) | number | 4. | no | none | | |
| REPODT | Date IRB reported | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| OTHACTN | If further action is required, describe | text | $80. | no | none | | |
| ADDCOMM | Additional comments | text | $80. | no | none | | |

### Edit Checks

| | |
|---|---|
| DEVI-0001 | If "Type" is "Randomization or Masking Error", "Specify" must be completed.<br>--->implies(DEVITYP == 'Randomization or Masking Error', RANDSP != null) |
| DEVI-0002 | If "Type" is "Dosing Error", "Specify" must be completed.<br>--->implies(DEVITYP == 'Dosing Error', DOSERSP != null) |
| DEVI-0003 | If "Type" is "Dosing Error", "Did this lead to an Overdoes" must be completed.<br>--->implies(DEVITYP == 'Dosing Error', OVERDOS != null) |
| DEVI-0004 | If "Type" is "Missed Visit", "Which visit missed" must be completed.<br>--->implies(DEVITYP == 'Missed Visit', MISSVIS != null) |
| DEVI-0005 | If "Which visit missed" is "Day", "Number" must be completed.<br>--->implies(MISSVIS == 'Day', DAYMISS != null) |
| DEVI-0005rev | If "Number" is completed, "Which visit missed" must be "Day".<br><br>--->revimplies(MISSVIS == 'Day', DAYMISS != null) |
| DEVI-0006 | If "Type" is "Mistimed Visit", "Which visit" must be completed.<br>--->implies(DEVITYP == 'Mistimed Visit', MISTIME != null) |
| DEVI-0007 | If "Which visit" is "Day", "Number" must be completed.<br>--->implies(MISTIME == 'Day', DAYTIME != null) |
| DEVI-0007rev | If "Number" is completed, "Which visit" must be "Day".<br><br>--->revimplies(MISTIME == 'Day', DAYTIME != null) |
| DEVI-0008 | If "Type" is "Mistimed Visit", "How far outside the visit window" must be completed.<br>--->implies(DEVITYP == 'Mistimed Visit', OUTWIND != null) |
| DEVI-0009 | If "Type" is "Missed Procedure or Laboratory Measure", "Which visit was the assessment missed" must be completed.<br>--->implies(DEVITYP == 'Missed Procedure or Laboratory Measure', MISPROC != null) |
| DEVI-0010 | If "Which visit was the assessment missed" is "Day", "Number" must be completed.<br>--->implies(MISPROC == 'Day', DAYPROC != null) |
| DEVI-0010rev | If "Number" is completed, "Which visit was the assessment missed" must be "Day".<br><br>--->revimplies(MISPROC == 'Day', DAYPROC != null) |
| DEVI-0011 | If "Type" is "Missed Procedure or Laboratory Measure", "Was the entire assessment missed" must be completed.<br>--->implies(DEVITYP == 'Missed Procedure or Laboratory Measure', PARTALL != null) |
| DEVI-0012 | If "Was the entire assessment missed" is "No", "Which part" must be completed.<br>--->implies(PARTALL == 'No', MISPART != null) |
| DEVI-0012rev | If "Which part" is completed, "Was the entire assessment missed" must be "No".<br><br>--->revimplies(PARTALL == 'No', MISPART != null) |
| DEVI-0013 | If "Was the entire assessment missed" is "Yes", "Which assessment" must be completed.<br>--->implies(PARTALL == 'Yes', MISSALL != null) |
| DEVI-0013rev | If "Which assessment" is completed, "Was the entire assessment missed" must be "Yes".<br><br>--->revimplies(PARTALL == 'Yes', MISSALL != null) |
| DEVI-0014 | If "Which assessment" is "Other", Specify must be completed.<br>--->implies(MISSALL == 'Other Assessment, specify', OTHASMT != null) |
| DEVI-0014rev | If Specify is completed, "Which assessment" must be "Other".<br><br>--->revimplies(MISSALL == 'Other Assessment, specify', OTHASMT != null) |
| DEVI-0015 | If "Type" is "Inclusion Criteria Not Met", "Inclusion Number 1" must be completed.<br>--->implies(DEVITYP == 'Inclusion Criteria Not Met', INCL1 != null) |
| DEVI-0016 | If "Type" is "Exclusion Criteria Not Met", "Exclusion Number 1" must be completed. |

|  |  |
|---|---|
| | --->implies(DEVITYP == 'Exclusion Criteria Not Met', EXCL1 != null) |
| DEVI-0017 | If "Type" is "Informed Consent", "Explain" must be completed. |
| | --->implies(DEVITYP == 'Informed Consent', INFORSP != null) |
| DEVI-0018 | If "Type" is "Other", Specify must be completed. |
| | --->implies(DEVITYP == 'Other', OTHERSP != null) |
| DEVI-0019 | If "Report to IRB required" is "Yes", "Date Reported" must be completed. |
| | --->implies(DEVIIRB == 'Yes', REPODT != null) |
| DEVI-0019rev | If "Date Reported" is completed, "Report to IRB required" must be "Yes". |
| | --->revimplies(DEVIIRB == 'Yes', REPODT != null) |
| DEVI-0020 | If "Type" is NOT "Randomization or Masking Error", "Specify" must be blank. |
| | --->implies(DEVITYP != 'Randomization or Masking Error', RANDSP == null) |
| DEVI-0021 | If "Type" is NOT "Dosing Error", "Specify" must be blank. |
| | --->implies(DEVITYP != 'Dosing Error', DOSERSP == null) |
| DEVI-0121 | If "Type" is NOT "Dosing Error", "Did this lead to an Overdoes" must be blank. |
| | --->implies(DEVITYP != 'Dosing Error', OVERDOS == null) |
| DEVI-0022 | If "Type" is NOT "Missed Visit", "Which visit missed" must be blank. |
| | --->implies(DEVITYP != 'Missed Visit', MISSVIS == null) |
| DEVI-0023 | If "Type" is NOT "Mistimed Visit", "Which visit" must be blank. |
| | --->implies(DEVITYP != 'Mistimed Visit', MISTIME == null) |
| DEVI-0024 | If "Type" is NOT "Missed Procedure or Laboratory Measure", "For which visit was the assessment missed" must be blank. |
| | --->implies(DEVITYP != 'Missed Procedure or Laboratory Measure', MISPROC == null) |
| DEVI-0025 | If "Type" is NOT "Inclusion Criteria Not Met", "Inclusion Number 1" must be blank. |
| | --->implies(DEVITYP != 'Inclusion Criteria Not Met', INCL1 == null) |
| DEVI-0026 | If "Type" is NOT "Exclusion Criteria Not Met", "Exclusion Number 1" must be blank. |
| | --->implies(DEVITYP != 'Exclusion Criteria Not Met', EXCL1 == null) |
| DEVI-0027 | If "Type" is NOT "Informed Consent", "Explain" must be blank. |
| | --->implies(DEVITYP != 'Informed Consent', INFORSP == null) |
| DEVI-0028 | If "Type" is NOT "Other", Specify must be blank. |
| | --->implies(DEVITYP != 'Other', OTHERSP == null) |
| DEVI-0029 | If "Type" is NOT "Missed Visit", "Number" must be blank. |
| | --->implies(DEVITYP != 'Missed Visit', DAYMISS == null) |
| DEVI-0030 | If "Type" is NOT "Mistimed Visit", "Number" must be blank. |
| | --->implies(DEVITYP != 'Mistimed Visit', DAYTIME == null) |
| DEVI-0031 | If "Type" is NOT "Mistimed Visit", "How far outside the visit window" must be blank. |
| | --->implies(DEVITYP != 'Mistimed Visit', OUTWIND == null) |
| DEVI-0032 | If "Type" is NOT "Missed Procedure or Laboratory Measure", "Number" must be blank. |
| | --->implies(DEVITYP != 'Missed Procedure or Laboratory Measure', DAYPROC == null) |
| DEVI-0033 | If "Type" is NOT "Missed Procedure or Laboratory Measure", "Was the entire assessment missed" must be blank. |
| | --->implies(DEVITYP != 'Missed Procedure or Laboratory Measure', PARTALL == null) |
| DEVI-0034 | If "Type" is NOT "Missed Procedure or Laboratory Measure", "Which part" must be blank. |
| | --->implies(DEVITYP != 'Missed Procedure or Laboratory Measure', MISPART == null) |
| DEVI-0035 | If "Type" is NOT "Missed Procedure or Laboratory Measure", "Which assessment" must be blank. |
| | --->implies(DEVITYP != 'Missed Procedure or Laboratory Measure', MISSALL == null) |
| DEVI-0036 | If "Type" is NOT "Missed Procedure or Laboratory Measure", "Other Specify" must be blank. |
| | --->implies(DEVITYP != 'Missed Procedure or Laboratory Measure', OTHASMT == null) |
| DEVI-0037 | If "Type" is NOT "Inclusion Criteria Not Met", "Inclusion Number 2" must be blank. |

|            | --->implies(DEVITYP != 'Inclusion Criteria Not Met', INCL2 == null) |
|------------|---------------------------------------------------------------------|
| DEVI-0038  | If "Type" is NOT "Inclusion Criteria Not Met", "Inclusion Number 3" must be blank. |
|            | --->implies(DEVITYP != 'Inclusion Criteria Not Met', INCL3 == null) |
| DEVI-0039  | If "Type" is NOT "Exclusion Criteria Not Met", "Exclusion Number 2" must be blank. |
|            | --->implies(DEVITYP != 'Exclusion Criteria Not Met', EXCL2 == null) |
| DEVI-0040  | If "Type" is NOT "Exclusion Criteria Not Met", "Exclusion Number 3" must be blank. |
|            | --->implies(DEVITYP != 'Exclusion Criteria Not Met', EXCL3 == null) |
| DEVI-0041  | "Date Form Competed" should be the same as or later than "Date of Protocol Deviation" |
|            | --->COMPDT >= DEVIDT |
| DEVI-0042  | "Results is an Adverse Experience" is YES, "Was the AE Serious" must be COMPLETED. |
|            | --->implies(DEVIAE == 'Yes', DEVISAE != null) |
| DEVI-0043  | "Results is an Adverse Experience" is NO, "Was the AE Serious" must be BLANK. |
|            | --->implies(DEVIAE == 'No', DEVISAE == null) |

## Datastream : EMER

## Associated Forms : Follow-up I - Interval Health History, Follow-up II - Interval Health History

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| EREASN1 | Primary reason ->Acute chest syndrome (ACS) ->Acute painful episode (sickle cell pain) ->Acute splenic sequestration ->Clinical stroke ->Fever ->Other | text | $40. | yes | value | | |
| EREASN2 | Secondary reason ->Acute chest syndrome (ACS) ->Acute painful episode (sickle cell pain) ->Acute splenic sequestration ->Clinical stroke ->Fever ->Other | text | $40. | yes | value | | |
| ERV1S | Other, specify | text | $40. | no | none | | |
| ERV2S | Other, specify | text | $40. | no | none | | |
| ERVADDA | Date Admitted (Day) | number | 2. | yes | none | | |
| ERVADMO | Date Admitted (Month) | number | 2. | yes | none | | |
| ERVADYR | Date Admitted (Year) | number | 4. | yes | none | | |
| ERVADDT | Date Admitted | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| ERVDSDA | Date Discharged (Day) | number | 2. | yes | none | | |
| ERVDSMO | Date Discharged (Month) | number | 2. | yes | none | | |
| ERVDSYR | Date Discharged (Year) | number | 4. | yes | none | | |
| ERVDSDT | Date Discharged | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |

### Edit Checks

| | |
|---|---|
| EMER-0003 | Since the Primary reason for ER Visit has been classified as "Other", "Specify" must be completed. --->implies(EREASN1 == 'Other', ERV1S != null) |
| EMER-0003rev | Since "Specify" is completed, the Primary reason for ER Visit must be classified as "Other". --->revimplies(EREASN1 == 'Other', ERV1S != null) |
| EMER-0005 | Since the Secondary reason for ER Visit has been classified as "Other", "Specify" must be completed. --->implies(EREASN2 == 'Other', ERV2S != null) |
| EMER-0005rev | Since "Specify" is completed the Secondary reason for ER Visit must be classified as "Other". --->revimplies(EREASN2 == 'Other', ERV2S != null) |

## Datastream : EXCL

## Associated Forms : Exclusion Criteria

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| EXCL1 | Question 1 ->No ->Yes | text | $3. | yes | value | | |
| EXCL2 | Question 2 ->No ->Yes | text | $3. | yes | value | | |
| EXCL3 | Question 3 ->No ->Yes | text | $3. | yes | value | | |
| EXCL4 | Question 4 ->No ->Yes | text | $3. | yes | value | | |
| EXCL5 | Question 5 ->No ->Yes | text | $3. | yes | value | | |
| EXCL6 | Question 6 ->No ->Yes | text | $3. | yes | value | | |
| EXCL7 | Question 7 ->No ->Yes | text | $3. | yes | value | | |
| EXCL8 | Question 8 ->N/A ->No ->Yes | text | $3. | yes | value | | |
| EXCL9 | Question 9 ->No ->Yes | text | $3. | yes | value | | |
| EXCL10 | Question 10 ->No ->Yes | text | $3. | yes | value | | |
| EXCL11 | Question 11 ->No ->Yes | text | $3. | yes | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

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EXCL-0001    For the subject to be eligible for this study, Exclusion 1 must be answered "No".
  --->EXCL1 == 'No'
EXCL-0002    For the subject to be eligible for this study, Exclusion 2 must be answered "No".
  --->EXCL2 == 'No'
EXCL-0003    For the subject to be eligible for this study, Exclusion 3 must be answered "No".
  --->EXCL3 == 'No'
EXCL-0004    For the subject to be eligible for this study, Exclusion 4 must be answered "No".
  --->EXCL4 == 'No'
EXCL-0005    For the subject to be eligible for this study, Exclusion 5 must be answered "No".

    --->EXCL5 == 'No'

EXCL-0006    For the subject to be eligible for this study, Exclusion 6 must be answered "No".
    --->EXCL6 == 'No'

EXCL-0007    For the subject to be eligible for this study, Exclusion 7 must be answered "No".
    --->EXCL7 == 'No'

EXCL-0008    For the subject to be eligible for this study, Exclusion 8 must be answered "No" OR "NA".
    --->EXCL8 == 'No' || EXCL8 == 'N/A'

EXCL-0009    For the subject to be eligible for this study, Exclusion 9 must be answered "No".
    --->EXCL9 == 'No'

EXCL-0010    For the subject to be eligible for this study, Exclusion 10 must be answered "No".
    --->EXCL10 == 'No'

EXCL-0011    For the subject to be eligible for this study, Exclusion 11 must be answered "No".
    --->EXCL11 == 'No'

## Datastream : FLU1

## Associated Forms : Follow-up I - Interval Health History

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed<br>->Lost to follow-up<br>->Other<br>->Serious Adverse Event<br>->Subject is still an in-patient at the hospital<br>->Subject or parent/guardian decision | text | $40. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| PAIN | Acute painful episode<br>->No<br>->Yes | text | $3. | no | value | | |
| HOME | How many pain crises treated at home | number | 2. | no | none | | |
| CLINIC | How many pain crises treated at clinic | number | 2. | no | none | | |
| HSPVST | Hospitalization<br>->No<br>->Yes | text | $3. | no | value | | |
| ERVISIT | ER visit not resulting in hospital<br>->No<br>->Yes | text | $3. | no | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

FLU1-0001 Since "Was the assessment completed" is equal to "No", a reason must be checked.
---->implies(COMPLET == 'No', REASON != null)

FLU1-0001rev Since a reason is checked, "Was the assessment completed" must be "No".

---->revimplies(COMPLET == 'No', REASON != null)

FLU1-0002 Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed.
---->implies(REASON == 'Other', OTHSP != null)

FLU1-0002rev Since "Specify" is completed, the reason that the assessment was not completed must be classified as "Other".
---->revimplies(REASON == 'Other', OTHSP != null)

FLU1-0101 Since "Was the assessment completed" is equal to "No", the rest of the form must be BLANK.
---->implies(COMPLET == 'No', PAIN == null && HOME == null && CLINIC == null && HSPVST == null && ERVISIT == null)

FLU1-0102 Since "Was the assessment completed" is equal to "Yes", Acute Painful Episode, Hospitalization and ER Visit must be completed.
---->implies(COMPLET == 'Yes', PAIN != null && HSPVST != null && ERVISIT != null)

FLU1-0003 Since "Acute Painful Episode" is equal to "Yes", "Were treated at home" must be completed.
---->implies(PAIN == 'Yes', HOME != null)

FLU1-0003rev Since "Were treated at home" is > ZERO, "Acute Painful Episode" must be "Yes".

---->implies(HOME > 0, PAIN == 'Yes')

FLU1-0004    Since "Acute Painful Episode" is equal to "Yes", "Were treated in a clinic or doctor's office, not hospital" must be completed.
--->implies(PAIN == 'Yes', CLINIC != null)

FLU1-0004rev    Since "Were treated in a clinic or doctor's office, not hospital" > ZERO,"Acute Painful Episode" must be "Yes".
--->implies(CLINIC > 0, PAIN == 'Yes')

FLU1-0005    Since "BOTH Home and Clinic pain crises" are equal to "ZERO", Acute Painful Episode must be No.
--->implies(HOME == 0 && CLINIC == 0, PAIN == 'No')

## Datastream : FLU2

## Associated Forms : Follow-up II - Interval Health History

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed<br>->Lost to follow-up<br>->Other<br>->Serious Adverse Event<br>->Subject is still an in-patient at the hospital<br>->Subject or parent/guardian decision | text | $40. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| PAIN | Acute painful episode<br>->No<br>->Yes | text | $3. | no | value | | |
| HOME | How many pain crises treated at home | number | 2. | no | none | | |
| CLINIC | How many pain crises treated at clinic | number | 2. | no | none | | |
| HSPVST | Hospitalization<br>->No<br>->Yes | text | $3. | no | value | | |
| ERVISIT | ER visit not resulting in hospital<br>->No<br>->Yes | text | $3. | no | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

| | |
|---|---|
| FLU2-0001 | Since "Was the assessment completed" is equal to "No", a reason must be checked.<br>--->implies(COMPLET == 'No', REASON != null) |
| FLU2-0001rev | Since a reason is checked, "Was the assessment completed" must be "No".<br>--->revimplies(COMPLET == 'No', REASON != null) |
| FLU2-0002 | Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed.<br>--->implies(REASON == 'Other', OTHSP != null) |
| FLU2-0002rev | Since "Specify" is completed, the reason that the assessment was not completed must be classified as "Other".<br>--->revimplies(REASON == 'Other', OTHSP != null) |
| FLU2-0101 | Since "Was the assessment completed" is equal to "No", the rest of the form must be BLANK.<br>--->implies(COMPLET == 'No', PAIN == null && HOME == null && CLINIC == null && HSPVST == null && ERVISIT == null) |
| FLU2-0102 | Since "Was the assessment completed" is equal to "Yes", Acute Painful Episode, Hospitalization and ER Visit must be completed.<br>--->implies(COMPLET == 'Yes', PAIN != null && HSPVST != null && ERVISIT != null) |
| FLU2-0003 | Since "Acute Painful Episode" is equal to "Yes", "Were treated at home" must be completed.<br>--->implies(PAIN == 'Yes', HOME != null) |
| FLU2-0003rev | Since "Were treated at home" is > ZERO, "Acute Painful Episode" must be "Yes".<br>--->implies(HOME > 0, PAIN == 'Yes') |

FLU2-0004    Since "Acute Painful Episode" is equal to "Yes", "Were treated in a clinic or doctor's office, not hospital" must be completed.

--->implies(PAIN == 'Yes', CLINIC != null)

FLU2-0004rev    Since "Were treated in a clinic or doctor's office, not hospital" > ZERO,"Acute Painful Episode" must be "Yes".

--->implies(CLINIC > 0, PAIN == 'Yes')

FLU2-0005    Since "BOTH Home and Clinic pain crises" are equal to "ZERO", Acute Painful Episode must be No.

--->implies(HOME == 0 && CLINIC == 0, PAIN == 'No')

## Datastream : FXRA

## Associated Forms : Chest Radiograph

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| XRAY2ND | Not Done | number | 1. | no | range | 1 | 1 |
| XRAY2DA | Date of X-Ray (Day) | number | 2. | no | none | | |
| XRAY2MO | Date of X-Ray (Month) | number | 2. | no | none | | |
| XRAY2YR | Date of X-Ray (Year) | number | 4. | no | none | | |
| XRAY2DT | Date of X-Ray | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| XRAY2HR | Time of X-Ray (Hour) | number | 2. | no | none | | |
| XRAY2MI | Time of X-Ray (Minute) | number | 2. | no | none | | |
| XRAY2TM | Time of X-Ray | time | TIME5. | no | range | 00:00 | 23:59 |
| PULYN2 | Pulminary infiltrate<br>->No<br>->Yes | text | $3. | no | value | | |
| IFYES2 | Pulminary infiltrate present<br>->Existing<br>->New | text | $8. | no | value | | |
| COMM2 | Comments | text | $200. | no | none | | |

#### Edit Checks

FXRA-0001    Either "Date of X-ray" OR "Not Done" must be completed.
--->xor(XRAY2DT != null, XRAY2ND != null)

FXRA-0101    Since "Not Done" is Checked, Rest of Follow Up II should be BLANK.
--->implies(XRAY2ND != null, XRAY2DT == null && XRAY2TM == null && PULYN2 != null && IFYES2 != null)

FXRA-0201    Since Date of X-ray is completed, "Pulmonary Infiltrate" must be completed.
--->implies(XRAY2DT != null, PULYN2 != null)

FXRA-0002    Since "Pulmonary Infiltrate" is equal to "Yes", "New" or "Existing" must be completed.
--->implies(PULYN2 == 'Yes', IFYES2 != null)

FXRA-0002rev    Since "New" or "Existing" is completed, "Pulmonary Infiltrate" must be "Yes".

--->revimplies(PULYN2 == 'Yes', IFYES2 != null)

FXRA-0003    Since "Pulmonary Infiltrate" is equal to "Yes", "Comments" cannot be BLANK.
--->implies(PULYN2 == 'Yes', COMM2 != null)

## Datastream : HDIS

## Associated Forms : Hospital Discharge

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| DISCDA | Date of Discharge (Day) | number | 2. | yes | none | | |
| DISCMO | Date of Discharge (Month) | number | 2. | yes | none | | |
| DISCYR | Date of Discharge (Year) | number | 4. | yes | none | | |
| DISCDT | Date of Discharge | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| DISCHR | Discharge Time (Hour) | number | 2. | yes | none | | |
| DISCMI | Discharge Time (Minute) | number | 2. | yes | none | | |
| DISCTM | Discharge Time | time | TIME5. | yes | range | 00:00 | 23:59 |
| SUPO2 | Subject using supplemental O2<br>->No<br>->Yes | text | $3. | yes | value | | |
| SUPO2DA | O2 Start Date (Day) | number | 2. | no | none | | |
| SUPO2MO | O2 Start Date (Month) | number | 2. | no | none | | |
| SUPO2YR | O2 Start Date (Year) | number | 4. | no | none | | |
| SUPO2DT | O2 Start Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| SUPO2HR | O2 Start Time (Hour) | number | 2. | no | none | | |
| SUPO2MI | O2 Start Time (Minute) | number | 2. | no | none | | |
| SUPO2TM | O2 Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| NOSUPO2 | Subject did not use supplemental O2 | number | 1. | no | range | 1 | 1 |
| FEVER | Subject have fever > or = 38.5<br>->No<br>->Yes | text | $3. | yes | value | | |
| FEVERDA | Fever Start Date (Day) | number | 2. | no | none | | |
| FEVERMO | Fever Start Date (Month) | number | 2. | no | none | | |
| FEVERYR | Fever Start Date (Year) | number | 4. | no | none | | |
| FEVERDT | Fever Start Date | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| FEVERHR | Fever Start Time (Hour) | number | 2. | no | none | | |
| FEVERMI | Fever Start Time (Minute) | number | 2. | no | none | | |
| FEVERTM | Fever Start Time | time | TIME5. | no | range | 00:00 | 23:59 |
| NOFEVER | Subject did not have fever | number | 1. | no | range | 1 | 1 |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

HDIS-0001   Since "Is the subject using supplemental O2 at hospital discharge" is equal to "No", "Date discontinued" and "Date and Time discontinued" OR "Subject did not use supplemental O2 between study enrollment and hospital discharge" must be completed.

--->implies(SUPO2 == 'No', xor((SUPO2DT != null && SUPO2TM != null && NOSUPO2 == null), (SUPO2DT == null && SUPO2TM == null && NOSUPO2 != null)))

HDIS-0101   Since "Is the subject using supplemental O2 at hospital discharge" is equal to "Yes", "Date discontinued" and "Time discontinued" AND "Subject did not use supplemental O2 between study enrollment and hospital discharge" must be BLANK.

--->implies(SUPO2 == 'Yes', SUPO2DT == null && SUPO2TM == null && NOSUPO2 == null)

HDIS-0002   Since "Does the subject have a fever >= 38.5°C at hospital discharge" is equal to "No", "Date stopped" and "Time stopped" OR "Subject did not have a fever between study enrollment and hospital discharge" must be completed.

--->implies(FEVER == 'No', xor((FEVERDT != null && FEVERTM != null && NOFEVER == null), (FEVERDT == null && FEVERTM == null && NOFEVER != null)))

Since "Does the subject have a fever >= 38.5°C at hospital discharge" is equal to "Yes", "Date

HDIS-0102  stopped" and "Time stopped" AND "Subject did not have a fever between study enrollment and hospital discharge" must be BLANK.
--->implies(FEVER == 'Yes', FEVERDT == null && FEVERTM == null && NOFEVER == null)

## Datastream : HEM1

## Associated Forms : Follow-up I - Hematology Labs

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed ->No ->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed ->Lost to follow-up ->Other ->Serious Adverse Event ->Subject is still an in-patient at the hospital ->Subject or parent/guardian decision | text | $40. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| COLLDA | Date of Collection (Day) | number | 2. | no | none | | |
| COLLMO | Date of Collection (Month) | number | 2. | no | none | | |
| COLLYR | Date of Collection (Year) | number | 4. | no | none | | |
| COLLDT | Date of Collection | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| COLLHR | Time of Collection (Hour) | number | 2. | no | none | | |
| COLLMI | Time of Collection (Minute) | number | 2. | no | none | | |
| COLLTM | Time of Collection | time | TIME5. | no | range | 00:00 | 23:59 |
| WBC | WBC | number | 5.1 | no | range | 1 | 99 |
| RBC | RBC | number | 4.2 | no | none | | |
| HGB | HGB | number | 4.1 | no | none | | |
| HCT | HCT | number | 4.1 | no | range | 6 | 54 |
| MCV | MCV | number | 5.1 | no | range | 50 | 130 |
| PLATE | Platelets | number | 4. | no | range | 100 | 900 |
| ABRETIC | Abs. Reticulocyte count | number | 4. | no | range | 0 | 700 |
| RETICPT | % Reticulocyte | number | 4.1 | no | range | 0 | 40 |
| COMMENT | Comments for page | text | $200. | no | none | | |

#### Edit Checks

HEM1-0001 Since "Was the assessment completed" is equal to "No", a reason must be checked.
--->implies(COMPLET == 'No', REASON != null)

HEM1-0002 Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed.
--->implies(REASON == 'Other', OTHSP != null)

HEM1-0002rev Since "Specify" is completed, the reason that the assessment was not completed must be classified as "Other".
--->revimplies(REASON == 'Other', OTHSP != null)

HEM1-0003 Since "Was the assessment completed" is equal to "No", "All Test Values" must be blank.
--->implies(COMPLET == 'No', RETICPT == null && ABRETIC == null && PLATE == null && MCV == null && HCT == null && HGB == null && RBC == null && WBC == null)

HEM1-0011 Since "Was the assessment completed" is equal to "Yes", Either "Abs. reticulocyte count" OR "% Reticulocyte" must be completed. If neither value can be completed, provide an override reason.
--->implies(COMPLET == 'Yes', (ABRETIC != null || RETICPT != null))

HEM1-0014 Since "Was the assessment completed" is equal to "Yes", "Platelets" should be completed.
--->implies(COMPLET == 'Yes', PLATE != null)

HEM1-0015 Since "Was the assessment completed" is equal to "Yes", "MCV" should be completed."

    ---&gt;implies(COMPLET == 'Yes', MCV != null)

HEM1-0016    Since "Was the assessment completed" is equal to "Yes", "HCT" should be completed.
    ---&gt;implies(COMPLET == 'Yes', HCT != null)

HEM1-0017    Since "Was the assessment completed" is equal to "Yes", "HGB" should be completed.
    ---&gt;implies(COMPLET == 'Yes', HGB != null)

HEM1-0018    Since "Was the assessment completed" is equal to "Yes", "RBC" should be completed.
    ---&gt;implies(COMPLET == 'Yes', RBC != null)

HEM1-0019    Since "Was the assessment completed" is equal to "Yes", "WBC" should be completed.
    ---&gt;implies(COMPLET == 'Yes', WBC != null)

HEM1-0020    Since "Was the assessment completed" is equal to "Yes", "Collection Time" should be completed.
    ---&gt;implies(COMPLET == 'Yes', COLLTM != null)

HEM1-0021    Since "Was the assessment completed" is equal to "Yes", "Collection Time" should be completed.
    ---&gt;implies(COMPLET == 'Yes', COLLDT != null)

## Datastream : HEM2

## Associated Forms : Follow-up II - Hematology Labs

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed<br>->Lost to follow-up<br>->Other<br>->Serious Adverse Event<br>->Subject is still an in-patient at the hospital<br>->Subject or parent/guardian decision | text | $40. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| COLLDA | Date of Collection (Day) | number | 2. | no | none | | |
| COLLMO | Date of Collection (Month) | number | 2. | no | none | | |
| COLLYR | Date of Collection (Year) | number | 4. | no | none | | |
| COLLDT | Date of Collection | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| COLLHR | Time of Collection (Hour) | number | 2. | no | none | | |
| COLLMI | Time of Collection (Minute) | number | 2. | no | none | | |
| COLLTM | Time of Collection | time | TIME5. | no | range | 00:00 | 23:59 |
| WBC | WBC | number | 5.1 | no | range | 1 | 99 |
| RBC | RBC | number | 4.2 | no | none | | |
| HGB | HGB | number | 4.1 | no | none | | |
| HCT | HCT | number | 4.1 | no | range | 6 | 54 |
| MCV | MCV | number | 5.1 | no | range | 50 | 130 |
| PLATE | Platelets | number | 4. | no | range | 100 | 900 |
| ABRETIC | Abs. Reticulocyte count | number | 4. | no | range | 0 | 700 |
| RETICPT | % Reticulocyte | number | 4.1 | no | range | 0 | 40 |
| COMMENT | Comments for page | text | $200. | no | none | | |

#### Edit Checks

HEM2-0001   Since "Was the assessment completed" is equal to "No", a reason must be checked.
   --->implies(COMPLET == 'No', REASON != null)

HEM2-0002   Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed.
   --->implies(REASON == 'Other', OTHSP != null)

HEM2-0002rev   Since "Specify" is completed, the reason that the assessment was not completed must be classified as "Other".
   --->revimplies(REASON == 'Other', OTHSP != null)

HEM2-0003   Since "Was the assessment completed" is equal to "No", "All Test Values" must be blank.
   --->implies(COMPLET == 'No', COLLDT == null && COLLTM == null && RETICPT == null && ABRETIC == null && PLATE == null && MCV == null && HCT == null && HGB == null && RBC == null && WBC == null)

HEM2-0011   Since "Was the assessment completed" is equal to "Yes", Either "Abs. reticulocyte count" OR "% Reticulocyte" must be completed. If neither value can be completed, provide an override reason.
   --->implies(COMPLET == 'Yes', (ABRETIC != null || RETICPT != null))

HEM2-0014   Since "Was the assessment completed" is equal to "Yes", "Platelets" should be completed.
   --->implies(COMPLET == 'Yes', PLATE != null)

| HEM2-0015 | Since "Was the assessment completed" is equal to "Yes", "MCV" should be completed."<br>--->implies(COMPLET == 'Yes', MCV != null) |
|---|---|
| HEM2-0016 | Since "Was the assessment completed" is equal to "Yes", "HCT" should be completed.<br>--->implies(COMPLET == 'Yes', HCT != null) |
| HEM2-0017 | Since "Was the assessment completed" is equal to "Yes", "HGB" should be completed.<br>--->implies(COMPLET == 'Yes', HGB != null) |
| HEM2-0018 | Since "Was the assessment completed" is equal to "Yes", "RBC" should be completed.<br>--->implies(COMPLET == 'Yes', RBC != null) |
| HEM2-0019 | Since "Was the assessment completed" is equal to "Yes", "WBC" should be completed.<br>--->implies(COMPLET == 'Yes', WBC != null) |
| HEM2-0020 | Since "Was the assessment completed" is equal to "Yes", "Collection Time" should be completed.<br>--->implies(COMPLET == 'Yes', COLLTM != null) |
| HEM2-0021 | Since "Was the assessment completed" is equal to "Yes", "Collection Time" should be completed.<br>--->implies(COMPLET == 'Yes', COLLDT != null) |

## Datastream : HEMA

## Associated Forms : Study Enrollment - Hematology Labs

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| COLLDA | Date of Collection (Day) | number | 2. | yes | none | | |
| COLLMO | Date of Collection (Month) | number | 2. | yes | none | | |
| COLLYR | Date of Collection (Year) | number | 4. | yes | none | | |
| COLLDT | Date of Collection | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| COLLHR | Time of Collection (Hour) | number | 2. | no | none | | |
| COLLMI | Time of Collection (Minute) | number | 2. | no | none | | |
| COLLTM | Time of Collection | time | TIME5. | no | range | 00:00 | 23:59 |
| NOTDO | Labs not done | number | 1. | no | range | 1 | 1 |
| WBC | WBC | number | 5.1 | no | range | 1 | 99 |
| RBC | RBC | number | 4.2 | no | none | | |
| HGB | HGB | number | 4.1 | no | none | | |
| HCT | HCT | number | 4.1 | no | range | 6 | 54 |
| MCV | MCV | number | 5.1 | no | range | 50 | 130 |
| PLATE | Platelets | number | 4. | no | range | 100 | 900 |
| ABRETIC | Abs. Reticulocyte count | number | 4. | no | range | 0 | 700 |
| RETICPT | % Reticulocyte | number | 4.1 | no | range | 0 | 40 |
| COMMENT | Comments for page | text | $200. | no | none | | |

#### Edit Checks

HEMA-0001   Since "Labs not done" is checked, "All Test Values" must be blank.
--->implies(NOTDO != null, RETICPT == null && ABRETIC == null && PLATE == null && MCV == null && HCT == null && HGB == null && RBC == null && WBC == null)

HEMA-0101   Since "Labs not done" is NOT checked, "All Test Values" must be completed.
--->implies(NOTDO == null, (RETICPT != null || ABRETIC != null) && PLATE != null && MCV != null && HCT != null && HGB != null && RBC != null && WBC != null)

HEMA-0009   Since "Labs not done" is checked, "Comments for page" must be completed.
--->implies(NOTDO != null, COMMENT != null)

HEMA-0010   Since "Labs not done" is NOT checked, Either "Abs. reticulocyte count" OR "% Reticulocyte" must be completed. If neither value can be completed, provide an override reason.
--->implies(NOTDO == null, (ABRETIC != null || RETICPT != null))

## Datastream : HEMD

## Associated Forms : Day {DAYNUM} on {COLLDT}

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| DAYNUM | Hospitalization day number | number | 2. | yes | none | | |
| COLLDA | Date of Collection (Day) | number | 2. | yes | none | | |
| COLLMO | Date of Collection (Month) | number | 2. | yes | none | | |
| COLLYR | Date of Collection (Year) | number | 4. | yes | none | | |
| COLLDT | Date of Collection | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| COLLHR | Time of Collection (Hour) | number | 2. | no | none | | |
| COLLMI | Time of Collection (Minute) | number | 2. | no | none | | |
| COLLTM | Time of Collection | time | TIME5. | no | range | 00:00 | 23:59 |
| NOTDO | Labs not done | number | 1. | no | range | 1 | 1 |
| WBC | WBC | number | 5.1 | no | range | 1 | 99 |
| RBC | RBC | number | 4.2 | no | none | | |
| HGB | HGB | number | 4.1 | no | none | | |
| HCT | HCT | number | 4.1 | no | range | 6 | 54 |
| MCV | MCV | number | 5.1 | no | range | 50 | 130 |
| PLATE | Platelets | number | 4. | no | range | 100 | 900 |
| ABRETIC | Abs. Reticulocyte count | number | 4. | no | range | 0 | 700 |
| RETICPT | % Reticulocyte | number | 4.1 | no | range | 0 | 40 |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

HEMD-0001   Since "Labs not done" is checked, "All Test Values" must be blank.
--->implies(NOTDO != null, RETICPT == null && ABRETIC == null && PLATE == null && MCV == null && HCT == null && HGB == null && RBC == null && WBC == null)

HEMD-0101   Since "Labs not done" is NOT checked, "All Test Values" must be completed.
--->implies(NOTDO == null, (RETICPT != null || ABRETIC != null) && PLATE != null && MCV != null && HCT != null && HGB != null && RBC != null && WBC != null)

HEMD-0009   Since "Labs not done" is checked, "Comments for page" must be completed.
--->implies(NOTDO != null, COMMENT != null)

HEMD-0010   Since "Labs not done" is NOT checked, Either "Abs. reticulocyte count" OR "% Reticulocyte" must be completed. If neither value can be completed, provide an override reason.
--->implies(NOTDO == null, (ABRETIC != null || RETICPT != null))

## Datastream : HMCM

## Associated Forms : Study Drug Home Record

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

*No Edit Checks*

## Datastream : HMSD

## Associated Forms : Study Drug Home Record

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| DOSEDA | Date of Dose (Day) | number | 2. | yes | none | | |
| DOSEMO | Date of Dose (Month) | number | 2. | yes | none | | |
| DOSEYR | Date of Dose (Year) | number | 4. | yes | none | | |
| DOSEDT | Date of Dose | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| DOSEHR | Time of Dose (Hour) | number | 2. | yes | none | | |
| DOSEMI | Time of Dose (Minute) | number | 2. | yes | none | | |
| DOSETM | Time of Dose | time | TIME5. | yes | range | 00:00 | 23:59 |
| COMM | Comments | text | $200. | no | none | | |
| DOSE | Dose action<br>->Dose taken<br>->Missed dose | text | $11. | yes | value | | |

### Edit Checks

HMSD-0002   If "Dose" is MISSED, Comments cannot be BLANK.
        --->implies(DOSE == 'Missed dose', COMM != null)

## Datastream : HOSP

## Associated Forms : Follow-up I - Interval Health History, Follow-up II - Interval Health History

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| REASON1 | Primary reason<br>->Acute chest syndrome (ACS)<br>->Acute painful episode (sickle cell pain)<br>->Acute splenic sequestration<br>->Clinical stroke<br>->Fever<br>->Other | text | $40. | yes | value | | |
| REASON2 | Secondary reason<br>->Acute chest syndrome (ACS)<br>->Acute painful episode (sickle cell pain)<br>->Acute splenic sequestration<br>->Clinical stroke<br>->Fever<br>->Other | text | $40. | yes | value | | |
| REAS1S | Other, specify | text | $40. | no | none | | |
| REAS2S | Other, specify | text | $40. | no | none | | |
| ADMITDA | Date Admitted (Day) | number | 2. | yes | none | | |
| ADMITMO | Date Admitted (Month) | number | 2. | yes | none | | |
| ADMITYR | Date Admitted (Year) | number | 4. | yes | none | | |
| ADMITDT | Date Admitted | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| DISCDA | Date Discharged (Day) | number | 2. | yes | none | | |
| DISCMO | Date Discharged (Month) | number | 2. | yes | none | | |
| DISCYR | Date Discharged (Year) | number | 4. | yes | none | | |
| DISCDT | Date Discharged | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |

### Edit Checks

| | |
|---|---|
| HOSP-0003 | Since the Primary reason for hospitalization has been classified as "Other", "Specify" must be completed.<br>--->implies(REASON1 == 'Other', REAS1S != null) |
| HOSP-0003rev | Since "Specify" is completed, the Primary reason for hospitalization must be classified as "Other"<br>--->revimplies(REASON1 == 'Other', REAS1S != null) |
| HOSP-0005 | Since the Secondary reason for hospitalization has been classified as "Other", "Specify" must be completed.<br>--->implies(REASON2 == 'Other', REAS2S != null) |
| HOSP-0005rev | Since "Specify" is completed, the Secondary reason for hospitalization must be classified as "Other".<br>--->revimplies(REASON2 == 'Other', REAS2S != null) |

## Datastream : HPCM

## Associated Forms : Study Drug Hospital Log

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

*No Edit Checks*

## Datastream : HPSD

## Associated Forms : Study Drug Hospital Log

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| DOSEDA | Date of Dose (Day) | number | 2. | yes | none | | |
| DOSEMO | Date of Dose (Month) | number | 2. | yes | none | | |
| DOSEYR | Date of Dose (Year) | number | 4. | yes | none | | |
| DOSEDT | Date of Dose | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| DOSEHR | Time of Dose (Hour) | number | 2. | yes | none | | |
| DOSEMI | Time of Dose (Minute) | number | 2. | yes | none | | |
| DOSETM | Time of Dose | time | TIME5. | yes | range | 00:00 | 23:59 |
| DOSE | Dose | number | 5.2 | no | none | | |
| COMM | Comments | text | $200. | no | none | | |
| MISSED | Missed Dose | number | 1. | no | range | 1 | 1 |
| ROUTE | Route<br>->IV<br>->PO | text | $2. | no | value | | |

#### Edit Checks

| | |
|---|---|
| HPSD-0001 | Either "Dose Value" OR "Not Done" must be completed. If neither value can be completed, provide an override reason.<br>--->xor(DOSE != null, MISSED != null) |
| HPSD-0002 | If "Dose" is MISSED, Comments cannot be BLANK.<br>--->implies(MISSED != null, COMM != null) |

## Datastream : INCL

## Associated Forms : Inclusion Criteria

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| INCL1 | Question 1 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| INCL2 | Question 2 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| INCL3 | Question 3 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| INCL3A | Temperature > or = 38.5 | number | 1. | no | range | 1 | 1 |
| INCL3B | Tachypnea | number | 1. | no | range | 1 | 1 |
| INCL3C | Dyspnea | number | 1. | no | range | 1 | 1 |
| INCL3D | Chest wall pain | number | 1. | no | range | 1 | 1 |
| INCL3E | Oxygen saturation | number | 1. | no | range | 1 | 1 |
| INCL4NW | Question 4 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| INCL4A | Temperature > or = 38.5 | number | 1. | no | range | 1 | 1 |
| INCL4B | Tachypnea | number | 1. | no | range | 1 | 1 |
| INCL4C | Dyspnea | number | 1. | no | range | 1 | 1 |
| INCL4D | Chest wall pain | number | 1. | no | range | 1 | 1 |
| INCL4E | Oxygen saturation | number | 1. | no | range | 1 | 1 |
| INCL4 | Question 5 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| INCL5 | Question 6 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| INCL6 | Question 7 | text | $3. | yes | value | | |
| | ->No | | | | | | |
| | ->Yes | | | | | | |
| INFODA | Date of informed consent (Day) | number | 2. | no | none | | |
| INFOMO | Date of informed consent (Month) | number | 2. | no | none | | |
| INFOYR | Date of informed consent (Year) | number | 4. | no | none | | |
| INFODT | Date of informed consent | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

| | |
|---|---|
| INCL-0003 | For the subject to be eligible for this study, Inclusion 1 must be answered "Yes". |
| | --->INCL1 == 'Yes' |
| INCL-0004 | For the subject to be eligible for this study, Inclusion 2 must be answered "Yes". |
| | --->INCL2 == 'Yes' |
| INCL-0005 | For the subject to be eligible for this study, Inclusion 3 must be answered "Yes". |
| | --->INCL3 == 'Yes' |
| INCL-0105 | For the subject to be eligible for this study, Inclusion 4 must be answered "Yes". |
| | --->INCL4NW == 'Yes' |

INCL-0006    For the subject to be eligible for this study, Inclusion 5 must be answered "Yes".
             --->INCL4 == 'Yes'
INCL-0007    For the subject to be eligible for this study, Inclusion 6 must be answered "Yes".
             --->INCL5 == 'Yes'
INCL-0008    For the subject to be eligible for this study, Inclusion 7 must be answered "Yes".
             --->INCL6 == 'Yes'
INCL-0009    Since Inclusion 7 is Yes, Date of informed consent should be completed.
             --->implies(INCL6 == 'Yes', INFODT != null)
INCL-0010    Since Inclusion 3 is "Yes", at least 2 symptoms must be checked.
             --->(INCL3A != null) ? tot = 1 : true ; (INCL3A == null) ? tot = 0 : true ; (INCL3B != null) ? tot =
             tot + 1 : true ; (INCL3C != null) ? tot = tot + 1 : true ; (INCL3D != null) ? tot = tot + 1 : true ;
             (INCL3E != null) ? tot = tot + 1 : true ; ( (INCL3 == 'Yes') ? tot >= 2 : true)
INCL-0011    Since Inclusion 3 is "No", the symptoms should be blank.
             --->implies(INCL3 == 'No', INCL3A == null && INCL3B == null && INCL3C == null && INCL3D
             == null && INCL3E != null)
INCL-0012    Since Inclusion 4 is "Yes", at least 1 symptom must be checked.
             --->implies(INCL4NW == 'Yes', INCL4A != null || INCL4B != null || INCL4C != null || INCL4D !=
             null || INCL4E != null)
INCL-0013    Since Inclusion 4 is "No", the symptoms should be blank.
             --->implies(INCL4NW == 'No', INCL4A == null && INCL4B == null && INCL4C == null &&
             INCL4D == null && INCL4E != null)

## Datastream : OPI1

## Associated Forms : Opioid Analgesia

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| DAY | Study day | number | 2. | yes | range | 0 | 60 |
| OPIOID | Opiod name | text | $13. | yes | value | | |
| | ->Codeine | | | | | | |
| | ->Hydrocodone | | | | | | |
| | ->Hydromorphone | | | | | | |
| | ->Meperidine | | | | | | |
| | ->Morphine | | | | | | |
| | ->Other | | | | | | |
| | ->Oxycodone | | | | | | |
| | ->Tentanyl | | | | | | |
| OPSP | Opiod specify | text | $40. | no | none | | |
| DOSE | Total dose per 24 hr | text | $20. | yes | none | | |
| UNIT | Unit | text | $5. | yes | value | | |
| | ->CAP | | | | | | |
| | ->G | | | | | | |
| | ->GTT | | | | | | |
| | ->MCG | | | | | | |
| | ->MG | | | | | | |
| | ->ML | | | | | | |
| | ->OTHER | | | | | | |
| | ->TAB | | | | | | |
| UNITSP | Unit specify | text | $20. | no | none | | |
| ROUTE | Route | text | $5. | yes | value | | |
| | ->IA | | | | | | |
| | ->IM | | | | | | |
| | ->INH | | | | | | |
| | ->INTRA | | | | | | |
| | ->IS | | | | | | |
| | ->IV | | | | | | |
| | ->OTHER | | | | | | |
| | ->PO | | | | | | |
| | ->PR | | | | | | |
| | ->SC | | | | | | |
| | ->SQ | | | | | | |
| | ->TOP | | | | | | |
| ROUTESP | Route specify | text | $20. | no | none | | |
| COMM | Comments | text | $200. | no | none | | |

### Edit Checks

OPI1-0001 If "Unit" is catagorized as "Other", "Specify" must be completed.
--->implies(UNIT == 'OTHER', UNITSP != null)

OPI1-0001rev If "Specify" is completed", Unit" must be catagorized as "Other".
--->revimplies(UNIT == 'OTHER', UNITSP != null)

OPI1-0002 If "Route" is catagorized as "Other", "Specify" must be completed.
--->implies(ROUTE == 'OTHER', ROUTESP != null)

OPI1-0002rev If "Specify" is completed", "Route" must be catagorized as "Other".

        --->revimplies(ROUTE == 'OTHER', ROUTESP != null)

OPI1-0003    If "Opioid Name" is "Other", "Specify" must be completed.

        --->implies(OPIOID == 'Other', OPSP != null)

OPI1-0003rev If "Specify" is completed", Opioid Name" must be "Other".

        --->revimplies(OPIOID == 'Other', OPSP != null)

## Datastream : OPI2

## Associated Forms : Opioid Analgesia

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| DAY | Study day | number | 2. | yes | range | 0 | 60 |
| OPIOID2 | Opiod name | text | $13. | yes | value | | |
| | ->Codeine | | | | | | |
| | ->Hydrocodone | | | | | | |
| | ->Hydromorphone | | | | | | |
| | ->Meperidine | | | | | | |
| | ->Morphine | | | | | | |
| | ->Other | | | | | | |
| | ->Oxycodone | | | | | | |
| | ->Tentanyl | | | | | | |
| OPSP2 | Opiod specify | text | $40. | no | none | | |
| INFU | Total continuous infusion (mg) | number | 5.2 | yes | none | | |
| DOSE | Total dose PCA doses (mg) | number | 5.2 | yes | none | | |
| BOLUS | Total other boluses (mg) | number | 5.2 | yes | none | | |
| COMM2 | Comments | text | $200. | no | none | | |

### Edit Checks

OPI2-0001    If "Opioid Name" is "Other", "Specify" must be completed.
     --->implies(OPIOID2 == 'Other', OPSP2 != null)
OPI2-0001rev If "Specify" is completed", Opioid Name" must be "Other".
     --->revimplies(OPIOID2 == 'Other', OPSP2 != null)

## Datastream : OPYN

## Associated Forms : Opioid Analgesia

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | High |
|---|---|---|---|---|---|---|---|
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

*No Edit Checks*

## Datastream : PREG

## Associated Forms : Pregnancy Test

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| PREGND | Not done<br>->Not done | text | $10. | no | value | | |
| REASON | Reason Not done<br>->Hysterectomy<br>->Other<br>->Postmenopausal<br>->Subject is too young (not sexually mature)<br>->Subject male<br>->Tubal ligation | text | $30. | no | value | | |
| RSNOTS | Other, specify | text | $100. | no | none | | |
| COLLDA | Date of Collection (Day) | number | 2. | no | none | | |
| COLLMO | Date of Collection (Month) | number | 2. | no | none | | |
| COLLYR | Date of Collection (Year) | number | 4. | no | none | | |
| COLLDT | Date of Collection | date | DATE9. | no | range | 2006-01-01 | 2008-12-31 |
| TYPE | Type of sample collected<br>->Serum<br>->Urine | text | $5. | no | value | | |
| RESULT | Result<br>->Negative<br>->Positive | text | $8. | no | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

PREG-0001    Since "Not done" is checked, a reason must be checked.
     --->implies(PREGND == 'Not done', REASON != null)

PREG-0002    Since "Not done" is checked, "Date of Collection" must not be completed.
     --->implies(PREGND == 'Not done', COLLDT == null)

PREG-0003    Since "Not done" is checked, "Type" must not be completed.
     --->implies(PREGND == 'Not done', TYPE == null)

PREG-0004    Since "Not done" is checked, "Result" must not be completed.
     --->implies(PREGND == 'Not done', RESULT == null)

PREG-0006    Since the reason has been classified as "Other", "Specify" must be completed.
     --->implies(REASON == 'Other', RSNOTS != null)

PREG-0006rev    Since "Specify" is completed, "Other" must be checked.

     --->revimplies(REASON == 'Other', RSNOTS != null)

PREG-0110    Since either "Not done" is NOT checked, "Reason" should be BLANK.
     --->implies(PREGND == null, REASON == null)

PREG-0010    Since either "Not done" is NOT checked, "Date of Collection" must be completed.
     --->implies(PREGND == null, COLLDT != null)

PREG-0011    Since either "Not done" is NOT checked, "Type" must be completed.
     --->implies(PREGND == null, TYPE != null)

PREG-0012    Since either "Not done" is NOT checked, "Result" must be completed.
     --->implies(PREGND == null, RESULT != null)

## <u>Datastream</u> : **RESP**

## <u>Associated Forms</u> : **Follow-up II - Respiratory Assessments**

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| ASMTDA | Date of Assessment (Day) | number | 2. | no | none | | |
| ASMTMO | Date of Assessment (Month) | number | 2. | no | none | | |
| ASMTYR | Date of Assessment (Year) | number | 4. | no | none | | |
| ASMTDT | Date of Assessment | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| COMPLET | Was assessment completed? ->No ->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed ->Lost to follow-up ->Other ->Serious adverse event ->Still an inpatient ->Subject/guardian decision | text | $46. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| CHEST | Was a 30-day chest radiograph taken ->No ->Yes | text | $3. | no | value | | |
| FVC1 | FVC value | number | 5.2 | no | none | | |
| FEV1 | FEV value | number | 5.2 | no | none | | |
| FEVFVC1 | FEVFVC value | number | 5.2 | no | none | | |
| FEF1 | FEF value | number | 5.2 | no | none | | |
| PEFR1 | PEFR value | number | 5.2 | no | none | | |
| DLCO1 | DLCO value | number | 5.2 | no | none | | |
| ND1 | DLCO value not done | number | 1. | no | range | 1 | 1 |
| CORHGB1 | DLCO value HGB status ->DLCO Value Corrected for HGB ->DLCO Value Not Corrected for HGB | text | $40. | no | value | | |
| FVC2 | FVC predicted value | number | 5.2 | no | none | | |
| FEV2 | FEV predicted value | number | 5.2 | no | none | | |
| FEVFVC2 | FEV predicted value | number | 5.2 | no | none | | |
| FEF2 | FEF predicted value | number | 5.2 | no | none | | |
| PEFR2 | PEFR predicted value | number | 5.2 | no | none | | |
| DLCO2 | DLCO predicted value | number | 5.2 | no | none | | |
| ND2 | DLCO predicted value not done | number | 1. | no | range | 1 | 1 |
| CORHGB2 | DLCO predicted HGB status ->DLCO Predicted Corrected for HGB ->DLCO Predicted Not Corrected for HGB | text | $40. | no | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### <u>Edit Checks</u>

RESP-0102  Since "Was the assessment completed" is equal to "No", Date of Assessment must be BLANK.
--->implies(COMPLET == 'No', ASMTDT == null)

RESP-0103  Since "Was the assessment completed" is equal to "Yes", Date of Assessment must be Completed.

|  | --->implies(COMPLET == 'Yes', ASMTDT != null) |
|---|---|
| RESP-0001 | Since "Was the assessment completed" is equal to "No", a reason must be checked. |
|  | --->implies(COMPLET == 'No', REASON != null) |
| RESP-0001rev | Since a reason is checked, "Was the assessment completed" must be "No". |
|  | --->revimplies(COMPLET == 'No', REASON != null) |
| RESP-0002 | Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed. |
|  | --->implies(REASON == 'Other', OTHSP != null) |
| RESP-0002rev | Since "Specify" is completed, the reason that the assessment was not completed must be classified as "Other". |
|  | --->revimplies(REASON == 'Other', OTHSP != null) |
| RESP-0101 | Since "Was the assessment completed" is equal to "No", Chest Radiograph AND Pulmonary Function must be BLANK. |
|  | --->implies(COMPLET == 'No', CHEST == null && FVC1 == null && FVC2 == null && FEV1 == null && FEV2 == null && FEVFVC1 == null && FEVFVC2 == null && FEF1 == null && FEF2 == null && PEFR1 == null && PEFR2 == null && DLCO1 == null && ND1 == null && CORHGB1 == null && DLCO2 == null && ND2 == null && CORHGB2 == null) |
| RESP-0003 | Either "DLCO Predicted Value" OR "Not Done" must be completed. If neither value can be completed, provide an override reason. |
|  | --->implies(COMPLET == 'Yes', xor(DLCO2 != null, ND2 != null)) |
| RESP-0004 | Either "DLCO Value" OR "Not Done" must be completed. If neither value can be completed, provide an override reason. |
|  | --->implies(COMPLET == 'Yes', xor(DLCO1 != null, ND1 != null)) |
| RESP-0105 | Either "DLCO Value HGB Status" OR "Not Done" must be completed. |
|  | --->implies(COMPLET == 'Yes', xor(CORHGB1 != null, ND1 != null)) |
| RESP-0106 | Either "DLCO Predicted HGB Status" OR "Not Done" must be completed. |
|  | --->implies(COMPLET == 'Yes', xor(CORHGB2 != null, ND2 != null)) |
| RESP-0005 | Since "Was the assessment completed" is "Yes", "PEFR Predicted Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', PEFR2 != null) |
| RESP-0006 | Since "Was the assessment completed" is "Yes", "PEFR Acutal Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', PEFR1 != null) |
| RESP-0007 | Since "Was the assessment completed" is "Yes", "FEF Acutal Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FEF2 != null) |
| RESP-0008 | Since "Was the assessment completed" is "Yes", "FEF Predicted Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FEF1 != null) |
| RESP-0009 | Since "Was the assessment completed" is "Yes", "FEV/FVC Predicted Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FEVFVC2 != null) |
| RESP-0010 | Since "Was the assessment completed" is "Yes", "FEV/FVC Acutal Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FEVFVC1 != null) |
| RESP-0011 | Since "Was the assessment completed" is "Yes", "FEV Predicted Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FEV2 != null) |
| RESP-0012 | Since "Was the assessment completed" is "Yes", "FEV Acutal Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FEV1 != null) |
| RESP-0013 | Since "Was the assessment completed" is "Yes", "FVC Predicted Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FVC2 != null) |
| RESP-0014 | Since "Was the assessment completed" is "Yes", "FVC Acutal Value" must be completed. |
|  | --->implies(COMPLET == 'Yes', FVC1 != null) |
| RESP-0015 | Since "Was the assessment completed" is "Yes", "Chest Radiograph taken" must be completed. |

--->implies(COMPLET == 'Yes', CHEST != null)

## Datastream : VTL1

## Associated Forms : Follow-up I Assessment

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed<br>->Lost to follow-up<br>->Other<br>->Serious adverse event<br>->Still an inpatient<br>->Subject/guardian decision | text | $30. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| ASSDA | Date of Assessment (Day) | number | 2. | no | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | no | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | no | none | | |
| ASSDT | Date of Assessment | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| ASSHR | Time of Assessment (Hour) | number | 2. | no | none | | |
| ASSMI | Time of Assessment (Minute) | number | 2. | no | none | | |
| ASSTM | Time of Assessment | time | TIME5. | no | range | 00:00 | 23:59 |
| TEMP | Temperature | number | 4.1 | no | range | 36.0 | 39.5 |
| RATE | Heart rate | number | 3. | no | range | 40 | 150 |
| RESP | Respirations | number | 2. | no | range | 16 | 40 |
| SYS | Systolic blood pressure | number | 3. | no | range | 50 | 250 |
| DIA | Diastolic blood pressure | number | 3. | no | range | 20 | 150 |
| O2SAT | O2 saturation | number | 3. | no | range | 80 | 100 |
| O2SATND | Asian | number | 1. | no | range | 1 | 1 |
| HYPER | New onset hypertension<br>->No<br>->Yes | text | $3. | no | value | | |
| REASON2 | Suspected reason<br>->Crying or irritated<br>->Fluid overload<br>->Other<br>->Severe pain<br>->Unknown | text | $19. | no | value | | |
| OTHSP2 | Other, specify | text | $40. | no | none | | |
| TREAT | Required treatment<br>->No<br>->Yes | text | $3. | no | value | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

VTL1-0001    Since "Was the assessment completed" is equal to "No", a reason must be checked.

--->implies(COMPLET == 'No', REASON != null)

VTL1-0001rev    Since "Was the assessment completed" is equal to "Yes", a reason should not be checked.

--->revimplies(COMPLET == 'No', REASON != null)

VTL1-0002    Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed.

|  | --->implies(REASON == 'Other', OTHSP != null) |
|---|---|
| VTL1-0002rev | Since "Specify" is completed, the reason that the assessment was not completed should be classified as "Other".<br>--->revimplies(REASON == 'Other', OTHSP != null) |
| VTL1-0101 | Since "Was the assessment completed" is equal to "No", the rest of the form must be BLANK.<br>--->implies(COMPLET == 'No', ASSDT == null && ASSTM == null && TEMP == null && RATE == null && RESP == null && SYS == null && DIA == null) |
| VTL1-0003 | Since "Was the assessment completed" is "Yes", "Date of Assessment" must be completed.<br>--->implies(COMPLET == 'Yes', ASSDT != null) |
| VTL1-0004 | Since "Was the assessment completed" is "Yes", "Time of Assessment" must be completed.<br>--->implies(COMPLET == 'Yes', ASSTM != null) |
| VTL1-0005 | Since "Was the assessment completed" is "Yes", "Temperature" must be completed.<br>--->implies(COMPLET == 'Yes', TEMP != null) |
| VTL1-0006 | Since "Was the assessment completed" is "Yes", "Heart Rate" must be completed.<br>--->implies(COMPLET == 'Yes', RATE != null) |
| VTL1-0007 | Since "Was the assessment completed" is "Yes", "Respirations" must be completed.<br>--->implies(COMPLET == 'Yes', RESP != null) |
| VTL1-0008 | Since "Was the assessment completed" is "Yes", "Systolic Blood Pressure" must be completed.<br>--->implies(COMPLET == 'Yes', SYS != null) |
| VTL1-0009 | Since "Was the assessment completed" is "Yes", "Diastolic Blood Pressure" must be completed.<br>--->implies(COMPLET == 'Yes', DIA != null) |
| VTL1-0203 | Since "Was the assessment completed" is equal to "Yes", "Does the subject have new onset hypertension (per protocol)" must be completed.<br>--->implies(COMPLET == 'Yes', HYPER != null) |
| VTL1-0203rev | Since "Does the subject have new onset hypertension (per protocol)" is completed, "Was the assessment completed" must be "Yes".<br>--->revimplies(COMPLET == 'Yes', HYPER != null) |
| VTL1-0200 | Since "Does the subject have new onset hypertension (per protocol)" is equal to "Yes", "What is the suspected reason" must be completed.<br>--->implies(HYPER == 'Yes', REASON2 != null) |
| VTL1-0200rev | Since "What is the suspected reason" is completed, "Does the subject have new onset hypertension (per protocol)" must be "Yes".<br>--->revimplies(HYPER == 'Yes', REASON2 != null) |
| VTL1-0201 | Since "What is the suspected reason" is "Other", "Other, Specify" must be completed.<br>--->implies(REASON2 == 'Other', OTHSP2 != null) |
| VTL1-0201rev | Since "Other, Specify" is completed, "What is the suspected reason" must be "Other"<br>--->revimplies(REASON2 == 'Other', OTHSP2 != null) |
| VTL1-0202 | Since "Does the subject have new onset hypertension (per protocol)" is equal to "Yes", "Did this require treatment" must be completed.<br>--->implies(HYPER == 'Yes', TREAT != null) |
| VTL1-0202rev | Since "Did this require treatment" is completed, "Does the subject have new onset hypertension (per protocol)" must be "Yes".<br>--->revimplies(HYPER == 'Yes', TREAT != null) |

## Datastream : VTL2

## Associated Forms : Follow-Up II Assessment

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| COMPLET | Was assessment completed<br>->No<br>->Yes | text | $3. | yes | value | | |
| REASON | Reason assessment not completed<br>->Lost to follow-up<br>->Other<br>->Serious adverse event<br>->Still an inpatient<br>->Subject/guardian decision | text | $30. | no | value | | |
| OTHSP | Other, specify | text | $40. | no | none | | |
| ASSDA | Date of Assessment (Day) | number | 2. | no | none | | |
| ASSMO | Date of Assessment (Month) | number | 2. | no | none | | |
| ASSYR | Date of Assessment (Year) | number | 4. | no | none | | |
| ASSDT | Date of Assessment | date | DATE9. | no | range | 2006-10-01 | 2010-10-01 |
| ASSHR | Time of Assessment (Hour) | number | 2. | no | none | | |
| ASSMI | Time of Assessment (Minute) | number | 2. | no | none | | |
| ASSTM | Time of Assessment | time | TIME5. | no | range | 00:00 | 23:59 |
| TEMP | Temperature | number | 4.1 | no | range | 36.0 | 39.5 |
| RATE | Heart rate | number | 3. | no | range | 40 | 150 |
| RESP | Respirations | number | 2. | no | range | 16 | 40 |
| SYS | Systolic blood pressure | number | 3. | no | range | 50 | 250 |
| DIA | Diastolic blood pressure | number | 3. | no | range | 20 | 150 |
| HYPER | New onset hypertension<br>->No<br>->Yes | text | $3. | no | value | | |
| REASON2 | Suspected reason<br>->Crying or irritated<br>->Fluid overload<br>->Other<br>->Severe pain<br>->Unknown | text | $19. | no | value | | |
| OTHSP2 | Other, specify | text | $40. | no | none | | |
| TREAT | Required treatment<br>->No<br>->Yes | text | $3. | no | value | | |
| WEIGHT | Weight | number | 5.1. | no | range | 22 | 120 |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

VTL2-0001    Since "Was the assessment completed" is equal to "No", a reason must be checked.
--->implies(COMPLET == 'No', REASON != null)

VTL2-0002    Since the reason that the assessment was not completed has been classified as "Other", "Specify" must be completed.
--->implies(REASON == 'Other', OTHSP != null)

VTL2-0002rev    Since "Specify" is completed, the reason that the assessment was not completed should be classified as "Other".
--->revimplies(REASON == 'Other', OTHSP != null)

VTL2-0101   Since "Was the assessment completed" is equal to "No", the rest of the form must be BLANK.
            --->implies(COMPLET == 'No', ASSDT == null && ASSTM == null && TEMP == null && RATE
            == null && RESP == null && SYS == null && DIA == null && WEIGHT == null)
VTL2-0003   Since "Was the assessment completed" is "Yes", "Date of Assessment" must be completed.
            --->implies(COMPLET == 'Yes', ASSDT != null)
VTL2-0004   Since "Was the assessment completed" is "Yes", "Time of Assessment" must be completed.
            --->implies(COMPLET == 'Yes', ASSTM != null)
VTL2-0005   Since "Was the assessment completed" is "Yes", "Temperature" must be completed.
            --->implies(COMPLET == 'Yes', TEMP != null)
VTL2-0006   Since "Was the assessment completed" is "Yes", "Heart Rate" must be completed.
            --->implies(COMPLET == 'Yes', RATE != null)
VTL2-0007   Since "Was the assessment completed" is "Yes", "Respirations" must be completed.
            --->implies(COMPLET == 'Yes', RESP != null)
VTL2-0008   Since "Was the assessment completed" is "Yes", "Systolic Blood Pressure" must be
            completed.
            --->implies(COMPLET == 'Yes', SYS != null)
VTL2-0009   Since "Was the assessment completed" is "Yes", "Diastolic Blood Pressure" must be
            completed.
            --->implies(COMPLET == 'Yes', DIA != null)
VTL2-0010   Since "Was the assessment completed" is "Yes", "Weight" must be completed.
            --->implies(COMPLET == 'Yes', WEIGHT != null)
VTL1-0203   Since "Was the assessment completed" is equal to "Yes", "Does the subject have new onset
            hypertension (per protocol)" must be completed.
            --->implies(COMPLET == 'Yes', HYPER != null)
VTL1-       Since "Does the subject have new onset hypertension (per protocol)" is completed, "Was the
0203rev     assessment completed" must be "Yes".
            --->revimplies(COMPLET == 'Yes', HYPER != null)
VTL2-0200   Since "Does the subject have new onset hypertension (per protocol)" is equal to "Yes", "What
            is the suspected reason" must be completed.
            --->implies(HYPER == 'Yes', REASON2 != null)
VTL2-       Since "What is the suspected reason" is completed, "Does the subject have new onset
0200rev     hypertension (per protocol)" must be "Yes".
            --->revimplies(HYPER == 'Yes', REASON2 != null)
VTL2-0201   Since "What is the suspected reason" is "Other", "Other, Specify" must be completed.
            --->implies(REASON2 == 'Other', OTHSP2 != null)
VTL2-       Since "Other, Specify" is completed, "What is the suspected reason" must be "Other"
0201rev
            --->revimplies(REASON2 == 'Other', OTHSP2 != null)
VTL2-0202   Since "Does the subject have new onset hypertension (per protocol)" is equal to "Yes", "Did
            this require treatment" must be completed.
            --->implies(HYPER == 'Yes', TREAT != null)
VTL2-       Since "Did this require treatment" is completed, "Does the subject have new onset
0202rev     hypertension (per protocol)" must be "Yes".
            --->revimplies(HYPER == 'Yes', TREAT != null)

## Datastream : XRAY

## Associated Forms : Chest Radiograph

| Variable Name | Variable Description & Valid Values | Variable Type | SAS Format | Required | Test Type | Range Check Low | Range Check High |
|---|---|---|---|---|---|---|---|
| XRAYDA | Date of X-Ray (Day) | number | 2. | yes | none | | |
| XRAYMO | Date of X-Ray (Month) | number | 2. | yes | none | | |
| XRAYYR | Date of X-Ray (Year) | number | 4. | yes | none | | |
| XRAYDT | Date of X-Ray | date | DATE9. | yes | range | 2006-10-01 | 2010-10-01 |
| XRAYHR | Time of X-Ray (Hour) | number | 2. | yes | none | | |
| XRAYMI | Time of X-Ray (Minute) | number | 2. | yes | none | | |
| XRAYTM | Time of X-Ray | time | TIME5. | yes | range | 00:00 | 23:59 |
| PULYN | Pulmonary infiltrate <br> ->No <br> ->Yes | text | $3. | yes | value | | |
| IFYES | Pulminary infiltrate present <br> ->Existing <br> ->New | text | $8. | no | value | | |
| COMM | Comments | text | $200. | no | none | | |
| COMMENT | Comments for page | text | $200. | no | none | | |

### Edit Checks

XRAY-0001    Since "Pulmonary Infiltrate" is equal to "Yes", "New" or "Existing" must be completed.
  --->implies(PULYN == 'Yes', IFYES != null)

XRAY-0001rev    Since "New" or "Existing" is completed, "Pulmonary Infiltrate" must be "Yes".

  --->revimplies(PULYN == 'Yes', IFYES != null)

XRAY-0002    Since "Pulmonary Infiltrate" is equal to "Yes", "Comments" cannot be BLANK.
  --->implies(PULYN == 'Yes', COMM != null)