

ALL.STUDYID=LUM001-305

ALL.USUBJID="LUM001-301-"||SUBJID

ALL.SUBJID=Subject ID from Form data

ALL.SITEID=SITEID from Form data

LUM001305 Study

Blank CRF Casebook

Study Published Date: 08-Nov-2018 Time: 04:43 Coordinated Universal Time (Server time)
Protocol: LUM001-305 Study Version: 8.3

ALL.VISITNUM: ALL.VISIT:

1 BASELINE
2 WEEK 1
3 WEEK 2
4 WEEK 3
5 WEEK 4
6 WEEK 6
7 WEEK 8
8 WEEK 10
9 WEEK 12
10 WEEK 16
11 WEEK 20
12 WEEK 24
13 WEEK 28
14 WEEK 32
15 WEEK 36
16 WEEK 40
17 WEEK 44
18 WEEK 48
19 POST-WEEK 48 FOLLOW-UP
20 RE-INITIATION DAY 0
21 RE-INITIATION WEEK 49
22 RE-INITIATION WEEK 50
23 RE-INITIATION WEEK 51
24 RE-INITIATION WEEK 52
25 WEEK 52

26 WEEK 56
27 WEEK 60
28 WEEK 64
29 WEEK 68
30 WEEK 72
31 WEEK 76
32 WEEK 80
33 WEEK 84
34 WEEK 88
35 WEEK 92
36 WEEK 96/ET
37 EXTENSION FOLLOW-UP
38 PA5 RE-INITIATION DAY -2
39 PA5 RE-INITIATION DAY 0
40 PA5 RE-INITIATION WEEK 1
41 PA5 RE-INITIATION WEEK 2
42 PA5 RE-INITIATION WEEK 3
43 PA5 RE-INITIATION WEEK 4
44 WEEK 100
45 WEEK 104
46 WEEK 108
47 WEEK 112
48 WEEK 116
49 WEEK 120
50 WEEK 124

51 WEEK 128
52 WEEK 132
53 WEEK 136
54 WEEK 140
55 WEEK 144/ET
56 WEEK 148
57 WEEK 152
58 WEEK 156
59 WEEK 160
60 WEEK 164
61 WEEK 168
62 WEEK 172
63 WEEK 176
64 WEEK 180
65 WEEK 184
66 WEEK 188
67 WEEK 192
68 WEEK 196
69 WEEK 200
70 WEEK 204
71 WEEK 208
72 WEEK 212
73 WEEK 216
74 WEEK 220

Time & Events Schedule

Legend: Expected Expected, Restricted Optional Optional, Restricted

| Name | Assessment | Day 0 | Week 1 | Week 2 | Week 3 | Week 4 | Week 6 | Week 8 | Week 10 | Week 12 | Week 16 |
|-------|--|-------|--------|--------|--------|--------|--------|--------|---------|---------|---------|
| DM | Informed Consent/Demography | | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | | |
| MH | Medical History | | | | | | | | | | |
| TC | Telephone Contact | | | | | | | | | | |
| VS | Vital Signs | | | | | | | | | | |
| LB2 | Clinical Laboratory Tests 2 | | | | | | | | | | |
| QS1 | Scratch Scale | | | | | | | | | | |
| PREG2 | Urine Pregnancy Test | | | | | | | | | | |
| EX | Study Drug Administration | | | | | | | | | | |
| SDC | Study Drug Compliance | | | | | | | | | | |
| DAD | Dose Adjustment | | | | | | | | | | |
| PE2 | Physical Examination2 | | | | | | | | | | |
| LB3 | Clinical Laboratory Tests 3 | | | | | | | | | | |
| QS2 | Questionnaires 2 | | | | | | | | | | |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | | | | | | | | | |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | | | | | | | | | |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | | | | | | | | | |

| Name | Assessment | Day 0 | Week 1 | Week 2 | Week 3 | Week 4 | Week 6 | Week 8 | Week 10 | Week 12 | Week 16 |
|------|---|-------|--------|--------|--------|--------|--------|--------|---------|---------|---------|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | | | | | | | | | | |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | | | | | | | | | |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | | | | | | | | | |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | | | | | | | | | |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | | | | | | | | | |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | | | | | | | | | |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | | | | | | | | | |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | | | | | | | | | |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | | | | | | | | | |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | | | | | | | | | |

| Name | Assessment | Day 0 | Week 1 | Week 2 | Week 3 | Week 4 | Week 6 | Week 8 | Week 10 | Week 12 | Week 16 |
|------|--|-------|--------|--------|--------|--------|--------|--------|---------|---------|---------|
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | | | | | | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | | | | | | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | | | | | | | | |
| QS3O | Family Impact Module PARENT REPORT | | | | | | | | | | |
| QS7 | Xanthoma Scale | | | | | | | | | | |
| QS5 | Caregiver Impression of Change | | | | | | | | | | |
| DS | Subject Summary | | | | | | | | | | |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | | | | | | | | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Day 0 | Week 1 | Week 2 | Week 3 | Week 4 | Week 6 | Week 8 | Week 10 | Week 12 | Week 16 |
|--------|-----------------------------|-------|--------|--------|--------|--------|--------|--------|---------|---------|---------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
| Comp | Completed | | | | | | | | | | |





















| Name | Assessment | Week 20 | Week 24 | Week 28 | Week 32 | Week 36 | Week 40 | Week 44 | Week 48 | Post-Week 48 Follow-up | Study Completion (Complete) |
|-------|--|---------|---------|---------|---------|---------|---------|---------|---------|------------------------|-----------------------------|
| DM | Informed Consent/Demography | | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | | |
| MH | Medical History | | | | | | | | | | |
| TC | Telephone Contact | ✓ | | ✓ | ✓ | | ✓ | | | ✓ | |
| VS | Vital Signs | | ✓ | | | ✓ | | | ✓ | | |
| LB2 | Clinical Laboratory Tests 2 | | ✓ | | | ✓ | | | ✓ | | |
| QS1 | Scratch Scale | | ✓ | | | ✓ | | | ✓ | | |
| PREG2 | Urine Pregnancy Test | | ✓ | | | ✓ | | | ✓ | | |
| EX | Study Drug Administration | | | | | | | | | | |
| SDC | Study Drug Compliance | | ✓ | | | ✓ | | ✓ | ✓ | | |
| DAD | Dose Adjustment | | | | | | | | | | |
| PE2 | Physical Examination2 | | ✓ | | | ✓ | | | ✓ | | |
| LB3 | Clinical Laboratory Tests 3 | | | | | | | | | | |
| QS2 | Questionnaires 2 | | ✓ | | | | | | ✓ | | |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | ✓ | | | | | | ✓ | | |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | ✓ | | | | | | ✓ | | |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | ✓ | | | | | | ✓ | | |

| Name | Assessment | Week 20 | Week 24 | Week 28 | Week 32 | Week 36 | Week 40 | Week 44 | Week 48 | Post-Week 48 Follow-up | Study Completion (Complete) |
|------|---|---------|---------|---------|---------|---------|---------|---------|---------|------------------------|-----------------------------|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | | | | | | | | | | |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | | | | | | | | | |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | | | | | | | | | |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | | | | | | | | | |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | | | | | | | | | |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | | | | | | | | | |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | | | | | | | | | |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | | | | | | | | | |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | | | | | | | | | |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | | | | | | | | | |

| Name | Assessment | Week 20 | Week 24 | Week 28 | Week 32 | Week 36 | Week 40 | Week 44 | Week 48 | Post-Week 48 Follow-up | Study Completion (Complete) |
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| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | | | | | | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | | | | | | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | | | | | | | | |
| QS3O | Family Impact Module PARENT REPORT | | | | | | | | | | |
| QS7 | Xanthoma Scale | | | | | | | | | | |
| QS5 | Caregiver Impression of Change | | | | | | | | | | |
| DS | Subject Summary | | | | | | | | | | |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | | | | | | | | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Week 20 | Week 24 | Week 28 | Week 32 | Week 36 | Week 40 | Week 44 | Week 48 | Post-Week 48 Follow-up | Study Completion (Complete) |
|--------|-----------------------------|---------|---------|---------|---------|---------|---------|---------|---------|------------------------|-----------------------------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
| Comp | Completed | | | | | | | | | | |

| Name | Assessment | Study Completion (Discontinue) | Re-Initiation Day 0 | Re-Initiation Week 49 | Re-Initiation Week 50 | Re-Initiation Week 51 | Re-Initiation Week 52 | Week 56 | Week 60 | Week 64 |
|-------|---|-----------------------------------|------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------------|------------|------------|
| DM | Informed Consent/Demography | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | |
| MH | Medical History | | | | | | | | | |
| TC | Telephone Contact | | | ✓ | | | ✓ | ✓ | | ✓ |
| VS | Vital Signs | | ✓ | | ✓ | | ✓ | | ✓ | |
| LB2 | Clinical Laboratory Tests 2 | | | | ✓ | | ✓ | | | |
| QS1 | Scratch Scale | | ✓ | | ✓ | | ✓ | | ✓ | |
| PREG2 | Urine Pregnancy Test | | ✓ | | ✓ | | ✓ | | ✓ | |
| EX | Study Drug Administration | | | | | | | | | |
| SDC | Study Drug Compliance | | | | ✓ | | ✓ | | ✓ | |
| DAD | Dose Adjustment | | | | | | | | | |
| PE2 | Physical Examination2 | | ✓ | | | | | | ✓ | |
| LB3 | Clinical Laboratory Tests 3 | | | | | | | | | |
| QS2 | Questionnaires 2 | | ✓ | | | | | | ✓ | |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | ✓ | | | | | | ✓ | |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | ✓ | | | | | | ✓ | |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | ✓ | | | | | | ✓ | |

| Name | Assessment | Study Completion (Discontinue) | Re-Initiation Day 0 | Re-Initiation Week 49 | Re-Initiation Week 50 | Re-Initiation Week 51 | Re-Initiation Week 52 | Week 52 | Week 56 | Week 60 | Week 64 |
|------|--|-----------------------------------|---|--------------------------|--------------------------|--------------------------|--------------------------|------------|------------|---|------------|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | |  | | | | | | |  | |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | |  | | | | | | |  | |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | |  | | | | | | |  | |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | |  | | | | | | |  | |
| QS3F | Pediatric QOL Inventory CHILD REPORT | |  | | | | | | |  | |
| QS3G | Pediatric QOL Inventory TEEN REPORT | |  | | | | | | |  | |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | |  | | | | | | |  | |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | |  | | | | | | |  | |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | |  | | | | | | |  | |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | |  | | | | | | |  | |

| Name | Assessment | Study Completion (Discontinue) | Re-Initiation Day 0 | Re-Initiation Week 49 | Re-Initiation Week 50 | Re-Initiation Week 51 | Re-Initiation Week 52 | Week 52 | Week 56 | Week 60 | Week 64 |
|------|---|-----------------------------------|------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------------|------------|------------|------------|
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | | | | | | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | | | | | | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | | | | | | | | |
| QS3O | Family Impact Module PARENT REPORT | | | | | | | | | | |
| QS7 | Xanthoma Scale | | | | | | | | | | |
| QS5 | Caregiver Impression of Change | | | | | | | | | | |
| DS | Subject Summary | | | | | | | | | | |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | | | | | | | | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Study Completion (Discontinue) | Re-Initiation Day 0 | Re-Initiation Week 49 | Re-Initiation Week 50 | Re-Initiation Week 51 | Re-Initiation Week 52 | Week 52 | Week 56 | Week 60 | Week 64 |
|--------|--------------------------------|-----------------------------------|------------------------|--------------------------|--------------------------|--------------------------|--------------------------|------------|------------|------------|------------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
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











| Name | Assessment | Week 68 | Week 72 | Week 76 | Week 80 | Week 84 | Week 88 | Week 92 | Week 96_ET | 30 Day Follow-up | Extension Completion |
|-------|--|---------|---------|---------|---------|---------|---------|---------|------------|------------------|----------------------|
| DM | Informed Consent/Demography | | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | | |
| MH | Medical History | | | | | | | | | | |
| TC | Telephone Contact | ✓ | | ✓ | ✓ | | ✓ | | | ✓ | |
| VS | Vital Signs | | ✓ | | | ✓ | | | ✓ | | |
| LB2 | Clinical Laboratory Tests 2 | | | | | | | | | | |
| QS1 | Scratch Scale | | ✓ | | | ✓ | | | ✓ | | |
| PREG2 | Urine Pregnancy Test | | ✓ | | | ✓ | | | ✓ | | |
| EX | Study Drug Administration | | | | | | | | | | |
| SDC | Study Drug Compliance | | ✓ | | | ✓ | | | ✓ | | |
| DAD | Dose Adjustment | | | | | | | | | | |
| PE2 | Physical Examination2 | | ✓ | | | ✓ | | | ✓ | | |
| LB3 | Clinical Laboratory Tests 3 | | | | | | | | | | |
| QS2 | Questionnaires 2 | | ✓ | | | ✓ | | | ✓ | | |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | ✓ | | | ✓ | | | ✓ | | |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | ✓ | | | ✓ | | | ✓ | | |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | ✓ | | | ✓ | | | ✓ | | |

| Name | Assessment | Week 68 | Week 72 | Week 76 | Week 80 | Week 84 | Week 88 | Week 92 | Week 96_ET | 30 Day Follow-up | Extension Completion |
|------|---|---------|---------|---------|---------|---------|---------|---------|------------|------------------|----------------------|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | ✓ | ✓ | | | ✓ | | | ✓ | | |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | ✓ | | | ✓ | | | ✓ | | |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | ✓ | | | ✓ | | | ✓ | | |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | ✓ | | | ✓ | | | ✓ | | |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | ✓ | | | ✓ | | | ✓ | | |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | ✓ | | | ✓ | | | ✓ | | |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | ✓ | | | ✓ | | | ✓ | | |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | ✓ | | | ✓ | | | ✓ | | |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | ✓ | | | ✓ | | | ✓ | | |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | ✓ | | | ✓ | | | ✓ | | |

| Name | Assessment | Week 68 | Week 72 | Week 76 | Week 80 | Week 84 | Week 88 | Week 92 | Week 96_ET | 30 Day Follow-up | Extension Completion |
|------|--|---------|---------|---------|---------|---------|---------|---------|------------|------------------|----------------------|
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | ✓ | | | ✓ | | | ✓ | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | ✓ | | | ✓ | | | ✓ | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | ✓ | | | ✓ | | | ✓ | | |
| QS3O | Family Impact Module PARENT REPORT | | ✓ | | | ✓ | | | ✓ | | |
| QS7 | Xanthoma Scale | | ✓ | | | ✓ | | | ✓ | | |
| QS5 | Caregiver Impression of Change | | ✓ | | | ✓ | | | ✓ | | |
| DS | Subject Summary | | | | | | | | | | ✓ |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | ✓ | | | ✓ | | | ✓ | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Week 68 | Week 72 | Week 76 | Week 80 | Week 84 | Week 88 | Week 92 | Week 96_ET | 30 Day Follow-up | Extension Completion |
|--------|-----------------------------|---------|---------|---------|---------|---------|---------|---------|------------|------------------|----------------------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
| Comp | Completed | | | | | | | | | | |

| Name | Assessment | Long Term Optional Treatment | PA5 Re-Initiation Day -2 | PA5 Re-Initiation Day 0 | PA5 Re-Initiation Week 1 | PA5 Re-Initiation Week 2 | PA5 Re-Initiation Week 3 | PA5 Re-Initiation Week 4 | Week 100 | Week 104 | Week 108 |
|-------|---|------------------------------|--------------------------|-------------------------|--------------------------|--------------------------|--------------------------|--------------------------|----------|----------|----------|
| DM | Informed Consent/Demography | | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | | |
| MH | Medical History | | | | | | | | | | |
| TC | Telephone Contact | | | | ✓ | | ✓ | | ✓ | ✓ | |
| VS | Vital Signs | | ✓ | ✓ | | ✓ | | ✓ | | | ✓ |
| LB2 | Clinical Laboratory Tests 2 | | | | | | | | | | |
| QS1 | Scratch Scale | | | ✓ | | ✓ | | ✓ | | | ✓ |
| PREG2 | Urine Pregnancy Test | | | ✓ | | ✓ | | ✓ | | | ✓ |
| EX | Study Drug Administration | | | | | | | | | | |
| SDC | Study Drug Compliance | | | | | ✓ | | ✓ | | | ✓ |
| DAD | Dose Adjustment | | | | | | | | | | |
| PE2 | Physical Examination2 | | ✓ | ✓ | | ✓ | | ✓ | | | ✓ |
| LB3 | Clinical Laboratory Tests 3 | | | ✓ | | ✓ | | ✓ | | | ✓ |
| QS2 | Questionnaires 2 | | | ✓ | | | | | | | ✓ |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | | ✓ | | | | | | | ✓ |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | | ✓ | | | | | | | ✓ |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | | ✓ | | | | | | | ✓ |

| Name | Assessment | Long Term Optional Treatment | PA5 Re- Initiation Day -2 | PA5 Re- Initiation Day 0 | PA5 Re- Initiation Week 1 | PA5 Re- Initiation Week 2 | PA5 Re- Initiation Week 3 | PA5 Re- Initiation Week 4 | Week 100 | Week 104 | Week 108 |
|------|--|------------------------------------|---------------------------------|---|---------------------------------|---------------------------------|---------------------------------|---------------------------------|-------------|-------------|---|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | | |  | | | | | | |  |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | |  | | | | | | |  |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | |  | | | | | | |  |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | |  | | | | | | |  |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | |  | | | | | | |  |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | |  | | | | | | |  |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | |  | | | | | | |  |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | |  | | | | | | |  |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | |  | | | | | | |  |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | |  | | | | | | |  |

| Name | Assessment | Long Term Optional Treatment | PA5 Re-Initiation Day - 2 | PA5 Re-Initiation Day 0 | PA5 Re-Initiation Week 1 | PA5 Re-Initiation Week 2 | PA5 Re-Initiation Week 3 | PA5 Re-Initiation Week 4 | Week 100 | Week 104 | Week 108 |
|------|--|------------------------------|---------------------------|-------------------------|--------------------------|--------------------------|--------------------------|--------------------------|----------|----------|----------|
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | | | | | | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | | | | | | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | | | | | | | | |
| QS3O | Family Impact Module PARENT REPORT | | | | | | | | | | |
| QS7 | Xanthoma Scale | | | | | | | | | | |
| QS5 | Caregiver Impression of Change | | | | | | | | | | |
| DS | Subject Summary | | | | | | | | | | |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | | | | | | | | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Long Term Optional Treatment | PA5 Re- Initiation Day -2 | PA5 Re- Initiation Day 0 | PA5 Re- Initiation Week 1 | PA5 Re- Initiation Week 2 | PA5 Re- Initiation Week 3 | PA5 Re- Initiation Week 4 | Week 100 | Week 104 | Week 108 |
|--------|--------------------------------|---------------------------------|------------------------------|-----------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|-------------|-------------|-------------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
| Comp | Completed | | | | | | | | | | |

| Name | Assessment | Week 112 | Week 116 | Week 120 | Week 124 | Week 128 | Week 132 | Week 136 | Week 140 | Week 144_ET | Week 148 |
|-------|--|----------|----------|----------|----------|----------|----------|----------|----------|-------------|----------|
| DM | Informed Consent/Demography | | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | | |
| MH | Medical History | | | | | | | | | | |
| TC | Telephone Contact | ✓ | ✓ | | ✓ | ✓ | | ✓ | | | ✓ |
| VS | Vital Signs | | | ✓ | | | ✓ | | | ✓ | ✓ |
| LB2 | Clinical Laboratory Tests 2 | | | | | | | | | ✓ | ✓ |
| QS1 | Scratch Scale | | | ✓ | | | ✓ | | | ✓ | ✓ |
| PREG2 | Urine Pregnancy Test | | | ✓ | | | ✓ | | | ✓ | ✓ |
| EX | Study Drug Administration | | | | | | | | | | |
| SDC | Study Drug Compliance | | | ✓ | | | ✓ | | ✓ | | |
| DAD | Dose Adjustment | | | | | | | | | | |
| PE2 | Physical Examination2 | | | ✓ | | | ✓ | | | ✓ | ✓ |
| LB3 | Clinical Laboratory Tests 3 | | | ✓ | | | ✓ | | | | |
| QS2 | Questionnaires 2 | | | | | | | | | | ✓ |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | | | | | | | ✓ | ✓ | ✓ |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | | | | | | | ✓ | ✓ | ✓ |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | | | | | | | ✓ | ✓ | ✓ |

| Name | Assessment | Week 112 | Week 116 | Week 120 | Week 124 | Week 128 | Week 132 | Week 136 | Week 140 | Week 144_ET | Week 148 |
|------|---|----------|----------|----------|----------|----------|----------|----------|----------|-------------|----------|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | | | | | | | | | 👍 | 👍 |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | | | | | | | | 👍 | 👍 |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | | | | | | | | 👍 | 👍 |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | | | | | | | | 👍 | 👍 |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | | | | | | | | 👍 | 👍 |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | | | | | | | | 👍 | 👍 |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | | | | | | | | 👍 | 👍 |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | | | | | | | | 👍 | 👍 |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | | | | | | | | 👍 | 👍 |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | | | | | | | | 👍 | 👍 |

| Name | Assessment | Week 112 | Week 116 | Week 120 | Week 124 | Week 128 | Week 132 | Week 136 | Week 140 | Week 144_ET | Week 148 |
|------|--|----------|----------|----------|----------|----------|----------|----------|----------|-------------|----------|
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | | | | | | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | | | | | | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | | | | | | | | |
| QS3O | Family Impact Module PARENT REPORT | | | | | | | | | | |
| QS7 | Xanthoma Scale | | | | | | | | | | |
| QS5 | Caregiver Impression of Change | | | | | | | | | | |
| DS | Subject Summary | | | | | | | | | | |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | | | | | | | | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Week 112 | Week 116 | Week 120 | Week 124 | Week 128 | Week 132 | Week 136 | Week 140 | Week 144_ET | Week 148 |
|--------|-----------------------------|----------|----------|----------|----------|----------|----------|----------|----------|-------------|----------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
| Comp | Completed | | | | | | | | | | |

| Name | Assessment | Long Term Optional Treatment Completion | Long Term Optional Treatment 2 | Week 152 | Week 156 | Week 160 | Week 164 | Week 168 | Week 172 | Week 176 | Week 180 |
|-------|--|---|--------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|
| DM | Informed Consent/Demography | | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | | |
| MH | Medical History | | | | | | | | | | |
| TC | Telephone Contact | | | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | |
| VS | Vital Signs | | | | ✓ | | | ✓ | | | ✓ |
| LB2 | Clinical Laboratory Tests 2 | | | | | | | | | | |
| QS1 | Scratch Scale | | | | ✓ | | | | | | ✓ |
| PREG2 | Urine Pregnancy Test | | | | ✓ | | | | | | ✓ |
| EX | Study Drug Administration | | | | ✓ | | | ✓ | | | ✓ |
| SDC | Study Drug Compliance | | | | ✓ | | | ✓ | | | ✓ |
| DAD | Dose Adjustment | | | | | | | | | | |
| PE2 | Physical Examination2 | | | | ✓ | | | ✓ | | | ✓ |
| LB3 | Clinical Laboratory Tests 3 | | | | ✓ | | | ✓ | | | ✓ |
| QS2 | Questionnaires 2 | | | | ✓ | | | | | | |
| QS3P | Pediatric QOL Inventory PARENT RPT - INFANT 1-12M | | | | ✓ | | | | | | |
| QS3Q | Pediatric QOL Inventory PARENT RPT - INFANT 13-24M | | | | ✓ | | | | | | |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | | | ✓ | | | | | | |

| Name | Assessment | Long Term Optional Treatment Completion | Long Term Optional Treatment 2 | Week 152 | Week 156 | Week 160 | Week 164 | Week 168 | Week 172 | Week 176 | Week 180 |
|------|--|--|-----------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | | | | | | | | | | |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | | | | | | | | | |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | | | | | | | | | |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | | | | | | | | | |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | | | | | | | | | |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | | | | | | | | | |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | | | | | | | | | |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | | | | | | | | | |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | | | | | | | | | |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | | | | | | | | | |

| Name | Assessment | Long Term Optional Treatment Completion | Long Term Optional Treatment 2 | Week 152 | Week 156 | Week 160 | Week 164 | Week 168 | Week 172 | Week 176 | Week 180 |
|------|--|---|--------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | | | | | | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | | | | | | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | | | | | | | | |
| QS3O | Family Impact Module PARENT REPORT | | | | | | | | | | |
| QS7 | Xanthoma Scale | | | | | | | | | | |
| QS5 | Caregiver Impression of Change | | | | | | | | | | |
| DS | Subject Summary | | | | | | | | | | |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | | | | | | | | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Long Term Optional Treatment Completion | Long Term Optional Treatment 2 | Week 152 | Week 156 | Week 160 | Week 164 | Week 168 | Week 172 | Week 176 | Week 180 |
|--------|-----------------------------|---|--------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
| Comp | Completed | | | | | | | | | | |












| Name | Assessment | Week 184 | Week 188 | Week 192 | Week 196 | Week 200 | Week 204 | Week 208 | Week 212 | Week 216 | Week 220 |
|-------|--|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| DM | Informed Consent/Demography | | | | | | | | | | |
| IE1 | Inclusion/Exclusion Criteria | | | | | | | | | | |
| MH | Medical History | | | | | | | | | | |
| TC | Telephone Contact | | | | | | | | | | |
| VS | Vital Signs | | | | | | | | | | |
| LB2 | Clinical Laboratory Tests 2 | | | | | | | | | | |
| QS1 | Scratch Scale | | | | | | | | | | |
| PREG2 | Urine Pregnancy Test | | | | | | | | | | |
| EX | Study Drug Administration | | | | | | | | | | |
| SDC | Study Drug Compliance | | | | | | | | | | |
| DAD | Dose Adjustment | | | | | | | | | | |
| PE2 | Physical Examination2 | | | | | | | | | | |
| LB3 | Clinical Laboratory Tests 3 | | | | | | | | | | |
| QS2 | Questionnaires 2 | | | | | | | | | | |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | | | | | | | | | |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | | | | | | | | | |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | | | | | | | | | |

| Name | Assessment | Week 184 | Week 188 | Week 192 | Week 196 | Week 200 | Week 204 | Week 208 | Week 212 | Week 216 | Week 220 |
|------|---|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | | | | | | | | | ✔ | ✔ |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | | | | | | | | ✔ | ✔ |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | | | | | | | | ✔ | ✔ |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | | | | | | | | ✔ | ✔ |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | | | | | | | | ✔ | ✔ |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | | | | | | | | ✔ | ✔ |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | | | | | | | | ✔ | ✔ |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | | | | | | | | ✔ | ✔ |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | | | | | | | | ✔ | ✔ |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | | | | | | | | ✔ | ✔ |

| Name | Assessment | Week 184 | Week 188 | Week 192 | Week 196 | Week 200 | Week 204 | Week 208 | Week 212 | Week 216 | Week 220 |
|------|--|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | | | | | | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | | | | | | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | | | | | | | | |
| QS3O | Family Impact Module PARENT REPORT | | | | | | | | | | |
| QS7 | Xanthoma Scale | | | | | | | | | | |
| QS5 | Caregiver Impression of Change | | | | | | | | | | |
| DS | Subject Summary | | | | | | | | | | |
| PRE | Protocol Extension | | | | | | | | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | | | | | | | | |
| MH2 | Medical History 2 | | | | | | | | | | |
| LB | Clinical Laboratory Tests | | | | | | | | | | |
| PRE2 | Long Term Optional Treatment | | | | | | | | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | | | | | | | | |
| DS2 | Subject Summary 2 | | | | | | | | | | |
| PRE3 | Long Term Optional Treatment 2 | | | | | | | | | | |
| CM | Concomitant Medications | | | | | | | | | | |
| EX2 | Study Drug Administration 2 | | | | | | | | | | |

| Name | Assessment | Week 184 | Week 188 | Week 192 | Week 196 | Week 200 | Week 204 | Week 208 | Week 212 | Week 216 | Week 220 |
|--------|-----------------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| AE | Adverse Events | | | | | | | | | | |
| SDA1 | Study Drug Accountability 1 | | | | | | | | | | |
| Scr | Screened | | | | | | | | | | |
| Enroll | Enrolled | | | | | | | | | | |
| Fail | Failed | | | | | | | | | | |
| Disc | Discontinued | | | | | | | | | | |
| Comp | Completed | | | | | | | | | | |

| Name | Assessment | Long Term Optional Treatment Completion 2 | Common | Unscheduled |
|-------|---|---|--------|-------------|
| DM | Informed Consent/Demography | | | |
| IE1 | Inclusion/Exclusion Criteria | | | |
| MH | Medical History | | | |
| TC | Telephone Contact | | | ✔ |
| VS | Vital Signs | | | ✔ |
| LB2 | Clinical Laboratory Tests 2 | | | ✔ |
| QS1 | Scratch Scale | | | ✔ |
| PREG2 | Urine Pregnancy Test | | | ✔ |
| EX | Study Drug Administration | | | ✔ |
| SDC | Study Drug Compliance | | | ✔ |
| DAD | Dose Adjustment | | | |
| PE2 | Physical Examination2 | | | ✔ |
| LB3 | Clinical Laboratory Tests 3 | | | |
| QS2 | Questionnaires 2 | | | |
| QS3P | Pediatric QOL Inventory PARENT RPT-INFANT 1-12M | | | |
| QS3Q | Pediatric QOL Inventory PARENT RPT-INFANT 13-24M | | | |
| QS3A | Pediatric QOL Inventory PARENT RPT (TODDLERS) | | | |
| QS3B | Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) | | | |
| QS3C | Pediatric QOL Inventory PARENT RPT (CHILDREN) | | | |
| QS3D | Pediatric QOL Inventory PARENT RPT (TEENS) | | | |
| QS3E | Pediatric QOL Inventory YOUNG CHILD REPORT | | | |
| QS3F | Pediatric QOL Inventory CHILD REPORT | | | |
| QS3G | Pediatric QOL Inventory TEEN REPORT | | | |
| QS3H | Multidimensional Fatigue Scale PARENT for TODDLERS | | | |
| QS3I | Multidimensional Fatigue Scale PARENT (YOUNG CHILD) | | | |
| QS3J | Multidimensional Fatigue Scale PARENT for CHILDREN | | | |
| QS3K | Multidimensional Fatigue Scale PARENT for TEENS | | | |
| QS3L | Multidimensional Fatigue Scale YOUNG CHILD | | | |
| QS3M | Multidimensional Fatigue Scale CHILD | | | |
| QS3N | Multidimensional Fatigue Scale TEEN | | | |

| Name | Assessment | Long Term Optional Treatment Completion 2 | Common | Unscheduled |
|--------|------------------------------------|---|--|---|
| QS30 | Family Impact Module PARENT REPORT | | | |
| QS7 | Xanthoma Scale | | | |
| QS5 | Caregiver Impression of Change | | | |
| DS | Subject Summary | | | |
| PRE | Protocol Extension | | | |
| IE2 | Inclusion/Exclusion Criteria 2 | | | |
| MH2 | Medical History 2 | | | |
| LB | Clinical Laboratory Tests | | |  |
| PRE2 | Long Term Optional Treatment | | | |
| IE3 | Inclusion/Exclusion Criteria 3 | | | |
| DS2 | Subject Summary 2 |  | | |
| PRE3 | Long Term Optional Treatment 2 | | | |
| CM | Concomitant Medications | |  | |
| EX2 | Study Drug Administration 2 | |  | |
| AE | Adverse Events | |  | |
| SDA1 | Study Drug Accountability 1 | |  | |
| Scr | Screened | |  | |
| Enroll | Enrolled | |  | |
| Fail | Failed | |  | |
| Disc | Discontinued | |  | |
| Comp | Completed | |  | |

| Event Labels | Names |
|--------------------------------|------------------|
| Day 0 | Day0 |
| Week 1 | Week1 |
| Week 2 | Week2 |
| Week 3 | Week3 |
| Week 4 | Week4 |
| Week 6 | Week6 |
| Week 8 | Week8 |
| Week 10 | Week10 |
| Week 12 | Week12 |
| Week 16 | Week16 |
| Week 20 | Week20 |
| Week 24 | Week24 |
| Week 28 | Week28 |
| Week 32 | Week32 |
| Week 36 | Week36 |
| Week 40 | Week40 |
| Week 44 | Week44 |
| Week 48 | Week48_ET |
| Post-Week 48 Follow-up | FollowUp |
| Study Completion (Complete) | StudyCompletion |
| Study Completion (Discontinue) | Study_Completion |
| Re-Initiation Day 0 | RID0 |
| Re-Initiation Week 49 | RIW49 |
| Re-Initiation Week 50 | RIW50 |
| Re-Initiation Week 51 | RIW51 |
| Re-Initiation Week 52 | RIW52 |
| Week 52 | Week52 |
| Week 56 | Week56 |
| Week 60 | Week60 |
| Week 64 | Week64 |
| Week 68 | Week68 |
| Week 72 | Week72 |
| Week 76 | Week76 |
| Week 80 | Week80 |
| Week 84 | Week84 |
| Week 88 | Week88 |
| Week 92 | Week92 |
| Week 96_ET | Week96_ET |
| 30 Day Follow-up | 30D_FU |
| Extension Completion | EC |
| Long Term Optional Treatment | PA5 |
| PA5 Re-Initiation Day -2 | PA5_RID2 |
| PA5 Re-Initiation Day 0 | PA5_RID0 |
| PA5 Re-Initiation Week 1 | PA5_RIW1 |
| PA5 Re-Initiation Week 2 | PA5_RIW2 |
| PA5 Re-Initiation Week 3 | PA5_RIW3 |
| PA5 Re-Initiation Week 4 | PA5_RIW4 |
| Week 100 | W100 |

| Event Labels | Names |
|---|-------------|
| Week 104 | W104 |
| Week 108 | W108 |
| Week 112 | W112 |
| Week 116 | W116 |
| Week 120 | W120 |
| Week 124 | W124 |
| Week 128 | W128 |
| Week 132 | W132 |
| Week 136 | W136 |
| Week 140 | W140 |
| Week 144_ET | W144_ET |
| Week 148 | W148 |
| Long Term Optional Treatment Completion | PA5_EC |
| Long Term Optional Treatment 2 | PA6 |
| Week 152 | W152 |
| Week 156 | W156 |
| Week 160 | W160 |
| Week 164 | W164 |
| Week 168 | W168 |
| Week 172 | W172 |
| Week 176 | W176 |
| Week 180 | W180 |
| Week 184 | W184 |
| Week 188 | W188 |
| Week 192 | W192 |
| Week 196 | W196 |
| Week 200 | W200 |
| Week 204 | W204 |
| Week 208 | W208 |
| Week 212 | W212 |
| Week 216 | W216 |
| Week 220 | W220 |
| Long Term Optional Treatment Completion 2 | PA6_EC |
| Common | Common |
| Unscheduled | Unscheduled |

DM=Demographics**Informed Consent/Demography (DM)**

DS.DSCAT="PROTOCOL MILESTONE"
 DS.DSTERM and DS.DECOD="INFORMED
 CONSENT OBTAINED"

INFORMED CONSENT

1. Date Parental Informed Consent signed **DM.RFICDTC** **DS.DSSTDTC** dd-mmm-yyyy
2. Young Adult Consent Not Applicable **SUPPDS.QVAL where SUPPDS.QNAM=ICYANA**
- **3. Date Young Adult Consent signed **SUPPDS.QVAL where SUPPDS.QNAM=ICYADAT**
4. Assent Not Applicable **SUPPDS.QVAL where SUPPDS.QNAM=ICANA**
- **5. Date Assent signed **SUPPDS.QVAL where SUPPDS.QNAM=ICADAT**

DEMOGRAPHY

6. Birth date **DM.BRTHDTC** dd-mmm-yyyy
- *6.1. Age Read Only: Derived **DM.AGE**
- *6.2. Age Units Read Only: Derived **DM.AGEU**
7. Sex List: SEX **DM.SEX**
- *7.1. Country Read Only: Derived **DM.COUNTRY**
8. Weight (kg) **[NOT SUBMITTED]**
- *8.1. Weight Units Li **[NOT SUBMITTED]**
- * Hidden Question
- ** Conditional Question

| List:NA | |
|----------------|-------|
| Label | Value |
| [Blank] | |
| Not Applicable | NA |

| List:SEX | |
|----------|-------|
| Label | Value |
| [Blank] | |
| Male | M |
| Female | F |

| List:WEIGHT | |
|-------------|-------|
| Label | Value |
| kg | kg |

IE=Inclusion/Exclusion Criteria Not Met**DM=Demographics****Inclusion/Exclusion Criteria (IE1)**

| 1. | Protocol Criteria Version | [NOT SUBMITTED] | | | |
|-------------|--|--------------------------------------|---------|---------------|---|
| 2. | Did the subject meet all eligibility criteria? | SUPPDM.QVAL where SUPPDM.QNAM=TIVERS | | | |
| 3. | Inclusion/Exclusion Criteria | | | | |
| 3.R. | Criterion Type | Criterion not met | Specify | Approval date | Sponsor approval? |
| 3.R.1. | Criterion Type | | | | List: IE 6 IE.IECAT |
| 3.R.2. | Criterion not met | | | | List: IENUM 6 IE.IETESTCD |
| 3.R.3. | Specify | | | | IE.IETESTCD |
| **3.R.4. | Date of approval | | | | SUPPIE.QVAL where SUPPIE.QNAM=IEAPPDAT m-yyyy |
| 3.R.5. | Lumena approval received? | | | | SUPPIE.QVAL where SUPPIE.QNAM=IEAPPR |
| Add New Row | | | | | |

** Conditional Question

| List:TIVERS | | List:YES_NO | | List:IE | |
|-------------------------|-------------------------|-------------|-------|-----------|-------|
| Label | Value | Label | Value | Label | Value |
| [Blank] | | [Blank] | | [Blank] | |
| Original - 14APR2013 | Original - 14APR2013 | Yes | Y | Inclusion | 1 |
| Amendment 1 - 29JAN2015 | Amendment 1 - 29JAN2015 | No | N | Exclusion | 2 |
| Amendment 2 - 12FEB2015 | Amendment 2 - 12FEB2015 | | | | |
| Amendment 4 - 27APR2016 | Amendment 4 - 27APR2016 | | | | |
| Amendment 5 - 13NOV2017 | Amendment 5 - 13NOV2017 | | | | |

| List:IENUM | |
|------------|-------|
| Label | Value |
| [Blank] | |
| 1 | 1 |
| 2 | 2 |
| 3 | 3 |
| 4 | 4 |
| 5 | 5 |
| 6 | 6 |
| 7 | 7 |
| 8 | 8 |
| 9 | 9 |
| 10 | 10 |

MH=Medical History

Medical History (MH)

MHCAT="GENERAL MEDICAL HISTORY SCREENING"

1. Any new significant medical history?

List: YES_NO 6 [NOT SUBMITTED]

2. Medical History

| 2.R. | Verbatim Term | Start Date (Day) | Start Date (Month) | Start Date (Year) | Ongoing |
|------------|--------------------|------------------|--------------------|-------------------|---|
| 2.R.1. | Verbatim term | | | | MH.MHTERM |
| *2.R.1.1. | MHTERM_Enc_TERM | | | | MH.MHLLT ed |
| *2.R.1.2. | MHTERM_Enc_CODE | | | | MH.MHLLTCD ed |
| *2.R.1.3. | MHTERM_Enc_TYPE | | | | [NOT SUBMITTED] |
| *2.R.1.4. | MHTERM_Enc_CAT1 | | | | MH.MHBODSYS, MH.MHBDSYCD, MH.MHSOC, MH.MHSOCCD |
| *2.R.1.5. | MHTERM_Enc_CAT2 | | | | MH.MHHLGT, MH.MHHLGTCD |
| *2.R.1.6. | MHTERM_Enc_CAT3 | | | | MH.MHHLT, MH.MHHLTCD |
| *2.R.1.7. | MHTERM_Enc_CAT4 | | | | MH.MHDECOD, MH.MHPTCD |
| *2.R.1.8. | MHTERM_Enc_CAT5 | | | | [NOT SUBMITTED] |
| *2.R.1.9. | MHTERM_Enc_CAT6 | | | | [NOT SUBMITTED] |
| *2.R.1.10. | MHTERM_Enc_CAT7 | | | | [NOT SUBMITTED] |
| *2.R.1.11. | MHTERM_Enc_CAT8 | | | | [NOT SUBMITTED] |
| *2.R.1.12. | MHTERM_Enc_CAT9 | | | | [NOT SUBMITTED] |
| 2.R.2. | Start Date (Day) | | | | List: DAY 6 |
| 2.R.3. | Start Date (Month) | | | | List: MONTH 6 MH.MHSTDTC |
| 2.R.4. | Start Date (Year) | | | | |
| *2.R.4.1. | Start Date | | | | Read Only: Derived |
| 2.R.5. | Ongoing? | | | | If Y then MH.MHENRTPT="ONGOING" and MH.MHENTPT = DM.RFICDTC |
| **2.R.6. | End Date (Day) | | | | List: DAY 6 |
| **2.R.7. | End Date (Month) | | | | List: MONTH 6 MH.MHENDTC |
| **2.R.8. | End Date (Year) | | | | |
| *2.R.8.1. | End Date | | | | Read Only: Derived |

Add New Row

* Hidden Question

** Conditional Question

| List:YES_NO | | List:DAY | | List:MONTH | |
|-------------|-------|----------|-------|------------|-------|
| Label | Value | Label | Value | Label | Value |
| [Blank] | | [Blank] | | [Blank] | |
| Yes | Y | 01 | 01 | JAN | JAN |
| No | N | 02 | 02 | FEB | FEB |
| | | 03 | 03 | MAR | MAR |
| | | 04 | 04 | APR | APR |
| | | 05 | 05 | MAY | MAY |
| | | 06 | 06 | JUN | JUN |
| | | 07 | 07 | JUL | JUL |

| | | | |
|----|----|-----|-----|
| 08 | 08 | AUG | AUG |
| 09 | 09 | SEP | SEP |
| 10 | 10 | OCT | OCT |
| 11 | 11 | NOV | NOV |
| 12 | 12 | DEC | DEC |
| 13 | 13 | UNK | UNK |
| 14 | 14 | | |
| 15 | 15 | | |
| 16 | 16 | | |
| 17 | 17 | | |
| 18 | 18 | | |
| 19 | 19 | | |
| 20 | 20 | | |
| 21 | 21 | | |
| 22 | 22 | | |
| 23 | 23 | | |
| 24 | 24 | | |
| 25 | 25 | | |
| 26 | 26 | | |
| 27 | 27 | | |
| 28 | 28 | | |
| 29 | 29 | | |
| 30 | 30 | | |
| 31 | 31 | | |
| UN | UN | | |

| List: YES | |
|-----------|-------|
| Label | Value |
| [Blank] | |
| YES | Y |

DS=Disposition

DS.DSCAT="DISPOSITION EVENT"

Protocol: LUM001-305

Study: LUM001305

SV: 8.3

FA=Findings About Events or Interventions

Telephone Contact (TC)

FA.FATESTCD="OCCUR"

FATEST="Occurrence"

Telephone Contact (TC)

FA.FACAT="TELEPHONE CONTACT"

FA.FAOBJ="Telephone Contact"

If Y and the visit is a follow-up visit
then DS.DSTERM="COMPLETED"
and DS.DSDECOD="COMPLETED"


1. Was subject/caregiver contacted by telephone?

FA.FAORRES Y

**2. Date of telephone contact

FA,FADTC

DS.DSSTDTC

 dd-mmm-yyyy

** Conditional Question

List: YES_NO

| Label | Value |
|---------|-------|
| [Blank] | |
| Yes | Y |
| No | N |

VS=Vital Signs**Vital Signs (VS)**

1. Were vital signs collected?

If N then VS.VSSTAT="NOT DONE"

**2. Date of measurements

VS.VSDTC



dd-mmm-yyyy

**3. Height (cm)

VS.VSORRES where VS.VSTESTCD=HEIGHT

*3.1. Height Unit

VS.VSORRESU where VS.VSTESTCD=HEIGHT

**4. Weight (kg)

VS.VSORRES where VS.VSTESTCD=WEIGHT

*4.1. Weight Unit

VS.VSORRESU where VS.VSTESTCD=WEIGHT

**5. Temperature (C)

VS.VSORRES where VS.VSTESTCD=TEMP

*5.1. Temperature Unit

VS.VSORRESU where VS.VSTESTCD=TEMP

**6. Heart Rate (bpm)

VS.VSORRES where VS.VSTESTCD=PULSE

*6.1. Heart Rate Unit

VS.VSORRESU where VS.VSTESTCD=PULSE

**7. Respiratory Rate (rpm)

VS.VSORRES where VS.VSTESTCD=RESP

*7.1. Respiratory Rate Unit

VS.VSORRESU where VS.VSTESTCD=RESP

**8. Systolic Blood Pressure (mmHg)

VS.VSORRES where VS.VSTESTCD=SYSBP

**9. Diastolic Blood Pressure (mmHg)

VS.VSORRES where VS.VSTESTCD=DIABP

*9.1. Blood Pressure Unit

VS.VSORRESU where VS.VSTESTCD=SYSBP or DIABP

* Hidden Question

** Conditional Question



| List: YES_NO | | List: HEIGHT | | List: WEIGHT | |
|--------------|-------|--------------|-------|--------------|-------|
| Label | Value | Label | Value | Label | Value |
| [Blank] | | cm | cm | kg | kg |
| Yes | Y | | | | |
| No | N | | | | |

| List: TEMP | | List: bpm | | List: rpm | |
|------------|-------|-----------|-----------|-----------|-------|
| Label | Value | Label | Value | Label | Value |
| C | C | BEATS/MIN | BEATS/MIN | rpm | rpm |

| List: mmHg | |
|------------|-------|
| Label | Value |
| mmHg | mmHg |

LB=Laboratory Test Results**Clinical Laboratory Tests 2 (LB2)**

1. Clinical Laboratory Tests

| 1.R. | Sample Type | Sample collected? | Collection Date | Sample ID |
|----------|---|-------------------|-----------------|---|
| 1.1.1. | Sample Type | | | [NOT SUBMITTED] |
| 1.1.2. | Was the sample collected? | | | [NOT SUBMITTED] |
| **1.1.3. | Collection Date | | [NOT SUBMITTED] |  dd-mmm-yyyy |
| **1.1.4. | Sample ID | | [NOT SUBMITTED] | |
| 1.2.1. | Sample Type | | | [NOT SUBMITTED] |
| 1.2.2. | Was the sample collected? | | | [NOT SUBMITTED] |
| **1.2.3. | Collection Date | | [NOT SUBMITTED] |  dd-mmm-yyyy |
| **1.2.4. | Sample ID | | [NOT SUBMITTED] | |
| 2. | Date of last dose prior to sample collection | | | SUPPLB.QVAL where SUPPLB.QNAM=LDDAT |
| 3. | Time of last dose prior to sample collection (hh:mm, 24-hour clock) | | | SUPPLB.QVAL where SUPPLB.QNAM=LDTIM |
| 4. | Date of last meal prior to sample collection | | | SUPPLB.QVAL where SUPPLB.QNAM=LMDAT |
| 5. | Time of last meal prior to sample collection (hh:mm, 24-hour clock) | | | SUPPLB.QVAL where SUPPLB.QNAM=LMTIM |

** Conditional Question

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

QS=Questionnaires**Scratch Scale (QS1)****QS.QSCAT = "CLINICIAN SCRATCH SCALE"**

1. Was Clinician Scratch Scale completed?

List: YES_NO If N then QS.QSSTAT="NOT DONE"

**2. Date of assessment

QS.QSDTC  dd-mmm-yyyy

**3. Clinician Scratch Scale score


QS.QSORRES where QS.QSTESTCD=QC_CS

** Conditional Question

| List:YES_NO | | List:SCRATCH | |
|-------------|-------|--|-------|
| Label | Value | Label | Value |
| [Blank] | | [Blank] | |
| Yes | Y | 0 - None | 0 |
| No | N | 1 - Rubbing or mild scratching when undistracted | 1 |
| | | 2 - Active scratching without evident skin abrasions | 2 |
| | | 3 - Abrasion evident | 3 |
| | | 4 - Cutaneous mutilation, haemorrhage and scarring evident | 4 |

LB=Laboratory Test Results

Urine Pregnancy Test (PREG2)

1. Sample Type List: UPREG 6 **LB.LBSPEC**
2. Was the sample collected? **If N or NA then LB.LBSTAT="NOT DONE" where LBTESTCD=HCG**
If NA then LB.LBREASND="NOT APPLICABLE" where LBTESTCD=HCG
- **3. Date collected **LB.LBDTC**  dd-mmm-yyyy
- **4. Results **LB.LBORRES where LBTESTCD=HCG**
- ** Conditional Question

| List:UPREG | |
|------------|-------|
| Label | Value |
| Urine | Urine |

| List:Y_N_NA | |
|----------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |
| Not Applicable | NA |

| List:POSNEG | |
|-------------|-------|
| Label | Value |
| [Blank] | |
| Positive | + |
| Negative | - |

DM=Demographics

Study Drug Administration (EX)

Study Drug Administration (EX)

EC=Exposure as Collected

1. Date of First Dose

DM.RFSTDTC  dd-mmm-yyyy

2. Volume of study drug solution (mL)

List: EXVOL_VAL  **EC.ECDOSE****List:EXVOL_VAL**

| Label | Value |
|---------|-------|
| [Blank] | |
| 0.5 | 0.5 |
| 1.0 | 1.0 |

FA=Findings About Events or Interventions

Protocol: LUM001-305

Study: LUM001305

SV: 8.3

Study Drug Compliance (SDC)

Study Drug Compliance (SDC)

FA.FACAT="STUDY DRUG COMPLIANCE"

FA.FATESTCD=COMP
FA.FATEST=Compliance
FA.FAOBJ=Study Drug Dosing

CO=Comments

1. Was study drug taken as prescribed?

List: YES_NO 6

FA.FAORRES

2. Date(s) of Dosing Error

EC=Exposure as Collected

2.R. Start Date End Date Comments Type of dosing error

2.R.1. Start Date of dosing error

FA.FADTC

EC.ECSTDTC

dd-mmm-yyyy

2.R.2. End Date of dosing error

SUPPFA.QVAL where SUPPFA.QNAM=ERRENDTC

EC.ECENDTC

dd-mmm-yyyy

2.R.3. Comments

SUPPFA.QVAL where SUPPFA.QNAM=ERRORCOM

SUPPFA.QVAL where SUPPDA.QNAM=ERRORCM2 and ERRORCM3

CO.COVAL

if comments is over 200 chars

2.R.4. Type of dosing error

FA.FATESTCD=ERRORTYP

FA.FAORRES if 2, 3, 4

EC.ECDOSE=0 if 1, 5

FA.FATEST=Type of Dosing

Add New Row

Error

FA.FAOBJ=Study Drug Dosing

Error

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| Label | Value |
|--------------------|-------|
| [Blank] | |
| Missed Dose | 1 |
| Underdose | 2 |
| Overdose | 3 |
| Other | 4 |
| Protocol Amendment | 5 |
| Gap | |

DM=Demographics

Dose Adjustment (DAD)

SUPPDM.QVAL where SUPPDM.QNAM=DOSADW12

1. Was the dose adjusted at Week 12?

List: YES_NO

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

PE=Physical Examination**Physical Examination2 (PE2)****PE.PECAT = "PHYSICAL EXAMINATION"**

1. Was the physical examination performed?

If N then PE.PESTAT="NOT DONE"****2. Exam Date****PE.PEDTC**

dd-mm-yyyy



****3. Are there any clinically significant abnormal findings that have been newly diagnosed or have worsened since the previous assessment ?****** Conditional Question****List: YES_NO**

| Label | Value |
|---------|-------|
| [Blank] | |
| Yes | Y |
| No | N |

If N then PE.PEORRES="NORMAL"**where PE.PETESTCD=PEALL****If Y then PE.PEORRES="ABNORMAL"****where PE.PETESTCD=PEALL**

LB=Laboratory Test Results**Clinical Laboratory Tests 3 (LB3)**

1. Clinical Laboratory Tests

| 1.R. | Sample Type | Sample collected? | Collection Date | Sample ID |
|----------|---------------------------|-------------------|-----------------|---|
| 1.1.1. | Sample Type | | | [NOT SUBMITTED] |
| 1.1.2. | Was the sample collected? | | | [NOT SUBMITTED] |
| **1.1.3. | Collection Date | | [NOT SUBMITTED] |  dd-mmm-yyyy |
| **1.1.4. | Sample ID | | | [NOT SUBMITTED] |
| 1.2.1. | Sample Type | | | [NOT SUBMITTED] |
| 1.2.2. | Was the sample collected? | | | [NOT SUBMITTED] |
| **1.2.3. | Collection Date | | [NOT SUBMITTED] |  dd-mmm-yyyy |
| **1.2.4. | Sample ID | | | [NOT SUBMITTED] |

2. Date of last meal prior to sample collection

SUPPLB.QVAL where SUPPLB.QNAM=LMDAT /y

3. Time of last meal prior to sample collection (hh:mm, 24-hour clock)

SUPPLB.QVAL where SUPPLB.QNAM=LMTIM

** Conditional Question

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

QS=Questionnaires**Questionnaires 2 (QS2)****If N then QS.QSSTAT="NOT DONE" where
QS.QSTESTCD=CPOVRALL**

1. Was the Pediatric QoL Inventory PARENT REPORT completed by caregiver?

**2. Date Pediatric QoL Inventory PARENT REPORT completed by caregiver

QS.QSDTC

dd-mmm-yyyy

**3. For which age category was the questionnaire completed? [NOT SUBMITTED] AG

If N or NA then QS.QSSTAT="NOT DONE",

4. Was the Pediatric QoL Inventory completed by subject?

List: Y_

**If NA then QS.QSREASND="NOT
APPLICABLE" where**

**5. Date Pediatric QoL Inventory completed by subject

QS.QSDTC

QS.QSTESTCD=CSOVRALL

**6. For which age category was the questionnaire completed? [NOT SUBMITTED] AG

If N or NA then QS.QSSTAT="NOT DONE",

7. Was the Multidimensional Fatigue Scale PARENT REPORT completed by caregiver?

List: Y_

**If NA then QS.QSREASND="NOT
APPLICABLE" where**

**8. Date Multidimensional Fatigue Scale PARENT REPORT completed by caregiver

QS.QSDTC

dd-mmm-yyyy

**9. For which age category was the questionnaire completed? [NOT SUBMITTED] AG

If N or NA then QS.QSSTAT="NOT DONE",

10. Was the Multidimensional Fatigue Scale completed by subject?

List: Y_

**If NA then QS.QSREASND="NOT
APPLICABLE" where**

**11. Date Multidimensional Fatigue Scale completed by subject

QS.QSDTC

QS.QSTESTCD=MSOVRALL

**12. For which age category was the questionnaire completed?

[NOT SUBMITTED]

13. Was the Family Impact Module PARENT REPORT completed by caregiver?

**If N then QS.QSSTAT="NOT DONE" where
QS.QSTESTCD=FPOVRALL**

**14. Date Family Impact Module PARENT REPORT completed by caregiver

QS.QSDTC

dd-mmm-yyyy

** Conditional Question

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| List: AGE1 | |
|---------------------------|-------|
| Label | Value |
| [Blank] | |
| INFANTS (1-12 months) | 5 |
| INFANTS (13-24 months) | 6 |
| TODDLERS (ages 2-4) | 1 |
| YOUNG CHILDREN (ages 5-7) | 2 |
| CHILDREN (ages 8-12) | 3 |
| TEENAGERS (ages 13-18) | 4 |

| List: Y_N_NA | |
|----------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |
| Not Applicable | NA |

| List: AGE2 | |
|-------------------------------|-------|
| Label | Value |
| [Blank] | |
| YOUNG CHILD REPORT (ages 5-7) | 2 |
| CHILD | |

| List: AGE3 | |
|---------------------------|-------|
| Label | Value |
| [Blank] | |
| TODDLERS (ages 2-4) | 1 |
| YOUNG CHILDREN (ages 5-7) | 2 |

| | | | |
|------------------------------------|---|---------------------------|---|
| REPORT (ages 8-12) | 3 | CHILDREN (ages 8-12) | 3 |
| TEENAGER REPORT (ages 13-18) | 4 | TEENAGERS (ages 13-18) | 4 |

QS=Questionnaires

Pediatric QOL Inventory PARENT RPT-INFANT 1-12M (QS3P)

QS.QSCAT="PEDIATRIC QOL INVENTORY INFANTS 1-12M PARENT"**Pediatric QOL Inventory PARENT RPT-INFANT 1-12M (QS3P)***In the past **ONE month**, how much of a **problem** has your child had with...***PHYSICAL FUNCTIONING (problems with...)****QS.QSSCAT="PHYSICAL FUNCTIONING"**

| | | | |
|----|--|--|--|
| 1. | QS.QSORRES where QS.QSTESTCD=CPI1PF01 | 1. Low energy level | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=CPI1PF02 | 2. Difficulty participating in active play | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=CPI1PF03 | 3. Having hurts or aches | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=CPI1PF04 | 4. Feeling tired | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=CPI1PF05 | 5. Being lethargic | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=CPI1PF06 | 6. Resting a lot | List: PEDSQL1 <input type="text" value="6"/> |

PHYSICAL SYMPTOMS (problems with...)**QS.QSSCAT="PHYSICAL SYMPTOMS"**

| | | | |
|-----|--|----------------------------------|--|
| 7. | QS.QSORRES where QS.QSTESTCD=CPI1PS01 | 1. Having gas | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=CPI1PS02 | 2. Spitting up after eating | List: PEDSQL1 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=CPI1PS03 | 3. Difficulty breathing | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=CPI1PS04 | 4. Being sick to his/her stomach | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=CPI1PS05 | 5. Difficulty Swallowing | List: PEDSQL1 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=CPI1PS06 | 6. Being constipated | List: PEDSQL1 <input type="text" value="6"/> |
| 13. | QS.QSORRES where QS.QSTESTCD=CPI1PS07 | 7. Having a rash | List: PEDSQL1 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=CPI1PS08 | 8. Having diarrhea | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=CPI1PS09 | 9. Wheezing | List: PEDSQL1 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=CPI1PS10 | 10. Vomiting | List: PEDSQL1 <input type="text" value="6"/> |

EMOTIONAL FUNCTIONING (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | | |
|-----|--|--|--|
| 17. | QS.QSORRES where QS.QSTESTCD=CPI1EF01 | 1. Feeling afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=CPI1EF02 | 2. Feeling angry | List: PEDSQL1 <input type="text" value="6"/> |
| 19. | QS.QSORRES where QS.QSTESTCD=CPI1EF03 | 3. Crying or fussing when left alone | List: PEDSQL1 <input type="text" value="6"/> |
| 20. | QS.QSORRES where QS.QSTESTCD=CPI1EF04 | 4. Difficulty soothing himself/herself when upset | List: PEDSQL1 <input type="text" value="6"/> |
| 21. | QS.QSORRES where QS.QSTESTCD=CPI1EF05 | 5. Difficulty falling asleep | List: PEDSQL1 <input type="text" value="6"/> |
| 22. | QS.QSORRES where QS.QSTESTCD=CPI1EF06 | 6. Crying or fussing while being cuddled | List: PEDSQL1 <input type="text" value="6"/> |
| 23. | QS.QSORRES where QS.QSTESTCD=CPI1EF07 | 7. Feeling sad | List: PEDSQL1 <input type="text" value="6"/> |
| 24. | QS.QSORRES where QS.QSTESTCD=CPI1EF08 | 8. Difficulty being soothed when picked up or held | List: PEDSQL1 <input type="text" value="6"/> |
| 25. | QS.QSORRES where QS.QSTESTCD=CPI1EF09 | 9. Difficulty sleeping mostly through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 26. | QS.QSORRES where QS.QSTESTCD=CPI1EF10 | 10. Crying a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 27. | QS.QSORRES where QS.QSTESTCD=CPI1EF11 | 11. Feeling cranky | List: PEDSQL1 <input type="text" value="6"/> |
| 28. | QS.QSORRES where QS.QSTESTCD=CPI1EF12 | 12. Difficulty taking naps during the day | List: PEDSQL1 <input type="text" value="6"/> |

SOCIAL FUNCTIONING (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | | |
|-----|--|------------------------------|--|
| 29. | QS.QSORRES where QS.QSTESTCD=CPI1SF01 | 1. Not smiling at others | List: PEDSQL1 <input type="text" value="6"/> |
| 30. | QS.QSORRES where QS.QSTESTCD=CPI1SF02 | 2. Not laughing when tickled | List: PEDSQL1 <input type="text" value="6"/> |

QS=Questionnaires

Protocol: LUM001-305

QS.QSSCAT="SOCIAL FUNCTIONING"

Study: LUM001305

SV: 8.3

Pediatric QOL Inventory PARENT RPT-INFANT 1-12M (QS3P)

31. QS.QSORRES where QS.QSTESTCD=CPI1SF03

3. Not making eye contact with a caregiver

List: PEDSQL1

32. QS.QSORRES where QS.QSTESTCD=CPI1SF04

4. Not laughing when cuddled

List: PEDSQL1

COGNITIVE FUNCTIONING (*problems with...*)

QS.QSSCAT="COGNITIVE FUNCTIONING"

33. QS.QSORRES where QS.QSTESTCD=CPI1CF01

1. Not imitating caregivers' actions

List: PEDSQL1

34. QS.QSORRES where QS.QSTESTCD=CPI1CF02

2. Not imitating caregivers' facial expressions

List: PEDSQL1

35. QS.QSORRES where QS.QSTESTCD=CPI1CF03

3. Not imitating caregivers' sounds

List: PEDSQL1

36. QS.QSORRES where QS.QSTESTCD=CPI1CF04

4. Not able to fix his/her attention on objects

List: PEDSQL1

List: PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**QS.QSCAT="PEDIATRIC QOL INVENTORY INFANTS 13-24M PARENT"****Pediatric QOL Inventory PARENT RPT-INFANT 13-24M (QS3Q)**In the past **ONE month**, how much of a **problem** has your child had with...

| PHYSICAL FUNCTIONING (problems with...) | | QS.QSSCAT="PHYSICAL FUNCTIONING" |
|--|--|--|
| 1. QS.QSORRES where QS.QSTESTCD=CPI2PF01 | 1. Low energy level | List: PEDSQL1 <input type="text" value="6"/> |
| 2. QS.QSORRES where QS.QSTESTCD=CPI2PF02 | 2. Difficulty participating in active play | List: PEDSQL1 <input type="text" value="6"/> |
| 3. QS.QSORRES where QS.QSTESTCD=CPI2PF03 | 3. Having hurts or aches | List: PEDSQL1 <input type="text" value="6"/> |
| 4. QS.QSORRES where QS.QSTESTCD=CPI2PF04 | 4. Feeling tired | List: PEDSQL1 <input type="text" value="6"/> |
| 5. QS.QSORRES where QS.QSTESTCD=CPI2PF05 | 5. Being lethargic | List: PEDSQL1 <input type="text" value="6"/> |
| 6. QS.QSORRES where QS.QSTESTCD=CPI2PF06 | 6. Resting a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 7. QS.QSORRES where QS.QSTESTCD=CPI2PF07 | 7. Feeling too tired to play | List: PEDSQL1 <input type="text" value="6"/> |
| 8. QS.QSORRES where QS.QSTESTCD=CPI2PF08 | 8. Difficulty walking | List: PEDSQL1 <input type="text" value="6"/> |
| 9. QS.QSORRES where QS.QSTESTCD=CPI2PF09 | 9. Difficulty running a short distance without falling | List: PEDSQL1 <input type="text" value="6"/> |
| PHYSICAL SYMPTOMS (problems with...) | | QS.QSSCAT="PHYSICAL SYMPTOMS" |
| 10. QS.QSORRES where QS.QSTESTCD=CPI2PS01 | 1. Having gas | List: PEDSQL1 <input type="text" value="6"/> |
| 11. QS.QSORRES where QS.QSTESTCD=CPI2PS02 | 2. Spitting up after eating | List: PEDSQL1 <input type="text" value="6"/> |
| 12. QS.QSORRES where QS.QSTESTCD=CPI2PS03 | 3. Difficulty breathing | List: PEDSQL1 <input type="text" value="6"/> |
| 13. QS.QSORRES where QS.QSTESTCD=CPI2PS04 | 4. Being sick to his/her stomach | List: PEDSQL1 <input type="text" value="6"/> |
| 14. QS.QSORRES where QS.QSTESTCD=CPI2PS05 | 5. Difficulty swallowing | List: PEDSQL1 <input type="text" value="6"/> |
| 15. QS.QSORRES where QS.QSTESTCD=CPI2PS06 | 6. Being constipated | List: PEDSQL1 <input type="text" value="6"/> |
| 16. QS.QSORRES where QS.QSTESTCD=CPI2PS07 | 7. Having a rash | List: PEDSQL1 <input type="text" value="6"/> |
| 17. QS.QSORRES where QS.QSTESTCD=CPI2PS08 | 8. Having diarrhea | List: PEDSQL1 <input type="text" value="6"/> |
| 18. QS.QSORRES where QS.QSTESTCD=CPI2PS09 | 9. Wheezing | List: PEDSQL1 <input type="text" value="6"/> |
| 19. QS.QSORRES where QS.QSTESTCD=CPI2PS10 | 10. Vomiting | List: PEDSQL1 <input type="text" value="6"/> |
| EMOTIONAL FUNCTIONING (problems with...) | | QS.QSSCAT="EMOTIONAL FUNCTIONING" |
| 20. QS.QSORRES where QS.QSTESTCD=CPI2EF01 | 1. Feeling afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 21. QS.QSORRES where QS.QSTESTCD=CPI2EF02 | 2. Feeling angry | List: PEDSQL1 <input type="text" value="6"/> |
| 22. QS.QSORRES where QS.QSTESTCD=CPI2EF03 | 3. Crying or fussing when left alone | List: PEDSQL1 <input type="text" value="6"/> |
| 23. QS.QSORRES where QS.QSTESTCD=CPI2EF04 | 4. Difficulty soothing himself/herself when upset | List: PEDSQL1 <input type="text" value="6"/> |
| 24. QS.QSORRES where QS.QSTESTCD=CPI2EF05 | 5. Difficulty falling asleep | List: PEDSQL1 <input type="text" value="6"/> |
| 25. QS.QSORRES where QS.QSTESTCD=CPI2EF06 | 6. Crying or fussing while being cuddled | List: PEDSQL1 <input type="text" value="6"/> |
| 26. QS.QSORRES where QS.QSTESTCD=CPI2EF07 | 7. Feeling sad | List: PEDSQL1 <input type="text" value="6"/> |
| 27. QS.QSORRES where QS.QSTESTCD=CPI2EF08 | 8. Difficulty being soothed when picked up or held | List: PEDSQL1 <input type="text" value="6"/> |
| 28. QS.QSORRES where QS.QSTESTCD=CPI2EF09 | 9. Difficulty sleeping mostly through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 29. QS.QSORRES where QS.QSTESTCD=CPI2EF10 | 10. Crying a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 30. QS.QSORRES where QS.QSTESTCD=CPI2EF11 | 11. Feeling cranky | List: PEDSQL1 <input type="text" value="6"/> |
| 31. QS.QSORRES where QS.QSTESTCD=CPI2EF12 | 12. Difficulty taking naps during the day | List: PEDSQL1 <input type="text" value="6"/> |

Protocol: LUM001-305

Study: LUM001305

SV: 8.3

Pediatric QOL Inventory PARENT RPT-INFANT 13-24M (QS3Q)

SOCIAL FUNCTIONING (problems with...)

| | | | |
|-----|---------------------------------------|--|--|
| 32. | QS.QSORRES where QS.QSTESTCD=CPI2SF01 | 1. Not smiling at others | List: PEDSQL1 <input type="text" value="6"/> |
| 33. | QS.QSORRES where QS.QSTESTCD=CPI2SF02 | 2. Not laughing when tickled | List: PEDSQL1 <input type="text" value="6"/> |
| 34. | QS.QSORRES where QS.QSTESTCD=CPI2SF03 | 3. Not making eye contact with a caregiver | List: PEDSQL1 <input type="text" value="6"/> |
| 35. | QS.QSORRES where QS.QSTESTCD=CPI2SF04 | 4. Not laughing when cuddled | List: PEDSQL1 <input type="text" value="6"/> |
| 36. | QS.QSORRES where QS.QSTESTCD=CPI2SF05 | 5. Being uncomfortable around other children | List: PEDSQL1 <input type="text" value="6"/> |

COGNITIVE FUNCTIONING (problems with...)

QS.QSSCAT="COGNITIVE FUNCTIONING"

| | | | |
|-----|---------------------------------------|---|--|
| 37. | QS.QSORRES where QS.QSTESTCD=CPI2CF01 | 1. Not imitating caregivers' actions | List: PEDSQL1 <input type="text" value="6"/> |
| 38. | QS.QSORRES where QS.QSTESTCD=CPI2CF02 | 2. Not imitating caregivers' facial expressions | List: PEDSQL1 <input type="text" value="6"/> |
| 39. | QS.QSORRES where QS.QSTESTCD=CPI2CF03 | 3. Not imitating caregivers' sounds | List: PEDSQL1 <input type="text" value="6"/> |
| 40. | QS.QSORRES where QS.QSTESTCD=CPI2CF04 | 4. Not able to fix his/her attention on objects | List: PEDSQL1 <input type="text" value="6"/> |
| 41. | QS.QSORRES where QS.QSTESTCD=CPI2CF05 | 5. Not imitating caregivers' speech | List: PEDSQL1 <input type="text" value="6"/> |
| 42. | QS.QSORRES where QS.QSTESTCD=CPI2CF06 | 6. Difficulty pointing to his/her body parts when asked | List: PEDSQL1 <input type="text" value="6"/> |
| 43. | QS.QSORRES where QS.QSTESTCD=CPI2CF07 | 7. Difficulty naming familiar objects | List: PEDSQL1 <input type="text" value="6"/> |
| 44. | QS.QSORRES where QS.QSTESTCD=CPI2CF08 | 8. Difficulty repeating words | List: PEDSQL1 <input type="text" value="6"/> |
| 45. | QS.QSORRES where QS.QSTESTCD=CPI2CF09 | 9. Difficulty keeping his/her attention on things | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=QuestionnairesPediatric QOL Inventory PARENT RPT (TODDLERS) (QS3A)
QS.QSCAT="PEDIATRIC QOL INVENTORY TODDLERS PARENT"**Pediatric QOL Inventory PARENT RPT (TODDLERS) (QS3A)**In the past **ONE month**, how much of a **problem** has your child had with...**QS.QSSCAT="PHYSICAL FUNCTIONING"****PHYSICAL FUNCTIONING (problems with...)**

| | | |
|---|---|--|
| 1. QS.QSORRES where QS.QSTESTCD=CPTOPF01 | 1. Walking | List: PEDSQL1 <input type="text" value="6"/> |
| 2. QS.QSORRES where QS.QSTESTCD=CPTOPF02 | 2. Running | List: PEDSQL1 <input type="text" value="6"/> |
| 3. QS.QSORRES where QS.QSTESTCD=CPTOPF03 | 3. Participating in active play or exercise | List: PEDSQL1 <input type="text" value="6"/> |
| 4. QS.QSORRES where QS.QSTESTCD=CPTOPF04 | 4. Lifting something heavy | List: PEDSQL1 <input type="text" value="6"/> |
| 5. QS.QSORRES where QS.QSTESTCD=CPTOPF05 | 5. Bathing | List: PEDSQL1 <input type="text" value="6"/> |
| 6. QS.QSORRES where QS.QSTESTCD=CPTOPF06 | 6. Helping to pick up his or her toys | List: PEDSQL1 <input type="text" value="6"/> |
| 7. QS.QSORRES where QS.QSTESTCD=CPTOPF07 | 7. Having hurts or aches | List: PEDSQL1 <input type="text" value="6"/> |
| 8. QS.QSORRES where QS.QSTESTCD=CPTOPF08 | 8. Low energy level | List: PEDSQL1 <input type="text" value="6"/> |

EMOTIONAL FUNCTIONING (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | |
|--|-----------------------------|--|
| 9. QS.QSORRES where QS.QSTESTCD=CPTOEF01 | 1. Feeling afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 10. QS.QSORRES where QS.QSTESTCD=CPTOEF02 | 2. Feeling sad or blue | List: PEDSQL1 <input type="text" value="6"/> |
| 11. QS.QSORRES where QS.QSTESTCD=CPTOEF03 | 3. Feeling angry | List: PEDSQL1 <input type="text" value="6"/> |
| 12. QS.QSORRES where QS.QSTESTCD=CPTOEF04 | 4. Trouble sleeping | List: PEDSQL1 <input type="text" value="6"/> |
| 13. QS.QSORRES where QS.QSTESTCD=CPTOEF05 | 5. Worrying | List: PEDSQL1 <input type="text" value="6"/> |

SOCIAL FUNCTIONING (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | |
|--|--|--|
| 14. QS.QSORRES where QS.QSTESTCD=CPTOSF01 | 1. Playing with other children | List: PEDSQL1 <input type="text" value="6"/> |
| 15. QS.QSORRES where QS.QSTESTCD=CPTOSF02 | 2. Other kids not wanting to play with him or her | List: PEDSQL1 <input type="text" value="6"/> |
| 16. QS.QSORRES where QS.QSTESTCD=CPTOSF03 | 3. Getting teased by other children | List: PEDSQL1 <input type="text" value="6"/> |
| 17. QS.QSORRES where QS.QSTESTCD=CPTOSF04 | 4. Not able to do things that other children his or her age can do | List: PEDSQL1 <input type="text" value="6"/> |
| 18. QS.QSORRES where QS.QSTESTCD=CPTOSF05 | 5. Keeping up when playing with other children | List: PEDSQL1 <input type="text" value="6"/> |

Please complete this section if your child attends school or daycare*SCHOOL FUNCTIONING (problems with...)****QS.QSSCAT="SCHOOL FUNCTIONING"**

| | | |
|--|---|--|
| 19. QS.QSORRES where QS.QSTESTCD=CPTOSC01 | 1. Doing the same school activities as peers | List: PEDSQL1 <input type="text" value="6"/> |
| 20. QS.QSORRES where QS.QSTESTCD=CPTOSC02 | 2. Missing school/daycare because of not feeling well | List: PEDSQL1 <input type="text" value="6"/> |
| 21. QS.QSORRES where QS.QSTESTCD=CPTOSC03 | 3. Missing school/daycare to go to the doctor or hospital | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=QuestionnairesPediatric QOL Inventory PARENT RPT (YOUNG CHILD) (QS3B)
QS.QSCAT="PEDIATRIC QOL INVENTORY YOUNG CHILDREN PARENT"**Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) (QS3B)**In the past **ONE month**, how much of a **problem** has your child had with...**PHYSICAL FUNCTIONING (problems with...)****QS.QSSCAT="PHYSICAL FUNCTIONING"**

| | | | |
|----|---------------------------------------|--|--|
| 1. | QS.QSORRES where QS.QSTESTCD=CPYCPF01 | 1. Walking more than one block | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=CPYCPF02 | 2. Running | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=CPYCPF03 | 3. Participating in sports activity or exercise | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=CPYCPF04 | 4. Lifting something heavy | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=CPYCPF05 | 5. Taking a bath or shower by him or herself | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=CPYCPF06 | 6. Doing chores, like picking up his or her toys | List: PEDSQL1 <input type="text" value="6"/> |
| 7. | QS.QSORRES where QS.QSTESTCD=CPYCPF07 | 7. Having hurts or aches | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=CPYCPF08 | 8. Low energy level | List: PEDSQL1 <input type="text" value="6"/> |

EMOTIONAL FUNCTIONING (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | | |
|-----|---------------------------------------|--|--|
| 9. | QS.QSORRES where QS.QSTESTCD=CPYCEF01 | 1. Feeling afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=CPYCEF02 | 2. Feeling sad or blue | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=CPYCEF03 | 3. Feeling angry | List: PEDSQL1 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=CPYCEF04 | 4. Trouble sleeping | List: PEDSQL1 <input type="text" value="6"/> |
| 13. | QS.QSORRES where QS.QSTESTCD=CPYCEF05 | 5. Worrying about what will happen to him or her | List: PEDSQL1 <input type="text" value="6"/> |

SOCIAL FUNCTIONING (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | | |
|-----|---------------------------------------|--|--|
| 14. | QS.QSORRES where QS.QSTESTCD=CPYCSF01 | 1. Getting along with other children | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=CPYCSF02 | 2. Other kids not wanting to be his or her friend | List: PEDSQL1 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=CPYCSF03 | 3. Getting teased by other children | List: PEDSQL1 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=CPYCSF04 | 4. Not able to do things that other children his or her age can do | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=CPYCSF05 | 5. Keeping up when playing with other children | List: PEDSQL1 <input type="text" value="6"/> |

SCHOOL FUNCTIONING (problems with...)**QS.QSSCAT="SCHOOL FUNCTIONING"**

| | | | |
|-----|---------------------------------------|---|--|
| 19. | QS.QSORRES where QS.QSTESTCD=CPYCSC01 | 1. Paying attention in class | List: PEDSQL1 <input type="text" value="6"/> |
| 20. | QS.QSORRES where QS.QSTESTCD=CPYCSC02 | 2. Forgetting things | List: PEDSQL1 <input type="text" value="6"/> |
| 21. | QS.QSORRES where QS.QSTESTCD=CPYCSC03 | 3. Keeping up with school activities | List: PEDSQL1 <input type="text" value="6"/> |
| 22. | QS.QSORRES where QS.QSTESTCD=CPYCSC04 | 4. Missing school because of not feeling well | List: PEDSQL1 <input type="text" value="6"/> |
| 23. | QS.QSORRES where QS.QSTESTCD=CPYCSC05 | 5. Missing school to go to the doctor or hospital | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**QS.QSCAT="PEDIATRIC QOL INVENTORY CHILDREN PARENT"****Pediatric QOL Inventory PARENT RPT (CHILDREN) (QS3C)**In the past **ONE month**, how much of a **problem** has your child had with...**PHYSICAL FUNCTIONING (problems with...)****QS.QSSCAT="PHYSICAL FUNCTIONING"**

| | | |
|---|---|--|
| 1. QS.QSORRES where QS.QSTESTCD=CPCHPF01 | 1. Walking more than one block | List: PEDSQL1 <input type="text" value="6"/> |
| 2. QS.QSORRES where QS.QSTESTCD=CPCHPF02 | 2. Running | List: PEDSQL1 <input type="text" value="6"/> |
| 3. QS.QSORRES where QS.QSTESTCD=CPCHPF03 | 3. Participating in sports activity or exercise | List: PEDSQL1 <input type="text" value="6"/> |
| 4. QS.QSORRES where QS.QSTESTCD=CPCHPF04 | 4. Lifting something heavy | List: PEDSQL1 <input type="text" value="6"/> |
| 5. QS.QSORRES where QS.QSTESTCD=CPCHPF05 | 5. Taking a bath or shower by him or herself | List: PEDSQL1 <input type="text" value="6"/> |
| 6. QS.QSORRES where QS.QSTESTCD=CPCHPF06 | 6. Doing chores around the house | List: PEDSQL1 <input type="text" value="6"/> |
| 7. QS.QSORRES where QS.QSTESTCD=CPCHPF07 | 7. Having hurts or aches | List: PEDSQL1 <input type="text" value="6"/> |
| 8. QS.QSORRES where QS.QSTESTCD=CPCHPF08 | 8. Low energy level | List: PEDSQL1 <input type="text" value="6"/> |

EMOTIONAL FUNCTIONING (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | |
|--|--|--|
| 9. QS.QSORRES where QS.QSTESTCD=CPCHEF01 | 1. Feeling afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 10. QS.QSORRES where QS.QSTESTCD=CPCHEF02 | 2. Feeling sad or blue | List: PEDSQL1 <input type="text" value="6"/> |
| 11. QS.QSORRES where QS.QSTESTCD=CPCHEF03 | 3. Feeling angry | List: PEDSQL1 <input type="text" value="6"/> |
| 12. QS.QSORRES where QS.QSTESTCD=CPCHEF04 | 4. Trouble sleeping | List: PEDSQL1 <input type="text" value="6"/> |
| 13. QS.QSORRES where QS.QSTESTCD=CPCHEF05 | 5. Worrying about what will happen to him or her | List: PEDSQL1 <input type="text" value="6"/> |

SOCIAL FUNCTIONING (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | |
|--|--|--|
| 14. QS.QSORRES where QS.QSTESTCD=CPCHSF01 | 1. Getting along with other children | List: PEDSQL1 <input type="text" value="6"/> |
| 15. QS.QSORRES where QS.QSTESTCD=CPCHSF02 | 2. Other kids not wanting to be his or her friend | List: PEDSQL1 <input type="text" value="6"/> |
| 16. QS.QSORRES where QS.QSTESTCD=CPCHSF03 | 3. Getting teased by other children | List: PEDSQL1 <input type="text" value="6"/> |
| 17. QS.QSORRES where QS.QSTESTCD=CPCHSF04 | 4. Not able to do things that other children his or her age can do | List: PEDSQL1 <input type="text" value="6"/> |
| 18. QS.QSORRES where QS.QSTESTCD=CPCHSF05 | 5. Keeping up when playing with other children | List: PEDSQL1 <input type="text" value="6"/> |

SCHOOL FUNCTIONING (problems with...)**QS.QSSCAT="SCHOOL FUNCTIONING"**

| | | |
|--|---|--|
| 19. QS.QSORRES where QS.QSTESTCD=CPCHSC01 | 1. Paying attention in class | List: PEDSQL1 <input type="text" value="6"/> |
| 20. QS.QSORRES where QS.QSTESTCD=CPCHSC02 | 2. Forgetting things | List: PEDSQL1 <input type="text" value="6"/> |
| 21. QS.QSORRES where QS.QSTESTCD=CPCHSC03 | 3. Keeping up with schoolwork | List: PEDSQL1 <input type="text" value="6"/> |
| 22. QS.QSORRES where QS.QSTESTCD=CPCHSC04 | 4. Missing school because of not feeling well | List: PEDSQL1 <input type="text" value="6"/> |
| 23. QS.QSORRES where QS.QSTESTCD=CPCHSC05 | 5. Missing school to go to the doctor or hospital | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**QS.QSCAT="PEDIATRIC QOL INVENTORY TEENAGERS PARENT"****Pediatric QOL Inventory PARENT RPT (TEENS) (QS3D)**In the past **ONE month**, how much of a **problem** has your teen had with...**PHYSICAL FUNCTIONING (problems with...)****QS.QSSCAT="PHYSICAL FUNCTIONING"**

| | | |
|---|---|--|
| 1. QS.QSORRES where QS.QSTESTCD=CPTEPF01 | 1. Walking more than one block | List: PEDSQL1 <input type="text" value="6"/> |
| 2. QS.QSORRES where QS.QSTESTCD=CPTEPF02 | 2. Running | List: PEDSQL1 <input type="text" value="6"/> |
| 3. QS.QSORRES where QS.QSTESTCD=CPTEPF03 | 3. Participating in sports activity or exercise | List: PEDSQL1 <input type="text" value="6"/> |
| 4. QS.QSORRES where QS.QSTESTCD=CPTEPF04 | 4. Lifting something heavy | List: PEDSQL1 <input type="text" value="6"/> |
| 5. QS.QSORRES where QS.QSTESTCD=CPTEPF05 | 5. Taking a bath or shower by him or herself | List: PEDSQL1 <input type="text" value="6"/> |
| 6. QS.QSORRES where QS.QSTESTCD=CPTEPF06 | 6. Doing chores around the house | List: PEDSQL1 <input type="text" value="6"/> |
| 7. QS.QSORRES where QS.QSTESTCD=CPTEPF07 | 7. Having hurts or aches | List: PEDSQL1 <input type="text" value="6"/> |
| 8. QS.QSORRES where QS.QSTESTCD=CPTEPF08 | 8. Low energy level | List: PEDSQL1 <input type="text" value="6"/> |

EMOTIONAL FUNCTIONING (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | |
|--|--|--|
| 9. QS.QSORRES where QS.QSTESTCD=CPTEEF01 | 1. Feeling afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 10. QS.QSORRES where QS.QSTESTCD=CPTEEF02 | 2. Feeling sad or blue | List: PEDSQL1 <input type="text" value="6"/> |
| 11. QS.QSORRES where QS.QSTESTCD=CPTEEF03 | 3. Feeling angry | List: PEDSQL1 <input type="text" value="6"/> |
| 12. QS.QSORRES where QS.QSTESTCD=CPTEEF04 | 4. Trouble sleeping | List: PEDSQL1 <input type="text" value="6"/> |
| 13. QS.QSORRES where QS.QSTESTCD=CPTEEF05 | 5. Worrying about what will happen to him or her | List: PEDSQL1 <input type="text" value="6"/> |

SOCIAL FUNCTIONING (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | |
|--|---|--|
| 14. QS.QSORRES where QS.QSTESTCD=CPTESF01 | 1. Getting along with other teens | List: PEDSQL1 <input type="text" value="6"/> |
| 15. QS.QSORRES where QS.QSTESTCD=CPTESF02 | 2. Other teens not wanting to be his or her friend | List: PEDSQL1 <input type="text" value="6"/> |
| 16. QS.QSORRES where QS.QSTESTCD=CPTESF03 | 3. Getting teased by other teens | List: PEDSQL1 <input type="text" value="6"/> |
| 17. QS.QSORRES where QS.QSTESTCD=CPTESF04 | 4. Not able to do things that other teens his or her age can do | List: PEDSQL1 <input type="text" value="6"/> |
| 18. QS.QSORRES where QS.QSTESTCD=CPTESF05 | 5. Keeping up with other teens | List: PEDSQL1 <input type="text" value="6"/> |

SCHOOL FUNCTIONING (problems with...)**QS.QSSCAT="SCHOOL FUNCTIONING"**

| | | |
|--|---|--|
| 19. QS.QSORRES where QS.QSTESTCD=CPTESC01 | 1. Paying attention in class | List: PEDSQL1 <input type="text" value="6"/> |
| 20. QS.QSORRES where QS.QSTESTCD=CPTESC02 | 2. Forgetting things | List: PEDSQL1 <input type="text" value="6"/> |
| 21. QS.QSORRES where QS.QSTESTCD=CPTESC03 | 3. Keeping up with schoolwork | List: PEDSQL1 <input type="text" value="6"/> |
| 22. QS.QSORRES where QS.QSTESTCD=CPTESC04 | 4. Missing school because of not feeling well | List: PEDSQL1 <input type="text" value="6"/> |
| 23. QS.QSORRES where QS.QSTESTCD=CPTESC05 | 5. Missing school to go to the doctor or hospital | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**QS.QSCAT="PEDIATRIC QOL INVENTORY YOUNG CHILD SUBJECT"****Pediatric QOL Inventory YOUNG CHILD REPORT (QS3E)**

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

PHYSICAL FUNCTIONING (problems with...)**QS.QSSCAT="PHYSICAL FUNCTIONING"**

- | | |
|--|---------------------------------------|
| 1. 1. Is it hard for you to walk | QS.QSORRES where QS.QSTESTCD=CSYCPF01 |
| 2. 2. Is it hard for you to run | QS.QSORRES where QS.QSTESTCD=CSYCPF02 |
| 3. 3. Is it hard for you to play sports or exercise | QS.QSORRES where QS.QSTESTCD=CSYCPF03 |
| 4. 4. Is it hard for you to pick up big things | QS.QSORRES where QS.QSTESTCD=CSYCPF04 |
| 5. 5. Is it hard for you to take a bath or shower | QS.QSORRES where QS.QSTESTCD=CSYCPF05 |
| 6. 6. Is it hard for you to do chores (like pick up your toys) | QS.QSORRES where QS.QSTESTCD=CSYCPF06 |
| 7. 7. Do you have hurts or aches | QS.QSORRES where QS.QSTESTCD=CSYCPF07 |
| 8. Where? | QS.QSORRES where QS.QSTESTCD=CSYCPF08 |
| 9. 8. Do you ever feel too tired to play | QS.QSORRES where QS.QSTESTCD=CSYCPF09 |

Remember, tell me how much of a problem this has been for you for the last few weeks.

EMOTIONAL FUNCTIONING (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

- | | |
|---|---------------------------------------|
| 10. 1. Do you feel scared | QS.QSORRES where QS.QSTESTCD=CSYCEF01 |
| 11. 2. Do you feel sad | QS.QSORRES where QS.QSTESTCD=CSYCEF02 |
| 12. 3. Do you feel mad | QS.QSORRES where QS.QSTESTCD=CSYCEF03 |
| 13. 4. Do you have trouble sleeping | QS.QSORRES where QS.QSTESTCD=CSYCEF04 |
| 14. 5. Do you worry about what will happen to you | QS.QSORRES where QS.QSTESTCD=CSYCEF05 |

SOCIAL FUNCTIONING (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

- | | |
|--|---------------------------------------|
| 15. 1. Is it hard for you to get along with other kids | QS.QSORRES where QS.QSTESTCD=CSYCSF01 |
| 16. 2. Do other kids say they do not want to play with you | QS.QSORRES where QS.QSTESTCD=CSYCSF02 |
| 17. 3. Do other kids tease you | QS.QSORRES where QS.QSTESTCD=CSYCSF03 |
| 18. 4. Can other kids do things you cannot do | QS.QSORRES where QS.QSTESTCD=CSYCSF04 |
| 19. 5. Is it hard for you to keep up when you play with other kids | QS.QSORRES where QS.QSTESTCD=CSYCSF05 |

SCHOOL FUNCTIONING (problems with...)**QS.QSSCAT="SCHOOL FUNCTIONING"**

- | | |
|--|---------------------------------------|
| 20. 1. Is it hard for you to pay attention in school | QS.QSORRES where QS.QSTESTCD=CSYCSC01 |
| 21. 2. Do you forget things | QS.QSORRES where QS.QSTESTCD=CSYCSC02 |
| 22. 3. Is it hard to keep up with schoolwork | QS.QSORRES where QS.QSTESTCD=CSYCSC03 |
| 23. 4. Do you miss school because of not feeling good | QS.QSORRES where QS.QSTESTCD=CSYCSC04 |
| 24. 5. Do you miss school because you have to go to the doctor's or hospital | QS.QSORRES where QS.QSTESTCD=CSYCSC05 |

List:PEDSQL2

| Label | Value |
|------------|-------|
| [Blank] | |
| Not at all | 0 |
| Sometimes | 2 |
| A lot | 4 |

QS=Questionnaires**QS.QSCAT="PEDIATRIC QOL INVENTORY CHILD SUBJECT"****Pediatric QOL Inventory CHILD REPORT (QS3F)**In the past **ONE month**, how much of a **problem** has this been for you...**ABOUT MY HEALTH AND ACTIVITIES (problems with...)****QS.QSSCAT="PHYSICAL FUNCTIONING"**

| | | |
|---|---|--|
| 1. QS.QSORRES where QS.QSTESTCD=CSCHPF01 | 1. It is hard for me to walk more than one block | List: PEDSQL1 <input type="text" value="6"/> |
| 2. QS.QSORRES where QS.QSTESTCD=CSCHPF02 | 2. It is hard for me to run | List: PEDSQL1 <input type="text" value="6"/> |
| 3. QS.QSORRES where QS.QSTESTCD=CSCHPF03 | 3. It is hard for me to do sports activity or exercise | List: PEDSQL1 <input type="text" value="6"/> |
| 4. QS.QSORRES where QS.QSTESTCD=CSCHPF04 | 4. It is hard for me to lift something heavy | List: PEDSQL1 <input type="text" value="6"/> |
| 5. QS.QSORRES where QS.QSTESTCD=CSCHPF05 | 5. It is hard for me to take a bath or shower by myself | List: PEDSQL1 <input type="text" value="6"/> |
| 6. QS.QSORRES where QS.QSTESTCD=CSCHPF06 | 6. It is hard for me to do chores around the house | List: PEDSQL1 <input type="text" value="6"/> |
| 7. QS.QSORRES where QS.QSTESTCD=CSCHPF07 | 7. I hurt or ache | List: PEDSQL1 <input type="text" value="6"/> |
| 8. QS.QSORRES where QS.QSTESTCD=CSCHPF08 | 8. I have low energy | List: PEDSQL1 <input type="text" value="6"/> |

ABOUT MY FEELINGS (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | |
|--|---|--|
| 9. QS.QSORRES where QS.QSTESTCD=CSCHEF01 | 1. I feel afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 10. QS.QSORRES where QS.QSTESTCD=CSCHEF02 | 2. I feel sad or blue | List: PEDSQL1 <input type="text" value="6"/> |
| 11. QS.QSORRES where QS.QSTESTCD=CSCHEF03 | 3. I feel angry | List: PEDSQL1 <input type="text" value="6"/> |
| 12. QS.QSORRES where QS.QSTESTCD=CSCHEF04 | 4. I have trouble sleeping | List: PEDSQL1 <input type="text" value="6"/> |
| 13. QS.QSORRES where QS.QSTESTCD=CSCHEF05 | 5. I worry about what will happen to me | List: PEDSQL1 <input type="text" value="6"/> |

HOW I GET ALONG WITH OTHERS (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | |
|--|--|--|
| 14. QS.QSORRES where QS.QSTESTCD=CSCHSF01 | 1. I have trouble getting along with other kids | List: PEDSQL1 <input type="text" value="6"/> |
| 15. QS.QSORRES where QS.QSTESTCD=CSCHSF02 | 2. Other kids do not want to be my friend | List: PEDSQL1 <input type="text" value="6"/> |
| 16. QS.QSORRES where QS.QSTESTCD=CSCHSF03 | 3. Other kids tease me | List: PEDSQL1 <input type="text" value="6"/> |
| 17. QS.QSORRES where QS.QSTESTCD=CSCHSF04 | 4. I cannot do things that other kids my age can do | List: PEDSQL1 <input type="text" value="6"/> |
| 18. QS.QSORRES where QS.QSTESTCD=CSCHSF05 | 5. It is hard to keep up when I play with other kids | List: PEDSQL1 <input type="text" value="6"/> |

ABOUT SCHOOL (problems with...)**QS.QSSCAT="SCHOOL FUNCTIONING"**

| | | |
|--|--|--|
| 19. QS.QSORRES where QS.QSTESTCD=CSCHSC01 | 1. It is hard to pay attention in class | List: PEDSQL1 <input type="text" value="6"/> |
| 20. QS.QSORRES where QS.QSTESTCD=CSCHSC02 | 2. I forget things | List: PEDSQL1 <input type="text" value="6"/> |
| 21. QS.QSORRES where QS.QSTESTCD=CSCHSC03 | 3. I have trouble keeping up with my schoolwork | List: PEDSQL1 <input type="text" value="6"/> |
| 22. QS.QSORRES where QS.QSTESTCD=CSCHSC04 | 4. I miss school because of not feeling well | List: PEDSQL1 <input type="text" value="6"/> |
| 23. QS.QSORRES where QS.QSTESTCD=CSCHSC05 | 5. I miss school to go to the doctor or hospital | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires

QS.QSCAT="PEDIATRIC QOL INVENTORY TEENAGER SUBJECT"

Pediatric QOL Inventory TEEN REPORT (QS3G)In the past **ONE month**, how much of a **problem** has this been for you...**ABOUT MY HEALTH AND ACTIVITIES (problems with...)****QS.QSSCAT="PHYSICAL FUNCTIONING"**

| | | |
|---|---|--|
| 1. QS.QSORRES where QS.QSTESTCD=CSTEPF01 | 1. It is hard for me to walk more than one block | List: PEDSQL1 <input type="text" value="6"/> |
| 2. QS.QSORRES where QS.QSTESTCD=CSTEPF02 | 2. It is hard for me to run | List: PEDSQL1 <input type="text" value="6"/> |
| 3. QS.QSORRES where QS.QSTESTCD=CSTEPF03 | 3. It is hard for me to do sports activity or exercise | List: PEDSQL1 <input type="text" value="6"/> |
| 4. QS.QSORRES where QS.QSTESTCD=CSTEPF04 | 4. It is hard for me to lift something heavy | List: PEDSQL1 <input type="text" value="6"/> |
| 5. QS.QSORRES where QS.QSTESTCD=CSTEPF05 | 5. It is hard for me to take a bath or shower by myself | List: PEDSQL1 <input type="text" value="6"/> |
| 6. QS.QSORRES where QS.QSTESTCD=CSTEPF06 | 6. It is hard for me to do chores around the house | List: PEDSQL1 <input type="text" value="6"/> |
| 7. QS.QSORRES where QS.QSTESTCD=CSTEPF07 | 7. I hurt or ache | List: PEDSQL1 <input type="text" value="6"/> |
| 8. QS.QSORRES where QS.QSTESTCD=CSTEPF08 | 8. I have low energy | List: PEDSQL1 <input type="text" value="6"/> |

ABOUT MY FEELINGS (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | |
|--|---|--|
| 9. QS.QSORRES where QS.QSTESTCD=CSTEEF01 | 1. I feel afraid or scared | List: PEDSQL1 <input type="text" value="6"/> |
| 10. QS.QSORRES where QS.QSTESTCD=CSTEEF02 | 2. I feel sad or blue | List: PEDSQL1 <input type="text" value="6"/> |
| 11. QS.QSORRES where QS.QSTESTCD=CSTEEF03 | 3. I feel angry | List: PEDSQL1 <input type="text" value="6"/> |
| 12. QS.QSORRES where QS.QSTESTCD=CSTEEF04 | 4. I have trouble sleeping | List: PEDSQL1 <input type="text" value="6"/> |
| 13. QS.QSORRES where QS.QSTESTCD=CSTEEF05 | 5. I worry about what will happen to me | List: PEDSQL1 <input type="text" value="6"/> |

HOW I GET ALONG WITH OTHERS (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | |
|---|--|--|
| 14. QS.QSORRES where QS.QSTESTCD=CTESF01 | 1. I have trouble getting along with other teens | List: PEDSQL1 <input type="text" value="6"/> |
| 15. QS.QSORRES where QS.QSTESTCD=CTESF02 | 2. Other teens do not want to be my friend | List: PEDSQL1 <input type="text" value="6"/> |
| 16. QS.QSORRES where QS.QSTESTCD=CTESF03 | 3. Other teens tease me | List: PEDSQL1 <input type="text" value="6"/> |
| 17. QS.QSORRES where QS.QSTESTCD=CTESF04 | 4. I cannot do things that other teens my age can do | List: PEDSQL1 <input type="text" value="6"/> |
| 18. QS.QSORRES where QS.QSTESTCD=CTESF05 | 5. It is hard to keep up with my peers | List: PEDSQL1 <input type="text" value="6"/> |

ABOUT SCHOOL (problems with...)**QS.QSSCAT="SCHOOL FUNCTIONING"**

| | | |
|---|--|--|
| 19. QS.QSORRES where QS.QSTESTCD=CTESC01 | 1. It is hard to pay attention in class | List: PEDSQL1 <input type="text" value="6"/> |
| 20. QS.QSORRES where QS.QSTESTCD=CTESC02 | 2. I forget things | List: PEDSQL1 <input type="text" value="6"/> |
| 21. QS.QSORRES where QS.QSTESTCD=CTESC03 | 3. I have trouble keeping up with my schoolwork | List: PEDSQL1 <input type="text" value="6"/> |
| 22. QS.QSORRES where QS.QSTESTCD=CTESC04 | 4. I miss school because of not feeling well | List: PEDSQL1 <input type="text" value="6"/> |
| 23. QS.QSORRES where QS.QSTESTCD=CTESC05 | 5. I miss school to go to the doctor or hospital | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**QS.QSCAT="MULTIDIMENSIONAL FATIGUE SCALE TODDLERS PARENT"****Multidimensional Fatigue Scale PARENT for TODDLERS (QS3H)***In the past **ONE month**, how much of a **problem** has this been for your child...***GENERAL FATIGUE (problems with...)****QS.QSSCAT="GENERAL FATIGUE"**

| | | | |
|----|---|---|--|
| 1. | QS.QSORRES where QS.QSTESTCD=MPTOGF01 | 1. Feeling tired | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=MPTOGF02 | 2. Feeling physically weak (not strong) | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=MPTOGF03 | 3. Feeling too tired to do things that he/she likes to do | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=MPTOGF04 | 4. Feeling too tired to spend time with his/her friends | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=MPTOGF05 | 5. Trouble finishing things | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=MPTOGF06 | 6. Trouble starting things | List: PEDSQL1 <input type="text" value="6"/> |

SLEEP/REST FATIGUE (problems with...)**QS.QSSCAT="SLEEP/REST FATIGUE"**

| | | | |
|-----|---|--|--|
| 7. | QS.QSORRES where QS.QSTESTCD=MPTORF01 | 1. Sleeping a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=MPTORF02 | 2. Difficulty sleeping through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=MPTORF03 | 3. Feeling tired when he/she wakes up in the morning | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=MPTORF04 | 4. Resting a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=MPTORF05 | 5. Taking a lot of naps | List: PEDSQL1 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=MPTORF06 | 6. Spending a lot of time in bed | List: PEDSQL1 <input type="text" value="6"/> |

COGNITIVE FATIGUE (problems with...)**QS.QSSCAT="COGNITIVE FATIGUE"**

| | | | |
|-----|---|--|--|
| 13. | QS.QSORRES where QS.QSTESTCD=MPTOCF01 | 1. Difficulty keeping his/her attention on things | List: PEDSQL1 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=MPTOCF02 | 2. Difficulty remembering what people tell him/her | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=MPTOCF03 | 3. Difficulty remembering what he/she just heard | List: PEDSQL1 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=MPTOCF04 | 4. Difficulty thinking quickly | List: PEDSQL1 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=MPTOCF05 | 5. Trouble remembering what he/she was just thinking | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=MPTOCF06 | 6. Trouble remembering more than one thing at a time | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=QuestionnairesMultidimensional Fatigue Scale PARENT (YOUNG CHILD (QS3I))
QS.QSCAT="MULTIDIMENSIONAL FATIGUE SCALE YOUNG CHILDREN PARENT"**Multidimensional Fatigue Scale PARENT (YOUNG CHILD (QS3I))**In the past **ONE month**, how much of a **problem** has this been for your child...**GENERAL FATIGUE (problems with...)**

QS.QSSCAT="GENERAL FATIGUE"

| | | | |
|----|---------------------------------------|---|--|
| 1. | QS.QSORRES where QS.QSTESTCD=MPYCGF01 | 1. Feeling tired | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=MPYCGF02 | 2. Feeling physically weak (not strong) | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=MPYCGF03 | 3. Feeling too tired to do things that he/she likes to do | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=MPYCGF04 | 4. Feeling too tired to spend time with his/her friends | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=MPYCGF05 | 5. Trouble finishing things | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=MPYCGF06 | 6. Trouble starting things | List: PEDSQL1 <input type="text" value="6"/> |

SLEEP/REST FATIGUE (problems with...)

QS.QSSCAT="SLEEP/REST FATIGUE"

| | | | |
|-----|---------------------------------------|--|--|
| 7. | QS.QSORRES where QS.QSTESTCD=MPYCRF01 | 1. Sleeping a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=MPYCRF02 | 2. Difficulty sleeping through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=MPYCRF03 | 3. Feeling tired when he/she wakes up in the morning | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=MPYCRF04 | 4. Resting a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=MPYCRF05 | 5. Taking a lot of naps | List: PEDSQL1 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=MPYCRF06 | 6. Spending a lot of time in bed | List: PEDSQL1 <input type="text" value="6"/> |

COGNITIVE FATIGUE (problems with...)

QS.QSSCAT="MENTAL FATIGUE"

| | | | |
|-----|---------------------------------------|--|--|
| 13. | QS.QSORRES where QS.QSTESTCD=MPYCCF01 | 1. Difficulty keeping his/her attention on things | List: PEDSQL1 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=MPYCCF02 | 2. Difficulty remembering what people tell him/her | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=MPYCCF03 | 3. Difficulty remembering what he/she just heard | List: PEDSQL1 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=MPYCCF04 | 4. Difficulty thinking quickly | List: PEDSQL1 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=MPYCCF05 | 5. Trouble remembering what he/she was just thinking | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=MPYCCF06 | 6. Trouble remembering more than one thing at a time | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**QS.QSCAT="MULTIDIMENSIONAL FATIGUE SCALE CHILDREN PARENT"**

Multidimensional Fatigue Scale PARENT for CHILDREN (QS3J)

Multidimensional Fatigue Scale PARENT for CHILDREN (QS3J)*In the past **ONE month**, how much of a **problem** has this been for your child...***GENERAL FATIGUE (problems with...)****QS.QSSCAT="GENERAL FATIGUE"**

| | | | |
|----|---------------------------------------|---|--|
| 1. | QS.QSORRES where QS.QSTESTCD=MPCHGF01 | 1. Feeling tired | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=MPCHGF02 | 2. Feeling physically weak (not strong) | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=MPCHGF03 | 3. Feeling too tired to do things that he/she likes to do | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=MPCHGF04 | 4. Feeling too tired to spend time with his/her friends | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=MPCHGF05 | 5. Trouble finishing things | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=MPCHGF06 | 6. Trouble starting things | List: PEDSQL1 <input type="text" value="6"/> |

SLEEP/REST FATIGUE (problems with...)**QS.QSSCAT="SLEEP/REST FATIGUE"**

| | | | |
|-----|---------------------------------------|--|--|
| 7. | QS.QSORRES where QS.QSTESTCD=MPCHRF01 | 1. Sleeping a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=MPCHRF02 | 2. Difficulty sleeping through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=MPCHRF03 | 3. Feeling tired when he/she wakes up in the morning | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=MPCHRF04 | 4. Resting a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=MPCHRF05 | 5. Taking a lot of naps | List: PEDSQL1 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=MPCHRF06 | 6. Spending a lot of time in bed | List: PEDSQL1 <input type="text" value="6"/> |

COGNITIVE FATIGUE (problems with...)**QS.QSSCAT="MENTAL FATIGUE"**

| | | | |
|-----|---------------------------------------|--|--|
| 13. | QS.QSORRES where QS.QSTESTCD=MPCHCF01 | 1. Difficulty keeping his/her attention on things | List: PEDSQL1 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=MPCHCF02 | 2. Difficulty remembering what people tell him/her | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=MPCHCF03 | 3. Difficulty remembering what he/she just heard | List: PEDSQL1 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=MPCHCF04 | 4. Difficulty thinking quickly | List: PEDSQL1 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=MPCHCF05 | 5. Trouble remembering what he/she was just thinking | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=MPCHCF06 | 6. Trouble remembering more than one thing at a time | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=QuestionnairesMultidimensional Fatigue Scale PARENT for TEENS (QS3K)
QS.QSCAT="MULTIDIMENSIONAL FATIGUE SCALE TEENAGERS PARENT"**Multidimensional Fatigue Scale PARENT for TEENS (QS3K)**In the past **ONE month**, how much of a **problem** has this been for your child...**GENERAL FATIGUE (problems with...)****QS.QSSCAT="GENERAL FATIGUE"**

| | | |
|--|---|--|
| 1. QS.QSORRES where QS.QSTESTCD=MPTEGF01 | 1. Feeling tired | List: PEDSQL1 <input type="text" value="6"/> |
| 2. QS.QSORRES where QS.QSTESTCD=MPTEGF02 | 2. Feeling physically weak (not strong) | List: PEDSQL1 <input type="text" value="6"/> |
| 3. QS.QSORRES where QS.QSTESTCD=MPTEGF03 | 3. Feeling too tired to do things that he/she likes to do | List: PEDSQL1 <input type="text" value="6"/> |
| 4. QS.QSORRES where QS.QSTESTCD=MPTEGF04 | 4. Feeling too tired to spend time with his/her friends | List: PEDSQL1 <input type="text" value="6"/> |
| 5. QS.QSORRES where QS.QSTESTCD=MPTEGF05 | 5. Trouble finishing things | List: PEDSQL1 <input type="text" value="6"/> |
| 6. QS.QSORRES where QS.QSTESTCD=MPTEGF06 | 6. Trouble starting things | List: PEDSQL1 <input type="text" value="6"/> |

SLEEP/REST FATIGUE (problems with...)**QS.QSSCAT="SLEEP/REST FATIGUE"**

| | | |
|---|--|--|
| 7. QS.QSORRES where QS.QSTESTCD=MPTERF01 | 1. Sleeping a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 8. QS.QSORRES where QS.QSTESTCD=MPTERF02 | 2. Difficulty sleeping through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 9. QS.QSORRES where QS.QSTESTCD=MPTERF03 | 3. Feeling tired when he/she wakes up in the morning | List: PEDSQL1 <input type="text" value="6"/> |
| 10. QS.QSORRES where QS.QSTESTCD=MPTERF04 | 4. Resting a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 11. QS.QSORRES where QS.QSTESTCD=MPTERF05 | 5. Taking a lot of naps | List: PEDSQL1 <input type="text" value="6"/> |
| 12. QS.QSORRES where QS.QSTESTCD=MPTERF06 | 6. Spending a lot of time in bed | List: PEDSQL1 <input type="text" value="6"/> |

COGNITIVE FATIGUE (problems with...)**QS.QSSCAT="MENTAL FATIGUE"**

| | | |
|---|--|--|
| 13. QS.QSORRES where QS.QSTESTCD=MPTECF01 | 1. Difficulty keeping his/her attention on things | List: PEDSQL1 <input type="text" value="6"/> |
| 14. QS.QSORRES where QS.QSTESTCD=MPTECF02 | 2. Difficulty remembering what people tell him/her | List: PEDSQL1 <input type="text" value="6"/> |
| 15. QS.QSORRES where QS.QSTESTCD=MPTECF03 | 3. Difficulty remembering what he/she just heard | List: PEDSQL1 <input type="text" value="6"/> |
| 16. QS.QSORRES where QS.QSTESTCD=MPTECF04 | 4. Difficulty thinking quickly | List: PEDSQL1 <input type="text" value="6"/> |
| 17. QS.QSORRES where QS.QSTESTCD=MPTECF05 | 5. Trouble remembering what he/she was just thinking | List: PEDSQL1 <input type="text" value="6"/> |
| 18. QS.QSORRES where QS.QSTESTCD=MPTECF06 | 6. Trouble remembering more than one thing at a time | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**QS.QSCAT="MULTIDIMENSIONAL FATIGUE SCALE YOUNG CHILD SUBJECT"****Multidimensional Fatigue Scale YOUNG CHILD (QS3L)**

Think about how you have been doing for the past few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

General Fatigue (PROBLEMS WITH...)**QS.QSSCAT="GENERAL FATIGUE"**

| | | | |
|----|--|---|--|
| 1. | QS.QSORRES where QS.QSTESTCD=MSYCGF01 | 1. Do you feel tired | List: PEDSQL2 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=MSYCGF02 | 2. Do you feel physically weak (not strong) | List: PEDSQL2 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=MSYCGF03 | 3. Do you feel too tired to do things that you like to do | List: PEDSQL2 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=MSYCGF04 | 4. Do you feel too tired to spend time with your friends | List: PEDSQL2 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=MSYCGF05 | 5. Do you have trouble finishing things | List: PEDSQL2 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=MSYCGF06 | 6. Do you have trouble starting things | List: PEDSQL2 <input type="text" value="6"/> |

Remember, tell me how much of a problem this has been for you for the last few weeks.

Sleep/Rest Fatigue (PROBLEMS WITH...)**QS.QSSCAT="SLEEP/REST FATIGUE"**

| | | | |
|-----|--|--|--|
| 7. | QS.QSORRES where QS.QSTESTCD=MSYCRF01 | 1. Do you sleep a lot | List: PEDSQL2 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=MSYCRF02 | 2. Is it hard for you to sleep through the night | List: PEDSQL2 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=MSYCRF03 | 3. Do you feel tired when you wake up in the morning | List: PEDSQL2 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=MSYCRF04 | 4. Do you rest a lot | List: PEDSQL2 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=MSYCRF05 | 5. Do you take a lot of naps | List: PEDSQL2 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=MSYCRF06 | 6. Do you spend a lot of time in bed | List: PEDSQL2 <input type="text" value="6"/> |

Cognitive Fatigue (PROBLEMS WITH...)**QS.QSSCAT="MENTAL FATIGUE"**

| | | | |
|-----|--|--|--|
| 13. | QS.QSORRES where QS.QSTESTCD=MSYCCF01 | 1. Is it hard for you to keep your attention on things | List: PEDSQL2 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=MSYCCF02 | 2. Is it hard for you to remember what people tell you | List: PEDSQL2 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=MSYCCF03 | 3. Is it hard for you to remember what you just heard | List: PEDSQL2 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=MSYCCF04 | 4. Is it hard for you to think quickly | List: PEDSQL2 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=MSYCCF05 | 5. Do you have trouble remembering what you were just thinking | List: PEDSQL2 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=MSYCCF06 | 6. Do you have trouble remembering more than one thing at a time | List: PEDSQL2 <input type="text" value="6"/> |

List: PEDSQL2

| Label | Value |
|------------|-------|
| [Blank] | |
| Not at all | 0 |
| Sometimes | 2 |
| A lot | 4 |

QS=Questionnaires

Multidimensional Fatigue Scale CHILD (QS3M)

QS.QSCAT="MULTIDIMENSIONAL FATIGUE SCALE CHILD SUBJECT"**Multidimensional Fatigue Scale CHILD (QS3M)***In the past **ONE month**, how much of a **problem** has this been for you***General Fatigue (PROBLEMS WITH...)****QS.QSSCAT="GENERAL FATIGUE"**

| | | | |
|----|--|--|--|
| 1. | QS.QSORRES where QS.QSTESTCD=MSCHGF01 | 1. I feel tired | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=MSCHGF02 | 2. I feel physically weak (not strong) | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=MSCHGF03 | 3. I feel too tired to do things that I like to do | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=MSCHGF04 | 4. I feel too tired to spend time with my friends | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=MSCHGF05 | 5. I have trouble finishing things | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=MSCHGF06 | 6. I have trouble starting things | List: PEDSQL1 <input type="text" value="6"/> |

Sleep/Rest Fatigue (PROBLEMS WITH...)**QS.QSSCAT="SLEEP/REST FATIGUE"**

| | | | |
|-----|--|---|--|
| 7. | QS.QSORRES where QS.QSTESTCD=MSCHRF01 | 1. I sleep a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=MSCHRF02 | 2. It is hard for me to sleep through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=MSCHRF03 | 3. I feel tired when I wake up in the morning | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=MSCHRF04 | 4. I rest a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=MSCHRF05 | 5. I take a lot of naps | List: PEDSQL1 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=MSCHRF06 | 6. I spend a lot of time in bed | List: PEDSQL1 <input type="text" value="6"/> |

Cognitive Fatigue (PROBLEMS WITH...)**QS.QSSCAT="MENTAL FATIGUE"**

| | | | |
|-----|--|---|--|
| 13. | QS.QSORRES where QS.QSTESTCD=MSCHCF01 | 1. It is hard for me to keep my attention on things | List: PEDSQL1 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=MSCHCF02 | 2. It is hard for me to remember what people tell me | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=MSCHCF03 | 3. It is hard for me to remember what I just heard | List: PEDSQL1 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=MSCHCF04 | 4. It is hard for me to think quickly | List: PEDSQL1 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=MSCHCF05 | 5. I have trouble remembering what I was just thinking | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=MSCHCF06 | 6. I have trouble remembering more than one thing at a time | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires

QS.QSCAT="MULTIDIMENSIONAL FATIGUE SCALE TEENAGER SUBJECT"

Multidimensional Fatigue Scale TEEN (QS3N)*In the past **ONE month**, how much of a **problem** has this been for you***General Fatigue (PROBLEMS WITH...)**

QS.QSSCAT="GENERAL FATIGUE"

| | | | |
|----|---------------------------------------|--|--|
| 1. | QS.QSORRES where QS.QSTESTCD=MSTEGF01 | 1. I feel tired | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=MSTEGF02 | 2. I feel physically weak (not strong) | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=MSTEGF03 | 3. I feel too tired to do things that I like to do | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=MSTEGF04 | 4. I feel too tired to spend time with my friends | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=MSTEGF05 | 5. I have trouble finishing things | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=MSTEGF06 | 6. I have trouble starting things | List: PEDSQL1 <input type="text" value="6"/> |

Sleep/Rest Fatigue (PROBLEMS WITH...)

QS.QSSCAT="SLEEP/REST FATIGUE"

| | | | |
|-----|---------------------------------------|---|--|
| 7. | QS.QSORRES where QS.QSTESTCD=MSTERF01 | 1. I sleep a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=MSTERF02 | 2. It is hard for me to sleep through the night | List: PEDSQL1 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=MSTERF03 | 3. I feel tired when I wake up in the morning | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=MSTERF04 | 4. I rest a lot | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=MSTERF05 | 5. I take a lot of naps | List: PEDSQL1 <input type="text" value="6"/> |
| 12. | QS.QSORRES where QS.QSTESTCD=MSTERF06 | 6. I spend a lot of time in bed | List: PEDSQL1 <input type="text" value="6"/> |

Cognitive Fatigue (PROBLEMS WITH...)

QS.QSSCAT="MENTAL FATIGUE"

| | | | |
|-----|---------------------------------------|---|--|
| 13. | QS.QSORRES where QS.QSTESTCD=MSTECF01 | 1. It is hard for me to keep my attention on things | List: PEDSQL1 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=MSTECF02 | 2. It is hard for me to remember what people tell me | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=MSTECF03 | 3. It is hard for me to remember what I just heard | List: PEDSQL1 <input type="text" value="6"/> |
| 16. | QS.QSORRES where QS.QSTESTCD=MSTECF04 | 4. It is hard for me to think quickly | List: PEDSQL1 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=MSTECF05 | 5. I have trouble remembering what I was just thinking | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=MSTECF06 | 6. I have trouble remembering more than one thing at a time | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires**Family Impact Module PARENT REPORT (QS30)****QS.QSCAT="FAMILY IMPACT MODULE PARENT"**

In the past **ONE month**, as a result of your child's health, how much of a problem have you had with...

PHYSICAL FUNCTIONING (problems with...)**QS.QSSCAT="PHYSICAL FUNCTIONING"**

| | | | |
|----|--------------------------------------|---|--|
| 1. | QS.QSORRES where QS.QSTESTCD=FP_PF01 | 1. I feel tired during the day | List: PEDSQL1 <input type="text" value="6"/> |
| 2. | QS.QSORRES where QS.QSTESTCD=FP_PF02 | 2. I feel tired when I wake up in the morning | List: PEDSQL1 <input type="text" value="6"/> |
| 3. | QS.QSORRES where QS.QSTESTCD=FP_PF03 | 3. I feel too tired to do the things I like to do | List: PEDSQL1 <input type="text" value="6"/> |
| 4. | QS.QSORRES where QS.QSTESTCD=FP_PF04 | 4. I get headaches | List: PEDSQL1 <input type="text" value="6"/> |
| 5. | QS.QSORRES where QS.QSTESTCD=FP_PF05 | 5. I feel physically weak | List: PEDSQL1 <input type="text" value="6"/> |
| 6. | QS.QSORRES where QS.QSTESTCD=FP_PF06 | 6. I feel sick to my stomach | List: PEDSQL1 <input type="text" value="6"/> |

EMOTIONAL FUNCTIONING (problems with...)**QS.QSSCAT="EMOTIONAL FUNCTIONING"**

| | | | |
|-----|--------------------------------------|--------------------------------|--|
| 7. | QS.QSORRES where QS.QSTESTCD=FP_EF01 | 1. I feel anxious | List: PEDSQL1 <input type="text" value="6"/> |
| 8. | QS.QSORRES where QS.QSTESTCD=FP_EF02 | 2. I feel sad | List: PEDSQL1 <input type="text" value="6"/> |
| 9. | QS.QSORRES where QS.QSTESTCD=FP_EF03 | 3. I feel angry | List: PEDSQL1 <input type="text" value="6"/> |
| 10. | QS.QSORRES where QS.QSTESTCD=FP_EF04 | 4. I feel frustrated | List: PEDSQL1 <input type="text" value="6"/> |
| 11. | QS.QSORRES where QS.QSTESTCD=FP_EF05 | 5. I feel helpless or hopeless | List: PEDSQL1 <input type="text" value="6"/> |

SOCIAL FUNCTIONING (problems with...)**QS.QSSCAT="SOCIAL FUNCTIONING"**

| | | | |
|-----|--------------------------------------|--|--|
| 12. | QS.QSORRES where QS.QSTESTCD=FP_SF01 | 1. I feel isolated from others | List: PEDSQL1 <input type="text" value="6"/> |
| 13. | QS.QSORRES where QS.QSTESTCD=FP_SF02 | 2. I have trouble getting support from others | List: PEDSQL1 <input type="text" value="6"/> |
| 14. | QS.QSORRES where QS.QSTESTCD=FP_SF03 | 3. It is hard to find time for social activities | List: PEDSQL1 <input type="text" value="6"/> |
| 15. | QS.QSORRES where QS.QSTESTCD=FP_SF04 | 4. I do not have enough energy for social activities | List: PEDSQL1 <input type="text" value="6"/> |

COGNITIVE FUNCTIONING (problems with...)**QS.QSSCAT="COGNITIVE FUNCTIONING"**

| | | | |
|-----|--------------------------------------|--|--|
| 16. | QS.QSORRES where QS.QSTESTCD=FP_CF01 | 1. It is hard for me to keep my attention on things | List: PEDSQL1 <input type="text" value="6"/> |
| 17. | QS.QSORRES where QS.QSTESTCD=FP_CF02 | 2. It is hard for me to remember what people tell me | List: PEDSQL1 <input type="text" value="6"/> |
| 18. | QS.QSORRES where QS.QSTESTCD=FP_CF03 | 3. It is hard for me to remember what I just heard | List: PEDSQL1 <input type="text" value="6"/> |
| 19. | QS.QSORRES where QS.QSTESTCD=FP_CF04 | 4. It is hard for me to think quickly | List: PEDSQL1 <input type="text" value="6"/> |
| 20. | QS.QSORRES where QS.QSTESTCD=FP_CF05 | 5. I have trouble remembering what I was just thinking | List: PEDSQL1 <input type="text" value="6"/> |

COMMUNICATION (problems with...)**QS.QSSCAT="COMMUNICATION"**

| | | | |
|-----|--------------------------------------|--|--|
| 21. | QS.QSORRES where QS.QSTESTCD=FP_CO01 | 1. I feel that others do not understand my family's situation | List: PEDSQL1 <input type="text" value="6"/> |
| 22. | QS.QSORRES where QS.QSTESTCD=FP_CO02 | 2. It is hard for me to talk about my child's health with others | List: PEDSQL1 <input type="text" value="6"/> |
| 23. | QS.QSORRES where QS.QSTESTCD=FP_CO03 | 3. It is hard for me to tell doctors and nurses how I feel | List: PEDSQL1 <input type="text" value="6"/> |

In the past **ONE month**, as a result of your child's health, how much of a problem have **you** had with...

WORRY (problems with...)**QS.QSSCAT="WORRY"**

| | | | |
|-----|--------------------------------------|--|--|
| 24. | QS.QSORRES where QS.QSTESTCD=FP_WO01 | 1. I worry about whether or not my child's medical treatments are working | List: PEDSQL1 <input type="text" value="6"/> |
| 25. | QS.QSORRES where QS.QSTESTCD=FP_WO02 | 2. I worry about the side effects of my child's medications/medical treatments | List: PEDSQL1 <input type="text" value="6"/> |

QS=Questionnaires

Protocol: LUM001-305

Study: LUM00130_ **QS.QSSCAT="WORRY"**

SV: 8.3

Family Impact Module PARENT REPORT (QS30)

| | | | |
|-----|---|---|--|
| 26. | QS.QSORRES where QS.QSTESTCD=FP_WO03 | 3. I worry about how others will react to my child's condition | List: PEDSQL1 <input type="text" value="6"/> |
| 27. | QS.QSORRES where QS.QSTESTCD=FP_WO04 | 4. I worry about how my child's illness is affecting other family members | List: PEDSQL1 <input type="text" value="6"/> |
| 28. | QS.QSORRES where QS.QSTESTCD=FP_WO05 | 5. I worry about my child's future | List: PEDSQL1 <input type="text" value="6"/> |

DIRECTIONS

Below is a list of things that might be a problem for **your family**. Please tell us **how much of a problem** each one has been for **your family** during the **past ONE month**.

*In the past **ONE month**, as a result of your child's health, how much of a problem has **your family** had with...*

DAILY ACTIVITIES (problems with...)

QS.QSSCAT="DAILY ACTIVITIES"

| | | | |
|-----|---|--|--|
| 29. | QS.QSORRES where QS.QSTESTCD=FP_DA01 | 1. Family activities taking more time and effort | List: PEDSQL1 <input type="text" value="6"/> |
| 30. | QS.QSORRES where QS.QSTESTCD=FP_DA02 | 2. Difficulty finding time to finish household tasks | List: PEDSQL1 <input type="text" value="6"/> |
| 31. | QS.QSORRES where QS.QSTESTCD=FP_DA03 | 3. Feeling too tired to finish household tasks | List: PEDSQL1 <input type="text" value="6"/> |

FAMILY RELATIONSHIPS (problems with...)

QS.QSSCAT="FAMILY RELATIONSHIPS"

| | | | |
|-----|---|---|--|
| 32. | QS.QSORRES where QS.QSTESTCD=FP_FR01 | 1. Lack of communication between family members | List: PEDSQL1 <input type="text" value="6"/> |
| 33. | QS.QSORRES where QS.QSTESTCD=FP_FR02 | 2. Conflicts between family members | List: PEDSQL1 <input type="text" value="6"/> |
| 34. | QS.QSORRES where QS.QSTESTCD=FP_FR03 | 3. Difficulty making decisions together as a family | List: PEDSQL1 <input type="text" value="6"/> |
| 35. | QS.QSORRES where QS.QSTESTCD=FP_FR04 | 4. Difficulty solving family problems together | List: PEDSQL1 <input type="text" value="6"/> |
| 36. | QS.QSORRES where QS.QSTESTCD=FP_FR05 | 5. Stress or tension between family members | List: PEDSQL1 <input type="text" value="6"/> |

List:PEDSQL1

| Label | Value |
|---------------|-------|
| [Blank] | |
| Never | 0 |
| Almost Never | 1 |
| Sometimes | 2 |
| Often | 3 |
| Almost Always | 4 |

QS=Questionnaires


Xanthoma Scale (QS7)

Xanthoma Scale (QS7)**QS.QSCAT = "CAREGIVER IMPRESSION CHANGE"****If N then QS.QSSTAT="NOT DONE"**

1. Was Xanthoma Scale completed?

List: YES_NO 6

**2. Date of assessment

QS.QSDTC dd-mm-yyyy

**3. Clinician Xanthoma Scale score

List: Xanthoma 6

**QS.QSORRES where
QS.QSTESTCD=QC_XS**

** Conditional Question

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| List: Xanthoma | |
|----------------|-------|
| Label | Value |
| [Blank] | |
| 0-None | 0 |
| 1-Minimal | 1 |
| 2-Moderate | 2 |
| 3-Disfiguring | 3 |
| 4-Disabling | 4 |

QS=Questionnaires

Caregiver Impression of Change (QS5)

QS.QSCAT = "CAREGIVER IMPRESSION CHANGE"**Caregiver Impression of Change (QS5)****If N then QS.QSSTAT="NOT DONE"**

1. Was caregiver impression of change completed?

List: YES_NO 6

**2. Date of assessment

QS.QSDTC dd-mm-yyyy

**3. How would you rate the change in your child's xanthoma severity since the start of the study?

List: PIC 6

**QS.QSORRES where
QS.QSTESTCD=QP_CIXAN**

** Conditional Question


| List:YES_NO | | List:PIC | |
|-------------|-------|-----------------|-------|
| Label | Value | Label | Value |
| [Blank] | | [Blank] | |
| Yes | Y | Much better | 1 |
| No | N | Better | 2 |
| | | A little better | 3 |
| | | No change | 4 |
| | | A little worse | 5 |
| | | Worse | 6 |
| | | Much worse | 7 |

DS=Disposition**DM=Demographics**Subject Summary (DS) **DS.DSCAT="DISPOSITION EVENT"**

1. Did the subject complete study treatment?

If Y then DS.DSTERM="COMPLETED"

**2. Date of Discontinuation

DS.DSSTDTC dd-mm-yyyy

**3. Reason for Discontinuation

List: NCOMPLT **6****DS.DSTERM and DS.DSDECOD**

4. Date of last dose

DM.RFENDTC**SUPPDS.QVAL where SUPPDS.QNAM=DSLDDAT**

5. Date of final study contact

SUPPDS.QVAL where SUPPDS.QNAM=DSCONDAT

**6. Reason for screen failure

List: SF **6****[NOT SUBMITTED]**

**7. Specify

DS.DSTERM

** Conditional Question

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| List: NCOMPLT | |
|--------------------------------------|-------|
| Label | Value |
| [Blank] | |
| Adverse Event | 1 |
| Death | 2 |
| Lost to follow-up | 4 |
| Non-compliance with study drug | 5 |
| Physician decision | 6 |
| Pregnancy | 7 |
| Progressive Disease | 8 |
| Protocol violation | 9 |
| Study terminated by sponsor | 11 |
| Withdrawal by caregiver | 12 |
| Withdrawal by subject | 13 |
| Roll-over to new LUM001/SHP625 study | 14 |
| Screen Failure | 15 |
| Other | 99 |

| List: SF | |
|-------------------------------------|-------|
| Label | Value |
| [Blank] | |
| Failed to meet eligibility criteria | 1 |
| Lost to follow-up | 2 |
| Withdrawal by caregiver | 3 |
| Withdrawal by subject | 4 |

DM=Demographics

Protocol Extension (PRE)

DS.DSCAT="PROTOCOL MILESTONE"
 DS.DSTERM="PA4 INFORMED CONSENT OBTAINED"
 DS.DSDECOD="PA4 INFORMED CONSENT OBTAINED"

1. Did the subject consent to the Protocol Extension Amendment?

SUPPDM.QVAL where SUPPDM.QNAM=PREYN

**2. Protocol Criteria Version

SUPPDM.QVAL where SUPPDM.QNAM=PREPCV

**3. Date of Consent

DS.DSSTDTC dd-mmm-yyyy

**4. Did the subject have a > 7 day gap in study dosing?

SUPPDM.QVAL where SUPPDM.QNAM=PREGAP

**5. Did the subject meet all eligibility criteria?

SUPPDM.QVAL where SUPPDM.QNAM=PREIEYN

** Conditional Question

| List:Y_N_NA_ | |
|----------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |
| Not Approached | NA_ |

| List:IEPRT2_ | |
|--------------|-----------|
| Label | Value |
| [Blank] | |
| Amendment | Amendment |
| 4 - | 4 - |
| 27APR2016 | 27APR2016 |

| List:YES_NO | |
|-------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

IE=Inclusion/Exclusion Criteria Not Met

Inclusion/Exclusion Criteria 2 (IE2)

1. Did the subject meet all eligibility criteria?

List: YES_NO [NOT SUBMITTED]

2. Inclusion/Exclusion Criteria

| 2.R. | Criterion Type | Criterion not met | Specify | Approval date | Sponsor approval? |
|----------|---------------------------|-------------------|---------|---------------|--|
| 2.R.1. | Criterion Type | | | | List: IE <input type="text"/> IE.IECAT |
| 2.R.2. | Criterion not met | | | | List: IENUM <input type="text"/> IE.IETESTCD |
| 2.R.3. | Specify | | | | IE.IETESTCD <input type="text"/> |
| **2.R.4. | Date of approval | | | | SUPPIE.QVAL where SUPPIE.QNAM=IEAPPDAT -yyyy |
| 2.R.5. | Lumena approval received? | | | | SUPPIE.QVAL where SUPPIE.QNAM=IEAPPR |

Add New Row

** Conditional Question

| List:YES_NO | | List:IE | | List:IENUM | |
|-------------|-------|-----------|-------|------------|-------|
| Label | Value | Label | Value | Label | Value |
| [Blank] | | [Blank] | | [Blank] | |
| Yes | Y | Inclusion | 1 | 1 | 1 |
| No | N | Exclusion | 2 | 2 | 2 |
| | | | | 3 | 3 |
| | | | | 4 | 4 |
| | | | | 5 | 5 |
| | | | | 6 | 6 |
| | | | | 7 | 7 |
| | | | | 8 | 8 |
| | | | | 9 | 9 |
| | | | | 10 | 10 |

MH=Medical History**MHCAT="GENERAL MEDICAL HISTORY RE-INITIATION DAY 0****Medical History 2 (MH2)**

1. Any new medical histories to report?

[NOT SUBMITTED]List: YES_NO **6**

Please only record events that started within a study gap period. A study gap period occurs between completing the prior core or follow up period and consenting to an additional followup period. However, all events that started within 30 days of last dose must be recorded on the Adverse Event form.

2. Medical History

| 2.R. | Verbatim Term | Start Date (Day) | Start Date (Month) | Start Date (Year) | Ongoing |
|------------|--------------------|------------------|--------------------|-------------------|---|
| | End Date (Day) | End Date (Month) | End Date (Year) | | |
| 2.R.1. | Verbatim term | | | | MH.MHTERM |
| *2.R.1.1. | MHTERM_Enc_TERM | | | | MH.MHLLT d |
| *2.R.1.2. | MHTERM_Enc_CODE | | | | MH.MHLLTCD d |
| *2.R.1.3. | MHTERM_Enc_TYPE | | | | [NOT SUBMITTED] |
| *2.R.1.4. | MHTERM_Enc_CAT1 | | | | MH.MHBODSYS, MH.MHBDSYCD, MH.MHSOC, MH.MHSOCCD |
| *2.R.1.5. | MHTERM_Enc_CAT2 | | | | MH.MHHLGT, MH.MHHLGTCD |
| *2.R.1.6. | MHTERM_Enc_CAT3 | | | | MH.MHHLT, MH.MHHLTCD |
| *2.R.1.7. | MHTERM_Enc_CAT4 | | | | MH.MHDECOD, MH.MHPTCD |
| *2.R.1.8. | MHTERM_Enc_CAT5 | | | | [NOT SUBMITTED] |
| *2.R.1.9. | MHTERM_Enc_CAT6 | | | | [NOT SUBMITTED] |
| *2.R.1.10. | MHTERM_Enc_CAT7 | | | | [NOT SUBMITTED] |
| *2.R.1.11. | MHTERM_Enc_CAT8 | | | | [NOT SUBMITTED] |
| *2.R.1.12. | MHTERM_Enc_CAT9 | | | | [NOT SUBMITTED] |
| 2.R.2. | Start Date (Day) | | | | List: DAY 6 |
| 2.R.3. | Start Date (Month) | | | | List: MONTH 6 MH.MHSTDTC |
| 2.R.4. | Start Date (Year) | | | | |
| *2.R.4.1. | Start Date | | | | Read Only: Derived |
| 2.R.5. | Ongoing? | | | | List: YES 6 MH.MHENRTPT |
| **2.R.6. | End Date (Day) | | | | List: DAY 6 |
| **2.R.7. | End Date (Month) | | | | List: MONTH 6 MH.MHENDTC |
| **2.R.8. | End Date (Year) | | | | |
| *2.R.8.1. | End Date | | | | Read Only: Derived |

Add New Row

* Hidden Question

** Conditional Question

| List: YES_NO | | List: DAY | | List: MONTH | |
|--------------|-------|-----------|-------|-------------|-------|
| Label | Value | Label | Value | Label | Value |
| [Blank] | | [Blank] | | [Blank] | |
| Yes | Y | 01 | 01 | JAN | JAN |
| No | N | 02 | 02 | FEB | FEB |
| | | 03 | 03 | MAR | MAR |
| | | 04 | 04 | APR | APR |
| | | 05 | 05 | MAY | MAY |

| | | | |
|----|----|-----|-----|
| 06 | 06 | JUN | JUN |
| 07 | 07 | JUL | JUL |
| 08 | 08 | AUG | AUG |
| 09 | 09 | SEP | SEP |
| 10 | 10 | OCT | OCT |
| 11 | 11 | NOV | NOV |
| 12 | 12 | DEC | DEC |
| 13 | 13 | UNK | UNK |
| 14 | 14 | | |
| 15 | 15 | | |
| 16 | 16 | | |
| 17 | 17 | | |
| 18 | 18 | | |
| 19 | 19 | | |
| 20 | 20 | | |
| 21 | 21 | | |
| 22 | 22 | | |
| 23 | 23 | | |
| 24 | 24 | | |
| 25 | 25 | | |
| 26 | 26 | | |
| 27 | 27 | | |
| 28 | 28 | | |
| 29 | 29 | | |
| 30 | 30 | | |
| 31 | 31 | | |
| UN | UN | | |

List: YES

| Label | Value |
|---------|-------|
| [Blank] | |
| YES | Y |

Clinical Laboratory Tests (LB)

1. Clinical Laboratory Tests

| 1.R. | Sample Type | Sample collected? | Collection Date | Sample ID |
|----------|---------------------------|-------------------|-----------------|----------------------------------|
| 1.1.1. | Sample Type | | | Blood |
| 1.1.2. | Was the sample collected? | | | List: YES_NO 6 |
| **1.1.3. | Collection Date | | | <input type="text"/> dd-mmm-yyyy |
| **1.1.4. | Sample ID | | | <input type="text"/> |
| 1.2.1. | Sample Type | | | Urine |
| 1.2.2. | Was the sample collected? | | | List: YES_NO 6 |
| **1.2.3. | Collection Date | | | <input type="text"/> dd-mmm-yyyy |
| **1.2.4. | Sample ID | | | <input type="text"/> |

** Conditional Question

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

DM=Demographics

Long Term Optional Treatment (PRE2)

DS.DSCAT="PROTOCOL MILESTONE"

DS.DSTERM="PA5 INFORMED CONSENT OBTAINED"

DS.DSDECOD="PA5 INFORMED CONSENT OBTAINED"

1. Did the subject consent to the long term optional treatment period?

SUPPDM.QVAL where SUPPDM.QNAM=PREYN2

**2. Protocol Criteria Version

SUPPDM.QVAL where SUPPDM.QNAM=PREPCV2

**3. Date Parental Informed Consent signed

DS.DSSTDTC



dd-mmm-yyyy

**4. Young Adult Consent Not Applicable

SUPPDS.QVAL where SUPPDS.QNAM=ICYANA

**5. Date Young Adult Consent signed

SUPPDS.QVAL where SUPPDS.QNAM=ICYADAT

**6. Assent Not Applicable

SUPPDS.QVAL where SUPPDS.QNAM=ICANA

**7. Date Assent signed

SUPPDS.QVAL where SUPPDS.QNAM=ICADAT

**8. What schedule did subject complete first?

[NOT SUBMITTED]

** Conditional Question

| List:YES_NO | |
|-------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| List:IEPRT3_ | |
|---------------------------|---------------------------|
| Label | Value |
| [Blank] | |
| Amendment 5 - 13NOV2017 | Amendment 5 - 13NOV2017 |
| Amendment 6 - 25-JUN-2018 | Amendment 6 - 25-JUN-2018 |

| List:NA | |
|----------------|-------|
| Label | Value |
| [Blank] | |
| Not Applicable | NA |

| List:PROD | |
|---------------------------------|-------|
| Label | Value |
| [Blank] | |
| D | D |
| E | E |
| Not Applicable - Screen Failure | NA |

IE=Inclusion/Exclusion Criteria Not Met

Inclusion/Exclusion Criteria 3 (IE3)

1. Did the subject meet all eligibility criteria?

List: YES_NO 6

[NOT SUBMITTED]

2. Inclusion/Exclusion Criteria

2.R. Criterion Type

Criterion not met

2.R.1. Criterion Type

List: IE 6

IE.IECAT

2.R.2. Criterion not met

List: IENUM2_ 6

IE.IETESTCD

Add New Row

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| List: IE | |
|-----------|-------|
| Label | Value |
| [Blank] | |
| Inclusion | 1 |
| Exclusion | 2 |

| List: IENUM2_ | |
|---------------|-------|
| Label | Value |
| [Blank] | |
| 1 | 1 |
| 2 | 2 |
| 3 | 3 |
| 4 | 4 |
| 5 | 5 |
| 6 | 6 |

DS=Disposition**DM=Demographics**Subject Summary 2 (DS2) **DS.DSCAT="DISPOSITION EVENT"**

1. Did the subject complete treatment under long term optional period?

If Y then DS.DSTERM="COMPLETED"

**2. Date of Discontinuation

DS.DSSTDTC

dd-mmm-yyyy

**3. Reason for Discontinuation

List: NCOMPLT **6****DS.DSTERM and DS.DSDECOD**

**4. Specify

DS.DSTERM

5. Date of last dose

DM.RFENDTC**SUPPDS.QVAL where SUPPDS.QNAM=DSLDDAT**

dd-mmm-yyyy

6. Date of final study contact

SUPPDS.QVAL where SUPPDS.QNAM=DSCONDAT

dd-mmm-yyyy

** Conditional Question

| List: YES_NO | | List: NCOMPLT | |
|--------------|-------|--------------------------------------|-------|
| Label | Value | Label | Value |
| [Blank] | | [Blank] | |
| Yes | Y | Adverse Event | 1 |
| No | N | Death | 2 |
| | | Lost to follow-up | 4 |
| | | Non-compliance with study drug | 5 |
| | | Physician decision | 6 |
| | | Pregnancy | 7 |
| | | Progressive Disease | 8 |
| | | Protocol violation | 9 |
| | | Study terminated by sponsor | 11 |
| | | Withdrawal by caregiver | 12 |
| | | Withdrawal by subject | 13 |
| | | Roll-over to new LUM001/SHP625 study | 14 |
| | | Screen Failure | 15 |
| | | Other | 99 |

DM=Demographics

Long Term Optional Treatment 2

DS.DSCAT="PROTOCOL MILESTONE"

DS.DSTERM="PA5 INFORMED CONSENT OBTAINED"

DS.DSDECOD="PA5 INFORMED CONSENT OBTAINED"

1. Did the subject consent to the long term optional treatment 2 period for Amendment 6?

SUPPDM.QVAL where SUPPDM.QNAM=PREYN3

- **2. Date Parental Informed Consent signed

DS.DSSTDTC



dd-mmm-yyyy

- **3. Young Adult Consent Not Applicable

SUPPDS.QVAL where SUPPDS.QNAM=ICYANA

- **4. Date Young Adult Consent signed

SUPPDS.QVAL where SUPPDS.QNAM=ICYADAT

- **5. Assent Not Applicable

SUPPDS.QVAL where SUPPDS.QNAM=ICANA

- **6. Date Assent signed

SUPPDS.QVAL where SUPPDS.QNAM=ICADAT

- ** Conditional Question

| List:YES_NO | | List:NA | |
|-------------|-------|------------|-------|
| Label | Value | Label | Value |
| [Blank] | | [Blank] | |
| Yes | Y | Not | NA |
| No | N | Applicable | |

CM=Concomitant Medications**Concomitant Medications (CM)**

1. Were any medications taken?

[NOT SUBMITTED]

2. Concomitant Medications

| Medication Name | Reported in core (301)? | Indication | Start Date (Day) | Start Date (Month) |
|-------------------|------------------------------------|---------------------|---------------------------------|--------------------|
| Start Date (Year) | Taken Prior to Day 0 of 305 Study? | Ongoing at Week 48? | Prior to entering the Amend #4? | Ongoing? |
| End Date (Day) | End Date (Month) | End Date (Year) | Dose | Dose Unit |
| Route | Frequency | | | |

2.R.1. Medication/Therapy Name

CM.CMTRT

*2.R.1.1. CMTRT_Enc_TERM

[NOT SUBMITTED]**SUPPCM.QVAL where SUPPCM.QNAM=CMDECOD2 if greater than 200 chars**

*2.R.1.2. CMTRT_Enc_CODE

CM.CMDECOD

*2.R.1.3. CMTRT_Enc_TYPE

[NOT SUBMITTED]

*2.R.1.4. CMTRT_Enc_CAT1

[NOT SUBMITTED]

*2.R.1.5. CMTRT_Enc_CAT2

CM.CMCLAS and CM.CMCLASCD

*2.R.1.6. CMTRT_Enc_CAT3

[NOT SUBMITTED]

*2.R.1.7. CMTRT_Enc_CAT4

[NOT SUBMITTED]

*2.R.1.8. CMTRT_Enc_CAT5

[NOT SUBMITTED]

*2.R.1.9. CMTRT_Enc_CAT6

[NOT SUBMITTED]

*2.R.1.10. CMTRT_Enc_CAT7

[NOT SUBMITTED]

*2.R.1.11. CMTRT_Enc_CAT8

[NOT SUBMITTED]

*2.R.1.12. CMTRT_Enc_CAT9

[NOT SUBMITTED]

2.R.2. Reported in core (301) study database?

SUPPCM.QVAL where SUPPCM.QNAM=COREREP

2.R.3. Indication

CM.CMINDC

2.R.4. Start Date (Day)

List: DAY

2.R.5. Start Date (Month)

List: MONTH **CM.CMSTDTC**

2.R.6. Start Date (Year)

*2.R.6.1. Start Date

Read Only: Derived

2.R.7. Taken Prior to Day 0 of 305 Study?

If Y then CM.CMCAT="PRIOR"

2.R.8. Was this medication ongoing at Week 48 of 305 study?

[NOT SUBMITTED]

2.R.9. Taken Prior to entering the Amendment #4 305 Extension?

[NOT SUBMITTED]

2.R.10. Ongoing at subject final visit?

If Y THEN CM.CMENRTPT = "ONGOING"

**2.R.11. End Date (Day)

List: DAY

**2.R.12. End Date (Month)

List: MONTH **CM.CMENDTC**

**2.R.13. End Date (Year)

*2.R.13.1. End Date

Read Only: Derived

2.R.14. Dose

**CM.CMDOSE for numeric
CM.CMDOSTXT for non numeric**

2.R.15. Dose Unit

List: DOSE **CM.CMDOSU**

**2.R.16. Other: Specify

CM.CMDOSU

CM=Concomitant Medications

Protocol: LUM001-305

Study: LUM001305

SV: 8.3

Concomitant Medications (CM)

| | |
|--------------------------|--|
| 2.R.17. Route | List: ROUTE <input type="text" value="6"/> CM.CMROUTE |
| **2.R.18. Other: Specify | CM.CMROUTE <input type="text"/> |
| 2.R.19. Frequency | List: FREQ <input type="text" value="6"/> CM.CMDOSFRQ |
| **2.R.20. Other: Specify | CM.CMDOSFRQ <input type="text"/> |
| Add New Row | |

* Hidden Question

** Conditional Question

| List: YES_NO | |
|--------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| List: DAY | |
|-----------|-------|
| Label | Value |
| [Blank] | |
| 01 | 01 |
| 02 | 02 |
| 03 | 03 |
| 04 | 04 |
| 05 | 05 |
| 06 | 06 |
| 07 | 07 |
| 08 | 08 |
| 09 | 09 |
| 10 | 10 |
| 11 | 11 |
| 12 | 12 |
| 13 | 13 |
| 14 | 14 |
| 15 | 15 |
| 16 | 16 |
| 17 | 17 |
| 18 | 18 |
| 19 | 19 |
| 20 | 20 |
| 21 | 21 |
| 22 | 22 |
| 23 | 23 |
| 24 | 24 |
| 25 | 25 |
| 26 | 26 |
| 27 | 27 |
| 28 | 28 |
| 29 | 29 |
| 30 | 30 |
| 31 | 31 |
| UN | UN |

| List: MONTH | |
|-------------|-------|
| Label | Value |
| [Blank] | |
| JAN | JAN |
| FEB | FEB |
| MAR | MAR |
| APR | APR |
| MAY | MAY |
| JUN | JUN |
| JUL | JUL |
| AUG | AUG |
| SEP | SEP |
| OCT | OCT |
| NOV | NOV |
| DEC | DEC |
| UNK | UNK |

| List: DOSE |
|------------|
|------------|

| List: ROUTE |
|-------------|
|-------------|

| List: FREQ |
|------------|
|------------|

| Label | Value | Label | Value | Label | Value |
|---------|---------|--------------------------|--------------------------|---------|---------|
| [Blank] | | [Blank] | | [Blank] | |
| TABLET | TABLET | ORAL | ORAL | BID | BID |
| CAPSULE | CAPSULE | INTRAVENOUS | INTRAVENOUS | ONCE | ONCE |
| mg | mg | SUBCUTANEOUS | SUBCUTANEOUS | PRN | PRN |
| ug | ug | TOPICAL | TOPICAL | Q6H | Q6H |
| g | g | TRANSDERMAL | TRANSDERMAL | Q8H | Q8H |
| mEq | mEq | RESPIRATORY (INHALATION) | RESPIRATORY (INHALATION) | Q12H | Q12H |
| mL | mL | NASAL | NASAL | Q3D | Q3D |
| oz | oz | INTRASINAL | INTRASINAL | QD | QD |
| L/min | L/min | OPHTHALMIC | OPHTHALMIC | QID | QID |
| gtt | gtt | INTRAMUSCULAR | INTRAMUSCULAR | QOD | QOD |
| IU | IU | VAGINAL | VAGINAL | QM | QM |
| U | U | RECTAL | RECTAL | QS | QS |
| PATCH | PATCH | SUBLINGUAL | SUBLINGUAL | TID | TID |
| PUFF | PUFF | BUCCAL | BUCCAL | TIS | TIS |
| SPRAY | SPRAY | INTRA-ARTICULAR | INTRA-ARTICULAR | UNKNOWN | UNKNOWN |
| Tbsp | Tbsp | AURICULAR (OTIC) | AURICULAR (OTIC) | Other | Other |
| tsp | tsp | UNKNOWN | UNKNOWN | | |
| UNKNOWN | UNKNOWN | OTHER | OTHER | | |
| OTHER | OTHER | | | | |

Study Drug Administration 2 (EX2)

1. Dose Escalation Period

| 1.R. | Start Date | End Date | Dose |
|--|------------|---|--|
| 1.R.1. | Start Date | <input type="text"/> | <input type="text" value="dd-mmm-yyyy"/> |
| 1.R.2. | End Date | <input type="text"/> | <input type="text" value="dd-mmm-yyyy"/> |
| 1.R.3. | Dose | List: EXDOSE <input type="text" value="6"/> | |
| <input type="button" value="Add New Row"/> | | | |

2. Stable Dosing and Optional Extension

| 2.R. | Start Date | End Date | Dose |
|--|------------|--|--|
| 2.R.1. | Start Date | <input type="text"/> | <input type="text" value="dd-mmm-yyyy"/> |
| 2.R.2. | End Date | <input type="text"/> | <input type="text" value="dd-mmm-yyyy"/> |
| 2.R.3. | Dose | List: EXDOSEB <input type="text" value="6"/> | |
| <input type="button" value="Add New Row"/> | | | |

| List:EXDOSE | | List:EXDOSEB | |
|---|-------|------------------|-------|
| Label | Value | Label | Value |
| [Blank] | | [Blank] | |
| 14ug/kg/day or LUM001- 301 Dose | 14 | 0 ug/kg/day | 0 |
| 35 ug/kg/day or LUM001- 301 Dose | 35 | 14 ug/kg/day | 14 |
| 70 ug/kg/day or LUM001- 301 Dose | 70 | 35 ug/kg/day | 35 |
| 140 ug/kg/day or LUM001- 301 Dose | 140 | 70 ug/kg/day | 70 |
| 280 ug/kg/day or LUM001- 301 Dose | 280 | 140 ug/kg/day | 140 |
| | | 280 ug/kg/day | 280 |

AE=Adverse Events

Adverse Events (AE)

1. Were any Adverse Events experienced?

[NOT SUBMITTED]

2. Adverse Events

| Verbatim Term | Reported in core (301)? | Serious? | Start Date (Day) | Start Date (Month) |
|---------------------|-------------------------|----------------------------|------------------|--------------------|
| Start Date (Year) | Outcome | End Date (Day) | End Date (Month) | End Date (Year) |
| Ongoing at Week 48? | Action Taken | Relationship | Severity | Life Threatening |
| Treatment: None | Treatment: Medication | Treatment: Hospitalization | Other: Specify | |

2.R.1. Verbatim Term

AE.AETERM

*2.R.1.1. AETERM_Enc_TERM

Re: **AE.AELLT**

*2.R.1.2. AETERM_Enc_CODE

Re: **AE.AELLTCD**

*2.R.1.3. AETERM_Enc_TYPE

Re: **[NOT SUBMITTED]**

*2.R.1.4. AETERM_Enc_CAT1

AE.AEBODSYS, AE.AEBDSYCD, and AE.AESOC, AE.AESOCCD

*2.R.1.5. AETERM_Enc_CAT2

Re: **AE.AEHLGT and AE.AEHLGTCD**

*2.R.1.6. AETERM_Enc_CAT3

Re: **AE.AEHLT and AE.AEHLTCD**

*2.R.1.7. AETERM_Enc_CAT4

Re: **AE.AEDECOD and AE.AEPTCD**

*2.R.1.8. AETERM_Enc_CAT5

Re: **[NOT SUBMITTED]**

*2.R.1.9. AETERM_Enc_CAT6

Re: **[NOT SUBMITTED]**

*2.R.1.10. AETERM_Enc_CAT7

Re: **[NOT SUBMITTED]**

*2.R.1.11. AETERM_Enc_CAT8

Re: **[NOT SUBMITTED]**

*2.R.1.12. AETERM_Enc_CAT9

Re: **[NOT SUBMITTED]**

2.R.2. Reported in core (301) study database?

SUPPAE.QVAL where SUPPAE.QNAM=COREREP

2.R.3. Is the Adverse Event Serious?

List: YES_NO **6****AE.AESER**

2.R.4. Start Date (Day)

List: DAY **6****AE.AESTDTC**

2.R.5. Start Date (Month)

List: MONTH **6**

2.R.6. Start Date (Year)

*2.R.6.1. Start Date

Read Only: Derived

2.R.7. Outcome

List: OUT **6****AE.AEOUT**

**2.R.8. End Date (Day)

List: DAY **6**

**2.R.9. End Date (Month)

List: MONTH **6****AE.AEENDTC**

**2.R.10. End Date (Year)

*2.R.10.1. End Date

Read Only: Derived

2.R.11. Was this event ongoing at Week 48 of 305 study?

List: YES_NO **6****[NOT SUBMITTED]**

2.R.12. Action Taken with Study Treatment

List: AEACN **6****AE.AEACN**

2.R.13. Relationship to Study Treatment

List: REL **6****AE.AEREL**

2.R.14. Was CTCAE grading used to assess severity?

If Y then AE.AEGRPID="CTCAE". N then AE.AEGRPID="NON-CTCAE"

2.R.15. Severity

AE.AETOXGR List: SEV **6**

**2.R.16. Was the Serious Event Life Threatening?

List: YES_NO **6****AE.AESLIFE**

AE=Adverse Events

Protocol: LUM001-305

Study: LUM001305

SV: 8.3
Adverse Events (AE)

| | | | |
|--------------------|--|--|-----------------|
| 2.R.17. | Treatment Required: None | List: YES <input type="text" value="6"/> | [NOT SUBMITTED] |
| **2.R.18. | Treatment Required: Medication Required | List: YES <input type="text" value="6"/> | AE.AECONTRT |
| **2.R.19. | Treatment Required: Hospitalization Required | List: YES <input type="text" value="6"/> | AE.AESHOSP |
| **2.R.20. | Treatment Required: Other | List: YES <input type="text" value="6"/> | [NOT SUBMITTED] |
| **2.R.21. | Other: Specify | AE.AEACNOTH <input type="text"/> | |
| Add New Row | | | |

* Hidden Question

** Conditional Question

| List:YES_NO | |
|-------------|-------|
| Label | Value |
| [Blank] | |
| Yes | Y |
| No | N |

| List:DAY | |
|----------|-------|
| Label | Value |
| [Blank] | |
| 01 | 01 |
| 02 | 02 |
| 03 | 03 |
| 04 | 04 |
| 05 | 05 |
| 06 | 06 |
| 07 | 07 |
| 08 | 08 |
| 09 | 09 |
| 10 | 10 |
| 11 | 11 |
| 12 | 12 |
| 13 | 13 |
| 14 | 14 |
| 15 | 15 |
| 16 | 16 |
| 17 | 17 |
| 18 | 18 |
| 19 | 19 |
| 20 | 20 |
| 21 | 21 |
| 22 | 22 |
| 23 | 23 |
| 24 | 24 |
| 25 | 25 |
| 26 | 26 |
| 27 | 27 |
| 28 | 28 |
| 29 | 29 |
| 30 | 30 |
| 31 | 31 |
| UN | UN |

| List:MONTH | |
|------------|-------|
| Label | Value |
| [Blank] | |
| JAN | JAN |
| FEB | FEB |
| MAR | MAR |
| APR | APR |
| MAY | MAY |
| JUN | JUN |
| JUL | JUL |
| AUG | AUG |
| SEP | SEP |
| OCT | OCT |
| NOV | NOV |
| DEC | DEC |
| UNK | UNK |

| List:OUT | |
|----------------------------------|-------|
| Label | Value |
| [Blank] | |
| Fatal | 1 |
| Not Recovered/not resolved | 2 |
| Recovered/Resolved | 3 |
| Recovered/Resolved with sequelae | 4 |
| Recovering/Resolving | 5 |
| Unknown | 88 |

| List:AEACN | |
|------------------|-------|
| Label | Value |
| [Blank] | |
| Dose not changed | 1 |
| Drug interrupted | 2 |
| Drug withdrawn | 3 |
| Dose reduced | 4 |
| Not Applicable | 5 |

| List:REL | |
|-------------------------------|-------|
| Label | Value |
| [Blank] | |
| 1 - Related | 1 |
| 2 - Possibly Related | 2 |
| 3 - Unlikely/Remotely Related | 3 |
| 4 - Not Related | 4 |

| List:SEV | |
|---------------------------|-------|
| Label | Value |
| [Blank] | |
| Grade 1: Mild | 1 |
| Grade 2: Moderate | 2 |
| Grade 3: Severe | 3 |
| Grade 4: Life-threatening | 4 |
| Grade 5: Fatal | 5 |


| List:YES | |
|----------|-------|
| Label | Value |
| [Blank] | |
| YES | Y |

DA=Drug Accountability


Study Drug Accountability 1 (SDA1)

DA.DATESTCD=DISPAMT
DA.DATEST=Dispensed Amount

1. Study Drug Accountability

| 1.R. | Unique Batch | Vial Weeks | Batch Vial Number | Dispensed Date |
|------------------------|----------------------------|------------|-------------------|--|
| 1.R.1. | Unique Batch- 117462/C/xx | | | <div>DA.DAREFID</div> |
| 1.R.2. | Vial Weeks (xx) or (xx-xx) | | | <div>DA.DAGRPID</div> |
| 1.R.3. | Batch Vial Number | | | <div>Read Only: Derived</div> <div>DA.DASPID</div> |
| 1.R.4. | Dispensed Date | | | <div>DA.DADTC</div> <div> dd-mmm-yyyy</div> |
| <div>Add New Row</div> | | | | |

Screened (Scr)

1. Subject ID:
2. Subject Initials:
3. Screen Date:  dd-mm-yyyy

Enrolled (Enroll)

1. Subject ID:

2. Enrolled Date:



dd-mmm-yyyy

Failed (Fail)

1. Failed Date:

 dd-mmm-yyyy

Discontinued (Disc)

1. Discontinued Date:

 dd-mmm-yyyy

Completed (Comp)

1. Completed Date:

 dd-mmm-yyyy