

LUM001301 Study

Blank CRF Casebook

Study Published Date: **09-Apr-2015** Time: **18:34 GMT (Server time)**
Protocol: **LUM001-301** Study Version: **2.0**

Time & Events Schedule

Legend: Expected Screening Day 0 Week 1 Week 2 Week 3 Week 4 Week 5 Week 6 Week 7 Week 8

Name	Assessment	Consent	Screening	Day 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
DM	Informed Consent/Demography											
MH	Medical History											
DH	Disease History											
PE	Physical Examination											
VS	Vital Signs											
EG	12-Lead ECG											
PREG	Serum Pregnancy Test											
LB	Clinical Laboratory Tests											
QS1	Scratch Scale											
IE1	Inclusion/Exclusion Criteria											
RAND	Randomization											
PE2	Physical Examination2											
QS7	Xanthoma Scale											
QS2	Questionnaires 2											
PREG2	Urine Pregnancy Test											
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)											

Name	Assessment	Consent	Screening	Day 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8
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			✔							





Name	Assessment	Consent	Screening	Day 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 8
QS3M	Multidimensional Fatigue Scale CHILD			✓							
QS3N	Multidimensional Fatigue Scale TEEN			✓							
QS3O	Family Impact Module PARENT REPORT			✓							
IE2	Inclusion/Exclusion Criteria 2			✓							
TC	Telephone Contact			✓			✓				
LB2	Clinical Laboratory Tests 2				✓			✓		✓	✓
SDC	Study Drug Compliance				✓			✓			✓
QS4	Patient Impression of Change										
QS5	Caregiver Impression of Change										
QS6	Caregiver Global Therapeutic Benefit										
DS	Subject Summary										
CM	Concomitant Medications										
AE	Adverse Events										
Scr	Screened										
Enroll	Enrolled										
Fail	Failed										
Disc	Discontinued										
Comp	Completed										
EX	Study Drug Administration										

Name	Assessment	Week 13_ET	Week 17 Follow-Up	Study Completion (Complete)	Study Completion (Discontinue)	Study Completion (Screen Fail)	Common	Unscheduled
DM	Informed Consent/Demography							
MH	Medical History							
DH	Disease History							
PE	Physical Examination							
VS	Vital Signs	✔						✔
EG	12-Lead ECG	✔						✔
PREG	Serum Pregnancy Test							
LB	Clinical Laboratory Tests							✔
QS1	Scratch Scale	✔						
IE1	Inclusion/Exclusion Criteria							
RAND	Randomization							
PE2	Physical Examination2	✔						✔
QS7	Xanthoma Scale	✔						
QS2	Questionnaires 2	✔						
PREG2	Urine Pregnancy Test	✔						✔
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	✔						

Name	Assessment	Week 13_ET	Week 17 Follow-Up	Study Completion (Complete)	Study Completion (Discontinue)	Study Completion (Screen Fail)	Common	Unscheduled
QS3N	Multidimensional Fatigue Scale TEEN	✔						
QS3O	Family Impact Module PARENT REPORT	✔						
IE2	Inclusion/Exclusion Criteria 2							
TC	Telephone Contact		✔					
LB2	Clinical Laboratory Tests 2	✔						
SDC	Study Drug Compliance	✔						
QS4	Patient Impression of Change	✔						
QS5	Caregiver Impression of Change	✔						
QS6	Caregiver Global Therapeutic Benefit	✔						
DS	Subject Summary			✔		✔		
CM	Concomitant Medications						✔	
AE	Adverse Events						✔	
Scr	Screened						✔	
Enroll	Enrolled						🔴	
Fail	Failed						🔴	
Disc	Discontinued						🔴	
Comp	Completed						🔴	
EX	Study Drug Administration						✔	

Event Labels	Names
Consent	Consent
Screening	Screening
Day 0	Day0
Week 1	Week1
Week 2	Week2
Week 3	Week3
Week 4	Week4
Week 5	Week5
Week 6	Week6
Week 8	Week8
Week 13_ET	Week13_ET
Week 17 Follow-Up	FollowUp
Study Completion (Complete)	StudyCompletion
Study Completion (Discontinue)	Study_Completion
Study Completion (Screen Fail)	Study_Completion_SF
Common	Common
Unscheduled	Unscheduled

Informed Consent/Demography (DM)

1.	Date Parental Informed Consent signed	<input type="text"/>	 dd-mmm-yyyy
2.	Young Adult Consent Not Applicable	List: NA <input type="text" value="6"/>	
**3.	Date Young Adult Consent signed	<input type="text"/>	 dd-mmm-yyyy
4.	Assent Not Applicable	List: NA <input type="text" value="6"/>	
**5.	Date Assent signed	<input type="text"/>	 dd-mmm-yyyy
6.	Birth date	<input type="text"/>	 dd-mmm-yyyy
	*6.1. Age	Read Only: Derived	
	*6.2. Age Units	Read Only: Derived	
7.	Sex	List: SEX <input type="text" value="6"/>	
8.	Ethnicity	List: ETHNIC <input type="text" value="6"/>	
Race (select all that apply):			
9.	American Indian or Alaska Native	List: YES <input type="text" value="6"/>	
10.	Asian	List: YES <input type="text" value="6"/>	
11.	Black or African American	List: YES <input type="text" value="6"/>	
12.	Native Hawaiian or Other Pacific Islander	List: YES <input type="text" value="6"/>	
13.	White	List: YES <input type="text" value="6"/>	
	*13.1. Country	Read Only: Derived	

* Hidden Question

** Conditional Question

List:NA	
Label	Value
[Blank]	
Not Applicable	NA

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

List:ETHNIC	
Label	Value
[Blank]	
Hispanic or Latino	1
Not Hispanic or Latino	2

List:YES	
Label	Value
[Blank]	
YES	Y

Medical History (MH)

1. Any medical history? List: YES_NO 6

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				<input type="text"/>
*2.R.1.1.	MHTERM_Enc_TERM				Read Only: Encoded
*2.R.1.2.	MHTERM_Enc_CODE				Read Only: Encoded
*2.R.1.3.	MHTERM_Enc_TYPE				Read Only: Encoded
*2.R.1.4.	MHTERM_Enc_CAT1				Read Only: Encoded
*2.R.1.5.	MHTERM_Enc_CAT2				Read Only: Encoded
*2.R.1.6.	MHTERM_Enc_CAT3				Read Only: Encoded
*2.R.1.7.	MHTERM_Enc_CAT4				Read Only: Encoded
*2.R.1.8.	MHTERM_Enc_CAT5				Read Only: Encoded
*2.R.1.9.	MHTERM_Enc_CAT6				Read Only: Encoded
*2.R.1.10.	MHTERM_Enc_CAT7				Read Only: Encoded
*2.R.1.11.	MHTERM_Enc_CAT8				Read Only: Encoded
*2.R.1.12.	MHTERM_Enc_CAT9				Read Only: Encoded
2.R.2.	Start Date (Day)				List: DAY 6
2.R.3.	Start Date (Month)				List: MONTH 6
2.R.4.	Start Date (Year)				<input type="text"/>
*2.R.4.1.	Start Date				Read Only: Derived
2.R.5.	Ongoing?				List: YES 6
**2.R.6.	End Date (Day)				List: DAY 6
**2.R.7.	End Date (Month)				List: MONTH 6
**2.R.8.	End Date (Year)				<input type="text"/>
*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
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

AUG	AUG
SEP	SEP
OCT	OCT
NOV	NOV
DEC	DEC
UNK	UNK

List: YES	
Label	Value
[Blank]	
YES	Y

Disease History (DH)

- 1. Date of original diagnosis of ALGS (Day) List: DAY
- 2. Date of original diagnosis of ALGS (Month) List: MONTH
- 3. Date of original diagnosis of ALGS (Year)
- *3.1. Date of original diagnosis of ALGS Read Only: Derived
- 4. Does the subject have family history of ALGS? List: Y_N_UNK
- 5. Is paucity present in the subject? List: Y_N_UNK
- 6. Any mutation present? List: MUTATION

Does the subject have additional clinical criteria?

If Yes, please select "Yes" for ALL that apply. If No, please leave as "Blank".

- 7. Chronic cholestasis List: YES
- 8. Cardiac disease List: YES
- 9. Renal abnormalities List: YES
- 10. Vascular abnormalities List: YES
- 11. Skeletal abnormalities List: YES
- 12. Ocular abnormalities List: YES
- 13. Characteristic facial features List: YES

If any additional clinical criteria is checked YES above, please ensure details are added to medical history and/or Physical Exam page.

- 14. Has the subject used anything to treat itch in the past? List: YES_NO

If Yes, please select "Yes" for ALL that apply under Topical Therapies and Oral Therapies. If No, please leave as "Blank".

Topical Therapies

- **15. Topical corticosteroids List: YES
- **16. Topical calcineurin inhibitors (e.g., Tacrolimus, Pimecrolimus) List: YES
- **17. Topical antihistamines (e.g., Doxepin, Diphenhydramine) List: YES
- **18. Menthol List: YES
- **19. Capsaicin List: YES
- **20. Salicyclic acid List: YES
- **21. Local anesthetics (e.g., Pramoxine, Lidocaine, etc.) List: YES

Oral Therapies

- **22. Androgens (e.g., Methyltestosterone, Stanozolol) List: YES
- **23. Anticholestatic agents (S-adenosylmethionine, Epomediol) List: YES
- **24. Anticonvulsants (e.g., Phenobarbital) List: YES
- **25. Antidepressants (e.g., SSRI's, NSRI's) List: YES
- **26. Antihistamines List: YES
- **27. Anti-oxidants List: YES
- **28. Binding Resins (e.g. Cholestyramine, Colestipol, Cholesevelam) List: YES

**29. Colchicine	List: YES <input type="checkbox"/>
**30. Cannabinoid Agonist (e.g., dronabinol)	List: YES <input type="checkbox"/>
**31. Enzyme Inducers (e.g., Rifampicin, rifampin)	List: YES <input type="checkbox"/>
**32. Immunosuppressants (e.g., Methotrexate)	List: YES <input type="checkbox"/>
**33. Opiate antagonists (e.g., Naltrexone, Naloxone)	List: YES <input type="checkbox"/>
**34. Serotonin antagonists (e.g., Ondansetron)	List: YES <input type="checkbox"/>
**35. Ursodiol (UDCA)	List: YES <input type="checkbox"/>
Other	
**36. Phototherapy	List: YES <input type="checkbox"/>
**37. Hemofiltration (MARS)	List: YES <input type="checkbox"/>
**38. Plasmapheresis	List: YES <input type="checkbox"/>
**39. Nasal biliary drainage	List: YES <input type="checkbox"/>
**40. Other	List: YES <input type="checkbox"/>
**41. If Other, specify	<input type="text"/>

* Hidden Question

** Conditional Question

List:DAY		List:MONTH		List:Y_N_UNK	
Label	Value	Label	Value	Label	Value
[Blank]		[Blank]		[Blank]	
01	01	JAN	JAN	Yes	Y
02	02	FEB	FEB	No	N
03	03	MAR	MAR	Unknown	U
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:MUTATION	
Label	Value
[Blank]	
JAGGED1	1
NOTCH2	2
Not identified	3

List:YES	
Label	Value
[Blank]	
YES	Y

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

Physical Examination (PE)

1. Was the physical examination performed?

List: YES_NO 6

**2. Exam Date

dd-mmm-yyyy

**3. Abnormalities Present?

List: YES_NO 6

4. Abnormalities

4.R. **Body System** **Abnormal Findings**

4.R.1. Body System

List: PEBODSYS 6

4.R.2. Abnormal Finding

5
 6


Add New Row

** Conditional Question

List: YES_NO		List: PEBODSYS	
Label	Value	Label	Value
[Blank]		[Blank]	
Yes	Y	General Appearance	1
No	N	Mental Status	2
		HEENT	3
		Skin	4
		Cardiovascular	5
		Respiratory	6
		Gastrointestinal (Abdomen)	7
		Extremities	8
		Neurologic	9
		Musculoskeletal	10
		Genitourinary	11
		Lymphatic	12
		Chest (Breasts)	13

Vital Signs (VS)

1. Were vital signs collected? List: YES_NO 6

**2. Date of measurements  dd-mmm-yyyy

**3. Height (cm)

*3.1. Height Unit List: HEIGHT 6

**4. Weight (kg)

*4.1. Weight Unit List: WEIGHT 6

**5. Temperature (C)

*5.1. Temperature Unit List: TEMP 6

**6. Heart Rate (bpm)

*6.1. Heart Rate Unit List: bpm 6

**7. Respiratory Rate (rpm)

*7.1. Respiratory Rate Unit List: rpm 6

**8. Systolic Blood Pressure (mmHg)

**9. Diastolic Blood Pressure (mmHg)

*9.1. Blood Pressure Unit List: mmHg 6

* Hidden Question

** Conditional Question

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

List: HEIGHT	
Label	Value
cm	cm

List: WEIGHT	
Label	Value
kg	kg

List: TEMP	
Label	Value
C	C

List: bpm	
Label	Value
BEATS/MIN	BEATS/MIN

List: rpm	
Label	Value
rpm	rpm

List: mmHg	
Label	Value
mmHg	mmHg


12-Lead ECG (EG)

- 1. Was the ECG performed? List: YES_NO 6
- **2. What was the ECG date?  dd-mmm-yyyy
- **3. What was the ECG time? (hh:mm, 24-hour clock)
- **4. Investigator's Interpretation List: ECG 6
- **5. If Abnormal, Specify
- **6. Was the ECG clinically significant? List: YES_NO 6

** Conditional Question

List: YES_NO		List: ECG	
Label	Value	Label	Value
[Blank]		[Blank]	
Yes	Y	Normal	1
No	N	Abnormal	2

Serum Pregnancy Test (PREG)



- 1. Sample Type
- 2. Was the sample collected?
- **3. Date collected 

** Conditional Question

List:SPREG		List:Y_N_NA	
Label	Value	Label	Value
Serum	Serum	[Blank]	
		Yes	Y
		No	N
		Not Applicable	NA

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?	<input type="text" value="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?	<input type="text" value="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

Scratch Scale (QS1)

1. Was Clinician Scratch Scale completed?

List: YES_NO

**2. Date of assessment

 dd-mmm-yyyy

**3. Clinician Scratch Scale score

List: SCRATCH

** 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

Inclusion/Exclusion Criteria (IE1)

1. Protocol Criteria Version List: TIVERS 6

2. Did the subject meet all eligibility criteria? List: YES_NO 6

3. Inclusion/Exclusion Criteria

3.R.	Criterion Type	Criterion not met	Sponsor approval?	Approval date
3.R.1.	Criterion Type			List: IE 6
3.R.2.	Criterion not met			List: IENUM 6
3.R.3.	Lumena approval received?			List: YES_NO 6
**3.R.4.	Date of approval			<input type="text" value=""/> dd-mmm-yyyy

[Add New Row](#)

** Conditional Question

List:TIVERS		List:YES_NO		List:IE	
Label	Value	Label	Value	Label	Value
[Blank]		[Blank]		[Blank]	
Original - 22Oct2013	Original - 22Oct2013	Yes	Y	Inclusion	1
Amendment 1 - 10Dec2013	Amendment 1 - 10Dec2013	No	N	Exclusion	2
Amendment 2 - 28Jan2015	Amendment 2 - 28Jan2015				
Amendment 3 - 11Feb2015	Amendment 3 - 11Feb2015				

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
11	11
12	12
13	13
14	14

15	15
16	16
17	17
18	18

Randomization (RAND)

1. Randomization Date



dd-mmm-yyyy

2. Randomization Number

Physical Examination2 (PE2)

1. Was the physical examination performed?

List: YES_NO 6

**2. Exam Date

 dd-mmm-yyyy

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

List: YES_NO 6

If Yes, please record physical examination findings on the Adverse Events CRF

** Conditional Question

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

Xanthoma Scale (QS7)

- 1. Was Xanthoma Scale completed? List: YES_NO 6
- **2. Date of assessment dd-mmm-yyyy
- **3. Clinician Xanthoma Scale score List: Xanthoma 6

** Conditional Question

List: YES_NO		List: Xanthoma	
Label	Value	Label	Value
[Blank]		[Blank]	
Yes	Y	0-None	0
No	N	1-Minimal	1
		2-Moderate	2
		3-Disfiguring	3
		4-Disabling	4

Questionnaires 2 (QS2)

- 1. Was the Pediatric QoL Inventory PARENT REPORT completed by caregiver? List: YES_NO 6
- **2. Date Pediatric QoL Inventory PARENT REPORT completed by caregiver dd-mmm-yyyy
- **3. For which age category was the questionnaire completed? List: AGE1 6
- 4. Was the Pediatric QoL Inventory completed by subject? List: Y_N_NA 6
- **5. Date Pediatric QoL Inventory completed by subject dd-mmm-yyyy
- **6. For which age category was the questionnaire completed? List: AGE2 6
- 7. Was the Multidimensional Fatigue Scale PARENT REPORT completed by caregiver? List: YES_NO 6
- **8. Date Multidimensional Fatigue Scale PARENT REPORT completed by caregiver dd-mmm-yyyy
- **9. For which age category was the questionnaire completed? List: AGE1 6
- 10. Was the Multidimensional Fatigue Scale completed by subject? List: Y_N_NA 6
- **11. Date Multidimensional Fatigue Scale completed by subject dd-mmm-yyyy
- **12. For which age category was the questionnaire completed? List: AGE2 6
- 13. Was the Family Impact Module PARENT REPORT completed by caregiver? List: YES_NO 6
- **14. Date Family Impact Module PARENT REPORT completed by caregiver dd-mmm-yyyy

** Conditional Question

List: YES_NO		List: AGE1		List: Y_N_NA	
Label	Value	Label	Value	Label	Value
[Blank]		[Blank]		[Blank]	
Yes	Y	INFANTS (1-12 months)	5	Yes	Y
No	N	INFANTS (13-24 months)	6	No	N
		TODDLERS (ages 2-4)	1	Not Applicable	NA
		YOUNG CHILDREN (ages 5-7)	2		
		CHILDREN (ages 8-12)	3		
		TEENAGERS (ages 13-18)	4		

List: AGE2	
Label	Value
[Blank]	
YOUNG CHILD REPORT (ages 5-7)	2
CHILD REPORT	3

(ages 8-12)

TEENAGER

REPORT 4

(ages 13-18)

Urine Pregnancy Test (PREG2)

1.	Sample Type	List: UPREG 6
2.	Was the sample collected?	List: Y_N_NA 6
**3.	Date collected	<input type="text"/> dd-mmm-yyyy
**4.	Results	List: POSNEG 6

** 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	-

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...)

1.	1. Low energy level	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Difficulty participating in active play	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Having hurts or aches	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Feeling tired	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Being lethargic	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Resting a lot	List: PEDSQL1 <input type="text" value="6"/>

PHYSICAL SYMPTOMS (problems with...)

7.	1. Having gas	List: PEDSQL1 <input type="text" value="6"/>
8.	2. Spitting up after eating	List: PEDSQL1 <input type="text" value="6"/>
9.	3. Difficulty breathing	List: PEDSQL1 <input type="text" value="6"/>
10.	4. Being sick to his/her stomach	List: PEDSQL1 <input type="text" value="6"/>
11.	5. Difficulty Swallowing	List: PEDSQL1 <input type="text" value="6"/>
12.	6. Being constipated	List: PEDSQL1 <input type="text" value="6"/>
13.	7. Having a rash	List: PEDSQL1 <input type="text" value="6"/>
14.	8. Having diarrhea	List: PEDSQL1 <input type="text" value="6"/>
15.	9. Wheezing	List: PEDSQL1 <input type="text" value="6"/>
16.	10. Vomiting	List: PEDSQL1 <input type="text" value="6"/>

EMOTIONAL FUNCTIONING (problems with...)

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

SOCIAL FUNCTIONING (problems with...)

29.	1. Not smiling at others	List: PEDSQL1 <input type="text" value="6"/>
30.	2. Not laughing when tickled	List: PEDSQL1 <input type="text" value="6"/>

- 31. 3. Not making eye contact with a caregiver List: PEDSQL1
- 32. 4. Not laughing when cuddled List: PEDSQL1
- COGNITIVE FUNCTIONING (problems with...)**
- 33. 1. Not imitating caregivers\' actions List: PEDSQL1
- 34. 2. Not imitating caregivers\' facial expressions List: PEDSQL1
- 35. 3. Not imitating caregivers\' sounds List: PEDSQL1
- 36. 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

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...)

1.	1. Low energy level	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Difficulty participating in active play	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Having hurts or aches	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Feeling tired	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Being lethargic	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Resting a lot	List: PEDSQL1 <input type="text" value="6"/>
7.	7. Feeling too tired to play	List: PEDSQL1 <input type="text" value="6"/>
8.	8. Difficulty walking	List: PEDSQL1 <input type="text" value="6"/>
9.	9. Difficulty running a short distance without falling	List: PEDSQL1 <input type="text" value="6"/>

PHYSICAL SYMPTOMS (problems with...)

10.	1. Having gas	List: PEDSQL1 <input type="text" value="6"/>
11.	2. Spitting up after eating	List: PEDSQL1 <input type="text" value="6"/>
12.	3. Difficulty breathing	List: PEDSQL1 <input type="text" value="6"/>
13.	4. Being sick to his/her stomach	List: PEDSQL1 <input type="text" value="6"/>
14.	5. Difficulty Swallowing	List: PEDSQL1 <input type="text" value="6"/>
15.	6. Being constipated	List: PEDSQL1 <input type="text" value="6"/>
16.	7. Having a rash	List: PEDSQL1 <input type="text" value="6"/>
17.	8. Having diarrhea	List: PEDSQL1 <input type="text" value="6"/>
18.	9. Wheezing	List: PEDSQL1 <input type="text" value="6"/>
19.	10. Vomiting	List: PEDSQL1 <input type="text" value="6"/>

EMOTIONAL FUNCTIONING (problems with...)

20.	1. Feeling afraid or scared	List: PEDSQL1 <input type="text" value="6"/>
21.	2. Feeling angry	List: PEDSQL1 <input type="text" value="6"/>
22.	3. Crying or fussing when left alone	List: PEDSQL1 <input type="text" value="6"/>
23.	4. Difficulty soothing himself/herself when upset	List: PEDSQL1 <input type="text" value="6"/>
24.	5. Difficulty falling asleep	List: PEDSQL1 <input type="text" value="6"/>
25.	6. Crying or fussing while being cuddled	List: PEDSQL1 <input type="text" value="6"/>
26.	7. Feeling sad	List: PEDSQL1 <input type="text" value="6"/>
27.	8. Difficulty being soothed when picked up or held	List: PEDSQL1 <input type="text" value="6"/>
28.	9. Difficulty sleeping mostly through the night	List: PEDSQL1 <input type="text" value="6"/>
29.	10. Crying a lot	List: PEDSQL1 <input type="text" value="6"/>
30.	11. Feeling cranky	List: PEDSQL1 <input type="text" value="6"/>
31.	12. Difficulty taking naps during the day	List: PEDSQL1 <input type="text" value="6"/>

SOCIAL FUNCTIONING (problems with...)

32.	1. Not smiling at others	List: PEDSQL1 <input type="text" value="6"/>
33.	2. Not laughing when tickled	List: PEDSQL1 <input type="text" value="6"/>
34.	3. Not making eye contact with a caregiver	List: PEDSQL1 <input type="text" value="6"/>
35.	4. Not laughing when cuddled	List: PEDSQL1 <input type="text" value="6"/>
36.	5. Being uncomfortable around other children	List: PEDSQL1 <input type="text" value="6"/>

COGNITIVE FUNCTIONING (problems with...)

37.	1. Not imitating caregivers' actions	List: PEDSQL1 <input type="text" value="6"/>
38.	2. Not imitating caregivers' facial expressions	List: PEDSQL1 <input type="text" value="6"/>
39.	3. Not imitating caregivers' sounds	List: PEDSQL1 <input type="text" value="6"/>
40.	4. Not able to fix his/her attention on objects	List: PEDSQL1 <input type="text" value="6"/>
41.	5. Not imitating caregivers' speech	List: PEDSQL1 <input type="text" value="6"/>
42.	6. Difficulty pointing to his/her body parts when asked	List: PEDSQL1 <input type="text" value="6"/>
43.	7. Difficulty naming familiar objects	List: PEDSQL1 <input type="text" value="6"/>
44.	8. Difficulty repeating words	List: PEDSQL1 <input type="text" value="6"/>
45.	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

Pediatric QOL Inventory PARENT RPT (TODDLERS) (QS3A)

In the past **ONE MONTH**, how much of a **problem** has your child had with...

PHYSICAL FUNCTIONING (problems with...)

1.	1. Walking	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Running	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Participating in active play and exercise	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Lifting something heavy	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Bathing	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Helping to pick up his or her toys	List: PEDSQL1 <input type="text" value="6"/>
7.	7. Having hurts or aches	List: PEDSQL1 <input type="text" value="6"/>
8.	8. Low energy level	List: PEDSQL1 <input type="text" value="6"/>

EMOTIONAL FUNCTIONING (problems with...)

9.	1. Feeling afraid or scared	List: PEDSQL1 <input type="text" value="6"/>
10.	2. Feeling sad or blue	List: PEDSQL1 <input type="text" value="6"/>
11.	3. Feeling angry	List: PEDSQL1 <input type="text" value="6"/>
12.	4. Trouble sleeping	List: PEDSQL1 <input type="text" value="6"/>
13.	5. Worrying	List: PEDSQL1 <input type="text" value="6"/>

SOCIAL FUNCTIONING (problems with...)

14.	1. Playing with other children	List: PEDSQL1 <input type="text" value="6"/>
15.	2. Other kids not wanting to play with him or her	List: PEDSQL1 <input type="text" value="6"/>
16.	3. Getting teased by other children	List: PEDSQL1 <input type="text" value="6"/>
17.	4. Not able to do things that other children his or her age can do	List: PEDSQL1 <input type="text" value="6"/>
18.	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 day care*

SCHOOL FUNCTIONING (problems with...)

19.	1. Doing the same school activities as peers	List: PEDSQL1 <input type="text" value="6"/>
20.	2. Missing school/day care because of not feeling well	List: PEDSQL1 <input type="text" value="6"/>
21.	3. Missing school/day care 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

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...)

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

EMOTIONAL FUNCTIONING (problems with...)

9.	1. Feeling afraid or scared	List: PEDSQL1 <input type="text" value="6"/>
10.	2. Feeling sad or blue	List: PEDSQL1 <input type="text" value="6"/>
11.	3. Feeling angry	List: PEDSQL1 <input type="text" value="6"/>
12.	4. Trouble sleeping	List: PEDSQL1 <input type="text" value="6"/>
13.	5. Worrying about what will happen to him or her	List: PEDSQL1 <input type="text" value="6"/>

SOCIAL FUNCTIONING (problems with...)

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

SCHOOL FUNCTIONING (problems with...)

19.	1. Paying attention in class	List: PEDSQL1 <input type="text" value="6"/>
20.	2. Forgetting things	List: PEDSQL1 <input type="text" value="6"/>
21.	3. Keeping up with school activities	List: PEDSQL1 <input type="text" value="6"/>
22.	4. Missing school because of not feeling well	List: PEDSQL1 <input type="text" value="6"/>
23.	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

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...)

1.	1. Walking more than one block	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Running	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Participating in sports activity or exercise	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Lifting something heavy	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Taking a bath or shower by him or herself	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Doing chores around the house	List: PEDSQL1 <input type="text" value="6"/>
7.	7. Having hurts or aches	List: PEDSQL1 <input type="text" value="6"/>
8.	8. Low energy level	List: PEDSQL1 <input type="text" value="6"/>

EMOTIONAL FUNCTIONING (problems with...)

9.	1. Feeling afraid or scared	List: PEDSQL1 <input type="text" value="6"/>
10.	2. Feeling sad or blue	List: PEDSQL1 <input type="text" value="6"/>
11.	3. Feeling angry	List: PEDSQL1 <input type="text" value="6"/>
12.	4. Trouble sleeping	List: PEDSQL1 <input type="text" value="6"/>
13.	5. Worrying about what will happen to him or her	List: PEDSQL1 <input type="text" value="6"/>

SOCIAL FUNCTIONING (problems with...)

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

SCHOOL FUNCTIONING (problems with...)

19.	1. Paying attention in class	List: PEDSQL1 <input type="text" value="6"/>
20.	2. Forgetting things	List: PEDSQL1 <input type="text" value="6"/>
21.	3. Keeping up with schoolwork	List: PEDSQL1 <input type="text" value="6"/>
22.	4. Missing school because of not feeling well	List: PEDSQL1 <input type="text" value="6"/>
23.	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

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...)

1.	1. Walking more than one block	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Running	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Participating in sports activity or exercise	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Lifting something heavy	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Taking a bath or shower by him or herself	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Doing chores around the house	List: PEDSQL1 <input type="text" value="6"/>
7.	7. Having hurts or aches	List: PEDSQL1 <input type="text" value="6"/>
8.	8. Low energy level	List: PEDSQL1 <input type="text" value="6"/>

EMOTIONAL FUNCTIONING (problems with...)

9.	1. Feeling afraid or scared	List: PEDSQL1 <input type="text" value="6"/>
10.	2. Feeling sad or blue	List: PEDSQL1 <input type="text" value="6"/>
11.	3. Feeling angry	List: PEDSQL1 <input type="text" value="6"/>
12.	4. Trouble sleeping	List: PEDSQL1 <input type="text" value="6"/>
13.	5. Worrying about what will happen to him or her	List: PEDSQL1 <input type="text" value="6"/>

SOCIAL FUNCTIONING (problems with...)

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

SCHOOL FUNCTIONING (problems with...)

19.	1. Paying attention in class	List: PEDSQL1 <input type="text" value="6"/>
20.	2. Forgetting things	List: PEDSQL1 <input type="text" value="6"/>
21.	3. Keeping up with schoolwork	List: PEDSQL1 <input type="text" value="6"/>
22.	4. Missing school because of not feeling well	List: PEDSQL1 <input type="text" value="6"/>
23.	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

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...)

- 1. 1. Is it hard for you to walk List: PEDSQL2
- 2. 2. Is it hard for you to run List: PEDSQL2
- 3. 3. Is it hard for you to play sports or exercise List: PEDSQL2
- 4. 4. Is it hard for you to pick up big things List: PEDSQL2
- 5. 5. Is it hard for you to take a bath or shower List: PEDSQL2
- 6. 6. Is it hard for you to do chores (like pick up your toys) List: PEDSQL2
- 7. 7. Do you have hurts or aches List: PEDSQL2
- **8. Where?
- 9. 8. Do you ever feel too tired to play List: PEDSQL2

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

EMOTIONAL FUNCTIONING (problems with...)

- 10. 1. Do you feel scared List: PEDSQL2
- 11. 2. Do you feel sad List: PEDSQL2
- 12. 3. Do you feel mad List: PEDSQL2
- 13. 4. Do you have trouble sleeping List: PEDSQL2
- 14. 5. Do you worry about what will happen to you List: PEDSQL2

SOCIAL FUNCTIONING (problems with...)

- 15. 1. Is it hard for you to get along with other kids List: PEDSQL2
- 16. 2. Do other kids say they do not want to play with you List: PEDSQL2
- 17. 3. Do other kids tease you List: PEDSQL2
- 18. 4. Can other kids do things you cannot do List: PEDSQL2
- 19. 5. Is it hard for you to keep up when you play with other kids List: PEDSQL2

SCHOOL FUNCTIONING (problems with...)

- 20. 1. Is it hard for you to pay attention in school List: PEDSQL2
- 21. 2. Do you forget things List: PEDSQL2
- 22. 3. Is it hard to keep up with schoolwork List: PEDSQL2
- 23. 4. Do you miss school because of not feeling good List: PEDSQL2
- 24. 5. Do you miss school because you have to go to the doctor's or hospital List: PEDSQL2

** Conditional Question

List:PEDSQL2	
Label	Value
[Blank]	
Not at all	0
Sometimes	2
A lot	4

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...)

1.	1. It is hard for me to walk more than one block	List: PEDSQL1 <input type="text" value="6"/>
2.	2. It is hard for me to run	List: PEDSQL1 <input type="text" value="6"/>
3.	3. It is hard for me to do sports activity or exercise	List: PEDSQL1 <input type="text" value="6"/>
4.	4. It is hard for me to lift something heavy	List: PEDSQL1 <input type="text" value="6"/>
5.	5. It is hard for me to have a bath or shower by myself	List: PEDSQL1 <input type="text" value="6"/>
6.	6. It is hard for me to do chores around the house	List: PEDSQL1 <input type="text" value="6"/>
7.	7. I hurt or ache	List: PEDSQL1 <input type="text" value="6"/>
8.	8. I have low energy	List: PEDSQL1 <input type="text" value="6"/>

ABOUT MY FEELINGS (problems with...)

9.	1. I feel afraid or scared	List: PEDSQL1 <input type="text" value="6"/>
10.	2. I feel sad or blue	List: PEDSQL1 <input type="text" value="6"/>
11.	3. I feel angry	List: PEDSQL1 <input type="text" value="6"/>
12.	4. I have trouble sleeping	List: PEDSQL1 <input type="text" value="6"/>
13.	5. I worry about what will happen to me	List: PEDSQL1 <input type="text" value="6"/>

HOW I GET ALONG WITH OTHERS (problems with...)

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

ABOUT SCHOOL (problems with...)

19.	1. It is hard to pay attention in class	List: PEDSQL1 <input type="text" value="6"/>
20.	2. I forget things	List: PEDSQL1 <input type="text" value="6"/>
21.	3. I have trouble keeping up with my schoolwork	List: PEDSQL1 <input type="text" value="6"/>
22.	4. I miss school because of not feeling well	List: PEDSQL1 <input type="text" value="6"/>
23.	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

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...)

1.	1. It is hard for me to walk more than one block	List: PEDSQL1 <input type="text" value="6"/>
2.	2. It is hard for me to run	List: PEDSQL1 <input type="text" value="6"/>
3.	3. It is hard for me to do sports activity or exercise	List: PEDSQL1 <input type="text" value="6"/>
4.	4. It is hard for me to lift something heavy	List: PEDSQL1 <input type="text" value="6"/>
5.	5. It is hard for me to have a bath or shower by myself	List: PEDSQL1 <input type="text" value="6"/>
6.	6. It is hard for me to do chores around the house	List: PEDSQL1 <input type="text" value="6"/>
7.	7. I have hurt or ache	List: PEDSQL1 <input type="text" value="6"/>
8.	8. I have low energy	List: PEDSQL1 <input type="text" value="6"/>

ABOUT MY FEELINGS (problems with...)

9.	1. I feel afraid or scared	List: PEDSQL1 <input type="text" value="6"/>
10.	2. I feel sad or blue	List: PEDSQL1 <input type="text" value="6"/>
11.	3. I feel angry	List: PEDSQL1 <input type="text" value="6"/>
12.	4. I have trouble sleeping	List: PEDSQL1 <input type="text" value="6"/>
13.	5. I worry about what will happen to me	List: PEDSQL1 <input type="text" value="6"/>

HOW I GET ALONG WITH OTHERS (problems with...)

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

ABOUT SCHOOL (problems with...)

19.	1. It is hard to pay attention in class	List: PEDSQL1 <input type="text" value="6"/>
20.	2. I forget things	List: PEDSQL1 <input type="text" value="6"/>
21.	3. I have trouble keeping up with my schoolwork	List: PEDSQL1 <input type="text" value="6"/>
22.	4. I miss school because of not feeling well	List: PEDSQL1 <input type="text" value="6"/>
23.	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

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...)

1.	1. Feeling tired	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Feeling physically weak (not strong)	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Feeling too tired to do things that he/she likes to do	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Feeling too tired to spend time with his/her friends	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Trouble finishing things	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Trouble starting things	List: PEDSQL1 <input type="text" value="6"/>

SLEEP/REST FATIGUE (problems with...)

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

COGNITIVE FATIGUE (problems with...)

13.	1. Difficulty keeping his/her attention on things	List: PEDSQL1 <input type="text" value="6"/>
14.	2. Difficulty remembering what people tell him/her	List: PEDSQL1 <input type="text" value="6"/>
15.	3. Difficulty remembering what he/she just heard	List: PEDSQL1 <input type="text" value="6"/>
16.	4. Difficulty thinking quickly	List: PEDSQL1 <input type="text" value="6"/>
17.	5. Trouble remembering what he/she was just thinking	List: PEDSQL1 <input type="text" value="6"/>
18.	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

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...)

1.	1. Feeling tired	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Feeling physically weak (not strong)	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Feeling too tired to do things that he/she likes to do	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Feeling too tired to spend time with his/her friends	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Trouble finishing things	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Trouble starting things	List: PEDSQL1 <input type="text" value="6"/>

SLEEP/REST FATIGUE (problems with...)

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

COGNITIVE FATIGUE (problems with...)

13.	1. Difficulty keeping his/her attention on things	List: PEDSQL1 <input type="text" value="6"/>
14.	2. Difficulty remembering what people tell him/her	List: PEDSQL1 <input type="text" value="6"/>
15.	3. Difficulty remembering what he/she just heard	List: PEDSQL1 <input type="text" value="6"/>
16.	4. Difficulty thinking quickly	List: PEDSQL1 <input type="text" value="6"/>
17.	5. Trouble remembering what he/she was just thinking	List: PEDSQL1 <input type="text" value="6"/>
18.	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

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...)

1.	1. Feeling tired	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Feeling physically weak (not strong)	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Feeling too tired to do things that he/she likes to do	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Feeling too tired to spend time with his/her friends	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Trouble finishing things	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Trouble starting things	List: PEDSQL1 <input type="text" value="6"/>

SLEEP/REST FATIGUE (problems with...)

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

COGNITIVE FATIGUE (problems with...)

13.	1. Difficulty keeping his/her attention on things	List: PEDSQL1 <input type="text" value="6"/>
14.	2. Difficulty remembering what people tell him/her	List: PEDSQL1 <input type="text" value="6"/>
15.	3. Difficulty remembering what he/she just heard	List: PEDSQL1 <input type="text" value="6"/>
16.	4. Difficulty thinking quickly	List: PEDSQL1 <input type="text" value="6"/>
17.	5. Trouble remembering what he/she was just thinking	List: PEDSQL1 <input type="text" value="6"/>
18.	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

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...)

1.	1. Feeling tired	List: PEDSQL1 <input type="text" value="6"/>
2.	2. Feeling physically weak (not strong)	List: PEDSQL1 <input type="text" value="6"/>
3.	3. Feeling too tired to do things that he/she likes to do	List: PEDSQL1 <input type="text" value="6"/>
4.	4. Feeling too tired to spend time with his/her friends	List: PEDSQL1 <input type="text" value="6"/>
5.	5. Trouble finishing things	List: PEDSQL1 <input type="text" value="6"/>
6.	6. Trouble starting things	List: PEDSQL1 <input type="text" value="6"/>

SLEEP/REST FATIGUE (problems with...)

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

COGNITIVE FATIGUE (problems with...)

13.	1. Difficulty keeping his/her attention on things	List: PEDSQL1 <input type="text" value="6"/>
14.	2. Difficulty remembering what people tell him/her	List: PEDSQL1 <input type="text" value="6"/>
15.	3. Difficulty remembering what he/she just heard	List: PEDSQL1 <input type="text" value="6"/>
16.	4. Difficulty thinking quickly	List: PEDSQL1 <input type="text" value="6"/>
17.	5. Trouble remembering what he/she was just thinking	List: PEDSQL1 <input type="text" value="6"/>
18.	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

Multidimensional Fatigue Scale YOUNG CHILD (QS3L)

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.

General Fatigue (PROBLEMS WITH...)

1.	1. Do you feel tired	List: PEDSQL2 <input type="text" value="6"/>
2.	2. Do you feel physically weak (not strong)	List: PEDSQL2 <input type="text" value="6"/>
3.	3. Do you feel too tired to do things that you like to do	List: PEDSQL2 <input type="text" value="6"/>
4.	4. Do you feel too tired to spend time with your friends	List: PEDSQL2 <input type="text" value="6"/>
5.	5. Do you have trouble finishing things	List: PEDSQL2 <input type="text" value="6"/>
6.	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...)

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

Cognitive Fatigue (PROBLEMS WITH...)

13.	1. Is it hard for you to keep your attention on things	List: PEDSQL2 <input type="text" value="6"/>
14.	2. Is it hard for you to remember what people tell you	List: PEDSQL2 <input type="text" value="6"/>
15.	3. Is it hard for you to remember what you just heard	List: PEDSQL2 <input type="text" value="6"/>
16.	4. Is it hard for you to think quickly	List: PEDSQL2 <input type="text" value="6"/>
17.	5. Do you have trouble remembering what you were just thinking	List: PEDSQL2 <input type="text" value="6"/>
18.	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

Multidimensional Fatigue Scale CHILD (QS3M)

In the past **ONE month**, how much of a **problem** has this been for you

General Fatigue (problems with...)

1.	1. I feel tired	List: PEDSQL1 <input type="text" value="6"/>
2.	2. I feel physically weak (not strong)	List: PEDSQL1 <input type="text" value="6"/>
3.	3. I feel too tired to do things that I like to do	List: PEDSQL1 <input type="text" value="6"/>
4.	4. I feel too tired to spend time with my friends	List: PEDSQL1 <input type="text" value="6"/>
5.	5. I have trouble finishing things	List: PEDSQL1 <input type="text" value="6"/>
6.	6. I have trouble starting things	List: PEDSQL1 <input type="text" value="6"/>

Sleep/Rest Fatigue (problems with...)

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

Cognitive Fatigue (problems with...)

13.	1. It is hard for me to keep my attention on things	List: PEDSQL1 <input type="text" value="6"/>
14.	2. It is hard for me to remember what people tell me	List: PEDSQL1 <input type="text" value="6"/>
15.	3. It is hard for me to remember what I just heard	List: PEDSQL1 <input type="text" value="6"/>
16.	4. It is hard for me to think quickly	List: PEDSQL1 <input type="text" value="6"/>
17.	5. I have trouble remembering what I was just thinking	List: PEDSQL1 <input type="text" value="6"/>
18.	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

Multidimensional Fatigue Scale TEEN (QS3N)

In the past **ONE month**, how much of a **problem** has this been for you

General Fatigue (problems with...)

1.	1. I feel tired	List: PEDSQL1 <input type="text" value="6"/>
2.	2. I feel physically weak (not strong)	List: PEDSQL1 <input type="text" value="6"/>
3.	3. I feel too tired to do things that I like to do	List: PEDSQL1 <input type="text" value="6"/>
4.	4. I feel too tired to spend time with my friends	List: PEDSQL1 <input type="text" value="6"/>
5.	5. I have trouble finishing things	List: PEDSQL1 <input type="text" value="6"/>
6.	6. I have trouble starting things	List: PEDSQL1 <input type="text" value="6"/>

Sleep/Rest Fatigue (problems with...)

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

Cognitive Fatigue (problems with...)

13.	1. It is hard for me to keep my attention on things	List: PEDSQL1 <input type="text" value="6"/>
14.	2. It is hard for me to remember what people tell me	List: PEDSQL1 <input type="text" value="6"/>
15.	3. It is hard for me to remember what I just heard	List: PEDSQL1 <input type="text" value="6"/>
16.	4. It is hard for me to think quickly	List: PEDSQL1 <input type="text" value="6"/>
17.	5. I have trouble remembering what I was just thinking	List: PEDSQL1 <input type="text" value="6"/>
18.	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

Family Impact Module PARENT REPORT (QS30)

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...)

1.	1. I feel tired during the day	List: PEDSQL1 <input type="text" value="6"/>
2.	2. I feel tired when I wake up in the morning	List: PEDSQL1 <input type="text" value="6"/>
3.	3. I feel too tired to do the things I like to do	List: PEDSQL1 <input type="text" value="6"/>
4.	4. I get headaches	List: PEDSQL1 <input type="text" value="6"/>
5.	5. I feel physically weak	List: PEDSQL1 <input type="text" value="6"/>
6.	6. I feel sick to my stomach	List: PEDSQL1 <input type="text" value="6"/>

EMOTIONAL FUNCTIONING (problems with...)

7.	1. I feel anxious	List: PEDSQL1 <input type="text" value="6"/>
8.	2. I feel sad	List: PEDSQL1 <input type="text" value="6"/>
9.	3. I feel angry	List: PEDSQL1 <input type="text" value="6"/>
10.	4. I feel frustrated	List: PEDSQL1 <input type="text" value="6"/>
11.	5. I feel helpless or hopeless	List: PEDSQL1 <input type="text" value="6"/>

SOCIAL FUNCTIONING (problems with...)

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

COGNITIVE FUNCTIONING (problems with...)

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

COMMUNICATION (problems with...)

21.	1. I feel that others do not understand my family's situation	List: PEDSQL1 <input type="text" value="6"/>
22.	2. It is hard for me to talk about my child's health with others	List: PEDSQL1 <input type="text" value="6"/>
23.	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...)

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

- 26. 3. I worry about how others will react to my child's condition List: PEDSQL1
- 27. 4. I worry about how my child's illness is affecting other family members List: PEDSQL1
- 28. 5. I worry about my child's future List: PEDSQL1

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...)

- 29. 1. Family activities taking more time and effort List: PEDSQL1
- 30. 2. Difficulty finding time to finish household tasks List: PEDSQL1
- 31. 3. Feeling too tired to finish household tasks List: PEDSQL1

FAMILY RELATIONSHIPS (problems with...)

- 32. 1. Lack of communication between family members List: PEDSQL1
- 33. 2. Conflicts between family members List: PEDSQL1
- 34. 3. Difficulty making decisions together as a family List: PEDSQL1
- 35. 4. Difficulty solving family problems together List: PEDSQL1
- 36. 5. Stress or tension between family members List: PEDSQL1

List:PEDSQL1	
Label	Value
[Blank]	
Never	0
Almost Never	1
Sometimes	2
Often	3
Almost Always	4

Inclusion/Exclusion Criteria 2 (IE2)

- 1. Protocol Criteria Version List: TIVERS 6
- 2. Did the subject continue to meet all eligibility criteria? List: YES_NO 6

3.R.	Criterion Type	Criterion not met	Sponsor approval?	Approval date
3.R.1.	Criterion Type			List: IE 6
3.R.2.	Criterion not met			List: IENUM 6
3.R.3.	Lumena approval received?			List: YES_NO 6
**3.R.4.	Date of approval			<input type="text"/> dd-mmm-yyyy
Add New Row				

** Conditional Question

List:TIVERS		List:YES_NO		List:IE	
Label	Value	Label	Value	Label	Value
[Blank]		[Blank]		[Blank]	
Original - 22Oct2013	Original - 22Oct2013	Yes	Y	Inclusion	1
Amendment 1 - 10Dec2013	Amendment 1 - 10Dec2013	No	N	Exclusion	2
Amendment 2 - 28Jan2015	Amendment 2 - 28Jan2015				
Amendment 3 - 11Feb2015	Amendment 3 - 11Feb2015				

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
11	11
12	12
13	13
14	14

15	15
16	16
17	17
18	18

Telephone Contact (TC)

1. Was subject/caregiver contacted by telephone?

List: YES_NO

**2. Date of telephone contact

 dd-mmm-yyyy

** Conditional Question

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

Clinical Laboratory Tests 2 (LB2)

1. Clinical Laboratory Tests

1.R. Sample Type	Sample collected?	Collection Date	Sample ID
Blood			
1.1.1. Sample Type			
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"/>
Urine			
1.2.1. Sample Type			
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"/>
2. Date of last dose prior to sample collection		<input type="text"/> dd-mmm-yyyy	
3. Time of last dose prior to sample collection (hh:mm, 24-hour clock)		<input type="text"/>	
4. Date of last meal prior to sample collection		<input type="text"/> dd-mmm-yyyy	
5. Time of last meal prior to sample collection (hh:mm, 24-hour clock)		<input type="text"/>	

** Conditional Question

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

Study Drug Compliance (SDC)

1. Was study drug taken as prescribed?

List: YES_NO 6

2. Date(s) of Dosing Error

2.R. **Date of Dosing Error** **Type of dosing error** **Comments**

2.R.1. Date of dosing error

dd-mmm-yyyy

2.R.2. Type of dosing error

List: EXMD 6

2.R.3. Comments

Add New Row

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

List: EXMD	
Label	Value
[Blank]	
Missed Dose	1
Underdose	2
Overdose	3
Other	4

Patient Impression of Change (QS4)

1. Was patient impression of change completed?

List: Y_N_NA 6

**2. Date of Assessment

dd-mmm-yyyy

**3. How much has your itching changed, if at all, since you started this study?

List: PIC 6

** Conditional Question

List:Y_N_NA		List:PIC	
Label	Value	Label	Value
[Blank]		[Blank]	
Yes	Y	Much better	1
No	N	Better	2
Not Applicable	NA	A little better	3
		No change	4
		A little worse	5
		Worse	6
		Much worse	7

Caregiver Impression of Change (QS5)

1. Was caregiver impression of change completed?

List: YES_NO 6

**2. Date of assessment

dd-mmm-yyyy

**3. How would you rate the change in your child's itch related symptoms since the start of the study?

List: PIC 6

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

List: PIC 6

** 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

Caregiver Global Therapeutic Benefit (QS6)

1. Was caregiver global therapeutic benefit completed?

List: YES_NO 6

**2. Date of Assessment

dd-mmm-yyyy

**3. Considering all aspects of your child's treatment, do you feel that the benefits of this treatment outweigh the side-effects?

List: PGTB 6

**4. What treatment do you think your child received in this study?

List: TREAT 6

** Conditional Question

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


List: PGTB	
Label	Value
[Blank]	
Definitely	1
Somewhat	2
About the same	3
Maybe not	4
Definitely not	5

List: TREAT	
Label	Value
[Blank]	
Placebo drug	Placebo drug
Active drug (LUM001)	Active drug (LUM001)


Subject Summary (DS)


1. Did the subject complete study treatment?

**2. Will the subject be entered into the LUM001-305 extension study?

**3. Date of Discontinuation  dd-mmm-yyyy

**4. Reason for Discontinuation

**5. Date of last dose  dd-mmm-yyyy

**6. Date of final study contact  dd-mmm-yyyy

**7. Reason for screen failure

**8. Criterion Type

**9. Criterion Number

**10. Specify

** Conditional Question

List:YES_NO		List:NCOMPLT		List:SF	
Label	Value	Label	Value	Label	Value
[Blank]		[Blank]		[Blank]	
Yes	Y	Adverse Event	1	Failed to meet eligibility criteria	1
No	N	Death	2	Lost to follow-up	2
		Lost to follow-up	4	Withdrawal by caregiver	3
		Non-compliance with study drug	5	Withdrawal by subject	4
		Physician decision	6		
		Pregnancy	7		
		Progressive Disease	8		
		Protocol violation	9		
		Screen Failure	10		
		Study terminated by sponsor	11		
		Withdrawal by caregiver	12		
		Withdrawal by subject	13		
		Other	99		

List:IE		List:IENUM	
Label	Value	Label	Value

[Blank]		[Blank]	
Inclusion	1	1	1
Exclusion	2	2	2
		3	3
		4	4
		5	5
		6	6
		7	7
		8	8
		9	9
		10	10
		11	11
		12	12
		13	13
		14	14
		15	15
		16	16
		17	17
		18	18

Concomitant Medications (CM)

1. Were any medications taken?

List: YES_NO 6

2. Concomitant Medications

Medication Name	Indication	Start Date (Day)	Start Date (Month)	Start Date (Year)
Prior?	Ongoing?	End Date (Day)	End Date (Month)	End Date (Year)
Dose	Dose Unit	Route	Frequency	

2.R.1. Medication/Therapy Name

*2.R.1.1. CMTRT_Enc_TERM

Read Only: Encoded

*2.R.1.2. CMTRT_Enc_CODE

Read Only: Encoded

*2.R.1.3. CMTRT_Enc_TYPE

Read Only: Encoded

*2.R.1.4. CMTRT_Enc_CAT1

Read Only: Encoded

*2.R.1.5. CMTRT_Enc_CAT2

Read Only: Encoded

*2.R.1.6. CMTRT_Enc_CAT3

Read Only: Encoded

*2.R.1.7. CMTRT_Enc_CAT4

Read Only: Encoded

*2.R.1.8. CMTRT_Enc_CAT5

Read Only: Encoded

*2.R.1.9. CMTRT_Enc_CAT6

Read Only: Encoded

*2.R.1.10. CMTRT_Enc_CAT7

Read Only: Encoded

*2.R.1.11. CMTRT_Enc_CAT8

Read Only: Encoded

*2.R.1.12. CMTRT_Enc_CAT9

Read Only: Encoded

2.R.2. Indication

2.R.3. Start Date (Day)

List: DAY 6

2.R.4. Start Date (Month)

List: MONTH 6

2.R.5. Start Date (Year)

*2.R.5.1. Start Date

Read Only: Derived


2.R.6. Taken Prior to Study?

List: YES_NO 6

2.R.7. Ongoing?

List: YES_NO 6

**2.R.8. If Ongoing, as of what date is it ongoing?

 dd-mmm-yyyy

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

List: DAY 6

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

List: MONTH 6

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

*2.R.11.1. End Date

Read Only: Derived

2.R.12. Dose

2.R.13. Dose Unit

List: DOSE 6

**2.R.14. Other: Specify

2.R.15. Route

List: ROUTE 6

**2.R.16. Other: Specify

2.R.17. Frequency

List: FREQ 6

**2.R.18. Other: Specify

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	
Label	Value
[Blank]	
TABLET	TABLET

List:ROUTE	
Label	Value
[Blank]	
ORAL	ORAL

List:FREQ	
Label	Value
[Blank]	
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				

Adverse Events (AE)

1. Were any Adverse Events experienced?

List: YES_NO 6

2. Adverse Events

	Verbatim Term	Serious?	Start Date (Day)	Start Date (Month)	Start Date (Year)
2.R.	Outcome	End Date (Day)	End Date (Month)	End Date (Year)	Action Taken
	Relationship	Severity	Life Threatening	Treatment: None	Treatment: Medication
	Treatment: Hospitalization	Other: Specify			

2.R.1. Verbatim Term

*2.R.1.1. AETERM_Enc_TERM

Read Only: Encoded

*2.R.1.2. AETERM_Enc_CODE

Read Only: Encoded

*2.R.1.3. AETERM_Enc_TYPE

Read Only: Encoded

*2.R.1.4. AETERM_Enc_CAT1

Read Only: Encoded

*2.R.1.5. AETERM_Enc_CAT2

Read Only: Encoded

*2.R.1.6. AETERM_Enc_CAT3

Read Only: Encoded

*2.R.1.7. AETERM_Enc_CAT4

Read Only: Encoded

*2.R.1.8. AETERM_Enc_CAT5

Read Only: Encoded

*2.R.1.9. AETERM_Enc_CAT6

Read Only: Encoded

*2.R.1.10. AETERM_Enc_CAT7

Read Only: Encoded

*2.R.1.11. AETERM_Enc_CAT8

Read Only: Encoded

*2.R.1.12. AETERM_Enc_CAT9

Read Only: Encoded

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

List: YES_NO 6

2.R.3. Start Date (Day)

List: DAY 6

2.R.4. Start Date (Month)

List: MONTH 6

2.R.5. Start Date (Year)

*2.R.5.1. Start Date

Read Only: Derived

2.R.6. Outcome

List: OUT 6

**2.R.7. End Date (Day)

List: DAY 6

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

List: MONTH 6

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

*2.R.9.1. End Date

Read Only: Derived

2.R.10. Action Taken with Study Treatment

List: AEACN 6

2.R.11. Relationship to Study Treatment

List: REL 6

2.R.12. Was CTCAE grading used to assess severity?

List: YES_NO 6

2.R.13. Severity

List: SEV 6

**2.R.14. Was the Serious Event Life Threatening?

List: YES_NO 6

2.R.15. Treatment Required: None

List: YES 6

**2.R.16. Treatment Required: Medication Required

List: YES 6

**2.R.17. Treatment Required: Hospitalization Required

**2.R.18. Treatment Required: Other

**2.R.19. Other: Specify

[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

List:AEACN	
Label	Value

List:REL	
Label	Value

[Blank]	
Fatal	1
Not Recovered/not resolved	2
Recovered/Resolved	3
Recovered/Resolved with sequelae	4
Recovering/Resolving	5
Unknown	88


[Blank]	
Dose not changed	1
Drug interrupted	2
Drug withdrawn	3
Dose reduced	4
Not Applicable	5

[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

Screened (Scr)

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

Study Drug Administration (EX)

1. Volume of study drug solution (mL)

List: EXVOL 6

2. Study Drug Administration

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

List:EXVOL		List:EXDOSE	
Label	Value	Label	Value
[Blank]		[Blank]	
0.5	0.5	Dose Level 1	14 ug/kg/day or placebo
1.0	1.0	Dose Level 2	35 ug/kg/day or placebo
		Dose Level 3	70 ug/kg/day or placebo
		Dose Level 4	70 or 140 ug/kg/day or placebo
		Dose Level 5	70 or 140 or 280 ug/kg/day or placebo
		Post-Dose Level 2 Down Titration	14 ug/kg/day or placebo
		Post-Dose Level 3 Down Titration	35 ug/kg/day or placebo
		Post-Dose Level 4 Down Titration	35 or 70 ug/kg/day or placebo
		Post-Dose Level 5 Down Titration	35 or 70 or 140 ug/kg/day or placebo