

Annotated Report for LUM001-305

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Protocol: LUM001-305

Assessment	CRF	Time & Events Schedule							
		Day0 (Day 0)	Week1 (Week 1)	Week2 (Week 2)	Week3 (Week 3)	Week4 (Week 4)	Week6 (Week 6)	Week8 (Week 8)	Week10 (Week 10)
Adverse Events	AE								
Caregiver Impression of Change	QS5								
Clinical Laboratory Tests	LB								
Clinical Laboratory Tests 2	LB2			E		E		E	
Clinical Laboratory Tests 3	LB3								
Completed	Comp								
Concomitant Medications	CM								
Discontinued	Disc								
Dose Adjustment	DAD								
Enrolled	Enroll								
Failed	Fail								
Family Impact Module PARENT REPORT	QS30								
Inclusion/Exclusion Criteria	IE1	E							
Inclusion/Exclusion Criteria 2	IE2								
Inclusion/Exclusion Criteria 3	IE3								

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week12 (Week 12)	Week16 (Week 16)	Week20 (Week 20)	Week24 (Week 24)	Week28 (Week 28)	Week32 (Week 32)	Week36 (Week 36)	Week40 (Week 40)	Week44 (Week 44)
Adverse Events	AE									
Caregiver Impression of Change	QS5									
Clinical Laboratory Tests	LB									
Clinical Laboratory Tests 2	LB2	E			E			E		
Clinical Laboratory Tests 3	LB3		E							
Completed	Comp									
Concomitant Medications	CM									
Discontinued	Disc									
Dose Adjustment	DAD		E							
Enrolled	Enroll									
Failed	Fail									
Family Impact Module PARENT REPORT	QS30				E					
Inclusion/Exclusion Criteria	IE1									
Inclusion/Exclusion Criteria 2	IE2									
Inclusion/Exclusion Criteria 3	IE3									

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule							
		Week48_ET (Week 48)	FollowUp (Post-Week 48 Follow-up)	StudyCompleti on (Study Completion (Complete))	Study_Completi on (Study Completion (Discontinue))	RID0 (Re-Initiation Day 0)	RIW49 (Re-Initiation Week 49)	RIW50 (Re-Initiation Week 50)	RIW51 (Re-Initiation Week 51)
Adverse Events	AE								
Caregiver Impression of Change	QS5	E							
Clinical Laboratory Tests	LB					E			
Clinical Laboratory Tests 2	LB2	E						E	E
Clinical Laboratory Tests 3	LB3								
Completed	Comp								
Concomitant Medications	CM								
Discontinued	Disc								
Dose Adjustment	DAD								
Enrolled	Enroll								
Failed	Fail								
Family Impact Module PARENT REPORT	QS30	E				E			
Inclusion/Exclusion Criteria	IE1								
Inclusion/Exclusion Criteria 2	IE2					E			
Inclusion/Exclusion Criteria 3	IE3								

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week52 (Week 52)	Week56 (Week 56)	Week60 (Week 60)	Week64 (Week 64)	Week68 (Week 68)	Week72 (Week 72)	Week76 (Week 76)	Week80 (Week 80)	Week84 (Week 84)
Adverse Events	AE									
Caregiver Impression of Change	QS5			E			E			E
Clinical Laboratory Tests	LB			E			E			E
Clinical Laboratory Tests 2	LB2									
Clinical Laboratory Tests 3	LB3									
Completed	Comp									
Concomitant Medications	CM									
Discontinued	Disc									
Dose Adjustment	DAD									
Enrolled	Enroll									
Failed	Fail									
Family Impact Module PARENT REPORT	QS30			E			E			E
Inclusion/Exclusion Criteria	IE1									
Inclusion/Exclusion Criteria 2	IE2									
Inclusion/Exclusion Criteria 3	IE3									

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week88 (Week 88)	Week92 (Week 92)	Week96_ET (Week 96_ET)	30D_FU (30 Day Follow-up)	EC (Extension Completion)	PA5 (Long Term Optional Treatment)	PA5_RID2 (PA5 Re-Initiation Day - 2)	PA5_RID0 (PA5 Re-Initiation Day 0)	PA5_RIW1 (PA5 Re-Initiation Week 1)
Adverse Events	AE									
Caregiver Impression of Change	QS5			E						
Clinical Laboratory Tests	LB			E			E			
Clinical Laboratory Tests 2	LB2									
Clinical Laboratory Tests 3	LB3							E		
Completed	Comp									
Concomitant Medications	CM									
Discontinued	Disc									
Dose Adjustment	DAD									
Enrolled	Enroll									
Failed	Fail									
Family Impact Module PARENT REPORT	QS30			E				E		
Inclusion/Exclusion Criteria	IE1									
Inclusion/Exclusion Criteria 2	IE2									
Inclusion/Exclusion Criteria 3	IE3						E			

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				PA5_RIW2 (PA5 Re- Initiation Week 2)	PA5_RIW3 (PA5 Re- Initiation Week 3)	PA5_RIW4 (PA5 Re- Initiation Week 4)	W100 (Week 100)	W104 (Week 104)	W108 (Week 108)	W112 (Week 112)
Adverse Events	AE									
Caregiver Impression of Change	QS5						E			
Clinical Laboratory Tests	LB									
Clinical Laboratory Tests 2	LB2									
Clinical Laboratory Tests 3	LB3	E		E			E			E
Completed	Comp									
Concomitant Medications	CM									
Discontinued	Disc									
Dose Adjustment	DAD									
Enrolled	Enroll									
Failed	Fail									
Family Impact Module PARENT REPORT	QS30						E			
Inclusion/Exclusion Criteria	IE1									
Inclusion/Exclusion Criteria 2	IE2									
Inclusion/Exclusion Criteria 3	IE3									

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule							
		W124 (Week 124)	W128 (Week 128)	W132 (Week 132)	W136 (Week 136)	W140 (Week 140)	W144_ET (Week 144_ET)	W148 (Week 148)	PA5_EC (Long Term Optional Treatment Completion)
Adverse Events	AE								
Caregiver Impression of Change	QS5						E	E	
Clinical Laboratory Tests	LB								
Clinical Laboratory Tests 2	LB2						E	E	
Clinical Laboratory Tests 3	LB3			E					
Completed	Comp								
Concomitant Medications	CM								
Discontinued	Disc								
Dose Adjustment	DAD								
Enrolled	Enroll								
Failed	Fail								
Family Impact Module PARENT REPORT	QS30						E	E	
Inclusion/Exclusion Criteria	IE1								
Inclusion/Exclusion Criteria 2	IE2								
Inclusion/Exclusion Criteria 3	IE3								E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		W152 (Week 152)	W156 (Week 156)	W160 (Week 160)	W164 (Week 164)	W168 (Week 168)	W172 (Week 172)	W176 (Week 176)	W180 (Week 180)	W184 (Week 184)
Adverse Events	AE									
Caregiver Impression of Change	QS5		E							
Clinical Laboratory Tests	LB									
Clinical Laboratory Tests 2	LB2									
Clinical Laboratory Tests 3	LB3		E			E		E		
Completed	Comp									
Concomitant Medications	CM									
Discontinued	Disc									
Dose Adjustment	DAD									
Enrolled	Enroll									
Failed	Fail									
Family Impact Module PARENT REPORT	QS30		E							
Inclusion/Exclusion Criteria	IE1									
Inclusion/Exclusion Criteria 2	IE2									
Inclusion/Exclusion Criteria 3	IE3									

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule							
		W188 (Week 188)	W192 (Week 192)	W196 (Week 196)	W200 (Week 200)	W204 (Week 204)	W208 (Week 208)	W212 (Week 212)	W216 (Week 216)
Adverse Events	AE								
Caregiver Impression of Change	QS5							E	E
Clinical Laboratory Tests	LB								
Clinical Laboratory Tests 2	LB2							E	E
Clinical Laboratory Tests 3	LB3		E			E			
Completed	Comp								
Concomitant Medications	CM								
Discontinued	Disc								
Dose Adjustment	DAD								
Enrolled	Enroll								
Failed	Fail								
Family Impact Module PARENT REPORT	QS30							E	E
Inclusion/Exclusion Criteria	IE1								
Inclusion/Exclusion Criteria 2	IE2								
Inclusion/Exclusion Criteria 3	IE3								

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF	Time & Events Schedule		
			PA6_EC (Long Term Optional Treatment Completion 2)	Common (Common)	Unscheduled (Unscheduled)
Adverse Events	AE		E		
Caregiver Impression of Change	QS5				
Clinical Laboratory Tests	LB			E	
Clinical Laboratory Tests 2	LB2			E	
Clinical Laboratory Tests 3	LB3				
Completed	Comp		O		
Concomitant Medications	CM		E		
Discontinued	Disc		O		
Dose Adjustment	DAD				
Enrolled	Enroll		O		
Failed	Fail		O		
Family Impact Module PARENT REPORT	QS30				
Inclusion/Exclusion Criteria	IE1				
Inclusion/Exclusion Criteria 2	IE2				
Inclusion/Exclusion Criteria 3	IE3				

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF	Time & Events Schedule							
			Day0 (Day 0)	Week1 (Week 1)	Week2 (Week 2)	Week3 (Week 3)	Week4 (Week 4)	Week6 (Week 6)	Week8 (Week 8)	Week10 (Week 10)
Informed Consent/Demography	DM	E								
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									
Medical History	MH	E								
Medical History 2	MH2									
Multidimensional Fatigue Scale CHILD	QS3M									
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I									
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J									
Multidimensional Fatigue Scale PARENT for TEENS	QS3K									
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H									

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week12 (Week 12)	Week16 (Week 16)	Week20 (Week 20)	Week24 (Week 24)	Week28 (Week 28)	Week32 (Week 32)	Week36 (Week 36)	Week40 (Week 40)	Week44 (Week 44)
Informed Consent/Demography	DM									
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									
Medical History	MH									
Medical History 2	MH2									
Multidimensional Fatigue Scale CHILD	QS3M				E					
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I				E					
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J				E					
Multidimensional Fatigue Scale PARENT for TEENS	QS3K				E					
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H				E					

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week48_ET (Week 48)	FollowUp (Post-Week 48 Follow-up)	StudyCompleti on (Study Completion (Complete))	Study_Completi on (Study Completion (Discontinue))	RID0 (Re-Initiation Day 0)	RIW49 (Re-Initiation Week 49)	RIW50 (Re-Initiation Week 50)	RIW51 (Re-Initiation Week 51)	RIW52 (Re-Initiation Week 52)
Informed Consent/Demography	DM									
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									
Medical History	MH									
Medical History 2	MH2					E				
Multidimensional Fatigue Scale CHILD	QS3M	E				E				
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I	E				E				
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J	E				E				
Multidimensional Fatigue Scale PARENT for TEENS	QS3K	E				E				
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H	E				E				

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week52 (Week 52)	Week56 (Week 56)	Week60 (Week 60)	Week64 (Week 64)	Week68 (Week 68)	Week72 (Week 72)	Week76 (Week 76)	Week80 (Week 80)	Week84 (Week 84)
Informed Consent/Demography	DM									
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									
Medical History	MH									
Medical History 2	MH2									
Multidimensional Fatigue Scale CHILD	QS3M			E			E			E
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I			E			E			E
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J			E			E			E
Multidimensional Fatigue Scale PARENT for TEENS	QS3K			E			E			E
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H			E			E			E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF	Time & Events Schedule							
			Week88 (Week 88)	Week92 (Week 92)	Week96_ET (Week 96_ET)	30D_FU (30 Day Follow -up)	EC (Extension Completion)	PA5 (Long Term Optional Treatment)	PA5_RID2 (PA5 Re- Initiation Day - 2)	PA5_RID0 (PA5 Re- Initiation Day 0)
Informed Consent/Demogra phy	DM									
Long Term Optional Treatment	PRE2						E			
Long Term Optional Treatment 2	PRE3									
Medical History	MH									
Medical History 2	MH2						E			
Multidimensional Fatigue Scale CHILD	QS3M			E					E	
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I			E					E	
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J			E					E	
Multidimensional Fatigue Scale PARENT for TEENS	QS3K			E					E	
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H			E					E	

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		PA5_RIW2 (PA5 Re- Initiation Week 2)	PA5_RIW3 (PA5 Re- Initiation Week 3)	PA5_RIW4 (PA5 Re- Initiation Week 4)	W100 (Week 100)	W104 (Week 104)	W108 (Week 108)	W112 (Week 112)	W116 (Week 116)	W120 (Week 120)
Informed Consent/Demography	DM									
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									
Medical History	MH									
Medical History 2	MH2									
Multidimensional Fatigue Scale CHILD	QS3M						E			
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I						E			
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J						E			
Multidimensional Fatigue Scale PARENT for TEENS	QS3K						E			
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H						E			

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		W124 (Week 124)	W128 (Week 128)	W132 (Week 132)	W136 (Week 136)	W140 (Week 140)	W144_ET (Week 144_ET)	W148 (Week 148)	PA5_EC (Long Term Optional Treatment Completion)	PA6 (Long Term Optional Treatment 2)
Informed Consent/Demography	DM									
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									E
Medical History	MH									
Medical History 2	MH2									
Multidimensional Fatigue Scale CHILD	QS3M						E	E		
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I						E	E		
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J						E	E		
Multidimensional Fatigue Scale PARENT for TEENS	QS3K						E	E		
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H						E	E		

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		W152 (Week 152)	W156 (Week 156)	W160 (Week 160)	W164 (Week 164)	W168 (Week 168)	W172 (Week 172)	W176 (Week 176)	W180 (Week 180)	W184 (Week 184)
Informed Consent/Demography	DM									
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									
Medical History	MH									
Medical History 2	MH2									
Multidimensional Fatigue Scale CHILD	QS3M		E							
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I		E							
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J		E							
Multidimensional Fatigue Scale PARENT for TEENS	QS3K		E							
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H		E							

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		W188 (Week 188)	W192 (Week 192)	W196 (Week 196)	W200 (Week 200)	W204 (Week 204)	W208 (Week 208)	W212 (Week 212)	W216 (Week 216)	W220 (Week 220)
Informed Consent/Demography	DM									
Long Term Optional Treatment	PRE2									
Long Term Optional Treatment 2	PRE3									
Medical History	MH									
Medical History 2	MH2									
Multidimensional Fatigue Scale CHILD	QS3M							E	E	
Multidimensional Fatigue Scale PARENT (YOUNG CHILD)	QS3I							E	E	
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J							E	E	
Multidimensional Fatigue Scale PARENT for TEENS	QS3K							E	E	
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H							E	E	

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF	Time & Events Schedule		
			PA6_EC (Long Term Optional Treatment Completion 2)	Common (Common)	Unscheduled (Unscheduled)
Informed Consent/Demogra phy	DM				
Long Term Optional Treatment	PRE2				
Long Term Optional Treatment 2	PRE3				
Medical History	MH				
Medical History 2	MH2				
Multidimensional Fatigue Scale CHILD	QS3M				
Multidimensional Fatigue Scale PARENT (YOUNG CHILD	QS3I				
Multidimensional Fatigue Scale PARENT for CHILDREN	QS3J				
Multidimensional Fatigue Scale PARENT for TEENS	QS3K				
Multidimensional Fatigue Scale PARENT for TODDLERS	QS3H				

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment	CRF	Time & Events Schedule							
		Day0 (Day 0)	Week1 (Week 1)	Week2 (Week 2)	Week3 (Week 3)	Week4 (Week 4)	Week6 (Week 6)	Week8 (Week 8)	Week10 (Week 10)
Multidimensional Fatigue Scale TEEN	QS3N								
Multidimensional Fatigue Scale YOUNG CHILD	QS3L								
Pediatric QOL Inventory CHILD REPORT	QS3F								
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C								
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D								
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A								
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B								
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P								
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q								

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment	CRF	Time & Events Schedule								
		Week12 (Week 12)	Week16 (Week 16)	Week20 (Week 20)	Week24 (Week 24)	Week28 (Week 28)	Week32 (Week 32)	Week36 (Week 36)	Week40 (Week 40)	Week44 (Week 44)
Multidimensional Fatigue Scale TEEN	QS3N				E					
Multidimensional Fatigue Scale YOUNG CHILD	QS3L				E					
Pediatric QOL Inventory CHILD REPORT	QS3F				E					
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C				E					
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D				E					
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A				E					
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B				E					
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P				E					
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q				E					

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week48_ET (Week 48)	FollowUp (Post-Week 48 Follow-up)	StudyCompleti on (Study Completion (Complete))	Study_Completi on (Study Completion (Discontinue))	RID0 (Re-Initiation Day 0)	RIW49 (Re-Initiation Week 49)	RIW50 (Re-Initiation Week 50)	RIW51 (Re-Initiation Week 51)	RIW52 (Re-Initiation Week 52)
Multidimensional Fatigue Scale TEEN	QS3N	E				E				
Multidimensional Fatigue Scale YOUNG CHILD	QS3L	E				E				
Pediatric QOL Inventory CHILD REPORT	QS3F	E				E				
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C	E				E				
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D	E				E				
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A	E				E				
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B	E				E				
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P	E				E				
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q	E				E				

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				Week52 (Week 52)	Week56 (Week 56)	Week60 (Week 60)	Week64 (Week 64)	Week68 (Week 68)	Week72 (Week 72)	Week76 (Week 76)
Multidimensional Fatigue Scale TEEN	QS3N			E			E			E
Multidimensional Fatigue Scale YOUNG CHILD	QS3L			E			E			E
Pediatric QOL Inventory CHILD REPORT	QS3F			E			E			E
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C			E			E			E
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D			E			E			E
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A			E			E			E
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B			E			E			E
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P			E			E			E
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q			E			E			E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week88 (Week 88)	Week92 (Week 92)	Week96_ET (Week 96_ET)	30D_FU (30 Day Follow-up)	EC (Extension Completion)	PA5 (Long Term Optional Treatment)	PA5_RID2 (PA5 Re-Initiation Day - 2)	PA5_RID0 (PA5 Re-Initiation Day 0)	PA5_RIW1 (PA5 Re-Initiation Week 1)
Multidimensional Fatigue Scale TEEN	QS3N			E					E	
Multidimensional Fatigue Scale YOUNG CHILD	QS3L			E					E	
Pediatric QOL Inventory CHILD REPORT	QS3F			E					E	
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C			E					E	
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D			E					E	
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A			E					E	
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B			E					E	
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P			E					E	
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q			E					E	

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		PA5_RIW2 (PA5 Re- Initiation Week 2)	PA5_RIW3 (PA5 Re- Initiation Week 3)	PA5_RIW4 (PA5 Re- Initiation Week 4)	W100 (Week 100)	W104 (Week 104)	W108 (Week 108)	W112 (Week 112)	W116 (Week 116)	W120 (Week 120)
Multidimensional Fatigue Scale TEEN	QS3N						E			
Multidimensional Fatigue Scale YOUNG CHILD	QS3L						E			
Pediatric QOL Inventory CHILD REPORT	QS3F						E			
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C						E			
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D						E			
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A						E			
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B						E			
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P						E			
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q						E			

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment	CRF	Time & Events Schedule								
		W124 (Week 124)	W128 (Week 128)	W132 (Week 132)	W136 (Week 136)	W140 (Week 140)	W144_ET (Week 144_ET)	W148 (Week 148)	PA5_EC (Long Term Optional Treatment Completion)	PA6 (Long Term Optional Treatment 2)
Multidimensional Fatigue Scale TEEN	QS3N						E	E		
Multidimensional Fatigue Scale YOUNG CHILD	QS3L						E	E		
Pediatric QOL Inventory CHILD REPORT	QS3F						E	E		
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C						E	E		
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D						E	E		
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A						E	E		
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B						E	E		
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P						E	E		
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q						E	E		

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E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				W152 (Week 152)	W156 (Week 156)	W160 (Week 160)	W164 (Week 164)	W168 (Week 168)	W172 (Week 172)	W176 (Week 176)
Multidimensional Fatigue Scale TEEN	QS3N		E							
Multidimensional Fatigue Scale YOUNG CHILD	QS3L		E							
Pediatric QOL Inventory CHILD REPORT	QS3F		E							
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C		E							
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D		E							
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A		E							
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B		E							
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P		E							
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q		E							

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				W188 (Week 188)	W192 (Week 192)	W196 (Week 196)	W200 (Week 200)	W204 (Week 204)	W208 (Week 208)	W212 (Week 212)
Multidimensional Fatigue Scale TEEN	QS3N								E	E
Multidimensional Fatigue Scale YOUNG CHILD	QS3L								E	E
Pediatric QOL Inventory CHILD REPORT	QS3F								E	E
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C								E	E
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D								E	E
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A								E	E
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B								E	E
Pediatric QOL Inventory PARENT RPT-INFANT 1-12M	QS3P								E	E
Pediatric QOL Inventory PARENT RPT-INFANT 13-24M	QS3Q								E	E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF	Time & Events Schedule		
			PA6_EC (Long Term Optional Treatment Completion 2)	Common (Common)	Unscheduled (Unscheduled)
Multidimensional Fatigue Scale TEEN	QS3N				
Multidimensional Fatigue Scale YOUNG CHILD	QS3L				
Pediatric QOL Inventory CHILD REPORT	QS3F				
Pediatric QOL Inventory PARENT RPT (CHILDREN)	QS3C				
Pediatric QOL Inventory PARENT RPT (TEENS)	QS3D				
Pediatric QOL Inventory PARENT RPT (TODDLERS)	QS3A				
Pediatric QOL Inventory PARENT RPT (YOUNG CHILD)	QS3B				
Pediatric QOL Inventory PARENT RPT-INFANT 1- 12M	QS3P				
Pediatric QOL Inventory PARENT RPT-INFANT 13- 24M	QS3Q				

Legend

E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted
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Assessment	CRF	Time & Events Schedule							
		Day0 (Day 0)	Week1 (Week 1)	Week2 (Week 2)	Week3 (Week 3)	Week4 (Week 4)	Week6 (Week 6)	Week8 (Week 8)	Week10 (Week 10)
Pediatric QOL Inventory TEEN REPORT	QS3G								
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E								
Physical Examination2	PE2								
Protocol Extension	PRE								
Questionnaires 2	QS2								
Scratch Scale	QS1			E		E		E	
Screened	Scr								
Study Drug Accountability 1	SDA1								
Study Drug Administration	EX			E					
Study Drug Administration 2	EX2								
Study Drug Compliance	SDC			E		E		E	
Subject Summary	DS								
Subject Summary 2	DS2								
Telephone Contact	TC		E		E		E		E
Urine Pregnancy Test	PREG2			E		E		E	
Vital Signs	VS			E		E		E	

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week12 (Week 12)	Week16 (Week 16)	Week20 (Week 20)	Week24 (Week 24)	Week28 (Week 28)	Week32 (Week 32)	Week36 (Week 36)	Week40 (Week 40)	Week44 (Week 44)
Pediatric QOL Inventory TEEN REPORT	QS3G				E					
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E				E					
Physical Examination2	PE2		E		E			E		
Protocol Extension	PRE									
Questionnaires 2	QS2				E					
Scratch Scale	QS1	E			E			E		
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC	E	E		E			E		E
Subject Summary	DS									
Subject Summary 2	DS2									
Telephone Contact	TC		E	E		E	E		E	
Urine Pregnancy Test	PREG2	E	E		E			E		
Vital Signs	VS	E	E		E			E		

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		Week48_ET (Week 48)	FollowUp (Post-Week 48 Follow-up)	StudyCompleti on (Study Completion (Complete))	Study_Completi on (Study Completion (Discontinue))	RID0 (Re-Initiation Day 0)	RIW49 (Re-Initiation Week 49)	RIW50 (Re-Initiation Week 50)	RIW51 (Re-Initiation Week 51)	RIW52 (Re-Initiation Week 52)
Pediatric QOL Inventory TEEN REPORT	QS3G	E				E				
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E	E				E				
Physical Examination2	PE2	E				E				
Protocol Extension	PRE			E	E					
Questionnaires 2	QS2	E				E				
Scratch Scale	QS1	E				E		E		E
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC	E						E		E
Subject Summary	DS			E	E					
Subject Summary 2	DS2									
Telephone Contact	TC		E				E		E	
Urine Pregnancy Test	PREG2	E				E		E		E
Vital Signs	VS	E				E		E		E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				Week52 (Week 52)	Week56 (Week 56)	Week60 (Week 60)	Week64 (Week 64)	Week68 (Week 68)	Week72 (Week 72)	Week76 (Week 76)
Pediatric QOL Inventory TEEN REPORT	QS3G			E			E			E
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E			E			E			E
Physical Examination2	PE2			E			E			E
Protocol Extension	PRE									
Questionnaires 2	QS2			E			E			E
Scratch Scale	QS1			E			E			E
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC			E			E			E
Subject Summary	DS									
Subject Summary 2	DS2									
Telephone Contact	TC	E	E		E	E		E	E	
Urine Pregnancy Test	PREG2			E			E			E
Vital Signs	VS			E			E			E

Legend

E = Expected

O = Optional

ER = Expected, Restricted

OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				Week88 (Week 88)	Week92 (Week 92)	Week96_ET (Week 96_ET)	30D_FU (30 Day Follow -up)	EC (Extension Completion)	PA5 (Long Term Optional Treatment)	PA5_RID2 (PA5 Re- Initiation Day - 2)
Pediatric QOL Inventory TEEN REPORT	QS3G			E					E	
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E			E					E	
Physical Examination2	PE2			E				E	E	
Protocol Extension	PRE									
Questionnaires 2	QS2			E					E	
Scratch Scale	QS1			E					E	
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC			E						
Subject Summary	DS					E				
Subject Summary 2	DS2									
Telephone Contact	TC	E	E		E					E
Urine Pregnancy Test	PREG2			E					E	
Vital Signs	VS			E				E	E	

Legend

E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted
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Assessment CRF		Time & Events Schedule								
		PA5_RIW2 (PA5 Re- Initiation Week 2)	PA5_RIW3 (PA5 Re- Initiation Week 3)	PA5_RIW4 (PA5 Re- Initiation Week 4)	W100 (Week 100)	W104 (Week 104)	W108 (Week 108)	W112 (Week 112)	W116 (Week 116)	W120 (Week 120)
Pediatric QOL Inventory TEEN REPORT	QS3G						E			
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E						E			
Physical Examination2	PE2	E		E			E			E
Protocol Extension	PRE									
Questionnaires 2	QS2						E			
Scratch Scale	QS1	E		E			E			E
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC	E		E			E			E
Subject Summary	DS									
Subject Summary 2	DS2									
Telephone Contact	TC		E		E	E		E	E	
Urine Pregnancy Test	PREG2	E		E			E			E
Vital Signs	VS	E		E			E			E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment CRF		Time & Events Schedule								
		W124 (Week 124)	W128 (Week 128)	W132 (Week 132)	W136 (Week 136)	W140 (Week 140)	W144_ET (Week 144_ET)	W148 (Week 148)	PA5_EC (Long Term Optional Treatment Completion)	PA6 (Long Term Optional Treatment 2)
Pediatric QOL Inventory TEEN REPORT	QS3G						E	E		
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E						E	E		
Physical Examination2	PE2			E			E	E		
Protocol Extension	PRE									
Questionnaires 2	QS2						E	E		
Scratch Scale	QS1			E			E	E		
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC			E			E			
Subject Summary	DS									
Subject Summary 2	DS2								E	
Telephone Contact	TC	E	E		E	E		E		
Urine Pregnancy Test	PREG2			E			E	E		
Vital Signs	VS			E			E	E		

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				W152 (Week 152)	W156 (Week 156)	W160 (Week 160)	W164 (Week 164)	W168 (Week 168)	W172 (Week 172)	W176 (Week 176)
Pediatric QOL Inventory TEEN REPORT	QS3G		E							
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E		E							
Physical Examination2	PE2		E			E			E	
Protocol Extension	PRE									
Questionnaires 2	QS2		E							
Scratch Scale	QS1		E			E			E	
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC		E			E			E	
Subject Summary	DS									
Subject Summary 2	DS2									
Telephone Contact	TC	E		E	E		E	E		E
Urine Pregnancy Test	PREG2		E			E			E	
Vital Signs	VS		E			E			E	

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				W188 (Week 188)	W192 (Week 192)	W196 (Week 196)	W200 (Week 200)	W204 (Week 204)	W208 (Week 208)	W212 (Week 212)
Pediatric QOL Inventory TEEN REPORT	QS3G								E	E
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E								E	E
Physical Examination2	PE2		E			E			E	E
Protocol Extension	PRE									
Questionnaires 2	QS2								E	E
Scratch Scale	QS1		E			E			E	E
Screened	Scr									
Study Drug Accountability 1	SDA1									
Study Drug Administration	EX									
Study Drug Administration 2	EX2									
Study Drug Compliance	SDC		E			E			E	
Subject Summary	DS									
Subject Summary 2	DS2									
Telephone Contact	TC	E		E	E		E	E		
Urine Pregnancy Test	PREG2		E			E			E	E
Vital Signs	VS		E			E			E	E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF	Time & Events Schedule		
			PA6_EC (Long Term Optional Treatment Completion 2)	Common (Common)	Unscheduled (Unscheduled)
Pediatric QOL Inventory TEEN REPORT	QS3G				
Pediatric QOL Inventory YOUNG CHILD REPORT	QS3E				
Physical Examination2	PE2			E	
Protocol Extension	PRE				
Questionnaires 2	QS2				
Scratch Scale	QS1			E	
Screened	Scr		E		
Study Drug Accountability 1	SDA1		E		
Study Drug Administration	EX				
Study Drug Administration 2	EX2		E		
Study Drug Compliance	SDC			E	
Subject Summary	DS				
Subject Summary 2	DS2	E			
Telephone Contact	TC			E	
Urine Pregnancy Test	PREG2			E	
Vital Signs	VS			E	

Legend

E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted
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Assessment	CRF	Time & Events Schedule							
		Day0 (Day 0)	Week1 (Week 1)	Week2 (Week 2)	Week3 (Week 3)	Week4 (Week 4)	Week6 (Week 6)	Week8 (Week 8)	Week10 (Week 10)
Xanthoma Scale	QS7								

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment	CRF	Time & Events Schedule								
		Week12 (Week 12)	Week16 (Week 16)	Week20 (Week 20)	Week24 (Week 24)	Week28 (Week 28)	Week32 (Week 32)	Week36 (Week 36)	Week40 (Week 40)	Week44 (Week 44)
Xanthoma Scale	QS7				E			E		

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				Week48_ET (Week 48)	FollowUp (Post-Week 48 Follow-up)	StudyCompleti on (Study Completion (Complete))	Study_Completi on (Study Completion (Discontinue))	RID0 (Re-Initiation Day 0)	RIW49 (Re-Initiation Week 49)	RIW50 (Re-Initiation Week 50)
Xanthoma Scale	QS7	E				E				

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				Week52 (Week 52)	Week56 (Week 56)	Week60 (Week 60)	Week64 (Week 64)	Week68 (Week 68)	Week72 (Week 72)	Week76 (Week 76)
Xanthoma Scale	QS7			E			E			E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				Week88 (Week 88)	Week92 (Week 92)	Week96_ET (Week 96_ET)	30D_FU (30 Day Follow -up)	EC (Extension Completion)	PA5 (Long Term Optional Treatment)	PA5_RID2 (PA5 Re- Initiation Day - 2)
Xanthoma Scale	QS7			E					E	

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				PA5_RIW2 (PA5 Re- Initiation Week 2)	PA5_RIW3 (PA5 Re- Initiation Week 3)	PA5_RIW4 (PA5 Re- Initiation Week 4)	W100 (Week 100)	W104 (Week 104)	W108 (Week 108)	W112 (Week 112)
Xanthoma Scale	QS7	E		E			E			E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				W124 (Week 124)	W128 (Week 128)	W132 (Week 132)	W136 (Week 136)	W140 (Week 140)	W144_ET (Week 144_ET)	W148 (Week 148)
Xanthoma Scale	QS7			E			E	E		

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				W152 (Week 152)	W156 (Week 156)	W160 (Week 160)	W164 (Week 164)	W168 (Week 168)	W172 (Week 172)	W176 (Week 176)
Xanthoma Scale	QS7		E			E			E	

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule						
				W188 (Week 188)	W192 (Week 192)	W196 (Week 196)	W200 (Week 200)	W204 (Week 204)	W208 (Week 208)	W212 (Week 212)
Xanthoma Scale	QS7		E			E			E	E

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Assessment		CRF		Time & Events Schedule		
				PA6_EC (Long Term Optional Treatment Completion 2)	Common (Common)	Unscheduled (Unscheduled)
Xanthoma Scale	QS7					

Legend			
E = Expected	O = Optional	ER = Expected, Restricted	OR = Optional, Restricted

Event - Publishing Event
Day 0 - Enrolled
Week 1 - Enrolled
Week 2 - Enrolled
Week 3 - Enrolled
Week 4 - Enrolled
Week 6 - Enrolled
Week 8 - Enrolled
Week 10 - Enrolled
Week 12 - Enrolled
Week 16 - Enrolled
Week 20 - Enrolled
Week 24 - Enrolled
Week 28 - Enrolled
Week 32 - Enrolled
Week 36 - Enrolled
Week 40 - Enrolled
Week 44 - Enrolled
Week 48 - Enrolled
Post-Week 48 Follow-up - Enrolled
Study Completion (Complete) - Completed
Study Completion (Discontinue) - Discontinued

Re-Initiation Day 0 - pScript
Re-Initiation Week 49 - pScript
Re-Initiation Week 50 - pScript
Re-Initiation Week 51 - pScript
Re-Initiation Week 52 - pScript
Week 52 - pScript
Week 56 - pScript
Week 60 - pScript
Week 64 - pScript
Week 68 - pScript
Week 72 - pScript
Week 76 - pScript
Week 80 - pScript
Week 84 - pScript
Week 88 - pScript
Week 92 - pScript
Week 96_ET - pScript
30 Day Follow-up - pScript
Extension Completion - pScript
Long Term Optional Treatment - Enrolled
PA5 Re-Initiation Day -2 - pScript
PA5 Re-Initiation Day 0 - pScript
PA5 Re-Initiation Week 1 - pScript

PA5 Re-Initiation Week 2 - pScript
PA5 Re-Initiation Week 3 - pScript
PA5 Re-Initiation Week 4 - pScript
Week 100 - pScript
Week 104 - pScript
Week 108 - pScript
Week 112 - pScript
Week 116 - pScript
Week 120 - pScript
Week 124 - pScript
Week 128 - pScript
Week 132 - pScript
Week 136 - pScript
Week 140 - pScript
Week 144_ET - pScript
Week 148 - pScript
Long Term Optional Treatment Completion - pScript
Long Term Optional Treatment 2 - pScript
Week 152 - pScript
Week 156 - pScript
Week 160 - pScript
Week 164 - pScript
Week 168 - pScript

Week 172 - pScript
Week 176 - pScript
Week 180 - pScript
Week 184 - pScript
Week 188 - pScript
Week 192 - pScript
Week 196 - pScript
Week 200 - pScript
Week 204 - pScript
Week 208 - pScript
Week 212 - pScript
Week 216 - pScript
Week 220 - pScript
Long Term Optional Treatment Completion 2 - pScript
Common - Screened

Form: Adverse Events (AE)

Event(s): Common

1 Were any Adverse Events experienced?
Item: AEYN
Domain: AE

Data Type: Text
Display Option: Select
MaxLen: 1
CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

2. Adverse Events

Columns:
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)
Action Taken
Ongoing at Week 48?
Relationship
Action Taken
Relationship
Severity
Life Threatening
Severity
Treatment: None
Life Threatening
Treatment: Medication

Treatment: None
Treatment: Hospitalization
Treatment: Medication
Treatment: Hospitalization
Other: Specify
Ongoing at Week 48?
Other: Specify

2.x.1	Verbatim Term Item: AETERM Domain: AE Verbatim	Data Type: Text Display Option: Encoded MaxLen: 200 Header Name: Verbatim Term Dictionary Name: MedDRA
2.x.1.1	AETERM_Enc_TERM Item: AETERM_ENC_TERM Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 200
2.x.1.2	AETERM_Enc_CODE Item: AETERM_ENC_CODE Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 30
2.x.1.3	AETERM_Enc_TYPE Item: AETERM_ENC_TYPE Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 25
2.x.1.4	AETERM_Enc_CAT1 Item: AETERM_ENC_CAT1 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.5	AETERM_Enc_CAT2 Item: AETERM_ENC_CAT2 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255

2.x.1.6	AETERM_Enc_CAT3 Item: AETERM_ENC_CAT3 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.7	AETERM_Enc_CAT4 Item: AETERM_ENC_CAT4 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.8	AETERM_Enc_CAT5 Item: AETERM_ENC_CAT5 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.9	AETERM_Enc_CAT6 Item: AETERM_ENC_CAT6 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.10	AETERM_Enc_CAT7 Item: AETERM_ENC_CAT7 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.11	AETERM_Enc_CAT8 Item: AETERM_ENC_CAT8 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.12	AETERM_Enc_CAT9 Item: AETERM_ENC_CAT9 Domain: AE	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.2	Reported in core (301) study database? Item: AEREP Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Reported in core (301)? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.3	Is the Adverse Event Serious? Item: AESER Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Serious?

CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

2.x.4	Start Date (Day) Item: AESTDATD Domain: AE	Data Type: Text Display Option: Select MaxLen: 2 Header Name: Start Date (Day) CodeList: DAY [[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]
2.x.5	Start Date (Month) Item: AESTDATM Domain: AE	Data Type: Text Display Option: Select MaxLen: 3 Header Name: Start Date (Month) CodeList: MONTH [[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]
2.x.6	Start Date (Year) Item: AESTDATY Domain: AE	Data Type: Text Display Option: Text MaxLen: 4 Header Name: Start Date (Year)
2.x.6.1	Start Date Item: AESTDAT Domain: AE Hidden	Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_AESTDAT) MaxLen: 11
2.x.7	Outcome Item: AEOUT Domain: AE	Data Type: Text Display Option: Select MaxLen: 2 Header Name: Outcome

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

2.x.8	End Date (Day) Item: AEENDATD Domain: AE Conditional [1]	<p>Data Type: Text Display Option: Select MaxLen: 2 Header Name: End Date (Day)</p> <p>CodeList: DAY [[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]</p>
2.x.9	End Date (Month) Item: AEENDATM Domain: AE Conditional [2]	<p>Data Type: Text Display Option: Select MaxLen: 3 Header Name: End Date (Month)</p> <p>CodeList: MONTH [[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]</p>
2.x.10	End Date (Year) Item: AEENDATY Domain: AE Conditional [3]	<p>Data Type: Text Display Option: Text MaxLen: 4 Header Name: End Date (Year)</p>
2.x.10.1	End Date Item: AEENDAT Domain: AE Hidden	<p>Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_AEENDAT) MaxLen: 11</p>

2.x.11	Was this event ongoing at Week 48 of 305 study? Item: AEONGO Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Ongoing at Week 48? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.12	Action Taken with Study Treatment Item: AEACN Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Action Taken CodeList: AEACN [[Blank] =],[Dose not changed = 1],[Drug interrupted = 2],[Drug withdrawn = 3],[Dose reduced = 4],[Not Applicable = 5]
2.x.13	Relationship to Study Treatment Item: AEREL Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Relationship CodeList: REL [[Blank] =],[Related = 1],[Possibly Related = 2],[Unlikely/Remotely Related = 3],[Not Related = 4]
2.x.14	Was CTCAE grading used to assess severity? Item: AECTCAE Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.15	Severity Item: AESEV Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Severity CodeList: SEV [[Blank] =],[Grade 1: Mild = 1],[Grade 2: Moderate = 2],[Grade 3: Severe = 3],[Grade 4: Life-threatening = 4],[Grade 5: Fatal = 5]

2.x.16	Was the Serious Event Life Threatening? Item: AELIFTHR Domain: AE Conditional [4]	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Life Threatening CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.17	Treatment Required: None Item: AETRT1 Domain: AE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Treatment: None CodeList: YES [[Blank] =],[YES = Y]
2.x.18	Treatment Required: Medication Required Item: AETRT2 Domain: AE Conditional [5]	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Treatment: Medication CodeList: YES [[Blank] =],[YES = Y]
2.x.19	Treatment Required: Hospitalization Required Item: AETRT3 Domain: AE Conditional [6]	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Treatment: Hospitalization CodeList: YES [[Blank] =],[YES = Y]
2.x.20	Treatment Required: Other Item: AETRT99 Domain: AE Conditional [7]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES [[Blank] =],[YES = Y]

2.x.21 Other: Specify
Item: AETRTSP
Domain: AE
Conditional [8]

Data Type: Text
Display Option: Text
MaxLen: 200
Header Name: Other: Specify

Item Design Notes	
Item No.	Design notes
1	Conditional on: AE.AEOUT Not Equal To 88
2	Conditional on: AE.AEOUT Not Equal To 88
3	Conditional on: AE.AEOUT Not Equal To 88
4	Conditional on: AE.AECTCAE Equal To N
5	Conditional on: AE.AETRT1 Not Equal To Y
6	Conditional on: AE.AETRT1 Not Equal To Y
7	Conditional on: AE.AETRT1 Not Equal To Y
8	Conditional on: AE.AETRT99 Equal To Y

Form: Caregiver Impression of Change (QS5)

Event(s): Week 48, Week 60, Week 72, Week 84, Week 96_ET, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

1	Was caregiver impression of change completed? Item: QSCIC Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date of assessment Item: QSCICDAT Domain: QS Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	How would you rate the change in your child's xanthoma severity since the start of the study? Item: QSCICCH Domain: QS Conditional [2]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PIC [[Blank] =],[Much better = 1],[Better = 2],[A little better = 3],[No change = 4],[A little worse = 5],[Worse = 6],[Much worse = 7]

Item Design Notes	
Item No.	Design notes
1	Conditional on: QS5.QSCIC Equal To Y
2	Conditional on: QS5.QSCIC Equal To Y

Form: Clinical Laboratory Tests (LB)

Event(s): Unscheduled, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day -2

1. Clinical Laboratory Tests

Columns:
Sample Type
Sample collected?
Collection Date
Sample ID

Key Sequence Values:

Key Sequence 1 - Sample Type
Blood
Urine

1.x.1	Sample Type Item: LBTYPE Domain: LB	Data Type: Text Display Option: Text MaxLen: 1 Header Name: Sample Type CodeList: LBTYPEA [Blood = 1],[Urine = 2]
1.x.2	Was the sample collected? Item: LBPERF Domain: LB	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Sample collected? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
1.x.3	Collection Date Item: LBDAT Domain: LB Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Collection Date

Form: Clinical Laboratory Tests 2 (LB2)

Event(s): **Unscheduled, Week 2, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Re-Initiation Week 50, Re-Initiation Week 52, Week 144_ET, Week 148, Week 216, Week 220**

1. Clinical Laboratory Tests

Columns:
Sample Type
Sample collected?
Collection Date
Sample ID

Key Sequence Values:

Key Sequence 1 - Sample Type
Blood
Urine

2	Date of last dose prior to sample collection Item: LDDAT Domain: LB	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Time of last dose prior to sample collection (hh:mm, 24-hour clock) Item: LDTIM Domain: LB	Data Type: Text Display Option: Text MaxLen: 5
4	Date of last meal prior to sample collection Item: LMDAT Domain: LB	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
5	Time of last meal prior to sample collection (hh:mm, 24-hour clock) Item: LMTIM Domain: LB	Data Type: Text Display Option: Text MaxLen: 5

1.x.1	Sample Type Item: LBTYPE_1 Domain: LB	Data Type: Text Display Option: Text MaxLen: 1 Header Name: Sample Type CodeList: LBTYPEA [Blood = 1],[Urine = 2]
1.x.2	Was the sample collected? Item: LBPERF_1 Domain: LB	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Sample collected? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
1.x.3	Collection Date Item: LBDAT_1 Domain: LB Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Collection Date
1.x.4	Sample ID Item: LBREFID_1 Domain: LB Conditional [2]	Data Type: Integer Display Option: Text MaxLen: 8 Header Name: Sample ID

Item Design Notes	
Item No.	Design notes
1	Conditional on: LB2.LBPERF Equal To Y
2	Conditional on: LB2.LBPERF Equal To Y

Form: Clinical Laboratory Tests 3 (LB3)

Event(s): Week 16, PA5 Re-Initiation Day 0, PA5 Re-Initiation Week 2, PA5 Re-Initiation Week 4, Week 108, Week 120, Week 132, Week 156, Week 168, Week 180, Week 192, Week 204

1. Clinical Laboratory Tests

Columns:
Sample Type
Sample collected?
Collection Date
Sample ID

Key Sequence Values:

Key Sequence 1 - Sample Type
Blood
Urine

2	Date of last meal prior to sample collection Item: LMDAT_1 Domain: LB	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Time of last meal prior to sample collection (hh:mm, 24-hour clock) Item: LMTIM_1 Domain: LB	Data Type: Text Display Option: Text MaxLen: 5
1.x.1	Sample Type Item: LBTYPE_2 Domain: LB	Data Type: Text Display Option: Text MaxLen: 1 Header Name: Sample Type CodeList: LBTYPEA [Blood = 1],[Urine = 2]
1.x.2	Was the sample collected? Item: LBPERF_2 Domain: LB	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Sample collected?

CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

1.x.3	Collection Date Item: LBDAT_2 Domain: LB Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Collection Date
1.x.4	Sample ID Item: LBREFID_2 Domain: LB Conditional [2]	Data Type: Integer Display Option: Text MaxLen: 8 Header Name: Sample ID

Item Design Notes	
Item No.	Design notes
1	Conditional on: LB3.LBPERF Equal To Y
2	Conditional on: LB3.LBPERF Equal To Y

Form: Completed (Comp)

Event(s): Common

1	Completed Date: Item: COMPDATE Domain: StatusForm	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
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Form: Concomitant Medications (CM)

Event(s): Common

1 Were any medications taken?
Item: CMYN
Domain: CM

Data Type: Text
Display Option: Select
MaxLen: 1
CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

2. Concomitant Medications

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

End Date (Month)
Dose
End Date (Year)
Dose Unit
Dose
Dose Unit
Dose
Route
Dose Unit
Route
Frequency
Route
Frequency
Frequency
Ongoing at Week 48?

2.x.1	Medication/Therapy Name Item: CMTRT Domain: CM Verbatim	Data Type: Text Display Option: Encoded MaxLen: 200 Header Name: Medication Name Dictionary Name: WHODrug
2.x.1.1	CMTRT_Enc_TERM Item: CMTRT_ENC_TERM Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 200
2.x.1.2	CMTRT_Enc_CODE Item: CMTRT_ENC_CODE Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 30

2.x.1.3	CMTRT_Enc_TYPE Item: CMTRT_ENC_TYPE Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 25
2.x.1.4	CMTRT_Enc_CAT1 Item: CMTRT_ENC_CAT1 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.5	CMTRT_Enc_CAT2 Item: CMTRT_ENC_CAT2 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.6	CMTRT_Enc_CAT3 Item: CMTRT_ENC_CAT3 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.7	CMTRT_Enc_CAT4 Item: CMTRT_ENC_CAT4 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.8	CMTRT_Enc_CAT5 Item: CMTRT_ENC_CAT5 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.9	CMTRT_Enc_CAT6 Item: CMTRT_ENC_CAT6 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.10	CMTRT_Enc_CAT7 Item: CMTRT_ENC_CAT7 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.11	CMTRT_Enc_CAT8 Item: CMTRT_ENC_CAT8 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.12	CMTRT_Enc_CAT9 Item: CMTRT_ENC_CAT9 Domain: CM	Data Type: Text Display Option: Encoded MaxLen: 255

2.x.2	Reported in core (301) study database? Item: CMREP Domain: CM	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Reported in core (301)? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.3	Indication Item: CMINDC Domain: CM	Data Type: Text Display Option: Text MaxLen: 200 Header Name: Indication
2.x.4	Start Date (Day) Item: CMSTDATD Domain: CM	Data Type: Text Display Option: Select MaxLen: 2 Header Name: Start Date (Day) CodeList: DAY [[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]
2.x.5	Start Date (Month) Item: CMSTDATM Domain: CM	Data Type: Text Display Option: Select MaxLen: 3 Header Name: Start Date (Month) CodeList: MONTH [[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]
2.x.6	Start Date (Year) Item: CMSTDATY Domain: CM	Data Type: Text Display Option: Text MaxLen: 4 Header Name: Start Date (Year)

2.x.6.1	Start Date Item: CMSTDAT Domain: CM Hidden	Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_CMSTDAT) MaxLen: 11
2.x.7	Taken Prior to Day 0 of 305 Study? Item: CMPRIOR Domain: CM	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Taken Prior to Day 0 of 305 Study? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.8	Was this medication ongoing at Week 48 of 305 study? Item: CMONGO2 Domain: CM	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Ongoing at Week 48? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.9	Taken Prior to entering the Amendment #4 305 Extension? Item: CMPRIOR2 Domain: CM	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Prior to entering the Amend #4? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.10	Ongoing at subject final visit? Item: CMONGO Domain: CM	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Ongoing? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2.x.11	End Date (Day) Item: CMENDATD Domain: CM Conditional [1]	Data Type: Text Display Option: Select MaxLen: 2 Header Name: End Date (Day)

CodeList: DAY [[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]

2.x.12	End Date (Month) Item: CMENDATM Domain: CM Conditional [2]	Data Type: Text Display Option: Select MaxLen: 3 Header Name: End Date (Month) CodeList: MONTH [[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]
2.x.13	End Date (Year) Item: CMENDATY Domain: CM Conditional [3]	Data Type: Text Display Option: Text MaxLen: 4 Header Name: End Date (Year)
2.x.13.1	End Date Item: CMENDAT Domain: CM Hidden	Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_CMENDAT) MaxLen: 11
2.x.14	Dose Item: CMDSTXT Domain: CM	Data Type: Text Display Option: Text MaxLen: 20 Header Name: Dose
2.x.15	Dose Unit Item: CMDOSU Domain: CM	Data Type: Text Display Option: Select MaxLen: 7 Header Name: Dose Unit

CodeList: DOSE [[Blank] =],[TABLET = TABLET],
 [CAPSULE = CAPSULE],[mg = mg],[ug = ug],[g = g],
 [mEq = mEq],[mL = mL],[oz = oz],[L/min = L/min],[ggt
 = gtt],[IU = IU],[U = U],[PATCH = PATCH],[PUFF =
 PUFF],[SPRAY = SPRAY],[Tbsp = Tbsp],[tsp = tsp],
 [UNKNOWN = UNKNOWN],[OTHER = OTHER]

2.x.16	Other: Specify Item: CMDOSSP Domain: CM Conditional [4]	Data Type: Text Display Option: Text MaxLen: 50
2.x.17	Route Item: CMROUTE Domain: CM	Data Type: Text Display Option: Select MaxLen: 24 Header Name: Route CodeList: ROUTE [[Blank] =],[ORAL = ORAL], [INTRAVENOUS = INTRAVENOUS], [SUBCUTANEOUS = SUBCUTANEOUS],[TOPICAL = TOPICAL],[TRANSDERMAL = TRANSDERMAL], [RESPIRATORY (INHALATION) = RESPIRATORY (INHALATION)],[NASAL = NASAL],[INTRASINAL = INTRASINAL],[OPHTHALMIC = OPHTHALMIC], [INTRAMUSCULAR = INTRAMUSCULAR],[VAGINAL = VAGINAL],[RECTAL = RECTAL],[SUBLINGUAL = SUBLINGUAL],[BUCCAL = BUCCAL],[INTRA- ARTICULAR = INTRA-ARTICULAR],[AURICULAR (OTIC) = AURICULAR (OTIC)],[UNKNOWN = UNKNOWN],[OTHER = OTHER]
2.x.18	Other: Specify Item: CMRTSPEC Domain: CM Conditional [5]	Data Type: Text Display Option: Text MaxLen: 50

2.x.19	Frequency Item: CMDOSFRQ Domain: CM	Data Type: Text Display Option: Select MaxLen: 7 Header Name: Frequency CodeList: FREQ [[Blank] =],[BID = BID],[ONCE = ONCE],[PRN = PRN],[Q6H = Q6H],[Q8H = Q8H],[Q12H = Q12H],[Q3D = Q3D],[QD = QD],[QID = QID],[QOD = QOD],[QM = QM],[QS = QS],[TID = TID],[TIS = TIS],[UNKNOWN = UNKNOWN],[Other = Other]
2.x.20	Other: Specify Item: CMFRSPEC Domain: CM Conditional [6]	Data Type: Text Display Option: Text MaxLen: 50

Item Design Notes	
Item No.	Design notes
1	Conditional on: CM.CMONGO Equal To N
2	Conditional on: CM.CMONGO Equal To N
3	Conditional on: CM.CMONGO Equal To N
4	Conditional on: CM.CMDOSU Equal To OTHER
5	Conditional on: CM.CMROUTE Equal To OTHER
6	Conditional on: CM.CMDOSFRQ Equal To OTHER

Form: Discontinued (Disc)

Event(s): Common

1	Discontinued Date: Item: DISCDATE Domain: StatusForm	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
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Form: Dose Adjustment (DAD)

Event(s): Week 16

1	Was the dose adjusted at Week 12? Item: DADYN Domain: DAD	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
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Form: Enrolled (Enroll)**Event(s): Common**

1	Subject ID: Item: ENRLID Domain: StatusForm	Data Type: Text Display Option: Text MaxLen: 35
2	Enrolled Date: Item: ENRLDATE Domain: StatusForm	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

Form: Failed (Fail)

Event(s): Common

1	Failed Date: Item: SCRNFALDATE Domain: StatusForm	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
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Form: Family Impact Module PARENT REPORT (QS30)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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 Item: QSPF1_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. I feel tired when I wake up in the morning Item: QSPF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. I feel too tired to do the things I like to do Item: QSPF3_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. I get headaches Item: QSPF4_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. I feel physically weak Item: QSPF5_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. I feel sick to my stomach Item: QSPF6_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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EMOTIONAL FUNCTIONING (problems with...)

7	1. I feel anxious Item: QSEF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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8	2. I feel sad Item: QSEF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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9	3. I feel angry Item: QSEF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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10	4. I feel frustrated Item: QSEF4_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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11	5. I feel helpless or hopeless Item: QSEF5_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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SOCIAL FUNCTIONING (problems with...)

12	1. I feel isolated from others Item: QSSF1_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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13	2. I have trouble getting support from others Item: QSSF2_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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14	3. It is hard to find time for social activities Item: QSSF3_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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15	4. I do not have enough energy for social activities Item: QSSF4_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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COGNITIVE FUNCTIONING (problems with...)

16	1. It is hard for me to keep my attention on things Item: QSCF1_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	2. It is hard for me to remember what people tell me Item: QSCF2_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	3. It is hard for me to remember what I just heard Item: QSCF3_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
19	4. It is hard for me to think quickly Item: QSCF4_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
20	5. I have trouble remembering what I was just thinking Item: QSCF5_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

COMMUNICATION (problems with...)

21	1. I feel that others do not understand my family's situation Item: QSCOMM1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	2. It is hard for me to talk about my child's health with others Item: QSCOMM2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	3. It is hard for me to tell doctors and nurses how I feel Item: QSCOMM3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
<p><p>In the past ONE month, as a result of your child's health, how much of a problem have you had with...</p><p>WORRY (problems with...)</p></p>		
24	1. I worry about whether or not my child's medical treatments are working Item: QSWRY1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
25	2. I worry about the side effects of my child's medications/medical treatments Item: QSWRY2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
26	3. I worry about how others will react to my child's condition Item: QSWRY3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
27	4. I worry about how my child's illness is affecting other family members Item: QSWRY4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
28	5. I worry about my child's future Item: QSWRY5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
<p>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.</p>		
<p>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...)</p>		
29	1. Family activities taking more time and effort Item: QSDA1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
30	2. Difficulty finding time to finish household tasks Item: QSDA2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
31	3. Feeling too tired to finish household tasks Item: QSDA3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
FAMILY RELATIONSHIPS (problems with...)		
32	1. Lack of communication between family members Item: QSFAM1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
33	2. Conflicts between family members Item: QSFAM2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
34	3. Difficulty making decisions together as a family Item: QSFAM3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
35	4. Difficulty solving family problems together Item: QSFAM4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
36	5. Stress or tension between family members Item: QSFAM5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Inclusion/Exclusion Criteria (IE1)

Event(s): Day 0

1	Protocol Criteria Version Item: TIVERS Domain: IE	Data Type: Text Display Option: Select MaxLen: 23 CodeList: TIVERS [[Blank] =],[Original - 14APR2013 = Original - 14APR2013],[Amendment 1 - 29JAN2015 = Amendment 1 - 29JAN2015],[Amendment 2 - 12FEB2015 = Amendment 2 - 12FEB2015],[Amendment 4 - 27APR2016 = Amendment 4 - 27APR2016],[Amendment 5 - 13NOV2017 = Amendment 5 - 13NOV2017]
2	Did the subject meet all eligibility criteria? Item: IEYN Domain: IE	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

3. Inclusion/Exclusion Criteria

Columns:
Criterion Type
Criterion not met
Specify
Approval date
Sponsor approval?

3.x.1	Criterion Type Item: IECAT Domain: IE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Criterion Type CodeList: IE [[Blank] =],[Inclusion = 1],[Exclusion = 2]
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3.x.2	Criterion not met Item: IETESTCD Domain: IE	Data Type: Text Display Option: Select MaxLen: 2 Header Name: Criterion not met CodeList: IENUM [[Blank] =],[1 = 1],[2 = 2],[3 = 3],[4 = 4],[5 = 5],[6 = 6],[7 = 7],[8 = 8],[9 = 9],[10 = 10]
3.x.3	Specify Item: IEOTHER Domain: IE	Data Type: Text Display Option: Text MaxLen: 200 Header Name: Specify
3.x.4	Date of approval Item: IEAPPDAT Domain: IE Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Approval date
3.x.5	Lumena approval received? Item: IEAPPR Domain: IE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Sponsor approval? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

Item Design Notes	
Item No.	Design notes
1	Conditional on: IE1.IEAPPR Equal To Y

Form: Inclusion/Exclusion Criteria 2 (IE2)

Event(s): Re-Initiation Day 0

1 Did the subject meet all eligibility criteria?
 Item: IEYN_2
 Domain: IE

Data Type: Text
 Display Option: Select
 MaxLen: 1
 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

2. Inclusion/Exclusion Criteria

Columns:
Criterion Type
Criterion not met
Specify
Approval date
Sponsor approval?

2.x.1 Criterion Type
 Item: IECAT_1
 Domain: IE

Data Type: Text
 Display Option: Select
 MaxLen: 1
 Header Name: Criterion Type
 CodeList: IE [[Blank] =],[Inclusion = 1],[Exclusion = 2]

2.x.2 Criterion not met
 Item: IETESTCD_1
 Domain: IE

Data Type: Text
 Display Option: Select
 MaxLen: 2
 Header Name: Criterion not met
 CodeList: IENUM [[Blank] =],[1 = 1],[2 = 2],[3 = 3],[4 = 4],[5 = 5],[6 = 6],[7 = 7],[8 = 8],[9 = 9],[10 = 10]

2.x.3 Specify
 Item: IEOTHER_1
 Domain: IE

Data Type: Text
 Display Option: Text
 MaxLen: 200
 Header Name: Specify

2.x.4	Date of approval Item: IEAPPDAT_1 Domain: IE Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Approval date
2.x.5	Lumena approval received? Item: IEAPPR_1 Domain: IE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Sponsor approval? CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

Item Design Notes

Item No.	Design notes
1	Conditional on: IE2.IEAPPR Equal To Y

Form: Inclusion/Exclusion Criteria 3 (IE3)

Event(s): Long Term Optional Treatment, Long Term Optional Treatment 2

1	Did the subject meet all eligibility criteria? Item: IEYN_3 Domain: IE	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
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2. Inclusion/Exclusion Criteria

Columns:
Criterion Type
Criterion not met

2.x.1	Criterion Type Item: IECAT_2 Domain: IE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Criterion Type CodeList: IE [[Blank] =],[Inclusion = 1],[Exclusion = 2]
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2.x.2	Criterion not met Item: IETESTC2 Domain: IE	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Criterion not met CodeList: IENUM2_ [[Blank] =],[1 = 1],[2 = 2],[3 = 3],[4 = 4],[5 = 5],[6 = 6]
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Form: Informed Consent/Demography (DM)

Event(s): Day 0

INFORMED CONSENT

1	Date Parental Informed Consent signed Item: ICDAT Domain: IC	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
2	Young Adult Consent Not Applicable Item: ICYANA Domain: IC	Data Type: Text Display Option: Select MaxLen: 2 CodeList: NA [[Blank] =],[Not Applicable = NA]
3	Date Young Adult Consent signed Item: ICYADAT Domain: IC Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
4	Assent Not Applicable Item: ICANA Domain: IC	Data Type: Text Display Option: Select MaxLen: 2 CodeList: NA [[Blank] =],[Not Applicable = NA]
5	Date Assent signed Item: ICADAT Domain: IC Conditional [2]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

DEMOGRAPHY

6	Birth date Item: BRTHDAT Domain: DM	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
6.1	Age Item: AGE Domain: DM Hidden	Data Type: Integer Display Option: Derived (D_AGE) MaxLen: 2

6.2	Age Units Item: AGEU Domain: DM Hidden	Data Type: Text Display Option: Derived (D_AGEU) MaxLen: 5
7	Sex Item: SEX Domain: DM	Data Type: Text Display Option: Select MaxLen: 1 CodeList: SEX [[Blank] =],[Male = M],[Female = F]
7.1	Country Item: COUNTRY Domain: DM Hidden	Data Type: Text Display Option: Derived (D_COUNTRY) MaxLen: 3
8	Weight (kg) Item: WEIGHT Domain: VS	Data Type: Float Display Option: Text MaxLen: 4 MaxPre: 1 (x.x)
8.1	Weight Units Item: VSWG TU Domain: VS Hidden	Data Type: Text Display Option: Select MaxLen: 2 CodeList: WEIGHT [kg = kg]

Item Design Notes	
Item No.	Design notes
1	Conditional on: DM.ICYANA Not Equal To NA
2	Conditional on: DM.ICANA Not Equal To NA

Item No.	Design notes
1	Conditional on: DM.ICYANA Not Equal To NA
2	Conditional on: DM.ICANA Not Equal To NA

Form: Long Term Optional Treatment (PRE2)

Event(s): Long Term Optional Treatment

1	Did the subject consent to the long term optional treatment period? Item: PREYN2 Domain: PRE	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Protocol Criteria Version Item: PREPCV2 Domain: PRE Conditional [1]	Data Type: Text Display Option: Select MaxLen: 25 CodeList: IEPRT3_ [[Blank] =],[Amendment 5 - 13NOV2017 = Amendment 5 - 13NOV2017], [Amendment 6 - 25-JUN-2018 = Amendment 6 - 25-JUN-2018]
3	Date Parental Informed Consent signed Item: ICDAT_1 Domain: IC Conditional [2]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
4	Young Adult Consent Not Applicable Item: ICYANA_1 Domain: IC Conditional [3]	Data Type: Text Display Option: Select MaxLen: 2 CodeList: NA [[Blank] =],[Not Applicable = NA]
5	Date Young Adult Consent signed Item: ICYADAT_1 Domain: IC Conditional [4]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
6	Assent Not Applicable Item: ICANA_1 Domain: IC Conditional [5]	Data Type: Text Display Option: Select MaxLen: 2

CodeList: NA [[Blank] =],[Not Applicable = NA]

7	Date Assent signed Item: ICADAT_1 Domain: IC Conditional [6]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
8	What schedule did subject complete first? Item: PREPROD Domain: PRE Conditional [7]	Data Type: Text Display Option: Select MaxLen: 2 CodeList: PROD [[Blank] =],[D = D],[E = E],[Not Applicable - Screen Failure = NA]

Item Design Notes	
Item No.	Design notes
1	Conditional on: PRE2.PREYN2 Equal To Y
2	Conditional on: PRE2.PREYN2 Equal To Y
3	Conditional on: PRE2.PREYN2 Equal To Y
4	Conditional on: PRE2.PREYN2 Equal To Y
5	Conditional on: PRE2.PREYN2 Equal To Y
6	Conditional on: PRE2.PREYN2 Equal To Y
7	Conditional on: PRE2.PREYN2 Equal To Y

Form: Long Term Optional Treatment 2 (PRE3)

Event(s): Long Term Optional Treatment 2

Form: Long Term Optional Treatment 2 (PRE3)**Event(s): Long Term Optional Treatment 2**

1	Did the subject consent to the long term optional treatment 2 period for Protocol Amendment 6? Item: PREYN2_1 Domain: PRE	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date Parental Informed Consent signed Item: ICDAT_2 Domain: IC Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Young Adult Consent Not Applicable Item: ICYANA_2 Domain: IC Conditional [2]	Data Type: Text Display Option: Select MaxLen: 2 CodeList: NA [[Blank] =],[Not Applicable = NA]
4	Date Young Adult Consent signed Item: ICYADAT_2 Domain: IC Conditional [3]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
5	Assent Not Applicable Item: ICANA_2 Domain: IC Conditional [4]	Data Type: Text Display Option: Select MaxLen: 2 CodeList: NA [[Blank] =],[Not Applicable = NA]
6	Date Assent signed Item: ICADAT_2 Domain: IC Conditional [5]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

Form: Long Term Optional Treatment 2 (PRE3)**Event(s): Long Term Optional Treatment 2**

Item Design Notes	
Item No.	Design notes
1	Conditional on: PRE3.PREYN2 Equal To Y
2	Conditional on: PRE3.PREYN2 Equal To Y
3	Conditional on: PRE3.PREYN2 Equal To Y
4	Conditional on: PRE3.PREYN2 Equal To Y
5	Conditional on: PRE3.PREYN2 Equal To Y

Form: Medical History (MH)

Event(s): Day 0

1	Any new significant medical history? Item: MHYN Domain: MH	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
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2. Medical History

Columns:
Verbatim Term
Start Date (Day)
Start Date (Month)
Start Date (Year)
Ongoing
End Date (Day)
End Date (Month)
End Date (Year)

2.x.1	Verbatim term Item: MHTERM Domain: MH Verbatim	Data Type: Text Display Option: Encoded MaxLen: 200 Header Name: Verbatim Term Dictionary Name: MedDRA
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2.x.1.1	MHTERM_Enc_TERM Item: MHTERM_ENC_TERM Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 200
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2.x.1.2	MHTERM_Enc_CODE Item: MHTERM_ENC_CODE Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 30
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2.x.1.3	MHTERM_Enc_TYPE Item: MHTERM_ENC_TYPE Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 25
2.x.1.4	MHTERM_Enc_CAT1 Item: MHTERM_ENC_CAT1 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.5	MHTERM_Enc_CAT2 Item: MHTERM_ENC_CAT2 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.6	MHTERM_Enc_CAT3 Item: MHTERM_ENC_CAT3 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.7	MHTERM_Enc_CAT4 Item: MHTERM_ENC_CAT4 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.8	MHTERM_Enc_CAT5 Item: MHTERM_ENC_CAT5 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.9	MHTERM_Enc_CAT6 Item: MHTERM_ENC_CAT6 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.10	MHTERM_Enc_CAT7 Item: MHTERM_ENC_CAT7 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.11	MHTERM_Enc_CAT8 Item: MHTERM_ENC_CAT8 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.12	MHTERM_Enc_CAT9 Item: MHTERM_ENC_CAT9 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255

2.x.2	Start Date (Day) Item: MHSTDATD Domain: MH	Data Type: Text Display Option: Select MaxLen: 2 Header Name: Start Date (Day) CodeList: DAY [[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]
2.x.3	Start Date (Month) Item: MHSTDATM Domain: MH	Data Type: Text Display Option: Select MaxLen: 3 Header Name: Start Date (Month) CodeList: MONTH [[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]
2.x.4	Start Date (Year) Item: MHSTDATY Domain: MH	Data Type: Text Display Option: Text MaxLen: 4 Header Name: Start Date (Year)
2.x.4.1	Start Date Item: MHSTDAT Domain: MH Hidden	Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_MHSTDAT) MaxLen: 11
2.x.5	Ongoing? Item: MHONGO Domain: MH	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Ongoing CodeList: YES [[Blank] =],[YES = Y]

2.x.6	End Date (Day) Item: MHENDATD Domain: MH Conditional [1]	Data Type: Text Display Option: Select MaxLen: 2 Header Name: End Date (Day) CodeList: DAY [[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]
2.x.7	End Date (Month) Item: MHENDATM Domain: MH Conditional [2]	Data Type: Text Display Option: Select MaxLen: 3 Header Name: End Date (Month) CodeList: MONTH [[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]
2.x.8	End Date (Year) Item: MHENDATY Domain: MH Conditional [3]	Data Type: Text Display Option: Text MaxLen: 4 Header Name: End Date (Year)
2.x.8.1	End Date Item: MHENDAT Domain: MH Hidden	Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_MHENDAT) MaxLen: 11

Form: Medical History (MH)**Event(s): Day 0**

Item Design Notes	
Item No.	Design notes
1	Conditional on: MH.MHONGO Equal To
2	Conditional on: MH.MHONGO Equal To
3	Conditional on: MH.MHONGO Equal To

Form: Medical History 2 (MH2)

Event(s): Re-Initiation Day 0, Long Term Optional Treatment

1	Any new medical histories to report? Item: MHYN_1 Domain: MH	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
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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

Columns:
Verbatim Term
Start Date (Day)
Start Date (Month)
Start Date (Year)
Ongoing
End Date (Day)
End Date (Month)
End Date (Year)

2.x.1	Verbatim term Item: MHTERM_1 Domain: MH Verbatim	Data Type: Text Display Option: Encoded MaxLen: 200 Header Name: Verbatim Term Dictionary Name: MedDRA
2.x.1.1	MHTERM_Enc_TERM Item: MHTERM_1_ENC_TERM Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 200

2.x.1.2	MHTERM_Enc_CODE Item: MHTERM_1_ENC_CODE Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 30
2.x.1.3	MHTERM_Enc_TYPE Item: MHTERM_1_ENC_TYPE Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 25
2.x.1.4	MHTERM_Enc_CAT1 Item: MHTERM_1_ENC_CAT1 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.5	MHTERM_Enc_CAT2 Item: MHTERM_1_ENC_CAT2 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.6	MHTERM_Enc_CAT3 Item: MHTERM_1_ENC_CAT3 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.7	MHTERM_Enc_CAT4 Item: MHTERM_1_ENC_CAT4 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.8	MHTERM_Enc_CAT5 Item: MHTERM_1_ENC_CAT5 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.9	MHTERM_Enc_CAT6 Item: MHTERM_1_ENC_CAT6 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.10	MHTERM_Enc_CAT7 Item: MHTERM_1_ENC_CAT7 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.1.11	MHTERM_Enc_CAT8 Item: MHTERM_1_ENC_CAT8 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255

2.x.1.12	MHTERM_Enc_CAT9 Item: MHTERM_1_ENC_CAT9 Domain: MH	Data Type: Text Display Option: Encoded MaxLen: 255
2.x.2	Start Date (Day) Item: MHSTDATD_1 Domain: MH	Data Type: Text Display Option: Select MaxLen: 2 Header Name: Start Date (Day) CodeList: DAY [[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]
2.x.3	Start Date (Month) Item: MHSTDATM_1 Domain: MH	Data Type: Text Display Option: Select MaxLen: 3 Header Name: Start Date (Month) CodeList: MONTH [[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]
2.x.4	Start Date (Year) Item: MHSTDATY_1 Domain: MH	Data Type: Text Display Option: Text MaxLen: 4 Header Name: Start Date (Year)
2.x.4.1	Start Date Item: MHSTDAT2 Domain: MH Hidden	Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_MHSTDAT2) MaxLen: 11
2.x.5	Ongoing? Item: MHONGO_1 Domain: MH	Data Type: Text Display Option: Select MaxLen: 1 Header Name: Ongoing

CodeList: YES [[Blank] =],[YES = Y]

2.x.6	End Date (Day) Item: MHENDATD_1 Domain: MH Conditional [1]	Data Type: Text Display Option: Select MaxLen: 2 Header Name: End Date (Day) CodeList: DAY [[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]
2.x.7	End Date (Month) Item: MHENDATM_1 Domain: MH Conditional [2]	Data Type: Text Display Option: Select MaxLen: 3 Header Name: End Date (Month) CodeList: MONTH [[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]
2.x.8	End Date (Year) Item: MHENDATY_1 Domain: MH Conditional [3]	Data Type: Text Display Option: Text MaxLen: 4 Header Name: End Date (Year)
2.x.8.1	End Date Item: MHENDAT2 Domain: MH Hidden	Data Type: Date (mm/dd/yyyy) Display Option: Derived (D_MHENDAT2) MaxLen: 11

Form: Medical History 2 (MH2)**Event(s): Re-Initiation Day 0, Long Term Optional Treatment**

Item Design Notes	
Item No.	Design notes
1	Conditional on: MH2.MHONGO Equal To
2	Conditional on: MH2.MHONGO Equal To
3	Conditional on: MH2.MHONGO Equal To

Form: Multidimensional Fatigue Scale CHILD (QS3M)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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

General Fatigue (PROBLEMS WITH...)

1	1. I feel tired Item: QSGF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. I feel physically weak (not strong) Item: QSGF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. I feel too tired to do things that I like to do Item: QSGF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. I feel too tired to spend time with my friends Item: QSGF4_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. I have trouble finishing things Item: QSGF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. I have trouble starting things Item: QSGF6_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
<hr/>		
Sleep/Rest Fatigue (PROBLEMS WITH...)		
7	1. I sleep a lot Item: QSSRF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	2. It is hard for me to sleep through the night Item: QSSRF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
9	3. I feel tired when I wake up in the morning Item: QSSRF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	4. I rest a lot Item: QSSRF4_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

11	5. I take a lot of naps Item: QSSRF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	6. I spend a lot of time in bed Item: QSSRF6_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
<hr/>		
Cognitive Fatigue (PROBLEMS WITH...)		
13	1. It is hard for me to keep my attention on things Item: QSCF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	2. It is hard for me to remember what people tell me Item: QSCF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	3. It is hard for me to remember what I just heard Item: QSCF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	4. It is hard for me to think quickly Item: QSCF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	5. I have trouble remembering what I was just thinking Item: QSCF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	6. I have trouble remembering more than one thing at a time Item: QSCF6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Multidimensional Fatigue Scale PARENT (YOUNG CHILD (QS3))

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

In the past ONE month, how much of a problem has this been for your child...

GENERAL FATIGUE (problems with...)

1	1. Feeling tired Item: QSGF1_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Feeling physically weak (not strong) Item: QSGF2_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Feeling too tired to do things that he/she likes to do Item: QSGF3_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Feeling too tired to spend time with his/her friends Item: QSGF4_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Trouble finishing things Item: QSGF5_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. Trouble starting things Item: QSGF6_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
<hr/>		
SLEEP/REST FATIGUE (problems with...)		
7	1. Sleeping a lot Item: QSSRF1_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	2. Difficulty sleeping through the night Item: QSSRF2_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
9	3. Feeling tired when he/she wakes up in the morning Item: QSSRF3_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	4. Resting a lot Item: QSSRF4_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

11	5. Taking a lot of naps Item: QSSRF5_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	6. Spending a lot of time in bed Item: QSSRF6_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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COGNITIVE FATIGUE (problems with...)		
13	1. Difficulty keeping his/her attention on things Item: QSMF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	2. Difficulty remembering what people tell him/her Item: QSMF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	3. Difficulty remembering what he/she just heard Item: QSMF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	4. Difficulty thinking quickly Item: QSMF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	5. Trouble remembering what he/she was just thinking Item: QSMF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	6. Trouble remembering more than one thing at a time Item: QSMF6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Multidimensional Fatigue Scale PARENT for CHILDREN (QS3J)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

In the past ONE month, how much of a problem has this been for your child...

GENERAL FATIGUE (problems with...)

1	1. Feeling tired Item: QSGF1_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Feeling physically weak (not strong) Item: QSGF2_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Feeling too tired to do things that he/she likes to do Item: QSGF3_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Feeling too tired to spend time with his/her friends Item: QSGF4_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Trouble finishing things Item: QSGF5_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. Trouble starting things Item: QSGF6_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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SLEEP/REST FATIGUE (problems with...)

7	1. Sleeping a lot Item: QSSRF1_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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8	2. Difficulty sleeping through the night Item: QSSRF2_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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9	3. Feeling tired when he/she wakes up in the morning Item: QSSRF3_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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10	4. Resting a lot Item: QSSRF4_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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11	5. Taking a lot of naps Item: QSSRF5_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	6. Spending a lot of time in bed Item: QSSRF6_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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COGNITIVE FATIGUE (problems with...)		
13	1. Difficulty keeping his/her attention on things Item: QSMF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	2. Difficulty remembering what people tell him/her Item: QSMF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	3. Difficulty remembering what he/she just heard Item: QSMF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	4. Difficulty thinking quickly Item: QSMF4_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	5. Trouble remembering what he/she was just thinking Item: QSMF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	6. Trouble remembering more than one thing at a time Item: QSMF6_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Multidimensional Fatigue Scale PARENT for TEENS (QS3K)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

In the past ONE month, how much of a problem has this been for your child...

GENERAL FATIGUE (problems with...)

1	1. Feeling tired Item: QSGF1_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Feeling physically weak (not strong) Item: QSGF2_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Feeling too tired to do things that he/she likes to do Item: QSGF3_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Feeling too tired to spend time with his/her friends Item: QSGF4_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Trouble finishing things Item: QSGF5_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. Trouble starting things Item: QSGF6_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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SLEEP/REST FATIGUE (problems with...)		
7	1. Sleeping a lot Item: QSSRF1_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	2. Difficulty sleeping through the night Item: QSSRF2_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
9	3. Feeling tired when he/she wakes up in the morning Item: QSSRF3_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	4. Resting a lot Item: QSSRF4_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

11	5. Taking a lot of naps Item: QSSRF5_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	6. Spending a lot of time in bed Item: QSSRF6_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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COGNITIVE FATIGUE (problems with...)		
13	1. Difficulty keeping his/her attention on things Item: QSMF1_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	2. Difficulty remembering what people tell him/her Item: QSMF2_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	3. Difficulty remembering what he/she just heard Item: QSMF3_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	4. Difficulty thinking quickly Item: QSMF4_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	5. Trouble remembering what he/she was just thinking Item: QSMF5_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	6. Trouble remembering more than one thing at a time Item: QSMF6_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Multidimensional Fatigue Scale PARENT for TODDLERS (QS3H)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

In the past ONE month, how much of a problem has this been for your child...

GENERAL FATIGUE (problems with...)

1	1. Feeling tired Item: QSGF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Feeling physically weak (not strong) Item: QSGF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Feeling too tired to do things that he/she likes to do Item: QSGF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Feeling too tired to spend time with his/her friends Item: QSGF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Trouble finishing things Item: QSGF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. Trouble starting things Item: QSGF6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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SLEEP/REST FATIGUE (problems with...)		
7	1. Sleeping a lot Item: QSSRF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	2. Difficulty sleeping through the night Item: QSSRF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
9	3. Feeling tired when he/she wakes up in the morning Item: QSSRF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	4. Resting a lot Item: QSSRF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

11	5. Taking a lot of naps Item: QSSRF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	6. Spending a lot of time in bed Item: QSSRF6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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COGNITIVE FATIGUE (problems with...)		
13	1. Difficulty keeping his/her attention on things Item: QSMF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	2. Difficulty remembering what people tell him/her Item: QSMF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	3. Difficulty remembering what he/she just heard Item: QSMF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	4. Difficulty thinking quickly Item: QSMF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	5. Trouble remembering what he/she was just thinking Item: QSMF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	6. Trouble remembering more than one thing at a time Item: QSMF6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Multidimensional Fatigue Scale TEEN (QS3N)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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

General Fatigue (PROBLEMS WITH...)

1	1. I feel tired Item: QSGF1_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. I feel physically weak (not strong) Item: QSGF2_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. I feel too tired to do things that I like to do Item: QSGF3_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. I feel too tired to spend time with my friends Item: QSGF4_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. I have trouble finishing things Item: QSGF5_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. I have trouble starting things Item: QSGF6_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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Sleep/Rest Fatigue (PROBLEMS WITH...)

7	1. I sleep a lot Item: QSSRF1_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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8	2. It is hard for me to sleep through the night Item: QSSRF2_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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9	3. I feel tired when I wake up in the morning Item: QSSRF3_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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10	4. I rest a lot Item: QSSRF4_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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11	5. I take a lot of naps Item: QSSRF5_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	6. I spend a lot of time in bed Item: QSSRF6_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
Cognitive Fatigue (PROBLEMS WITH...)		
13	1. It is hard for me to keep my attention on things Item: QSCF1_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	2. It is hard for me to remember what people tell me Item: QSCF2_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	3. It is hard for me to remember what I just heard Item: QSCF3_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	4. It is hard for me to think quickly Item: QSCF4_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	5. I have trouble remembering what I was just thinking Item: QSCF5_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	6. I have trouble remembering more than one thing at a time Item: QSCF6_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Multidimensional Fatigue Scale YOUNG CHILD (QS3L)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

<p>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.</p>

<p>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.</p>

<p>General Fatigue (PROBLEMS WITH...) </p>

1	1. Do you feel tired Item: QSGF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
2	2. Do you feel physically weak (not strong) Item: QSGF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
3	3. Do you feel too tired to do things that you like to do Item: QSGF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
4	4. Do you feel too tired to spend time with your friends Item: QSGF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
5	5. Do you have trouble finishing things Item: QSGF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]

6	6. Do you have trouble starting things Item: QSGF6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
<hr/>		
Remember, tell me how much of a problem this has been for you for the last few weeks. <hr/>		
7	1. Do you sleep a lot Item: QSSRF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
8	2. Is it hard for you to sleep through the night Item: QSSRF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
9	3. Do you feel tired when you wake up in the morning Item: QSSRF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
10	4. Do you rest a lot Item: QSSRF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
11	5. Do you take a lot of naps Item: QSSRF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]

12	6. Do you spend a lot of time in bed Item: QSSRF6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
<hr/>		
<p>Cognitive Fatigue (PROBLEMS WITH...)</p>		
13	1. Is it hard for you to keep your attention on things Item: QSCF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
14	2. Is it hard for you to remember what people tell you Item: QSCF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
15	3. Is it hard for you to remember what you just heard Item: QSCF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
16	4. Is it hard for you to think quickly Item: QSCF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
17	5. Do you have trouble remembering what you were just thinking Item: QSCF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]

18 6. Do you have trouble remembering more than one thing at a
time
Item: QSCF6
Domain: QS

Data Type: Text
Display Option: Select
MaxLen: 1

CodeList: PEDSQL2 [[Blank] =],[Not at all = 0],
[Sometimes = 2],[A lot = 4]

Form: Pediatric QOL Inventory CHILD REPORT (QS3F)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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 Item: QSHA1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. It is hard for me to run Item: QSHA2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. It is hard for me to do sports activity or exercise Item: QSHA3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. It is hard for me to lift something heavy Item: QSHA4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. It is hard for me to take a bath or shower by myself Item: QSHA5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
6	6. It is hard for me to do chores around the house Item: QSHA6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
7	7. I hurt or ache Item: QSHA7 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	8. I have low energy Item: QSHA8 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
ABOUT MY FEELINGS (problems with...)		
9	1. I feel afraid or scared Item: QSFL1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	2. I feel sad or blue Item: QSFL2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
11	3. I feel angry Item: QSFL3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	4. I have trouble sleeping Item: QSFL4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	5. I worry about what will happen to me Item: QSFL5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
HOW I GET ALONG WITH OTHERS (problems with...)		
14	1. I have trouble getting along with other kids Item: QSGET1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	2. Other kids do not want to be my friend Item: QSGET2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
16	3. Other kids tease me Item: QSGET3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	4. I cannot do things that other kids my age can do Item: QSGET4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	5. It is hard to keep up when I play with other kids Item: QSGET5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
ABOUT SCHOOL (problems with...)		
19	1. It is hard to pay attention in class Item: QSASC1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
20	2. I forget things Item: QSASC2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
21	3. I have trouble keeping up with my schoolwork Item: QSASC3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	4. I miss school because of not feeling well Item: QSASC4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	5. I miss school to go to the doctor or hospital Item: QSASC5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Pediatric QOL Inventory PARENT RPT (CHILDREN) (QS3C)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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 Item: QSPF1_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Running Item: QSPF2_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Participating in sports activity or exercise Item: QSPF3_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Lifting something heavy Item: QSPF4_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Taking a bath or shower by him or herself Item: QSPF5_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. Doing chores around the house Item: QSPF6_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
7	7. Having hurts or aches Item: QSPF7_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	8. Low energy level Item: QSPF8_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
EMOTIONAL FUNCTIONING (problems with...)		
9	1. Feeling afraid or scared Item: QSEF1_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	2. Feeling sad or blue Item: QSEF2_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

11	3. Feeling angry Item: QSEF3_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	4. Trouble sleeping Item: QSEF4_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	5. Worrying about what will happen to him or her Item: QSEF5_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SOCIAL FUNCTIONING (problems with...)		
14	1. Getting along with other children Item: QSSF1_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	2. Other kids not wanting to be his or her friend Item: QSSF2_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	3. Getting teased by other children Item: QSSF3_6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	4. Not able to do things that other children his or her age can do Item: QSSF4_6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	5. Keeping up when playing with other children Item: QSSF5_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SCHOOL FUNCTIONING (problems with...)		
19	1. Paying attention in class Item: QSCHF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
20	2. Forgetting things Item: QSCHF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

21	3. Keeping up with schoolwork Item: QSCHF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	4. Missing school because of not feeling well Item: QSCHF4_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	5. Missing school to go to the doctor or hospital Item: QSCHF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Pediatric QOL Inventory PARENT RPT (TEENS) (QS3D)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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 Item: QSPF1_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Running Item: QSPF2_6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Participating in sports activity or exercise Item: QSPF3_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Lifting something heavy Item: QSPF4_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Taking a bath or shower by him or herself Item: QSPF5_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
6	6. Doing chores around the house Item: QSPF6_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
7	7. Having hurts or aches Item: QSPF7_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	8. Low energy level Item: QSPF8_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
EMOTIONAL FUNCTIONING (problems with...)		
9	1. Feeling afraid or scared Item: QSEF1_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	2. Feeling sad or blue Item: QSEF2_6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
11	3. Feeling angry Item: QSEF3_6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	4. Trouble sleeping Item: QSEF4_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	5. Worrying about what will happen to him or her Item: QSEF5_1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SOCIAL FUNCTIONING (problems with...)		
14	1. Getting along with other teens Item: QSSF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	2. Other teens not wanting to be his or her friend Item: QSSF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
16	3. Getting teased by other teens Item: QSSF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	4. Not able to do things that other teens his or her age can do Item: QSSF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	5. Keeping up with other teens Item: QSSF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SCHOOL FUNCTIONING (problems with...)		
19	1. Paying attention in class Item: QSCHF1_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
20	2. Forgetting things Item: QSCHF2_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
21	3. Keeping up with schoolwork Item: QSCHF3_1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	4. Missing school because of not feeling well Item: QSCHF4_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	5. Missing school to go to the doctor or hospital Item: QSCHF5_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Pediatric QOL Inventory PARENT RPT (TODDLERS) (QS3A)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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

PHYSICAL FUNCTIONING (problems with...)

1	1. Walking Item: QSPF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Running Item: QSPF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Participating in active play or exercise Item: QSPF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Lifting something heavy Item: QSPF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Bathing Item: QSPF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
6	6. Helping to pick up his or her toys Item: QSPF6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
7	7. Having hurts or aches Item: QSPF7 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	8. Low energy level Item: QSPF8 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
EMOTIONAL FUNCTIONING (problems with...)		
9	1. Feeling afraid or scared Item: QSEF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	2. Feeling sad or blue Item: QSEF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
11	3. Feeling angry Item: QSEF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	4. Trouble sleeping Item: QSEF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	5. Worrying Item: QSEF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SOCIAL FUNCTIONING (problems with...)		
14	1. Playing with other children Item: QSSF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	2. Other kids not wanting to play with him or her Item: QSSF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
16	3. Getting teased by other children Item: QSSF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	4. Not able to do things that other children his or her age can do Item: QSSF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	5. Keeping up when playing with other children Item: QSSF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
<p>*Please complete this section if your child attends school or daycare

SCHOOL FUNCTIONING (problems with...)</p>		
19	1. Doing the same school activities as peers Item: QSNF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

20	2. Missing school/daycare because of not feeling well Item: QSNF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
21	3. Missing school/daycare to go to the doctor or hospital Item: QSNF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Pediatric QOL Inventory PARENT RPT (YOUNG CHILD) (QS3B)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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 Item: QSPF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Running Item: QSPF2_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Participating in sports activity or exercise Item: QSPF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Lifting something heavy Item: QSPF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Taking a bath or shower by him or herself Item: QSPF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. Doing chores, like picking up his or her toys Item: QSPF6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
7	7. Having hurts or aches Item: QSPF7_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	8. Low energy level Item: QSPF8_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
EMOTIONAL FUNCTIONING (problems with...)		
9	1. Feeling afraid or scared Item: QSEF1_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	2. Feeling sad or blue Item: QSEF2_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

11	3. Feeling angry Item: QSEF3_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	4. Trouble sleeping Item: QSEF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	5. Worrying about what will happen to him or her Item: QSEF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SOCIAL FUNCTIONING (problems with...)		
14	1. Getting along with other children Item: QSSF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	2. Other kids not wanting to be his or her friend Item: QSSF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	3. Getting teased by other children Item: QSSF3_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	4. Not able to do things that other children his or her age can do Item: QSSF4_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	5. Keeping up when playing with other children Item: QSSF5_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SCHOOL FUNCTIONING (problems with...)		
19	1. Paying attention in class Item: QSCHF1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
20	2. Forgetting things Item: QSCHF2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

21	3. Keeping up with school activities Item: QSCHF3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	4. Missing school because of not feeling well Item: QSCHF4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	5. Missing school to go to the doctor or hospital Item: QSCHF5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

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

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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

PHYSICAL FUNCTIONING (problems with...)

1	1. Low energy level Item: QSPF1_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Difficulty participating in active play Item: QSPF2_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Having hurts or aches Item: QSPF3_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Feeling tired Item: QSPF4_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Being lethargic Item: QSPF5_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
6	6. Resting a lot Item: QSPF6_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
PHYSICAL SYMPTOMS (problems with...)		
7	1. Having gas Item: QSPS1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	2. Spitting up after eating Item: QSPS2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
9	3. Difficulty breathing Item: QSPS3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	4. Being sick to his/her stomach Item: QSPS4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
11	5. Difficulty Swallowing Item: QSPS5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	6. Being constipated Item: QSPS6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	7. Having a rash Item: QSPS7 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	8. Having diarrhea Item: QSPS8 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	9. Wheezing Item: QSPS9 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
16	10. Vomiting Item: QSPS10 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
EMOTIONAL FUNCTIONING (problems with...)		
17	1. Feeling afraid or scared Item: QSEF1_6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	2. Feeling angry Item: QSEF2_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
19	3. Crying or fussing when left alone Item: QSEF3_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
20	4. Difficulty soothing himself/herself when upset Item: QSEF4_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
21	5. Difficulty falling asleep Item: QSEF5_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	6. Crying or fussing while being cuddled Item: QSEF6 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	7. Feeling sad Item: QSEF7 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
24	8. Difficulty being soothed when picked up or held Item: QSEF8 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
25	9. Difficulty sleeping mostly through the night Item: QSEF9 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
26	10. Crying a lot Item: QSEF10 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
27	11. Feeling cranky Item: QSEF11 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
28	12. Difficulty taking naps during the day Item: QSEF12 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
SOCIAL FUNCTIONING (problems with...)		
29	1. Not smiling at others Item: QSSF1_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
30	2. Not laughing when tickled Item: QSSF2_5 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
31	3. Not making eye contact with a caregiver Item: QSSF3_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
32	4. Not laughing when cuddled Item: QSSF4_4 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
COGNITIVE FUNCTIONING (problems with...)		
33	1. Not imitating caregivers' actions Item: QSCF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
34	2. Not imitating caregivers' facial expressions Item: QSCF2_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
35	3. Not imitating caregivers' sounds Item: QSCF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost
Never = 1],[Sometimes = 2],[Often = 3],[Almost
Always = 4]

36 4. Not able to fix his/her attention on objects
Item: QSCF4_2
Domain: QS

Data Type: Text
Display Option: Select
MaxLen: 1

CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost
Never = 1],[Sometimes = 2],[Often = 3],[Almost
Always = 4]

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

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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

PHYSICAL FUNCTIONING (problems with...)

1	1. Low energy level Item: QSPF1_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. Difficulty participating in active play Item: QSPF2_3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. Having hurts or aches Item: QSPF3_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. Feeling tired Item: QSPF4_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. Being lethargic Item: QSPF5_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

6	6. Resting a lot Item: QSPF6_5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
7	7. Feeling too tired to play Item: QSPF7_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	8. Difficulty walking Item: QSPF8_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
9	9. Difficulty running a short distance without falling Item: QSPF9 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
PHYSICAL SYMPTOMS (problems with...)		
10	1. Having gas Item: QSPS1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

11	2. Spitting up after eating Item: QSPS2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	3. Difficulty breathing Item: QSPS3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	4. Being sick to his/her stomach Item: QSPS4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
14	5. Difficulty swallowing Item: QSPS5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	6. Being constipated Item: QSPS6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

16	7. Having a rash Item: QSPS7_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	8. Having diarrhea Item: QSPS8_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	9. Wheezing Item: QSPS9_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
19	10. Vomiting Item: QSPS10_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
EMOTIONAL FUNCTIONING (problems with...)		
20	1. Feeling afraid or scared Item: QSEF1_7 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

21	2. Feeling angry Item: QSEF2_3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	3. Crying or fussing when left alone Item: QSEF3_3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	4. Difficulty soothing himself/herself when upset Item: QSEF4_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
24	5. Difficulty falling asleep Item: QSEF5_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
25	6. Crying or fussing while being cuddled Item: QSEF6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

26	7. Feeling sad Item: QSEF7_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
27	8. Difficulty being soothed when picked up or held Item: QSEF8_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
28	9. Difficulty sleeping mostly through the night Item: QSEF9_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
29	10. Crying a lot Item: QSEF10_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
30	11. Feeling cranky Item: QSEF11_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

31	12. Difficulty taking naps during the day Item: QSEF12_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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SOCIAL FUNCTIONING (problems with...)

32	1. Not smiling at others Item: QSSF1_5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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33	2. Not laughing when tickled Item: QSSF2_5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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34	3. Not making eye contact with a caregiver Item: QSSF3_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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35	4. Not laughing when cuddled Item: QSSF4_4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
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36	5. Being uncomfortable around other children Item: QSSF5_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
<hr/>		
COGNITIVE FUNCTIONING (problems with...)		
37	1. Not imitating caregivers' actions Item: QSCF1_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
38	2. Not imitating caregivers' facial expressions Item: QSCF2_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
39	3. Not imitating caregivers' sounds Item: QSCF3_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
40	4. Not able to fix his/her attention on objects Item: QSCF4_2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

41	5. Not imitating caregivers' speech Item: QSCF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
42	6. Difficulty pointing to his/her body parts when asked Item: QSCF6_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
43	7. Difficulty naming familiar objects Item: QSCF7 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
44	8. Difficulty repeating words Item: QSCF8 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
45	9. Difficulty keeping his/her attention on things Item: QSCF9 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Pediatric QOL Inventory TEEN REPORT (QS3G)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

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 Item: QSHA1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
2	2. It is hard for me to run Item: QSHA2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
3	3. It is hard for me to do sports activity or exercise Item: QSHA3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
4	4. It is hard for me to lift something heavy Item: QSHA4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
5	5. It is hard for me to take a bath or shower by myself Item: QSHA5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
6	6. It is hard for me to do chores around the house Item: QSHA6_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
7	7. I hurt or ache Item: QSHA7_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
8	8. I have low energy Item: QSHA8_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
ABOUT MY FEELINGS (problems with...)		
9	1. I feel afraid or scared Item: QSFL1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
10	2. I feel sad or blue Item: QSFL2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
11	3. I feel angry Item: QSFL3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
12	4. I have trouble sleeping Item: QSFL4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
13	5. I worry about what will happen to me Item: QSFL5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
HOW I GET ALONG WITH OTHERS (problems with...)		
14	1. I have trouble getting along with other teens Item: QSGET1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
15	2. Other teens do not want to be my friend Item: QSGET2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
16	3. Other teens tease me Item: QSGET3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
17	4. I cannot do things that other teens my age can do Item: QSGET4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
18	5. It is hard to keep up with my peers Item: QSGET5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
ABOUT SCHOOL (problems with...)		
19	1. It is hard to pay attention in class Item: QSASC1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
20	2. I forget things Item: QSASC2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
21	3. I have trouble keeping up with my schoolwork Item: QSASC3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
22	4. I miss school because of not feeling well Item: QSASC4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]
23	5. I miss school to go to the doctor or hospital Item: QSASC5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL1 [[Blank] =],[Never = 0],[Almost Never = 1],[Sometimes = 2],[Often = 3],[Almost Always = 4]

Form: Pediatric QOL Inventory YOUNG CHILD REPORT (QS3E)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

<p>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.</p><p>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.</p><p>PHYSICAL FUNCTIONING (problems with...)</p>

1	1. Is it hard for you to walk Item: QSPF1_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
2	2. Is it hard for you to run Item: QSPF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
3	3. Is it hard for you to play sports or exercise Item: QSPF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
4	4. Is it hard for you to pick up big things Item: QSPF4_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
5	5. Is it hard for you to take a bath or shower Item: QSPF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
6	6. Is it hard for you to do chores (like pick up your toys) Item: QSPF6_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
7	7. Do you have hurts or aches Item: QSPF7_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
8	Where? Item: QSWHERE Domain: QS	Data Type: Text Display Option: Text MaxLen: 200
9	8. Do you ever feel too tired to play Item: QSPF8_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
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 Item: QSEF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
11	2. Do you feel sad Item: QSEF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
12	3. Do you feel mad Item: QSEF3_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]

13	4. Do you have trouble sleeping Item: QSEF4_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
14	5. Do you worry about what will happen to you Item: QSEF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
SOCIAL FUNCTIONING (problems with...)		
15	1. Is it hard for you to get along with other kids Item: QSSF1_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
16	2. Do other kids say they do not want to play with you Item: QSSF2_3 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
17	3. Do other kids tease you Item: QSSF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
18	4. Can other kids do things you cannot do Item: QSSF4_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]

19	5. Is it hard for you to keep up when you play with other kids Item: QSSF5_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
<hr/>		
SCHOOL FUNCTIONING (problems with...)		
20	1. Is it hard for you to pay attention in school Item: QSCHF1_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
21	2. Do you forget things Item: QSCHF2_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
22	3. Is it hard to keep up with schoolwork Item: QSCHF3_2 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
23	4. Do you miss school because of not feeling good Item: QSCHF4_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]
24	5. Do you miss school because you have to go to the doctor's or hospital Item: QSCHF5_1 Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: PEDSQL2 [[Blank] =],[Not at all = 0], [Sometimes = 2],[A lot = 4]

Form: Pediatric QOL Inventory YOUNG CHILD REPORT (QS3E)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

Form: Physical Examination2 (PE2)

Event(s): **Unscheduled, Week 16, Week 24, Week 36, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day -2, PA5 Re-Initiation Day 0, PA5 Re-Initiation Week 2, PA5 Re-Initiation Week 4, Week 108, Week 120, Week 132, Week 144_ET, Week 148, Week 156, Week 168, Week 180, Week 192, Week 204, Week 216, Week 220**

1	Was the physical examination performed? Item: PEYN Domain: PE	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Exam Date Item: PEDAT Domain: PE Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Are there any clinically significant abnormal findings that have been newly diagnosed or have worsened since the previous assessment ? Item: PEFIND Domain: PE Conditional [2]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

Item Design Notes	
Item No.	Design notes
1	Conditional on: PE2.PEYN Equal To Y
2	Conditional on: PE2.PEYN Equal To Y

Form: Protocol Extension (PRE)**Event(s): Study Completion (Complete), Study Completion (Discontinue)**

1	Did the subject consent to the Protocol Extension Amendment? Item: PREYN Domain: PRE	Data Type: Text Display Option: Select MaxLen: 3 CodeList: Y_N_NA_ [[Blank] =],[Yes = Y],[No = N],[Not Approached = NA_]
2	Protocol Criteria Version Item: PREPCV Domain: PRE Conditional [1]	Data Type: Text Display Option: Select MaxLen: 23 CodeList: IEPRT2_ [[Blank] =],[Amendment 4 - 27APR2016 = Amendment 4 - 27APR2016]
3	Date of Consent Item: PREDAT Domain: PRE Conditional [2]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
4	Did the subject have a > 7 day gap in study dosing? Item: PREGAP Domain: PRE Conditional [3]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
5	Did the subject meet all eligibility criteria? Item: IEYN_1 Domain: IE Conditional [4]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]

Form: Protocol Extension (PRE)**Event(s): Study Completion (Complete), Study Completion (Discontinue)**

Item Design Notes	
Item No.	Design notes
1	Conditional on: PRE.PREYN Equal To Y
2	Conditional on: PRE.PREYN Equal To Y
3	Conditional on: PRE.PREYN Equal To Y
4	Conditional on: PRE.PREGAP Equal To Y

Form: Questionnaires 2 (QS2)

Event(s): Week 24, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, Week 108, Week 144_ET, Week 148, Week 156, Week 216, Week 220

1	Was the Pediatric QoL Inventory PARENT REPORT completed by caregiver? Item: QSQOLPR Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date Pediatric QoL Inventory PARENT REPORT completed by caregiver Item: QSQPRDAT Domain: QS Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	For which age category was the questionnaire completed? Item: QSQPRAGE Domain: QS Conditional [2]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: AGE1 [[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]
4	Was the Pediatric QoL Inventory completed by subject? Item: QSQOLSB Domain: QS	Data Type: Text Display Option: Select MaxLen: 2 CodeList: Y_N_NA [[Blank] =],[Yes = Y],[No = N],[Not Applicable = NA]
5	Date Pediatric QoL Inventory completed by subject Item: QSQSBDAT Domain: QS Conditional [3]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
6	For which age category was the questionnaire completed? Item: QSQSBAGE Domain: QS Conditional [4]	Data Type: Text Display Option: Select MaxLen: 1

		CodeList: AGE2 [[Blank] =],[YOUNG CHILD REPORT (ages 5-7) = 2],[CHILD REPORT (ages 8-12) = 3],[TEENAGER REPORT (ages 13-18) = 4]
7	Was the Multidimensional Fatigue Scale PARENT REPORT completed by caregiver? Item: QSFATPR Domain: QS	Data Type: Text Display Option: Select MaxLen: 2 CodeList: Y_N_NA [[Blank] =],[Yes = Y],[No = N],[Not Applicable = NA]
8	Date Multidimensional Fatigue Scale PARENT REPORT completed by caregiver Item: QSFPRDAT Domain: QS Conditional [5]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
9	For which age category was the questionnaire completed? Item: QSFPRAGE Domain: QS Conditional [6]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: AGE3 [[Blank] =],[TODDLERS (ages 2-4) = 1],[YOUNG CHILDREN (ages 5-7) = 2],[CHILDREN (ages 8-12) = 3],[TEENAGERS (ages 13-18) = 4]
10	Was the Multidimensional Fatigue Scale completed by subject? Item: QSFATSBJ Domain: QS	Data Type: Text Display Option: Select MaxLen: 2 CodeList: Y_N_NA [[Blank] =],[Yes = Y],[No = N],[Not Applicable = NA]
11	Date Multidimensional Fatigue Scale completed by subject Item: QSFSDAT Domain: QS Conditional [7]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

12	For which age category was the questionnaire completed? Item: QSFBAGE Domain: QS Conditional [8]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: AGE2 [[Blank] =],[YOUNG CHILD REPORT (ages 5-7) = 2],[CHILD REPORT (ages 8-12) = 3],[TEENAGER REPORT (ages 13-18) = 4]
13	Was the Family Impact Module PARENT REPORT completed by caregiver? Item: QSFAMPR Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
14	Date Family Impact Module PARENT REPORT completed by caregiver Item: QSFAMDAT Domain: QS Conditional [9]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

Item Design Notes	
Item No.	Design notes
1	Conditional on: QS2.QSQOLPR Equal To Y
2	Conditional on: QS2.QSQOLPR Equal To Y
3	Conditional on: QS2.QSQOLSB Equal To Y
4	Conditional on: QS2.QSQOLSB Equal To Y
5	Conditional on: QS2.QSFATPR Equal To Y
6	Conditional on: QS2.QSFATPR Equal To Y
7	Conditional on: QS2.QSFATSBJ Equal To Y
8	Conditional on: QS2.QSFATSBJ Equal To Y
9	Conditional on: QS2.QSFAMPR Equal To Y

Form: Scratch Scale (QS1)

Event(s): **Unscheduled, Week 2, Week 4, Week 8, Week 12, Week 24, Week 36, Week 48, Re-Initiation Day 0, Re-Initiation Week 50, Re-Initiation Week 52, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, PA5 Re-Initiation Week 2, PA5 Re-Initiation Week 4, Week 108, Week 120, Week 132, Week 144_ET, Week 148, Week 156, Week 168, Week 180, Week 192, Week 204, Week 216, Week 220**

1	Was Clinician Scratch Scale completed? Item: QSCSS Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date of assessment Item: QSCSSDAT Domain: QS Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Clinician Scratch Scale score Item: QSSCORE Domain: QS Conditional [2]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: SCRATCH [[Blank] =],[0 - None = 0],[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]

Item Design Notes	
Item No.	Design notes
1	Conditional on: QS1.QSCSS Equal To Y
2	Conditional on: QS1.QSCSS Equal To Y

Form: Screened (Scr)**Event(s): Common**

1	Subject ID: Item: SCRNIC Domain: StatusForm	Data Type: Text Display Option: Text MaxLen: 35
2	Subject Initials: Item: SCRNICENT Domain: StatusForm	Data Type: Text Display Option: Text MaxLen: 10
3	Screen Date: Item: SCRNICDATE Domain: StatusForm	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

Form: Study Drug Accountability 1 (SDA1)

Event(s): Common

1. Study Drug Accountability

Columns:
Unique Batch
Vial Weeks
Batch Vial Number
Dispensed Date

1.x.1	Unique Batch- 117462/C/xx Item: SDABNUM Domain: SDA	Data Type: Integer Display Option: Text MaxLen: 3 Header Name: Unique Batch
1.x.2	Vial Weeks (xx) or (xx-xx) Item: SDAWEEK Domain: SDA	Data Type: Text Display Option: Text MaxLen: 7 Header Name: Vial Weeks
1.x.3	Batch Vial Number Item: SDACNUM Domain: SDA	Data Type: Text Display Option: Derived (D_BATCH) MaxLen: 50 Header Name: Batch Vial Number
1.x.4	Dispensed Date Item: SDADTC Domain: SDA	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Dispensed Date

Form: Study Drug Administration (EX)**Event(s): Week 2**

1	Date of First Dose Item: EXSTDAT Domain: EX	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
2	Volume of study drug solution (mL) Item: EXVOL Domain: EX	Data Type: Text Display Option: Select MaxLen: 3 CodeList: EXVOL_VAL [[Blank] =],[0.5 = 0.5],[1.0 = 1.0]

Form: Study Drug Administration 2 (EX2)

Event(s): Common

1. Dose Escalation Period

Columns:
Start Date
End Date
Dose

1.x.1	Start Date Item: EXSTDAT_1 Domain: EX	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Start Date
1.x.2	End Date Item: EXENDAT Domain: EX	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: End Date
1.x.3	Dose Item: EXDOSTXT Domain: EX	Data Type: Text Display Option: Select MaxLen: 3 Header Name: Dose CodeList: EXDOSE [[Blank] =],[14ug/kg/day or LUM001-301 Dose = 14],[35 ug/kg/day or LUM001-301 Dose = 35],[70 ug/kg/day or LUM001-301 Dose = 70],[140 ug/kg/day or LUM001-301 Dose = 140],[280 ug/kg/day or LUM001-301 Dose = 280]

2. Stable Dosing and Optional Extension

Columns:
Start Date
End Date
Dose

2.x.1	Start Date Item: EXSTDAT2 Domain: EX	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Start Date
2.x.2	End Date Item: EXENDAT2 Domain: EX	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: End Date
2.x.3	Dose Item: EXDOSE2 Domain: EX	Data Type: Text Display Option: Select MaxLen: 3 Header Name: Dose CodeList: EXDOSEB [[Blank] =],[0 ug/kg/day = 0],[14 ug/kg/day = 14],[35 ug/kg/day = 35],[70 ug/kg/day = 70],[140 ug/kg/day = 140],[280 ug/kg/day = 280]

Form: Study Drug Compliance (SDC)

Event(s): **Unscheduled, Week 2, Week 4, Week 8, Week 12, Week 16, Week 24, Week 36, Week 44, Week 48, Re-Initiation Week 50, Re-Initiation Week 52, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Week 2, PA5 Re-Initiation Week 4, Week 108, Week 120, Week 132, Week 144_ET, Week 156, Week 168, Week 180, Week 192, Week 204, Week 216**

1	Was study drug taken as prescribed? Item: EXYN Domain: EX	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
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2. Date(s) of Dosing Error

Columns:
Date of Dosing Error
Start Date
Type of dosing error
End Date
Comments
Type of dosing error

2.x.1	Start Date of dosing error Item: EXMDDAT Domain: EX	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: Start Date
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2.x.2	End Date of dosing error Item: EXMEDAT Domain: EX	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11 Header Name: End Date
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2.x.3	Comments Item: EXCOM Domain: EX	Data Type: Text Display Option: Text MaxLen: 200 Header Name: Comments
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2.x.4 Type of dosing error
 Item: EXDE
 Domain: EX

Data Type: Text
Display Option: Select
MaxLen: 1
Header Name: Type of dosing error
CodeList: EXMD [[Blank] =],[Missed Dose = 1],
[Underdose = 2],[Overdose = 3],[Other = 4],[Protocol
Amendment Gap = 5]

Form: Subject Summary (DS)

Event(s): Study Completion (Complete), Study Completion (Discontinue), Extension Completion

1	Did the subject complete study treatment? Item: DSCOMP Domain: DS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date of Discontinuation Item: DSSTDAT Domain: DS Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Reason for Discontinuation Item: DSTERM Domain: DS Conditional [2]	Data Type: Text Display Option: Select MaxLen: 2 CodeList: NCOMPLT [[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],[Other = 99],[Roll-over to new LUM001/SHP625 study = 14],[Screen Failure = 15]
4	Date of last dose Item: DSLDDAT Domain: DS	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
5	Date of final study contact Item: DSCONDAT Domain: DS	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
6	Reason for screen failure Item: SFREAS Domain: DS Conditional [3]	Data Type: Text Display Option: Select MaxLen: 1

CodeList: SF [[Blank] =],[Failed to meet eligibility criteria = 1],[Lost to follow-up = 2],[Withdrawal by caregiver = 3],[Withdrawal by subject = 4]

7	Specify Item: DSTERMSP Domain: DS Conditional [4]	Data Type: Text Display Option: Text MaxLen: 200
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Item Design Notes	
Item No.	Design notes
1	Conditional on: DS.DSCOMP Equal To N
2	Conditional on: DS.DSCOMP Equal To N
3	Conditional on: DS.DSCOMP Equal To N
4	Conditional on: DS.DSCOMP Equal To N
5	Conditional on: DS.DSTERM Equal To 15

Form: Subject Summary 2 (DS2)

Event(s): Long Term Optional Treatment Completion, Long Term Optional Treatment Completion 2

Event(s): Long Term Optional Treatment Completion, Long Term Optional Treatment Completion 2

1	Did the subject complete treatment under long term optional period? Item: DSCOMP_1 Domain: DS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date of Discontinuation Item: DSSTDAT_1 Domain: DS Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Reason for Discontinuation Item: DSTERM_1 Domain: DS Conditional [2]	Data Type: Text Display Option: Select MaxLen: 2 CodeList: NCOMPLT [[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],[Other = 99],[Roll-over to new LUM001/SHP625 study = 14],[Screen Failure = 15]
4	Specify Item: DSTERMSP_1 Domain: DS Conditional [3]	Data Type: Text Display Option: Text MaxLen: 200
5	Date of last dose Item: DSLDDAT_1 Domain: DS	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
6	Date of final study contact Item: DSCONDAT_1 Domain: DS	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

Form: Subject Summary 2 (DS2)**Event(s): Long Term Optional Treatment Completion, Long Term Optional Treatment Completion 2**

Item Design Notes	
Item No.	Design notes
1	Conditional on: DS2.DSCOMP Equal To N
2	Conditional on: DS2.DSCOMP Equal To N
3	Conditional on: DS2.DSCOMP Equal To N

Form: Telephone Contact (TC)

Event(s): **Unscheduled, Week 1, Week 3, Week 6, Week 10, Week 16, Week 20, Week 28, Week 32, Week 40, Post-Week 48 Follow-up, 30 Day Follow-up, Re-Initiation Week 49, Re-Initiation Week 51, Week 52, Week 56, Week 64, Week 68, Week 76, Week 80, Week 88, Week 92, PA5 Re-Initiation Week 1, PA5 Re-Initiation Week 3, Week 100, Week 104, Week 112, Week 116, Week 124, Week 128, Week 136, Week 140, Week 148, Week 152, Week 160, Week 164, Week 172, Week 176, Week 184, Week 188, Week 196, Week 200, Week 208, Week 212**

1	Was subject/caregiver contacted by telephone? Item: TCYN Domain: TC	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date of telephone contact Item: TCDAT Domain: TC Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11

Item Design Notes	
Item No.	Design notes
1	Conditional on: TC.TCYN Equal To Y

Form: Urine Pregnancy Test (PREG2)

Event(s): **Unscheduled, Week 2, Week 4, Week 8, Week 12, Week 16, Week 24, Week 36, Week 48, Re-Initiation Day 0, Re-Initiation Week 50, Re-Initiation Week 52, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, PA5 Re-Initiation Week 2, PA5 Re-Initiation Week 4, Week 108, Week 120, Week 132, Week 144_ET, Week 148, Week 156, Week 168, Week 180, Week 192, Week 204, Week 216, Week 220**

1	Sample Type Item: PGTYPEU Domain: PREG	Data Type: Text Display Option: Select MaxLen: 5 CodeList: UPREG [Urine = Urine]
2	Was the sample collected? Item: PREGPERF Domain: PREG	Data Type: Text Display Option: Select MaxLen: 2 CodeList: Y_N_NA [[Blank] =],[Yes = Y],[No = N],[Not Applicable = NA]
3	Date collected Item: PREGDAT Domain: PREG Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
4	Results Item: PREGRES Domain: PREG Conditional [2]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: POSNEG [[Blank] =],[Positive = +],[Negative = -]

Item Design Notes	
Item No.	Design notes
1	Conditional on: PREG2.PREGPERF Equal To Y
2	Conditional on: PREG2.PREGPERF Equal To Y

Form: Vital Signs (VS)

Event(s): **Unscheduled, Week 2, Week 4, Week 8, Week 12, Week 16, Week 24, Week 36, Week 48, Re-Initiation Day 0, Re-Initiation Week 50, Re-Initiation Week 52, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day -2, PA5 Re-Initiation Day 0, PA5 Re-Initiation Week 2, PA5 Re-Initiation Week 4, Week 108, Week 120, Week 132, Week 144_ET, Week 148, Week 156, Week 168, Week 180, Week 192, Week 204, Week 216, Week 220**

1	Were vital signs collected? Item: VSPERF Domain: VS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date of measurements Item: VSDAT Domain: VS Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Height (cm) Item: HEIGHT Domain: VS Conditional [2]	Data Type: Integer Display Option: Text MaxLen: 3
3.1	Height Unit Item: VSHGTU Domain: VS Hidden	Data Type: Text Display Option: Select MaxLen: 2 CodeList: HEIGHT [cm = cm]
4	Weight (kg) Item: WEIGHT_1 Domain: VS Conditional [3]	Data Type: Float Display Option: Text MaxLen: 4 MaxPre: 1 (x.x)
4.1	Weight Unit Item: VSWG TU_1 Domain: VS Hidden	Data Type: Text Display Option: Select MaxLen: 2 CodeList: WEIGHT [kg = kg]
5	Temperature (C) Item: TEMP Domain: VS Conditional [4]	Data Type: Float Display Option: Text MaxLen: 4 MaxPre: 1 (x.x)

5.1	Temperature Unit Item: VSTEMPU Domain: VS Hidden	Data Type: Text Display Option: Select MaxLen: 1 CodeList: TEMP [C = C]
6	Heart Rate (bpm) Item: HR Domain: VS Conditional [5]	Data Type: Integer Display Option: Text MaxLen: 3
6.1	Heart Rate Unit Item: VSHRU Domain: VS Hidden	Data Type: Text Display Option: Select MaxLen: 9 CodeList: bpm [BEATS/MIN = BEATS/MIN]
7	Respiratory Rate (rpm) Item: RR Domain: VS Conditional [6]	Data Type: Integer Display Option: Text MaxLen: 2
7.1	Respiratory Rate Unit Item: VSRRU Domain: VS Hidden	Data Type: Text Display Option: Select MaxLen: 3 CodeList: rpm [rpm = rpm]
8	Systolic Blood Pressure (mmHg) Item: SYSBP Domain: VS Conditional [7]	Data Type: Integer Display Option: Text MaxLen: 3

9	Diastolic Blood Pressure (mmHg) Item: DIABP Domain: VS Conditional [8]	Data Type: Integer Display Option: Text MaxLen: 3
9.1	Blood Pressure Unit Item: VSBPU Domain: VS Hidden	Data Type: Text Display Option: Select MaxLen: 4 CodeList: mmHg [mmHg = mmHg]

Item Design Notes	
Item No.	Design notes
1	Conditional on: VS.VSPERF Equal To Y
2	Conditional on: VS.VSPERF Equal To Y
3	Conditional on: VS.VSPERF Equal To Y
4	Conditional on: VS.VSPERF Equal To Y
5	Conditional on: VS.VSPERF Equal To Y
6	Conditional on: VS.VSPERF Equal To Y
7	Conditional on: VS.VSPERF Equal To Y
8	Conditional on: VS.VSPERF Equal To Y

Form: Xanthoma Scale (QS7)

Event(s): Week 24, Week 36, Week 48, Re-Initiation Day 0, Week 60, Week 72, Week 84, Week 96_ET, PA5 Re-Initiation Day 0, PA5 Re-Initiation Week 2, PA5 Re-Initiation Week 4, Week 108, Week 120, Week 132, Week 144_ET, Week 148, Week 156, Week 168, Week 180, Week 192, Week 204, Week 216, Week 220

1	Was Xanthoma Scale completed? Item: QS7CXS Domain: QS	Data Type: Text Display Option: Select MaxLen: 1 CodeList: YES_NO [[Blank] =],[Yes = Y],[No = N]
2	Date of assessment Item: QS7XSDAT Domain: QS Conditional [1]	Data Type: Date (mm/dd/yyyy) Display Option: Date MaxLen: 11
3	Clinician Xanthoma Scale score Item: QS7XSCORE Domain: QS Conditional [2]	Data Type: Text Display Option: Select MaxLen: 1 CodeList: Xanthoma [[Blank] =],[0-None = 0],[1-Minimal = 1],[2-Moderate = 2],[3-Disfiguring = 3],[4-Disabling = 4]

Item Design Notes	
Item No.	Design notes
1	Conditional on: QS7.QS7CXS Equal To Y
2	Conditional on: QS7.QS7CXS Equal To Y

Domains

Domain: AE							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
AEYN	Text	EDC	YES_NO			0	1
AETERM	Text	Encoding		MedDRA		0	200
AESER	Text	EDC	YES_NO			0	1
AESTDATD	Text	EDC	DAY			0	2
AESTDATM	Text	EDC	MONTH			0	3
AESTDATY	Text	EDC				0	4
AESTDAT	DateTime	Derived			D_AESTDAT	0	11
AEOUT	Text	EDC	OUT			0	2
AEENDATD	Text	EDC	DAY			0	2
AEENDATM	Text	EDC	MONTH			0	3
AEENDATY	Text	EDC				0	4
AEENDAT	DateTime	Derived			D_AEENDAT	0	11
AEACN	Text	EDC	AEACN			0	1
AEREL	Text	EDC	REL			0	1
AECTCAE	Text	EDC	YES_NO			0	1
AESEV	Text	EDC	SEV			0	1
AELIFTHR	Text	EDC	YES_NO			0	1

AETRT1	Text	EDC	YES			0	1
AETRT2	Text	EDC	YES			0	1
AETRT3	Text	EDC	YES			0	1
AETRT99	Text	EDC	YES			0	1
AETRTSP	Text	EDC				0	200
AEREP	Text	EDC	YES_NO			0	1
AETERM_Enc_TERM	Text	Encoding				0	200
AETERM_Enc_CODE	Text	Encoding				0	30
AETERM_Enc_TYPE	Text	Encoding				0	25
AETERM_Enc_CAT1	Text	Encoding				0	255
AETERM_Enc_CAT2	Text	Encoding				0	255
AETERM_Enc_CAT3	Text	Encoding				0	255
AETERM_Enc_CAT4	Text	Encoding				0	255
AETERM_Enc_CAT5	Text	Encoding				0	255
AETERM_Enc_CAT6	Text	Encoding				0	255
AETERM_Enc_CAT7	Text	Encoding				0	255
AETERM_Enc_CAT8	Text	Encoding				0	255
AETERM_Enc_CAT9	Text	Encoding				0	255
AEONGO	Text	EDC	YES_NO			0	1

Domain: CM							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
CMYN	Text	EDC	YES_NO			0	1

CMTRT	Text	Encoding		WHODrug		0	200
CMINDC	Text	EDC				0	200
CMSTDATD	Text	EDC	DAY			0	2
CMSTDATM	Text	EDC	MONTH			0	3
CMSTDATY	Text	EDC				0	4
CMSTDAT	DateTime	Derived			D_CMSTDAT	0	11
CMPRIOR	Text	EDC	YES_NO			0	1
CMONGO	Text	EDC	YES_NO			0	1
CMENDATD	Text	EDC	DAY			0	2
CMENDATM	Text	EDC	MONTH			0	3
CMENDATY	Text	EDC				0	4
CMENDAT	DateTime	Derived			D_CMENDAT	0	11
CMDSTXT	Text	EDC				0	20
CMDOSU	Text	EDC	DOSE			0	7
CMDOSSP	Text	EDC				0	50
CMROUTE	Text	EDC	ROUTE			0	24
CMRTSPEC	Text	EDC				0	50
CMDOSFRQ	Text	EDC	FREQ			0	7
CMFRSPEC	Text	EDC				0	50
CMREP	Text	EDC	YES_NO			0	1
CMPRIOR2	Text	EDC	YES_NO			0	1
CMTRT_Enc_TERM	Text	Encoding				0	200
CMTRT_Enc_CODE	Text	Encoding				0	30

CMTRT_Enc_TYPE	Text	Encoding				0	25
CMTRT_Enc_CAT1	Text	Encoding				0	255
CMTRT_Enc_CAT2	Text	Encoding				0	255
CMTRT_Enc_CAT3	Text	Encoding				0	255
CMTRT_Enc_CAT4	Text	Encoding				0	255
CMTRT_Enc_CAT5	Text	Encoding				0	255
CMTRT_Enc_CAT6	Text	Encoding				0	255
CMTRT_Enc_CAT7	Text	Encoding				0	255
CMTRT_Enc_CAT8	Text	Encoding				0	255
CMTRT_Enc_CAT9	Text	Encoding				0	255
CMONGO2	Text	EDC	YES_NO			0	1

Domain: DAD

Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
DADYN	Text	EDC	YES_NO			0	1

Domain: DM

Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
BRTHDAT	DateTime	EDC				0	11
AGE	Integer	Derived			D_AGE	0	2
AGEU	Text	Derived			D_AGEU	0	5
SEX	Text	EDC	SEX			0	1

COUNTRY	Text	Derived			D_COUNTRY	0	3
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Domain: DS							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
DSCOMP	Text	EDC	YES_NO			0	1
DSSTDAT	DateTime	EDC				0	11
DSTERMSP	Text	EDC				0	200
DSLDDAT	DateTime	EDC				0	11
DSCONDAT	DateTime	EDC				0	11
DSTERM	Text	EDC	NCOMPLT			0	2
SFREAS	Text	EDC	SF			0	1

Domain: EX							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
EXYN	Text	EDC	YES_NO			0	1
EXCOM	Text	EDC				0	200
EXDE	Text	EDC	EXMD			0	1
EXVOL	Text	EDC	EXVOL_VAL			0	3
EXMDDAT	DateTime	EDC				0	11
EXSTDAT	DateTime	EDC				0	11
EXDOSE2	Text	EDC	EXDOSEB			0	3
EXSTDAT2	DateTime	EDC				0	11
EXENDAT2	DateTime	EDC				0	11

EXENDAT	DateTime	EDC				0	11
EXDOSTXT	Text	EDC	EXDOSE			0	3
EXMEDAT	DateTime	EDC				0	11

Domain: IC							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
ICDAT	DateTime	EDC				0	11
ICYADAT	DateTime	EDC				0	11
ICYANA	Text	EDC	NA			0	2
ICADAT	DateTime	EDC				0	11
ICANA	Text	EDC	NA			0	2

Domain: IE							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
IEYN	Text	EDC	YES_NO			0	1
TIVERS	Text	EDC	TIVERS			0	23
IETESTCD	Text	EDC	IENUM			0	2
IEAPPR	Text	EDC	YES_NO			0	1
IEAPPDAT	DateTime	EDC				0	11
IEOTHER	Text	EDC				0	200
IECAT	Text	EDC	IE			0	1
IETESTC2	Text	EDC	IENUM2_			0	1

Domain: LB							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
LBTYPE	Text	EDC	LBTYPEA			0	1
LBPERF	Text	EDC	YES_NO			0	1
LBDAT	DateTime	EDC				0	11
LBREFID	Integer	EDC				0	8
LDDAT	DateTime	EDC				0	11
LDTIM	Text	EDC				0	5
LMDAT	DateTime	EDC				0	11
LMTIM	Text	EDC				0	5

Domain: MH							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
MHYN	Text	EDC	YES_NO			0	1
MHSTDAT	DateTime	Derived			D_MHSTDAT	0	11
MHENDAT	DateTime	Derived			D_MHENDAT	0	11
MHTERM	Text	Encoding		MedDRA		0	200
MHSTDATD	Text	EDC	DAY			0	2
MHSTDATM	Text	EDC	MONTH			0	3
MHSTDATY	Text	EDC				0	4
MHONGO	Text	EDC	YES			0	1
MHENDATD	Text	EDC	DAY			0	2
MHENDATM	Text	EDC	MONTH			0	3

MHENDATY	Text	EDC				0	4
MHSTDAT2	DateTime	Derived			D_MHSTDAT2	0	11
MHENDAT2	DateTime	Derived			D_MHENDAT2	0	11
MHTERM_Enc_TERM	Text	Encoding				0	200
MHTERM_Enc_CODE	Text	Encoding				0	30
MHTERM_Enc_TYPE	Text	Encoding				0	25
MHTERM_Enc_CAT1	Text	Encoding				0	255
MHTERM_Enc_CAT2	Text	Encoding				0	255
MHTERM_Enc_CAT3	Text	Encoding				0	255
MHTERM_Enc_CAT4	Text	Encoding				0	255
MHTERM_Enc_CAT5	Text	Encoding				0	255
MHTERM_Enc_CAT6	Text	Encoding				0	255
MHTERM_Enc_CAT7	Text	Encoding				0	255
MHTERM_Enc_CAT8	Text	Encoding				0	255
MHTERM_Enc_CAT9	Text	Encoding				0	255

Domain: PE							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
PEYN	Text	EDC	YES_NO			0	1
PEDAT	DateTime	EDC				0	11
PEFIND	Text	EDC	YES_NO			0	1

Domain: PRE							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
PREYN	Text	EDC	Y_N_NA_			0	3
PREPCV	Text	EDC	IEPRT2_			0	23
PREDAT	DateTime	EDC				0	11
PREGAP	Text	EDC	YES_NO			0	1
PREYN2	Text	EDC	YES_NO			0	1
PREPROD	Text	EDC	PROD			0	2
PREPCV2	Text	EDC	IEPRT3_			0	25

Domain: PREG							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
PGTYPEU	Text	EDC	UPREG			0	5
PREGPERF	Text	EDC	Y_N_NA			0	2
PREGDAT	DateTime	EDC				0	11
PREGRES	Text	EDC	POSNEG			0	1

Domain: QS							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
QSCSS	Text	EDC	YES_NO			0	1
QSCSSDAT	DateTime	EDC				0	11
QSSCORE	Text	EDC	SCRATCH			0	1
QSQOLPR	Text	EDC	YES_NO			0	1

QSQPRDAT	DateTime	EDC				0	11
QSQPRAGE	Text	EDC	AGE1			0	1
QSQOLSB	Text	EDC	Y_N_NA			0	2
QSQSBDAT	DateTime	EDC				0	11
QSQSBAE	Text	EDC	AGE2			0	1
QSFATPR	Text	EDC	Y_N_NA			0	2
QSFPRDAT	DateTime	EDC				0	11
QSFPRAGE	Text	EDC	AGE3			0	1
QSFATSBJ	Text	EDC	Y_N_NA			0	2
QSFSDAT	DateTime	EDC				0	11
QSFBAE	Text	EDC	AGE2			0	1
QSFAMPR	Text	EDC	YES_NO			0	1
QSFAMDAT	DateTime	EDC				0	11
QSPF1	Text	EDC	PEDSQL1			0	1
QSPF1_1	Text	EDC	PEDSQL1			0	1
QSPF1_2	Text	EDC	PEDSQL2			0	1
QSPF1_3	Text	EDC	PEDSQL1			0	1
QSPF2	Text	EDC	PEDSQL1			0	1
QSPF2_1	Text	EDC	PEDSQL2			0	1
QSPF2_2	Text	EDC	PEDSQL1			0	1
QSPF3	Text	EDC	PEDSQL1			0	1
QSPF3_1	Text	EDC	PEDSQL1			0	1
QSPF3_2	Text	EDC	PEDSQL2			0	1

QSPF3_3	Text	EDC	PEDSQL1			0	1
QSPF4	Text	EDC	PEDSQL1			0	1
QSPF4_1	Text	EDC	PEDSQL1			0	1
QSPF4_2	Text	EDC	PEDSQL2			0	1
QSPF4_3	Text	EDC	PEDSQL1			0	1
QSPF5	Text	EDC	PEDSQL1			0	1
QSPF5_1	Text	EDC	PEDSQL1			0	1
QSPF5_2	Text	EDC	PEDSQL2			0	1
QSPF5_3	Text	EDC	PEDSQL1			0	1
QSPF6	Text	EDC	PEDSQL1			0	1
QSPF6_1	Text	EDC	PEDSQL1			0	1
QSPF6_2	Text	EDC	PEDSQL1			0	1
QSPF6_3	Text	EDC	PEDSQL2			0	1
QSPF6_4	Text	EDC	PEDSQL1			0	1
QSPF7	Text	EDC	PEDSQL1			0	1
QSPF7_1	Text	EDC	PEDSQL2			0	1
QSWHERE	Text	EDC				0	200
QSPF8	Text	EDC	PEDSQL1			0	1
QSPF8_1	Text	EDC	PEDSQL2			0	1
QSEF1	Text	EDC	PEDSQL1			0	1
QSEF1_1	Text	EDC	PEDSQL2			0	1
QSEF1_2	Text	EDC	PEDSQL1			0	1
QSEF2	Text	EDC	PEDSQL1			0	1

QSEF2_1	Text	EDC	PEDSQL2			0	1
QSEF2_2	Text	EDC	PEDSQL1			0	1
QSEF3	Text	EDC	PEDSQL1			0	1
QSEF3_1	Text	EDC	PEDSQL2			0	1
QSEF3_2	Text	EDC	PEDSQL1			0	1
QSEF4	Text	EDC	PEDSQL1			0	1
QSEF4_1	Text	EDC	PEDSQL1			0	1
QSEF4_2	Text	EDC	PEDSQL2			0	1
QSEF4_3	Text	EDC	PEDSQL1			0	1
QSEF5	Text	EDC	PEDSQL1			0	1
QSEF5_1	Text	EDC	PEDSQL1			0	1
QSEF5_2	Text	EDC	PEDSQL2			0	1
QSEF5_3	Text	EDC	PEDSQL1			0	1
QSSF1	Text	EDC	PEDSQL1			0	1
QSSF1_1	Text	EDC	PEDSQL1			0	1
QSSF1_2	Text	EDC	PEDSQL1			0	1
QSSF1_3	Text	EDC	PEDSQL2			0	1
QSSF1_4	Text	EDC	PEDSQL1			0	1
QSSF2	Text	EDC	PEDSQL1			0	1
QSSF2_1	Text	EDC	PEDSQL1			0	1
QSSF2_2	Text	EDC	PEDSQL1			0	1
QSSF2_3	Text	EDC	PEDSQL2			0	1
QSSF2_4	Text	EDC	PEDSQL1			0	1

QSSF3	Text	EDC	PEDSQL1			0	1
QSSF3_1	Text	EDC	PEDSQL1			0	1
QSSF3_2	Text	EDC	PEDSQL2			0	1
QSSF3_3	Text	EDC	PEDSQL1			0	1
QSSF4	Text	EDC	PEDSQL1			0	1
QSSF4_1	Text	EDC	PEDSQL1			0	1
QSSF4_2	Text	EDC	PEDSQL2			0	1
QSSF4_3	Text	EDC	PEDSQL1			0	1
QSSF5	Text	EDC	PEDSQL1			0	1
QSSF5_1	Text	EDC	PEDSQL1			0	1
QSSF5_2	Text	EDC	PEDSQL2			0	1
QSNF1	Text	EDC	PEDSQL1			0	1
QSNF2	Text	EDC	PEDSQL1			0	1
QSNF3	Text	EDC	PEDSQL1			0	1
QSCHF1	Text	EDC	PEDSQL1			0	1
QSCHF1_1	Text	EDC	PEDSQL2			0	1
QSCHF2	Text	EDC	PEDSQL1			0	1
QSCHF2_1	Text	EDC	PEDSQL2			0	1
QSCHF3	Text	EDC	PEDSQL1			0	1
QSCHF3_1	Text	EDC	PEDSQL1			0	1
QSCHF3_2	Text	EDC	PEDSQL2			0	1
QSCHF4	Text	EDC	PEDSQL1			0	1
QSCHF4_1	Text	EDC	PEDSQL2			0	1

QSCHF5	Text	EDC	PEDSQL1			0	1
QSCHF5_1	Text	EDC	PEDSQL2			0	1
QSHA1	Text	EDC	PEDSQL1			0	1
QSHA2	Text	EDC	PEDSQL1			0	1
QSHA3	Text	EDC	PEDSQL1			0	1
QSHA4	Text	EDC	PEDSQL1			0	1
QSHA5	Text	EDC	PEDSQL1			0	1
QSHA6	Text	EDC	PEDSQL1			0	1
QSHA7	Text	EDC	PEDSQL1			0	1
QSHA8	Text	EDC	PEDSQL1			0	1
QSFL1	Text	EDC	PEDSQL1			0	1
QSFL2	Text	EDC	PEDSQL1			0	1
QSFL3	Text	EDC	PEDSQL1			0	1
QSFL4	Text	EDC	PEDSQL1			0	1
QSFL5	Text	EDC	PEDSQL1			0	1
QSGET1	Text	EDC	PEDSQL1			0	1
QSGET1_1	Text	EDC	PEDSQL1			0	1
QSGET2	Text	EDC	PEDSQL1			0	1
QSGET2_1	Text	EDC	PEDSQL1			0	1
QSGET3	Text	EDC	PEDSQL1			0	1
QSGET3_1	Text	EDC	PEDSQL1			0	1
QSGET4	Text	EDC	PEDSQL1			0	1
QSGET4_1	Text	EDC	PEDSQL1			0	1

QSGT5	Text	EDC	PEDSQL1			0	1
QSGT5_1	Text	EDC	PEDSQL1			0	1
QSASC1	Text	EDC	PEDSQL1			0	1
QSASC2	Text	EDC	PEDSQL1			0	1
QSASC3	Text	EDC	PEDSQL1			0	1
QSASC3_1	Text	EDC	PEDSQL1			0	1
QSASC4	Text	EDC	PEDSQL1			0	1
QSASC4_1	Text	EDC	PEDSQL1			0	1
QSASC5	Text	EDC	PEDSQL1			0	1
QSASC5_1	Text	EDC	PEDSQL1			0	1
QSGF1	Text	EDC	PEDSQL1			0	1
QSGF1_1	Text	EDC	PEDSQL2			0	1
QSGF1_2	Text	EDC	PEDSQL1			0	1
QSGF2	Text	EDC	PEDSQL1			0	1
QSGF2_1	Text	EDC	PEDSQL2			0	1
QSGF2_2	Text	EDC	PEDSQL1			0	1
QSGF3	Text	EDC	PEDSQL1			0	1
QSGF3_1	Text	EDC	PEDSQL2			0	1
QSGF3_2	Text	EDC	PEDSQL1			0	1
QSGF4	Text	EDC	PEDSQL1			0	1
QSGF4_1	Text	EDC	PEDSQL2			0	1
QSGF4_2	Text	EDC	PEDSQL1			0	1
QSGF5	Text	EDC	PEDSQL1			0	1

QSGF5_1	Text	EDC	PEDSQL2			0	1
QSGF5_2	Text	EDC	PEDSQL1			0	1
QSGF6	Text	EDC	PEDSQL1			0	1
QSGF6_1	Text	EDC	PEDSQL2			0	1
QSGF6_2	Text	EDC	PEDSQL1			0	1
QSSRF1	Text	EDC	PEDSQL1			0	1
QSSRF1_1	Text	EDC	PEDSQL2			0	1
QSSRF1_2	Text	EDC	PEDSQL1			0	1
QSSRF2	Text	EDC	PEDSQL1			0	1
QSSRF2_1	Text	EDC	PEDSQL2			0	1
QSSRF2_2	Text	EDC	PEDSQL1			0	1
QSSRF3	Text	EDC	PEDSQL1			0	1
QSSRF3_1	Text	EDC	PEDSQL2			0	1
QSSRF3_2	Text	EDC	PEDSQL1			0	1
QSSRF4	Text	EDC	PEDSQL1			0	1
QSSRF4_1	Text	EDC	PEDSQL2			0	1
QSSRF4_2	Text	EDC	PEDSQL1			0	1
QSSRF5	Text	EDC	PEDSQL1			0	1
QSSRF5_1	Text	EDC	PEDSQL2			0	1
QSSRF5_2	Text	EDC	PEDSQL1			0	1
QSSRF6	Text	EDC	PEDSQL1			0	1
QSSRF6_1	Text	EDC	PEDSQL2			0	1
QSSRF6_2	Text	EDC	PEDSQL1			0	1

QSMF1	Text	EDC	PEDSQL1			0	1
QSMF2	Text	EDC	PEDSQL1			0	1
QSMF3	Text	EDC	PEDSQL1			0	1
QSMF4	Text	EDC	PEDSQL1			0	1
QSMF5	Text	EDC	PEDSQL1			0	1
QSMF6	Text	EDC	PEDSQL1			0	1
QSCF1	Text	EDC	PEDSQL2			0	1
QSCF1_1	Text	EDC	PEDSQL1			0	1
QSCF2	Text	EDC	PEDSQL2			0	1
QSCF2_1	Text	EDC	PEDSQL1			0	1
QSCF3	Text	EDC	PEDSQL2			0	1
QSCF3_1	Text	EDC	PEDSQL1			0	1
QSCF4	Text	EDC	PEDSQL2			0	1
QSCF4_1	Text	EDC	PEDSQL1			0	1
QSCF5	Text	EDC	PEDSQL2			0	1
QSCF5_1	Text	EDC	PEDSQL1			0	1
QSCF6	Text	EDC	PEDSQL2			0	1
QSCF6_1	Text	EDC	PEDSQL1			0	1
QSCOMM1	Text	EDC	PEDSQL1			0	1
QSCOMM2	Text	EDC	PEDSQL1			0	1
QSCOMM3	Text	EDC	PEDSQL1			0	1
QSWRY1	Text	EDC	PEDSQL1			0	1
QSWRY2	Text	EDC	PEDSQL1			0	1

QSWRY3	Text	EDC	PEDSQL1			0	1
QSWRY4	Text	EDC	PEDSQL1			0	1
QSWRY5	Text	EDC	PEDSQL1			0	1
QSDA1	Text	EDC	PEDSQL1			0	1
QSDA2	Text	EDC	PEDSQL1			0	1
QSDA3	Text	EDC	PEDSQL1			0	1
QSFAM1	Text	EDC	PEDSQL1			0	1
QSFAM2	Text	EDC	PEDSQL1			0	1
QSFAM3	Text	EDC	PEDSQL1			0	1
QSFAM4	Text	EDC	PEDSQL1			0	1
QSFAM5	Text	EDC	PEDSQL1			0	1
QSCIC	Text	EDC	YES_NO			0	1
QSCICDAT	DateTime	EDC				0	11
QSCICCH	Text	EDC	PIC			0	1
QS7CXS	Text	EDC	YES_NO			0	1
QS7XSDAT	DateTime	EDC				0	11
QS7XSCRE	Text	EDC	Xanthoma			0	1
QSPF1_4	Text	EDC	PEDSQL1			0	1
QSPF2_3	Text	EDC	PEDSQL1			0	1
QSPF3_4	Text	EDC	PEDSQL1			0	1
QSPF4_4	Text	EDC	PEDSQL1			0	1
QSPF5_4	Text	EDC	PEDSQL1			0	1
QSPF6_5	Text	EDC	PEDSQL1			0	1

QSPS1	Text	EDC	PEDSQL1			0	1
QSPS2	Text	EDC	PEDSQL1			0	1
QSPS3	Text	EDC	PEDSQL1			0	1
QSPS4	Text	EDC	PEDSQL1			0	1
QSPS5	Text	EDC	PEDSQL1			0	1
QSPS6	Text	EDC	PEDSQL1			0	1
QSPS7	Text	EDC	PEDSQL1			0	1
QSPS8	Text	EDC	PEDSQL1			0	1
QSPS9	Text	EDC	PEDSQL1			0	1
QSPS10	Text	EDC	PEDSQL1			0	1
QSEF2_3	Text	EDC	PEDSQL1			0	1
QSEF3_3	Text	EDC	PEDSQL1			0	1
QSEF4_4	Text	EDC	PEDSQL1			0	1
QSEF5_4	Text	EDC	PEDSQL1			0	1
QSEF6	Text	EDC	PEDSQL1			0	1
QSEF7	Text	EDC	PEDSQL1			0	1
QSEF8	Text	EDC	PEDSQL1			0	1
QSEF9	Text	EDC	PEDSQL1			0	1
QSEF10	Text	EDC	PEDSQL1			0	1
QSEF11	Text	EDC	PEDSQL1			0	1
QSEF12	Text	EDC	PEDSQL1			0	1
QSSF1_5	Text	EDC	PEDSQL1			0	1
QSSF2_5	Text	EDC	PEDSQL1			0	1

QSSF3_4	Text	EDC	PEDSQL1			0	1
QSSF4_4	Text	EDC	PEDSQL1			0	1
QSCF1_2	Text	EDC	PEDSQL1			0	1
QSCF2_2	Text	EDC	PEDSQL1			0	1
QSCF3_2	Text	EDC	PEDSQL1			0	1
QSCF4_2	Text	EDC	PEDSQL1			0	1
QSPF7_3	Text	EDC	PEDSQL1			0	1
QSPF8_2	Text	EDC	PEDSQL1			0	1
QSPF9	Text	EDC	PEDSQL1			0	1
QSSF5_3	Text	EDC	PEDSQL1			0	1
QSCF5_2	Text	EDC	PEDSQL1			0	1
QSCF6_2	Text	EDC	PEDSQL1			0	1
QSCF7	Text	EDC	PEDSQL1			0	1
QSCF8	Text	EDC	PEDSQL1			0	1
QSCF9	Text	EDC	PEDSQL1			0	1

Domain: SDA							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
SDABNUM	Integer	EDC				0	3
SDA WEEK	Text	EDC				0	7
SDACNUM	Text	Derived			D_BATCH	0	50
SDADTC	DateTime	EDC				0	11

Domain: StatusForm							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
SCRNIDENT	Text	EDC				0	10
SCRNID	Text	EDC				0	35
SCRNDATE	DateTime	EDC				0	11
ENRLID	Text	EDC				0	35
ENRLDATE	DateTime	EDC				0	11
SCRNFAILDATE	DateTime	EDC				0	11
DISCDATE	DateTime	EDC				0	11
COMPDATE	DateTime	EDC				0	11

Domain: TC							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
TCYN	Text	EDC	YES_NO			0	1
TCDAT	DateTime	EDC				0	11

Domain: VS							
Item Name	Data Type	Source	Code List Name	Dictionary	Derivation	Max Precision	Max Length
VSPERF	Text	EDC	YES_NO			0	1
VSDAT	DateTime	EDC				0	11
TEMP	Float	EDC				1	4
VSTEMPU	Text	EDC	TEMP			0	1
HR	Integer	EDC				0	3

VSHRU	Text	EDC	bpm			0	9
RR	Integer	EDC				0	2
VSRRU	Text	EDC	rpm			0	3
SYSBP	Integer	EDC				0	3
DIABP	Integer	EDC				0	3
VSBPU	Text	EDC	mmHg			0	4
HEIGHT	Integer	EDC				0	3
VSHGTU	Text	EDC	HEIGHT			0	2
WEIGHT	Float	EDC				1	4
VSWG TU	Text	EDC	WEIGHT			0	2

Code Lists

Code List: AEACN (AEACN)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Dose not changed	1
	Drug interrupted	2
	Drug withdrawn	3
	Dose reduced	4
	Not Applicable	5

Code List: AGE1 (AGE1)		
Code Prefix	Code Label	Code 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
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Code List: AGE2 (AGE2)		
Code Prefix	Code Label	Code Value
	[Blank]	
	YOUNG CHILD REPORT (ages 5-7)	2
	CHILD REPORT (ages 8-12)	3
	TEENAGER REPORT (ages 13-18)	4

Code List: AGE3 (AGE3)		
Code Prefix	Code Label	Code Value
	[Blank]	
	TODDLERS (ages 2-4)	1
	YOUNG CHILDREN (ages 5-7)	2
	CHILDREN (ages 8-12)	3
	TEENAGERS (ages 13-18)	4

Code List: bpm (bpm)		
Code Prefix	Code Label	Code Value
	BEATS/MIN	BEATS/MIN

Code List: DAY (DAY)		
Code Prefix	Code Label	Code 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

Code List: DOSE (DOSE)		
Code Prefix	Code Label	Code Value
	[Blank]	
	TABLET	TABLET
	CAPSULE	CAPSULE
	mg	mg
	ug	ug
	g	g
	mEq	mEq
	mL	mL

	oz	oz
	L/min	L/min
	gtt	gtt
	IU	IU
	U	U
	PATCH	PATCH
	PUFF	PUFF
	SPRAY	SPRAY
	Tbsp	Tbsp
	tsp	tsp
	UNKNOWN	UNKNOWN
	OTHER	OTHER

Code List: EXDOSE (EXDOSE)		
Code Prefix	Code Label	Code Value
	[Blank]	
	14ug/kg/day or LUM001-301 Dose	14
	35 ug/kg/day or LUM001-301 Dose	35
	70 ug/kg/day or LUM001-301 Dose	70
	140 ug/kg/day or LUM001-301 Dose	140
	280 ug/kg/day or LUM001-301 Dose	280

Code List: EXDOSE (EXDOSEB)		
Code Prefix	Code Label	Code Value
	[Blank]	
	0 ug/kg/day	0
	14 ug/kg/day	14
	35 ug/kg/day	35
	70 ug/kg/day	70
	140 ug/kg/day	140
	280 ug/kg/day	280

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

	Protocol Amendment Gap	5
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Code List: ExVol (EXVOL_VAL)		
Code Prefix	Code Label	Code Value
	[Blank]	
	0.5	0.5
	1.0	1.0

Code List: FREQ (FREQ)		
Code Prefix	Code Label	Code Value
	[Blank]	
	BID	BID
	ONCE	ONCE
	PRN	PRN
	Q6H	Q6H
	Q8H	Q8H
	Q12H	Q12H
	Q3D	Q3D
	QD	QD
	QID	QID
	QOD	QOD
	QM	QM
	QS	QS

	TID	TID
	TIS	TIS
	UNKNOWN	UNKNOWN
	Other	Other

Code List: HEIGHT (HEIGHT)		
Code Prefix	Code Label	Code Value
	cm	cm

Code List: IE (IE)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Inclusion	1
	Exclusion	2

Code List: IENUM (IENUM)		
Code Prefix	Code Label	Code Value
	[Blank]	
	[Blank]	
	1	1
	1	1
	2	2
	2	2

	3	3
	3	3
	4	4
	4	4
	5	5
	5	5
	6	6
	6	6
	7	7
	7	7
	8	8
	8	8
	9	9
	9	9
	10	10

Code List: IENUM (IENUM2_)		
Code Prefix	Code Label	Code Value
	[Blank]	
	1	1
	2	2
	3	3
	4	4

	5	5
	6	6

Code List: IEPROT2 (IEPRT2_)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Amendment 4 - 27APR2016	Amendment 4 - 27APR2016

Code List: IEPROT3 (IEPRT3_)		
Code Prefix	Code Label	Code Value
	[Blank]	
	[Blank]	
	Amendment 5 - 13NOV2017	Amendment 5 - 13NOV2017
	Amendment 5 - 13NOV2017	Amendment 5 - 13NOV2017
	Amendment 6 - 25-JUN-2018	Amendment 6 - 25-JUN-2018

Code List: LBTYPEA (LBTYPEA)		
Code Prefix	Code Label	Code Value
	Blood	1
	Urine	2

Code List: mmHg (mmHg)		
Code Prefix	Code Label	Code Value
	mmHg	mmHg

Code List: MONTH (MONTH)		
Code Prefix	Code Label	Code 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

Code List: NA (NA)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Not Applicable	NA

Code List: NCOMPLT (NCOMPLT)		
Code Prefix	Code Label	Code Value
	[Blank]	
	[Blank]	
	[Blank]	
	Adverse Event	1
	Adverse Event	1
	Adverse Event	1
	Death	2
	Death	2
	Death	2
	Lost to follow-up	4
	Lost to follow-up	4
	Lost to follow-up	4
	Non-compliance with study drug	5
	Non-compliance with study drug	5
	Non-compliance with study drug	5
	Physician decision	6

	Physician decision	6
	Physician decision	6
	Pregnancy	7
	Pregnancy	7
	Pregnancy	7
	Progressive Disease	8
	Progressive Disease	8
	Progressive Disease	8
	Protocol violation	9
	Protocol violation	9
	Protocol violation	9
	Study terminated by sponsor	11
	Study terminated by sponsor	11
	Study terminated by sponsor	11
	Withdrawal by caregiver	12
	Withdrawal by caregiver	12
	Withdrawal by caregiver	12
	Withdrawal by subject	13
	Withdrawal by subject	13
	Withdrawal by subject	13
	Roll-over to new LUM001/SHP625 study	14
	Roll-over to new LUM001/SHP625 study	14
	Other	99

	Screen Failure	15
	Other	99
	Other	99

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

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

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

Code List: PIC (PIC)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Much better	1
	Better	2
	A little better	3
	No change	4
	A little worse	5
	Worse	6
	Much worse	7

Code List: POSITIVE/NEGATIVE (POSNEG)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Positive	+

	Negative	-
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Code List: Procedures (PROD)		
Code Prefix	Code Label	Code Value
	[Blank]	
	D	D
	E	E
	Not Applicable - Screen Failure	NA

Code List: REL (REL)		
Code Prefix	Code Label	Code Value
	[Blank]	
1	Related	1
2	Possibly Related	2
3	Unlikely/Remotely Related	3
4	Not Related	4

Code List: ROUTE (ROUTE)		
Code Prefix	Code Label	Code Value
	[Blank]	
	ORAL	ORAL
	INTRAVENOUS	INTRAVENOUS
	SUBCUTANEOUS	SUBCUTANEOUS

	TOPICAL	TOPICAL
	TRANSDERMAL	TRANSDERMAL
	RESPIRATORY (INHALATION)	RESPIRATORY (INHALATION)
	NASAL	NASAL
	INTRASINAL	INTRASINAL
	OPHTHALMIC	OPHTHALMIC
	INTRAMUSCULAR	INTRAMUSCULAR
	VAGINAL	VAGINAL
	RECTAL	RECTAL
	SUBLINGUAL	SUBLINGUAL
	BUCCAL	BUCCAL
	INTRA-ARTICULAR	INTRA-ARTICULAR
	AURICULAR (OTIC)	AURICULAR (OTIC)
	UNKNOWN	UNKNOWN
	OTHER	OTHER

Code List: rpm (rpm)		
Code Prefix	Code Label	Code Value
	rpm	rpm

Code List: SCRATCH (SCRATCH)		
Code Prefix	Code Label	Code Value
	[Blank]	

	0 - None	0
	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

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

Code List: SEX (SEX)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Male	M
	Female	F

Code List: Reason for screen failure (SF)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Failed to meet eligibility criteria	1
	Lost to follow-up	2
	Withdrawal by caregiver	3
	Withdrawal by subject	4

Code List: TEMP (TEMP)		
Code Prefix	Code Label	Code Value
	C	C

Code List: Protocol Criteria Version (TIVERS)		
Code Prefix	Code Label	Code Value
	[Blank]	
	[Blank]	
	[Blank]	
	Original - 14APR2013	Original - 14APR2013
	Original - 14APR2013	Original - 14APR2013
	Original - 14APR2013	Original - 14APR2013
	Amendment 1 - 29JAN2015	Amendment 1 - 29JAN2015
	Amendment 1 - 29JAN2015	Amendment 1 - 29JAN2015
	Amendment 1 - 29JAN2015	Amendment 1 - 29JAN2015

	Amendment 2 - 12FEB2015	Amendment 2 - 12FEB2015
	Amendment 2 - 12FEB2015	Amendment 2 - 12FEB2015
	Amendment 2 - 12FEB2015	Amendment 2 - 12FEB2015
	Amendment 4 - 27APR2016	Amendment 4 - 27APR2016
	Amendment 4 - 27APR2016	Amendment 4 - 27APR2016
	Amendment 5 - 13NOV2017	Amendment 5 - 13NOV2017

Code List: UPREG (UPREG)

Code Prefix	Code Label	Code Value
	Urine	Urine

Code List: WEIGHT (WEIGHT)

Code Prefix	Code Label	Code Value
	kg	kg

Code List: Xanthoma (Xanthoma)

Code Prefix	Code Label	Code Value
	[Blank]	
	0-None	0
	1-Minimal	1
	2-Moderate	2
	3-Disfiguring	3

	4-Disabling	4
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Code List: Y_N_NA (Y_N_NA)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Yes	Y
	No	N
	Not Applicable	NA

Code List: Y_N_NAapproached (Y_N_NA_)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Yes	Y
	No	N
	Not Approached	NA_

Code List: YES (YES)		
Code Prefix	Code Label	Code Value
	[Blank]	
	YES	Y

Code List: YES_NO (YES_NO)		
Code Prefix	Code Label	Code Value
	[Blank]	
	Yes	Y
	No	N