



HDClarity Data Dictionary

Version 2.1

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1 Visit Plan

Forms are organized by visit type, that is, General, Screening, Sampling, Phone Contact, Repeat Sampling, Repeat Phone Contact, Events or Premature End visits.

Form Name	General	Screening	Sampling	Phone Contact	Repeat Sampling	Repeat Phone Contact	Events	End
Demog	✓							
CAG	✓							
Comorbid	✓							
PharmacoTx	✓							
Non-PharmacoTx	✓							
NutSuppl	✓							
Mortality	✓							
Enrollment CLR		✓						
Eligibility Check (1)			✓					
Eligibility Check (2)					✓			
Checklist		✓						
Checklist SMP			✓		✓			
Safety Lab Exam		✓						

Form Name	General	Screening	Sampling	Phone Contact	Repeat Sampling	Repeat Phone Contact	Events	End
CSF			✓		✓			
CSF Quality			✓		✓			
Blood Processing			✓		✓			
AE Log							✓	
SAE							✓	
Variable		✓	✓		✓			
Motor		✓	✓		✓			
TFC		✓						
Function		✓						
Cognitive		✓						
PBA-s		✓						
Phone Contact (1)				✓				
Phone Contact (2)						✓		
End								✓

2 Key Variables of a Visit

Label	Domain	Cat.	Variable	Type	Parameter	Coding	Unit	Transformation
Participant ID	---	---	sjid	text				HDID of participant
Creation date		---	ctime	date				
Site name	---	---	site	text				
Participant status	SC	---	sjstate	text				
Visit name	SV	---	vname	text	- Screening - Sampling - Repeat Sampling - Baseline - Follow-Up			
Visit date	SV	---	vtime	date				
Visit status	SV	---	vstate	text	- plausible - reviewing - completed			
Unique visit number	---	---	vinst	number				
Form Number	---	---	nr	number				
Row Number	---	---	enr	number				Unique row index number. Only for datafile "csfquality"

3 Form “Demographics (Demog)”

This form is part of the General visit.

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of birth	DM		brthdtc	date			
Gender	DM		sex	single choice	- female - male	- f - m	
Ethnicity	DM		race	single choice	- American Indian/Native American/Amerindian - Alaska Native/Inuit - African - North - African - South - American - Black - Asian - West - Asian - East - Caucasian - Native Hawaiian or Other Pacific Islander - Hispano or Latino Origin - mixed - other	- 8 - 5 - 12 - 11 - 2 - 13 - 14 - 1 - 4 - 3 - 15 - 6	
Handedness	DM		handed	single choice	- right - left - mixed	- 1 - 2 - 3	

4 Form “CAG Report (CAG)”

This form is part of the General visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of report	LB		lbdtc	date			

Section: CAG Analysis

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Specimen type	LB		lbspec	single choice	- blood - brain (postmortem)	- 1 - 2	
CAG analysis results (number of CAG repeats)							
Were the exact repeat lengths given in the laboratory report?	SUPPLB		lbrpt	boolean	- yes - no	- 1 - 0	
Allele 1 CAG repeat length (smaller allele)	LB		allele1l	number			
Allele 2 CAG repeat length (larger allele)	LB		allele2l	number			
Analyzing laboratory	LB		lbnam	text			
Comments	SUPPLB		cmt	boolean	- yes - no	- 1 - 0	
Enter comment	CO	Local CAG	coval	text			

5 Form “Comorbid Conditions (Comorbid)”

This form is part of the General visit.

Section: Past Disorders and Comorbidities

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Condition	MH		mhterm	text array	- Term - Modified Term - Code - Certainty	- term - modify - decod - certainty	
Body system code	MH		mhbodsys	single choice	- cardiovascular - pulmonary - neurologic - ENT - gynecologic/urologic - reproductive - gastrointestinal - metabolic/endocrine - hemato/lymphatic - dermatological - psychiatric - musculoskeletal - allergy/immunologic - ophthalmological - hepatobiliary - renal - other	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 - 11 - 12 - 13 - 14 - 15 - 16 - 17	

Start date	MH		mhstdtc	date		
Ongoing	MH		mhenrf	boolean	- yes - no	- 1 - 0
End date	MH		mhendtc	date		

6 Form “Pharmacotherapy (PharmacoTx)”

This form is part of the General visit.

Section: Medications (Pharmacotherapy)

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Drug name	CM		cmtrt	text array	- Term - Modified Term - Code - Certainty	- term - modify - decod - certainty	
Indication	CM		cmindc	text array	- Term - Modified Term - Code - Certainty	- term - modify - decod - certainty	
Dose / Unit	CM		cmdose	text array	- -	- cmdostxt - cmdosu	
Daily intake	CM		cmfrq	number array		- 1 - 2 - 3 - 4	
Frequency	CM		cmdosfrq	single choice	- daily - every 2nd day - every 3rd day - weekly - every 2nd week - monthly - every 2nd month	- 1 - 2 - 3 - 4 - 5 - 6 - 7	

					- every 3rd month - annually - as needed	- 8 - 9 - 10	
Route	CM		cmroute	single choice	- p.o. - p.r. - s.c. - i.m. - i.v. - nasal - td - sl - inh - other	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10	
Start date	CM		cmstdtc	date			
Ongoing	CM		cmenrf	boolean	- yes - no	- 1 - 0	
Stop date	CM		cmendtc	date			

7 Form “Non-Pharmacologic Therapies (NonPharmacoTx)”

This form is part of the General visit.

Section: Non-Pharmacologic Therapies

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Therapy	CM	Non-Pharmacologic Therapies	cmtrt	single choice	- Physical therapy - Occupational therapy - Psychotherapy - Counseling - Speech/Language therapy - Swallowing therapy - Music therapy - Relaxation therapy (meditation, massage, yoga, etc.) - Acupuncture	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9	
Number of times	SUPPCM	Non-Pharmacologic Therapies	cmfrq	number			
Frequency	CM	Non-Pharmacologic Therapies	cmdosfrq	single choice	- daily - weekly - monthly - as needed	- 1 - 2 - 3 - 4	
Start date	CM	Non-Pharmacologic Therapies	cmstdtc	date			
Ongoing	CM	Non-Pharmacologic Therapies	cmenrf	boolean	- yes - no	- 1 - 0	
Stop date	CM	Non-Pharmacologic Therapies	cmendtc	date			

8 Form “Nutritional Supplements (NutSuppl)”

This form is part of the General visit.

Section: Nutritional Supplements

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Supplement	CM	Nutritional Supplements	cmtrt	text			
Type	CM	Nutritional Supplements	cmcat	single choice	- vitamin & supplements - herbs (extracts) - herbs (teas) - other natural remedies - aromatherapies - homeopathic remedies	- 1 - 2 - 3 - 4 - 5 - 6	
Dose	CM	Nutritional Supplements	cmdostxt	number			
Unit	CM	Nutritional Supplements	cmdosunit	single choice	- g - mg - IU - spoons - tablets - drops - capsule - other	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8	
Daily intake	SUPPCM	Nutritional Supplements	cmfrq	number array		- 1 - 2 - 3	- - -

						- 4	
Frequency	CM	Nutritional Supplements	cmdosfrq	single choice	- daily - every other day - every third day - weekly - every other week - monthly - every other month - every quarter - annually - as needed	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10	
Start date	CM	Nutritional Supplements	cmstdtc	date			
Ongoing	CM	Nutritional Supplements	cmenrf	boolean	- yes - no	- 1 - 0	
Stop date	CM	Nutritional Supplements	cmendtc	date			

9 Form “Mortality”

This form is part of the General visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Assessment date	DS		dsdtc	date			

Section: Death Report Form

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of death	DS		dssdtc	date			
Place of death	DS		dsplace	single choice	- home - hospital - nursing home - hospice care - unknown	- 1 - 2 - 3 - 4 - 5	
Cause of death	DS		dsend	single choice	- pneumonia - other infection - cancer - stroke - trauma - suicide - other	- 1 - 2 - 3 - 4 - 5 - 6 - 7	
Please specify	DS		dsendoth	text			
Was an autopsy performed?	DS		dsautop	single choice	- no - yes	- 0 - 1	

					- unknown	- 2	
Result of autopsy	DS		dsautopr	text			
Information obtained primarily from	DS		dsinfo	single choice	- spouse/family - friend - physician/nurse - patient's medical record - obituary in newspaper - death certificate - other	- 1 - 2 - 3 - 4 - 5 - 6 - 7	
Please specify	DS		infooth	text			
Comments?	DS		dscom	boolean	- yes - no	- 1 - 0	
Comment	CO		coval	text			

10 Form “Enrollment into HD Clarity (Enrollment CLR)”

This form is part of the Screening visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of visit	SV		svstdtc	date			

Section: Enrollment into HD Clarity

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Participant is capable of providing informed consent or has a legal representative	SC		ics1	boolean	- yes - no	- 1 - 0	
IC procedures were completed and documented	SC		ics2	boolean	- yes - no	- 1 - 0	
Date of informed consent	DM		rfstdtc	date			
Signed by	SC		sgntr	single choice	- participant - legal representative	- 1 - 2	
Is there a local CAG report available that specifies exact allele repeat lengths?	SC		ics5	single choice	- yes - no - not required	- 1 - 2 - 3	
Has eligibility been confirmed with Central Coordination?	SC		ics6	boolean	- yes - no	- 1 - 0	
If the participant is premanifest, how is then their DBS?	SC		ics7	single choice	- DBS < 250 (early premanifest) - DBS ≥ 250 (late premanifest) - not applicable	- 1 - 2 - 3	

Enroll-HD core assessment completed within 60 days from screening	SC		ics3	boolean	- yes - no	- 1 - 0	
If No, have you received approval from the Chief Investigator to repeat the core assessments at this visit	SC		ics3a	boolean	- yes - no	- 1 - 0	
Was this participant recruited into Enroll-HD because of participation in HD Clarity	SC		ics4	boolean	- yes - no	- 1 - 0	

Section: Inclusion Criteria

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
21-75 years of age, inclusive	IE		ic1	boolean	- yes - no	- 1 - 0	
Capable of complying with study procedures, including fasting, blood sampling and lumbar puncture	IE		ic2	boolean	- yes - no	- 1 - 0	
Results of the safety laboratory examinations within normal limits	IE		ic3	boolean	- yes - no	- 1 - 0	

Section: Exclusion Criteria

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Current use of investigational drugs or participation in a clinical drug trial	IE		ec1	boolean	- yes - no	- 1 - 0	
Current intoxication, drug or alcohol abuse or dependence	IE		ec2	boolean	- yes - no	- 1 - 0	

Use of inappropriate (e.g., non-therapeutically high) dosages of HD Rx	IE		ec3	boolean	- yes - no	- 1 - 0	
Change of dosages of HD Rx over the past 30 days from sampling	IE		ec4	boolean	- yes - no	- 1 - 0	
Significant medical, neurological or psychiatric co-morbidity likely, in the judgment of the Investigator, to impair participant's ability to complete study procedures	IE		ec5	boolean	- yes - no	- 1 - 0	
Needle phobia	IE		ec6	boolean	- yes - no	- 1 - 0	
Frequent headache	IE		ec7	boolean	- yes - no	- 1 - 0	
Significant lower spinal deformity or major surgery at lumbar spine	IE		ec8	boolean	- yes - no	- 1 - 0	
Antiplatelet or anticoagulant therapy within the past 14 days, including but not limited to: aspirin, clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban and apixaban	IE		ec9	boolean	- yes - no	- 1 - 0	
Clotting or bruising disorder	IE		ec10	boolean	- yes - no	- 1 - 0	
Predictable non-compliance as assessed by investigator	IE		ec11	boolean	- yes - no	- 1 - 0	
Inability or unwillingness to undertake any experimental procedure	IE		ec12	boolean	- yes - no	- 1 - 0	

History or physical examination discloses any reason to suspect abnormal bleeding tendency, e.g. easy bruising, petechial rash	IE		ec13	boolean	- yes - no	- 1 - 0	
History or physical examination discloses any reason to suspect new focal neurological lesion, e.g. new headache, optic disc swelling, asymmetric focal long tract signs	IE		ec14	boolean	- yes - no	- 1 - 0	
Standard neurological examination discloses any reason to suspect raised intracranial pressure or a focal neurological lesion/neurological signs not readily explained by HD	IE		ec15	boolean	- yes - no	- 1 - 0	
General physical examination1 discloses any reason to suspect spinal deformity or abnormal bleeding tendency, e.g. easy bruising, petechial rash	IE		ec16	boolean	- yes - no	- 1 - 0	

Section: Eligibility

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Did the participant pass the eligibility criteria?	IE		elgbl	boolean	- yes - no	- 1 - 0	

Section: Waiver

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Has the CI granted a waiver for all	IE		wvr	boolean	- yes	- 1	

unmet criteria?					- no	- 0	
Please comment	IE		wvr_cmt	text			

Section: Local Participant Classification

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Disease burden score at time of screening visit	SC		dbs	number			
HDClarity classification at time of screening visit	SC		hdcat	single choice	- early pre-manifest HD - late pre-manifest HD - early HD - moderate HD - advanced HD - healthy control	- 1 - 2 - 3 - 4 - 5 - 6	

11 Form “Eligibility Check - Sampling (Eligibility Check)”

This form is part of the Sampling visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of visit	SV		svstdtc	date			

Section: Eligibility Check

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of Screening visit	IE		scr_visit	date			
Sampling visit within 30 days of the Screening visit	IE		svtf	boolean	- yes - no	- 1 - 0	
Confirmation of consent	IE		ics	boolean	- yes - no	- 1 - 0	

Section: Confirmation of Inclusion Criteria

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
21-75 years of age, inclusive	IE		ic1	boolean	- yes - no	- 1 - 0	
Capable of complying with study procedures, including fasting, blood sampling and lumbar puncture	IE		ic2	boolean	- yes - no	- 1 - 0	
Compliance with instructions to fast	IE		ic3	boolean	- yes - no	- 1 - 0	

Section: Confirmation of Exclusion Criteria

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Current use of investigational drugs or participation in a clinical drug trial	IE		ec1	boolean	- yes - no	- 1 - 0	
Current intoxication, drug or alcohol abuse or dependence	IE		ec2	boolean	- yes - no	- 1 - 0	
Use of inappropriate (e.g., non-therapeutically high) dosages of HD Rx	IE		ec3	boolean	- yes - no	- 1 - 0	
Change of dosages of HD Rx over the past 30 days from sampling	IE		ec4	boolean	- yes - no	- 1 - 0	
Significant medical, neurological or psychiatric co-morbidity likely, in the judgment of the Investigator, to impair participant's ability to complete study procedures	IE		ec5	boolean	- yes - no	- 1 - 0	
Needle phobia	IE		ec6	boolean	- yes - no	- 1 - 0	
Frequent headache	IE		ec7	boolean	- yes - no	- 1 - 0	
Significant lower spinal deformity or major surgery at lumbar spine	IE		ec8	boolean	- yes - no	- 1 - 0	
Antiplatelet or anticoagulant therapy within the past 14 days, including but not limited to: aspirin, clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban and apixaban	IE		ec9	boolean	- yes - no	- 1 - 0	
Clotting or bruising disorder	IE		ec10	boolean	- yes	- 1	

					- no	- 0	
Predictable non-compliance as assessed by investigator	IE		ec11	boolean	- yes - no	- 1 - 0	
Inability or unwillingness to undertake any experimental procedure	IE		ec12	boolean	- yes - no	- 1 - 0	
History or physical examination discloses any reason to suspect abnormal bleeding tendency, e.g. easy bruising, petechial rash	IE		ec13	boolean	- yes - no	- 1 - 0	
History or physical examination discloses any reason to suspect new focal neurological lesion, e.g. new headache, optic disc swelling, asymmetric focal long tract signs	IE		ec14	boolean	- yes - no	- 1 - 0	
Standard neurological examination discloses any reason to suspect raised intracranial pressure or a focal neurological lesion/neurological signs not readily explained by HD	IE		ec15	boolean	- yes - no	- 1 - 0	
General physical examination discloses any reason to suspect spinal deformity or abnormal bleeding tendency, e.g. easy bruising, petechial rash	IE		ec16	boolean	- yes - no	- 1 - 0	

Section: Additional Information

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
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Use of any anti-inflammatory medication within the past 14 days	IE		ainf1	boolean	- yes - no	- 1 - 0	
Use of any dietary supplements containing tryptophan, leucine, niacin or niacinamide in the past 14 days	IE		ainf2	boolean	- yes - no	- 1 - 0	
Use of any antidepressant medication within the past 30 days?	IE		ainf3	boolean	- yes - no	- 1 - 0	
Use of any antipsychotic medication within the past 30 days?	IE		ainf4	boolean	- yes - no	- 1 - 0	

Section: Eligibility

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Did the participant pass the eligibility criteria?	IE		elgbl	single choice	- yes - no	- 1 - 2	
Waiver							
Has the CI granted a waiver for all unmet criteria?	IE		wvr	boolean	- yes - no	- 1 - 0	

12 Form “Eligibility Check – Repeat Sampling (Eligibility Check)”

This form is part of the Repeat Sampling visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of visit	SV		svstdtc	date			

Section: Eligibility Check

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of Sampling visit	IE		smp_visit	date			
Repeat Sampling visit within 28-56 days of the Baseline Sampling visit	IE		svtf	boolean	- yes - no	- 1 - 0	
Confirmation of consent	IE		ics	boolean	- yes - no	- 1 - 0	

Section: Confirmation of Inclusion Criteria

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
21-75 years of age, inclusive	IE		ic1	boolean	- yes - no	- 1 - 0	
Capable of complying with study procedures, including fasting, blood sampling and lumbar puncture	IE		ic2	boolean	- yes - no	- 1 - 0	
Compliance with instructions to fast	IE		ic3	boolean	- yes - no	- 1 - 0	

Section: Confirmation of Exclusion Criteria

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Current use of investigational drugs or participation in a clinical drug trial	IE		ec1	boolean	- yes - no	- 1 - 0	
Current intoxication, drug or alcohol abuse or dependence	IE		ec2	boolean	- yes - no	- 1 - 0	
Use of inappropriate (e.g., non-therapeutically high) dosages of HD Rx	IE		ec3	boolean	- yes - no	- 1 - 0	
Change of dosages of HD Rx over the past 30 days from sampling	IE		ec4	boolean	- yes - no	- 1 - 0	
Significant medical, neurological or psychiatric co-morbidity likely, in the judgment of the Investigator, to impair participant's ability to complete study procedures	IE		ec5	boolean	- yes - no	- 1 - 0	
Needle phobia	IE		ec6	boolean	- yes - no	- 1 - 0	
Frequent headache	IE		ec7	boolean	- yes - no	- 1 - 0	
Significant lower spinal deformity or major surgery at lumbar spine	IE		ec8	boolean	- yes - no	- 1 - 0	
Antiplatelet or anticoagulant therapy within the past 14 days, including but not limited to: aspirin, clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban and apixaban	IE		ec9	boolean	- yes - no	- 1 - 0	
Clotting or bruising disorder	IE		ec10	boolean	- yes	- 1	

					- no	- 0	
Predictable non-compliance as assessed by investigator	IE		ec11	boolean	- yes - no	- 1 - 0	
Inability or unwillingness to undertake any experimental procedure	IE		ec12	boolean	- yes - no	- 1 - 0	
History or physical examination discloses any reason to suspect abnormal bleeding tendency, e.g. easy bruising, petechial rash	IE		ec13	boolean	- yes - no	- 1 - 0	
History or physical examination discloses any reason to suspect new focal neurological lesion, e.g. new headache, optic disc swelling, asymmetric focal long tract signs	IE		ec14	boolean	- yes - no	- 1 - 0	
Standard neurological examination discloses any reason to suspect raised intracranial pressure or a focal neurological lesion/neurological signs not readily explained by HD	IE		ec15	boolean	- yes - no	- 1 - 0	
General physical examination discloses any reason to suspect spinal deformity or abnormal bleeding tendency, e.g. easy bruising, petechial rash	IE		ec16	boolean	- yes - no	- 1 - 0	

Section: Additional Information

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
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Use of any anti-inflammatory medication within the past 14 days	IE		ainf1	boolean	- yes - no	- 1 - 0	
Use of any dietary supplements containing tryptophan, leucine, niacin or niacinamide in the past 14 days	IE		ainf2	boolean	- yes - no	- 1 - 0	
Use of any antidepressant medication within the past 30 days?	IE		ainf3	boolean	- yes - no	- 1 - 0	
Use of any antipsychotic medication within the past 30 days?	IE		ainf4	boolean	- yes - no	- 1 - 0	

Section: Eligibility

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Did the participant pass the eligibility criteria?	IE		elgbl	single choice	- yes - no	- 1 - 2	
Waiver							
Has the CI granted a waiver for all unmet criteria?	IE		wvr	boolean	- yes - no	- 1 - 0	

13 Form “Visit Checklist (Checklist)”

This form is part of the Screening visit.

Section: Have the following forms been completed for this visit?

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
General Variable	SV		vc1	boolean	- yes - no	- 1 - 0	
Comorbid	SV		vc2	boolean	- yes - no	- 1 - 0	
Pharmacotherapy	SV		vc3	boolean	- yes - no	- 1 - 0	
Nutritional Supplements	SV		vc4	boolean	- yes - no	- 1 - 0	
Non-Pharmacotherapy	SV		vc5	boolean	- yes - no	- 1 - 0	

14 Form “Visit Checklist – Sampling (Checklist SMP)”

This form is part of the Sampling and Repeat Sampling visit.

Section: Have you checked and updated (where necessary) the following?

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Comorbid	SV		vc2	boolean	- yes - no	- 1 - 0	
Pharmacotherapy	SV		vc3	boolean	- yes - no	- 1 - 0	
Nutritional Supplements	SV		vc4	boolean	- yes - no	- 1 - 0	
Non-Pharmacotherapy	SV		vc5	boolean	- yes - no	- 1 - 0	
Have you repeated the UHDRS motor exam	SV		v8	boolean	- yes - no	- 1 - 0	

Section: Safety Evaluation prior to CSF Collection

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Did your repeat physical examination conducted today reveal any reason to suspect abnormal bleeding tendency, e.g. easy bruising, petechial rash?	IE		secsf1	boolean	- yes - no	- 1 - 0	
Did your repeat neurological examination conducted today reveal	IE		secsf2	boolean	- yes - no	- 1 - 0	

any reason to suspect new focal neurological lesion, e.g. new headache, optic disc swelling, asymmetric focal long tract signs?							
Vital signs satisfactory	IE		secsf3	boolean	- yes - no	- 1 - 0	

15 Form “Safety Laboratory Examinations (Safety Lab Exam)”

This form is part of the Screening visit.

Section: Laboratory Examinations for Safety - Screening

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
15 ml of venous blood drawn for evaluation by the local laboratory	LB		lbsmpl1	boolean	- yes - no	- 1 - 0	
Date of blood draw	LB		lbdatt1	date			
White Cell Count							
Actual	LB		wbcres1	number			
Lower limit	LB		wbclo1	number			
Upper limit	LB		wbchi1	number			
Neutrophil Count							
Actual	LB		ncres1	number			
Lower limit	LB		nclo1	number			
Upper limit	LB		nchi1	number			
Lymphocyte Count							
Actual	LB		lcres1	number			
Lower limit	LB		lclo1	number			
Upper limit	LB		lchi1	number			
Hemoglobin (Hb)							
Actual	LB		hbres1	number			

Lower limit	LB		hblo1	number			
Upper limit	LB		hbhi1	number			
Platelets							
Actual	LB		pltres1	number			
Lower limit	LB		pltlo1	number			
Upper limit	LB		plthi1	number			
Prothrombin Time (PT)							
Actual	LB		ptres1	number			
Lower limit	LB		ptlo1	number			
Upper limit	LB		pthi1	number			
Activated Partial Thromboplastin time (APTT)							
Actual	LB		apttres1	number			
Lower limit	LB		apttlo1	number			
Upper limit	LB		apthi1	number			
CRP							
Actual	LB		crpres1	number			
Lower limit	LB		crplo1	number			
Upper limit	LB		crphi1	number			
Safety lab result	LB		lbres1	single choice	- passed - failed	- 1 - 2	

Section: Laboratory Examinations for Safety - Rescreening

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Second blood draw for rescreening	LB		lbsmpl2	boolean	- yes	- 1	

					- no	- 0	
Date of blood draw	LB		lbdatt2	date			
White Cell Count							
Actual	LB		wbcres2	number			
Lower limit	LB		wbclo2	number			
Upper limit	LB		wbchi2	number			
Neutrophil Count							
Actual	LB		ncres2	number			
Lower limit	LB		nclo2	number			
Upper limit	LB		nchi2	number			
Lymphocyte Count							
Actual	LB		lcres2	number			
Lower limit	LB		lclo2	number			
Upper limit	LB		lchi2	number			
Hemoglobin (Hb)							
Actual	LB		hbres2	number			
Lower limit	LB		hblo2	number			
Upper limit	LB		hbhi2	number			
Platelets							
Actual	LB		pltres2	number			
Lower limit	LB		pltlo2	number			
Upper limit	LB		plthi2	number			
Prothrombin Time (PT)							

Actual	LB		ptres2	number			
Lower limit	LB		ptlo2	number			
Upper limit	LB		pthi2	number			
Activated Partial Thromboplastin time (APTT)							
Actual	LB		apttres2	number			
Lower limit	LB		apttlo2	number			
Upper limit	LB		apttthi2	number			
CRP							
Actual	LB		crpres2	number			
Lower limit	LB		crplo2	number			
Upper limit	LB		crphi2	number			
Safety lab result	LB		lbres2	single choice	- passed - failed	- 1 - 2	

16 Form “CSF Collection and Processing (CSF)”

This form is part of the Sampling and Repeat Sampling visit.

Section: CSF Collection

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
LAB-ID	LB		labid	text			
Kit ID	SUPPLB	LB	kitid	text			
Date and time CSF collection procedure is started	SUPPLB	LB	csfpdct	datetime			
Total volume of CSF obtained	LB		lblpvol	number			ml
Total volume of usable CSF obtained	SUPPLB	LB	lblpvolu	number			ml
Time CSF collection procedure is completed	SUPPLB	LB	lblpetim	datetime			
Number of LP attempts	SUPP	LB	lblpcnt	single choice	- 1 - 2 - 3	- 1 - 2 - 3	

Section: LP Attempt #1

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Investigator ID	LB		invid1	number			
Lumbar space used for lumbar puncture (LP)	SUPP	LB	lpsp1	single choice	- L4/5 space - L3/4 space - other	- 1 - 2 - 3	
Please enter used lumbar space	SUPP	LB	lpsp1spc	text			

Initial participant posture							
Lateral decubitus	LB		ipp1ld	boolean	- yes - no	- 1 - 0	
Upright	LB		ipp1up	boolean	- yes - no	- 1 - 0	
Was patient transferred to lateral decubitus position before CSF collection	SUPPLB	LB	ipp1upt	boolean	- yes - no	- 1 - 0	
Local anaesthesia (2% lidocaine) used	SUPP	LB	lp1ca1	boolean	- yes - no	- 1 - 0	
Volume of lidocaine used	LB		lp1ca1v	number			ml
Why lidocaine was not used	SUPP	LB	lp1ca1r	single choice	- Allergy - Other Contraindications - Patient Request - Investigator Preference - Other	- 1 - 2 - 3 - 4 - 5	
Number of needle passes to obtain CSF	SUPPLB	LB	lpnnp1	single choice	- 1 - 2 - 3 - 4 - 5	- 1 - 2 - 3 - 4 - 5	
Was the first ml of CSF blood contaminated?	SUPPLB	LB	lp1bc1	boolean	- yes - no	- 1 - 0	
Was the second ml of CSF blood contaminated?	SUPPLB	LB	lp1bc2	boolean	- yes - no	- 1 - 0	
Was the third ml of CSF blood contaminated?	SUPPLB	LB	lp1bc3	boolean	- yes - no	- 1 - 0	

Section: LP Attempt #2

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Investigator ID	LB		invid2	number			
Lumbar space used for lumbar puncture (LP)	SUPP	LB	lpsp2	single choice	- L4/5 space - L3/4 space - other	- 1 - 2 - 3	
Please enter used lumbar space	SUPP	LB	lpsp2spc	text			
Initial participant posture							
Lateral decubitus	LB		ipp2ld	boolean	- yes - no	- 1 - 0	
Upright	LB		ipp2up	boolean	- yes - no	- 1 - 0	
Was patient transferred to lateral decubitus position before CSF collection	SUPPLB	LB	ipp2upt	boolean	- yes - no	- 1 - 0	
Local anaesthesia (2% lidocaine) used	SUPP	LB	lplca2	boolean	- yes - no	- 1 - 0	
Volume of lidocaine used	LB		lplca2v	number			ml
Why lidocaine was not used	SUPP	LB	lplca2r	single choice	- Allergy - Other Contraindications - Patient Request - Investigator Preference - Other	- 1 - 2 - 3 - 4 - 5	
Number of needle passes to obtain CSF	SUPPLB	LB	lpnnp2	single choice	- 1 - 2 - 3 - 4	- 1 - 2 - 3 - 4	

					- 5	- 5	
Was the first ml of CSF blood contaminated?	SUPPLB	LB	lp2bc1	boolean	- yes - no	- 1 - 0	
Was the second ml of CSF blood contaminated?	SUPPLB	LB	lp2bc2	boolean	- yes - no	- 1 - 0	
Was the third ml of CSF blood contaminated?	SUPPLB	LB	lp2bc3	boolean	- yes - no	- 1 - 0	

Section: LP Attempt #3

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Investigator ID	LB		invid3	number			
Lumbar space used for lumbar puncture (LP)	SUPP	LB	lpsp3	single choice	- L4/5 space - L3/4 space - other	- 1 - 2 - 3	
Please enter used lumbar space	SUPP	LB	lpsp3spc	text			
Initial participant posture							
Lateral decubitus	LB		ipp3ld	boolean	- yes - no	- 1 - 0	
Upright	LB		ipp3up	boolean	- yes - no	- 1 - 0	
Was patient transferred to lateral decubitus position before CSF collection	SUPPLB	LB	ipp3upt	boolean	- yes - no	- 1 - 0	
Local anaesthesia (2% lidocaine) used	SUPP	LB	lplca3	boolean	- yes - no	- 1 - 0	
Volume of lidocaine used	LB		lplca3v	number			ml

Why lidocaine was not used	SUPP	LB	lpca3r	single choice	- Allergy - Other Contraindications - Patient Request - Investigator Preference - Other	- 1 - 2 - 3 - 4 - 5	
Number of needle passes to obtain CSF	SUPPLB	LB	lpnp3	single choice	- 1 - 2 - 3 - 4 - 5	- 1 - 2 - 3 - 4 - 5	
Was the first ml of CSF blood contaminated?	SUPPLB	LB	lp3bc1	boolean	- yes - no	- 1 - 0	
Was the second ml of CSF blood contaminated?	SUPPLB	LB	lp3bc2	boolean	- yes - no	- 1 - 0	
Was the third ml of CSF blood contaminated?	SUPPLB	LB	lp3bc3	boolean	- yes - no	- 1 - 0	

Section: CSF Processing

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Time CSF processing is started	SUPPLB	LB	csfstim	datetime			
Time CSF processing is completed	SUPPLB	LB	csfctim	datetime			
CSF Tube Rack ID	SUPPLB	LB	csfrkid	text			
CSF aliquot							
Tube ID	SUPPLB	LB	csfaid	text			
Quantity	SUPPLB	LB	csfaqty	number			
Cells from CSF							

Tube ID	SUPPLB	LB	csfcid	text			
Quantity	SUPPLB	LB	csfcqty	number			

17 Form “CSF Quality”

This form is part of the Sampling and Repeat Sampling visit.

Section: Onsite CSF Sample Quality control

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Microscopic erythrocyte count in CSF in triplicate							
1. Count	LB		erycnt1	number			erys/ μ l
2. Count	LB		erycnt2	number			erys/ μ l
3. Count	LB		erycnt3	number			erys/ μ l
Flag	SUPPLB	LB	eryflag	boolean	- yes - no	- 1 - 0	
Microscopic leukocyte count in CSF in triplicate							
1. Count	SUPPLB	LB	leukcnt1	number			cells/ μ l
2. Count	SUPPLB	LB	leukcnt2	number			cells/ μ l
3. Count	SUPPLB	LB	leukcnt3	number			cells/ μ l
Flag	SUPPLB	LB	leukflag	boolean	- yes - no	- 1 - 0	

Section: CSF Quality Control on Hemoglobin

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Results							
HbA conc 1	LB		hbac1	number			ng/ml

HbA conc 2	LB		hbac2	number			ng/ml
HbA conc 3	LB		hbac3	number			ng/ml
Mean HbA conc	LB		hbacm	number			ng/ml
SD	LB		sd	number			
CV%	LB		cv	number			
Comments	LB		cmt	text			
Analysis lab	LB		lab	text			
Assay type	LB		assay	text			
Assay date	LB		assaydtc	date			
Report#	LB		rptno	text			

18 Form “Blood Processing”

This form is part of the Sampling and Repeat Sampling visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
LAB-ID	LB		labid	text			
Kit ID	SUPPLB	LB	kitid	text			
Date and time of blood draw	LB		lbdtc	datetime			
Lithium Heparin Collection Tube							
Tube ID	LB		lhtid	text			
Quantity	SUPPLB	LB	lhqty	number			
Serum Collection Tube							
Tube ID	LB		sstid	text			
Quantity	SUPPLB	LB	sstqty	number			

Section: Blood Processing

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Serum							
Tubes ID	LB		sertid	text			
Quantity	SUPPLB	LB	seraqty	number			
Tube rack ID	LB		sertrid	text			
Time serum processing is started	SUPPLB	LB	serstim	datetime			

Time serum processing is completed	SUPPLB	LB	serctim	datetime			
Plasma							
Tubes ID	LB		plsmtid	text			
Quantity	SUPPLB	LB	plsmqty	number			
Tube rack ID	LB		plsmtrid	text			
Time plasma processing is started	SUPPLB	LB	plsmstim	datetime			
Time plasma processing is completed	SUPPLB	LB	plsmctim	datetime			

Section: On site Sample Storage

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date and time CSF samples are stored on site	SUPPLB	LB	cstrgdtc	datetime			
Date and time blood-derived samples are stored on site	SUPPLB	LB	bstrgdtc	datetime			

19 Form “Adverse Events Log (AE)”

This form is part of the Events visit.

Section: General Information

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Has the participant had any Adverse Events during this study	AE		aeyn	boolean	- yes - no	- 1 - 0	

Section: Details

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
rows, infinite							
Date of report	AE		aedat	date			
AE verbatim term	AE		aeterm	text array	- Term - Modified Term - - Certainty	- term - modify - decod - certaint y	
Start date	AE		aestdat	date			
End date	AE		aeendat	date			
Ongoing?	AE		aeongo	boolean	- yes - no	- 1 - 0	
Severity	AE		aesev	single choice	- mild - moderate - severe	- 1 - 2 - 3	

					- life-threatening - death	- 4 - 5	
Relationship to study procedure	AE		aerel	single choice	- probably related - possibly related - unrelated	- 1 - 2 - 3	
Which study procedure	AE		aerelnst	single choice	- lumbar puncture (low pressure syndrome) - lumbar puncture (other complication) - other study procedure	- 1 - 2 - 3	
Outcome	AE		aeout	single choice	- resolved; no sequelae - ongoing; no treatment - ongoing; undergoing treatment - residual effects present; no treatment - residual effects present; undergoing treatment - death - unknown	- 1 - 2 - 3 - 4 - 5 - 6 - 7	
Expected	SUPPAE		aeexp	boolean	- yes - no	- 1 - 0	
SAE	AE		aeser	boolean	- yes - no	- 1 - 0	

20 Form “Serious Adverse Event (SAE)”

This form is part of the Events visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of serious adverse event report	AE		aedat	date			

Section: Serious Adverse Event

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
AE number	AE		aenum	number			
Start date of serious adverse event	AE		aestdat	date			
Is the serious adverse event ongoing	AE		aeongo	boolean	- yes - no	- 1 - 0	
Stop date of serious adverse event	AE		aeendat	date			
Was this an expected serious adverse event	AE		aeexp	boolean	- yes - no	- 1 - 0	
Brief description of participant							
Sex	AE		sex	single choice	- female - male	- f - m	
Age	AE		age	number			
SAE verbatim term	AE		aeterm	text array	- Term - Modified Term - - Certainty	- term - modify - decod - certaint	

						y	
Brief description of the nature of the serious adverse event	SUPPAE		aetermbd	text			
Category (outcome) of the serious adverse event							
Death	AE		aesdth	boolean	- yes - no	- 1 - 0	
Disability/incapacity	AE		aesdisab	boolean	- yes - no	- 1 - 0	
Life-threatening	AE		aeslife	boolean	- yes - no	- 1 - 0	
Congenital anomaly/birth defect	AE		aescong	boolean	- yes - no	- 1 - 0	
Hospitalization-initial or prolonged	AE		aeshosp	boolean	- yes - no	- 1 - 0	
Required intervention to prevent permanent impairment	AE		aesinter	boolean	- yes - no	- 1 - 0	
None of the above	AE		aesnone	boolean	- yes - no	- 1 - 0	
Outcome	AE		aeout	single choice	- resolved; no sequelae - ongoing; no treatment - ongoing; undergoing treatment - residual effects present; no treatment - residual effects present; undergoing treatment - death - unknown	- 1 - 2 - 3 - 4 - 5 - 6 - 7	
Describe any medical, behavioral, or	SUPPAE		aerelnst	text			

other interventions taken as a result of this SAE							
Status of this report							
Final report	AE		aerver	boolean	- yes - no	- 1 - 0	
Was the participant withdrawn from the research due to this SAE	AE		aedis	boolean	- yes - no	- 1 - 0	

Section: SAE Notification

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of notification	AE		aenotdat	date			

21 Form “Variable Items (Variable)”

This form is part of the Screening, Sampling and Repeat Sampling visit.

Section: Vital Signs

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Weight (kg)	VS		weight	number			
Weight (lbs)	VS		weight_2	number			
Height (cm)	VS		height	number			
Height (inches)	VS		height_2	number			
BMI	VS		bmi	number			

22 Form “UHDRS Motor/Diagnostic Confidence (Motor)”

This form is part of the Screening, Sampling and Repeat Sampling visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Assessment date	QS	Motor	qsdtc	date			
Motor score (TMS)	QS		motscore	number			
Motor score (TMS) incomplete	QS		miscore	number			

Section: Motor Assessment

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Ocular pursuit							
Horizontal	QS		ocularh	single choice	-complete (normal) -jerky movement -interrupted pursuits/full range -incomplete range -cannot pursue	-0 -1 -2 -3 -4	
Vertical	QS		ocularv	single choice	-complete (normal) -jerky movement -interrupted pursuits/full range -incomplete range -cannot pursue	-0 -1 -2 -3 -4	
Saccade initiation							
Horizontal	QS		sacinith	single choice	-normal	-0	

					-increased latency only -suppressible blinks or head movements to initiate -unsuppressible head movements -cannot initiate saccades	-1 -2 -3 -4	
Vertical	QS		sacinitv	single choice	-normal -increased latency only -suppressible blinks or head movements to initiate -unsuppressible head movements -cannot initiate saccades	-0 -1 -2 -3 -4	
Saccade velocity							
Horizontal	QS		sacvelh	single choice	-normal -mild slowing -moderate slowing -severely slow, full range -incomplete range	-0 -1 -2 -3 -4	
Vertical	QS		sacvelv	single choice	-normal -mild slowing -moderate slowing -severely slow, full range -incomplete range	-0 -1 -2 -3 -4	
Dysarthria	QS		dysarth	single choice	-normal -unclear, no need to repeat -must repeat to be understood -mostly incomprehensible -anarthria	-0 -1 -2 -3 -4	
Tongue protrusion	QS		tongue	single choice	-can hold tongue fully protruded for 10 sec	-0 -1	

					-cannot keep fully protruded for 10 sec -cannot keep fully protruded for 5 sec -cannot fully protrude tongue -cannot protrude tongue beyond lips	-2 -3 -4	
Finger taps							
Right	QS		fingtapr	single choice	-normal ($\geq 15/5$ sec.) -mild slowing, reduction in amplitude (11-14/5 sec.) -moderately impaired (7-10/5 sec.) -severely impaired (3-6/5 sec.) -can barely perform task (0-2/5 sec.)	-0 -1 -2 -3 -4	
Left	QS		fingtapl	single choice	-normal ($\geq 15/5$ sec.) -mild slowing, reduction in amplitude (11-14/5 sec.) -moderately impaired (7-10/5 sec.) -severely impaired (3-6/5 sec.) -can barely perform task (0-2/5 sec.)	-0 -1 -2 -3 -4	
Pronate/supinate-hands							
Right	QS		prosupr	single choice	-normal -mild slowing and/or irregular -moderate slowing and irregular -severe slowing and irregular	-0 -1 -2 -3	

					-cannot perform	-4	
Left	QS		prosupl	single choice	-normal -mild slowing and/or irregular -moderate slowing and irregular -severe slowing and irregular -cannot perform	-0 -1 -2 -3 -4	
Luria	QS		luria	single choice	-≥4 in 10 sec, no cue -<4 in 10 sec, no cue -≥4 in 10 sec with cues -<4 in 10 sec with cues -cannot perform	-0 -1 -2 -3 -4	
Rigidity-arms							
Right	QS		rigarmr	single choice	-absent -slight or present only with activation -mild to moderate -severe, full range of motion -severe with limited range	-0 -1 -2 -3 -4	
Left	QS		rigarml	single choice	-absent -slight or present only with activation -mild to moderate -severe, full range of motion -severe with limited range	-0 -1 -2 -3 -4	
Bradykinesia-body	QS		brady	single choice	-normal -minimally slow (?normal) -mildly but clearly slow -moderately slow, some hesitation	-0 -1 -2 -3 -4	

					-markedly slow, long delays in initiation		
Maximal dystonia							
Trunk	QS		dysttrnk	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
RUE	QS		dystrue	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
LUE	QS		dystlue	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
RLE	QS		dystrle	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
LLE	QS		dystlle	single choice	-absent -slight/intermittent	-0 -1	

					-mild/common or moderate/intermittent -moderate/common -marked/prolonged	-2 -3 -4	
Maximal chorea							
Face	QS		chorface	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
BOL	QS		chorbol	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
Trunk	QS		chortrnk	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
RUE	QS		chorrue	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	

LUE	QS		chorlue	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
RLE	QS		chorrle	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
LLE	QS		chorlle	single choice	-absent -slight/intermittent -mild/common or moderate/intermittent -moderate/common -marked/prolonged	-0 -1 -2 -3 -4	
Gait	QS		gait	single choice	-normal gait, narrow base -wide base and/or slow -wide base and walks with difficulty -walks only with assistance -cannot attempt	-0 -1 -2 -3 -4	
Tandem walking	QS		tandem	single choice	-normal for 10 steps -1 to 3 deviations from straight line ->3 deviations -cannot complete -cannot attempt	-0 -1 -2 -3 -4	

Retropulsion pull test	QS		retropls	single choice	-normal -recovers spontaneously -would fall if not caught -tends to fall spontaneously -cannot stand	-0 -1 -2 -3 -4	
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Section: Diagnostic Confidence

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Diagnostic confidence level (DCL)	QS	DCL	diagconf	single choice	-normal (no abnormalities) -non-specific motor abnormalities (less than 50 % confidence) -motor abnormalities that may be signs of HD (50 - 89 % confidence) -motor abnormalities that are likely signs of HD (90 - 98 % confidence) -motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence)	-0 -1 -2 -3 -4	

23 Form “UHDRS Total Functional Capacity (TFC)”

This form is part of the Screening visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Assessment date	QS	TFC	qsdtc	date			
Functional score	QS		tfcscore	number			

Section: Functional Capacity

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Occupation	QS		occupatn	single choice	-unable -marginal work only -reduced capacity for usual job -normal	-0 -1 -2 -3	
Finances	QS		finances	single choice	-unable -major assistance -slight assistance -normal	-0 -1 -2 -3	
Domestic chores	QS		chores	single choice	-unable -impaired -normal	-0 -1 -2	
ADL	QS		adl	single choice	-total care -gross tasks only -minimal impairment -normal	-0 -1 -2 -3	

Care level	QS		carelevl	single choice	-full time skilled nursing -home or chronic care -home	-0 -1 -2	
Information Sources							
Was the information obtained from	QS	TFC	tfcsrc	single choice	-participant only -participant and family/companion	-1 -2	

24 Form “UHDRS Functional Assessment/Independence Scale (Function)”

This form is part of the Screening visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Assessment date	QS	Function	qsdtc	date			
Functional assessment score	QS	Function	fascore	number			
Functional score incomplete	QS	Function	fiscore	number			
Independence scale in %	QS	Function	indpsclp	number			

Section: Functional Assessment

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Could subject engage in gainful employment in his/her accustomed work	QS	Function	emplusl	boolean	-yes -no	-1 -0	
Could subject engage in any kind of gainful employment?	QS	Function	emplany	boolean	-yes -no	-1 -0	
Could subject engage in any kind of volunteer or non-gainful work?	QS	Function	volunt	boolean	-yes -no	-1 -0	
Could subject manage his/her finances (monthly) without any help?	QS	Function	fafinan	boolean	-yes -no	-1 -0	
Could subject shop for groceries without help?	QS	Function	grocery	boolean	-yes -no	-1 -0	
Could subject handle money as a	QS	Function	cash	boolean	-yes	-1	

purchaser in a simple cash (shop) transaction?					-no	-0	
Could subject supervise children without help?	QS	Function	supchild	boolean	-yes -no	-1 -0	
Could subject operate an automobile safely and independently?	QS	Function	drive	boolean	-yes -no	-1 -0	
Could subject do his/her own housework without help?	QS	Function	housewrk	boolean	-yes -no	-1 -0	
Could subject do his/her own laundry (wash/dry) without help?	QS	Function	laundry	boolean	-yes -no	-1 -0	
Could participant prepare his/her own meals without help?	QS	Function	prepmeal	boolean	-yes -no	-1 -0	
Could subject use the telephone without help?	QS	Function	telephon	boolean	-yes -no	-1 -0	
Could subject take his/her own medications without help?	QS	Function	ownmeds	boolean	-yes -no	-1 -0	
Could subject feed himself/herself without help?	QS	Function	feedself	boolean	-yes -no	-1 -0	
Could subject dress himself/herself without help?	QS	Function	dress	boolean	-yes -no	-1 -0	
Could subject bathe himself/herself without help?	QS	Function	bathe	boolean	-yes -no	-1 -0	
Could subject use public transport to get to places without help?	QS	Function	pubtrans	boolean	-yes -no	-1 -0	
Could subject walk to places in his/her neighbourhood without help?	QS	Function	walknbr	boolean	-yes -no	-1 -0	
Could subject walk without falling?	QS	Function	walkfall	boolean	-yes	-1	

					-no	-0	
Could subject walk without help?	QS	Function	walkhelp	boolean	-yes -no	-1 -0	
Could subject comb hair without help?	QS	Function	comb	boolean	-yes -no	-1 -0	
Could subject transfer between chairs without help?	QS	Function	trnchair	boolean	-yes -no	-1 -0	
Could subject get in and out of bed without help?	QS	Function	bed	boolean	-yes -no	-1 -0	
Could subject use toilet/commode without help?	QS	Function	toilet	boolean	-yes -no	-1 -0	
Could subject's care still be provided at home?	QS	Function	carehome	boolean	-yes -no	-1 -0	
Information sources							
Was the functional assessment information obtained from	QS	Function	fasrc	single choice	-subject only -subject and family/companion	-1 -2	

Section: Independence Scale

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Subject's independence in %	QS	Independence	indepscl	single choice	-no special care needed - -no physical care needed if difficult tasks are avoided - -pre-disease level of employment changes or ends; cannot perform household chores to pre-disease level, may need help with finances	-100 -95 -90 -85 -80 -75 -70 -65 -60	

					-	-55	
					-self-care maintained for bathing, limited household duties, e.g. cooking and use of knives, driving terminates; unable to manage finances	-50 -45 -40 -35 -30	
					-	-25	
					-needs minor assistance in dressing, toileting, bathing; food must be cut for subject	-20 -15 -10	
					-	-5	
					-24-hour supervision appropriate; assistance required for bathing, eating, toileting		
					-		
					-chronic care facility needed; limited self feeding, liquified diet		
					-		
					-subject provides minimal assistance in own feeding, bathing, toileting		
					-		
					-no speech, must be fed		
					-		
					-tube fed, total bed care		
					-		

25 Form “Core Cognitive Assessment (Cognitive)”

This form is part of the Screening visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Assessment date	QS	Cognitive Assessment	qsdtc	date			

Section: Core Cognitive Assessment

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Symbol Digit Modality Test completed	QS	SDMT	sdmt	boolean	-yes -no	-1 -0	
Total correct	QS	SDMT	sdmt1	number			
Total errors	QS	SDMT	sdmt2	number			
Verbal Fluency Test (Category) completed	QS	Categorical Verbal Fluency	verfct	boolean	-yes -no	-1 -0	
Category	QS	Categorical Verbal Fluency	verfctd	single choice	-animals -other	-1 -2	
Please specify	SUPPQS	Categorical Verbal Fluency	verfctds	text			
Total correct 0-15 seconds	SUPPQS	Categorical Verbal Fluency	verfct1	number			
Total correct 16-30 seconds	SUPPQS	Categorical Verbal	verfct2	number			

		Fluency					
Total correct 31-45 seconds	SUPPQS	Categorical Verbal Fluency	verfct3	number			
Total correct 46-60 seconds	SUPPQS	Categorical Verbal Fluency	verfct4	number			
Total correct (1 min)	SUPPQS	Categorical Verbal Fluency	verfct5	number			
Total intrusion errors	SUPPQS	Categorical Verbal Fluency	verfct6	number			
Total perseverative errors	SUPPQS	Categorical Verbal Fluency	verfct7	number			
Stroop Color Naming Test completed	QS	Stroop Color Naming	scnt	boolean	-yes -no	-1 -0	
Total correct	QS	Stroop Color Naming	scnt1	number			
Total errors	QS	Stroop Color Naming	scnt2	number			
Total self-corrected errors	QS	Stroop Color Naming	scnt3	number			
Stroop Word Reading Test completed	QS	Stroop Word Reading	swrt	boolean	-yes -no	-1 -0	
Total correct	QS	Stroop Word Reading	swrt1	number			
Total errors	QS	Stroop Word Reading	swrt2	number			
Total self-corrected errors	QS	Stroop Word Reading	swrt3	number			

26 Form “Problem Behaviours Assessment – Short (PBA-s)”

This form is part of the Screening visits.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Assessment date	QS	PBA-s	qsdtc	date			
Domain scores							
Depression	QS		depscore	number			
Irritability/aggression	QS		irascore	number			
Psychosis	QS		psyscore	number			
Apathy	QS		aptscore	number			
Executive function	QS		exfscore	number			

Section: Problem Behaviours Assessment for HD

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
1. Depressed mood							
a. Severity	QS	PBA-s	pbas1sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas1fr	single choice	-never/almost never -seldom (less than once/week)	-0 -1	

					-sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-2 -3 -4	
c. Worst	QS	PBA-s	pbas1wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
2. Suicidal ideation							
a. Severity	QS	PBA-s	pbas2sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas2fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas2wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
3. Anxiety							
a. Severity	QS	PBA-s	pbas3sv	single choice	-absent -slight, questionable -mild (present, not a problem)	-0 -1 -2	

					-moderate (symptom causing problem) -severe (almost intolerable for carer)	-3 -4	
b. Frequency	QS	PBA-s	pbas3fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas3wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
4. Irritability							
a. Severity	QS	PBA-s	pbas4sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas4fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas4wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	

5. Angry or aggressive behaviour							
a. Severity	QS	PBA-s	pbas5sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas5fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas5wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
6. Lack of initiative (apathy)							
a. Severity	QS	PBA-s	pbas6sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas6fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas6wo	single choice	-absent	-0	

					-slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-1 -2 -3 -4	
7. Perseverative thinking or behaviour							
a. Severity	QS	PBA-s	pbas7sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas7fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas7wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
8. Obsessive-Compulsive Behaviours							
a. Severity	QS	PBA-s	pbas8sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas8fr	single choice	-never/almost never -seldom (less than once/week)	-0 -1	

					-sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-2 -3 -4	
c. Worst	QS	PBA-s	pbas8wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
9. Delusions / paranoid thinking							
a. Severity	QS	PBA-s	pbas9sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas9fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas9wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
10. Hallucinations							
a. Severity	QS	PBA-s	pbas10sv	single choice	-absent -slight, questionable -mild (present, not a problem)	-0 -1 -2	

					-moderate (symptom causing problem) -severe (almost intolerable for carer)	-3 -4	
Modality of hallucinations	QS	PBA-s	pbas10sm	multiple choice	-auditory -visual -tactile -olfactory -gustatory	-1 -2 -3 -4 -5	
b. Frequency	QS	PBA-s	pbas10fr	single choice	-never/almost never -seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-0 -1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas10wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
Modality of hallucinations	QS	PBA-s	pbas10wm	multiple choice	-auditory -visual -tactile -olfactory -gustatory	-1 -2 -3 -4 -5	
11. Disoriented Behaviour							
a. Severity	QS	PBA-s	pbas11sv	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	
b. Frequency	QS	PBA-s	pbas11fr	single choice	-never/almost never	-0	

					-seldom (less than once/week) -sometimes (up to four times a week) -frequently (most days/5, 6 or 7 times a week) -daily/almost daily for most (or all) of day	-1 -2 -3 -4	
c. Worst	QS	PBA-s	pbas11wo	single choice	-absent -slight, questionable -mild (present, not a problem) -moderate (symptom causing problem) -severe (almost intolerable for carer)	-0 -1 -2 -3 -4	

Section: Information

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
i) Is informant a relative?	QS	PBA	pbainfo	single choice	-spouse or partner -parent -sibling -child -other relative -friend or neighbor -professional care worker -other -no informant - participant came alone	-1 -2 -3 -4 -5 -6 -7 -8 -9	
ii) Is informant a household member?	QS	PBA	pbahshd	single choice	-household member (i.e. relative or friend who lives with participant) -not a household member but has frequent contact with participant (most days) -not a household member and sees participant less than three or four times a week -staff of residential care home or hospital	-1 -2 -3 -4	

General comments	CO	PBA	coval	text			
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27 Form “Phone Contact - Sampling (Phone Contact)”

This form is part of the Phone Contact visit.

Section: Phone Contact

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Did the participant receive phone contact from the site after the sampling visit?	SV		pc1	boolean	-yes -no	-1 -0	
Date of contact	SV		pc11	date			
Time of contact	SV		pc12	datetime			
Reason	SV		pc10	single choice	-unable to contact participant after multiple attempts -participant withdrew consent to be contacted -contact was not attempted	-1 -2 -3	
Were there any adverse events?	SV		pc2	boolean	-yes -no	-1 -0	
Is this participant interested in attending a repeat sampling visit?	SV		pc3	boolean	-yes -no	-1 -0	

28 Form “Phone Contact – Repeat Sampling (Phone Contact)”

This form is part of the Repeat Phone Contact visit.

Section: Phone Contact

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Did the participant receive phone contact from the site after the sampling visit?	SV		pc1	boolean	-yes -no	-1 -0	
Date of contact	SV		pc11	date			
Time of contact	SV		pc12	datetime			
Reason	SV		pc10	single choice	-unable to contact participant after multiple attempts -participant withdrew consent to be contacted -contact was not attempted	-1 -2 -3	
Were there any adverse events?	SV		pc2	boolean	-yes -no	-1 -0	

29 Form “Premature End of Study (End)”

This form is part of the Premature End visit.

Section: General

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Date of end of study report	DS		dsdte	date			

Section:End of Study

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit
Specify primary reason for participant's premature discontinuation from study	DS		dsterm	single choice	-event or intercurrent illness of a nature requiring withdrawal -request of primary care physician, site investigator -participant's request (includes carer/spouse/authorized representative?s request) -lost to follow up -institutionalized (will not be followed further) -specific adverse event -other	-1 -2 -3 -4 -5 -6	
Please specify the reason for the participant's request	DS		dsreas	single choice	-unable to travel -participant unwilling to continue -participant moved away from the study site	-1 -2 -3	
Please specify	DS		termoth	text			

AE number	DS		aenum	number			
Did the participant request the removal of data	DS		dsrdt	boolean	-yes -no	-1 -0	

References

- [1] University College London/CHDI Foundation Inc., Clinical Study Protocol, *HDClarity: a multi-site cerebrospinal fluid collection initiative to facilitate therapeutic development for Huntington’s disease*, 6 October 2015 (Version No. 001)

- [2] University College London/CHDI Foundation Inc., Data Management Requirements for HDClarity Study, *HDClarity: a multi-site cerebrospinal fluid collection initiative to facilitate therapeutic development for Huntington’s disease A study that will use Enroll-HD*

Revision History

Document	Summary of Changes
Version 1.0	Initial version of HD Clarity Data Dictionary
Version 1.0.1	Update Eligibility Check Forms (Waiver)
Version 1.1-1.4	Update Enrolment (Visibility of ENR Participant Category, Local CAG Report, HDClarity Classification) and CSF Quality (IRBM Variables)
Version 2.1	Description of key variables added