CLR4-SPC-0001-EN-1.0

HDClarity 4.0 Data Dictionary

Specification

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1 Preamble

This document provides the data dictionary (database structure, codebook) of the HDClarity 4.0 eCRF (*electronic Case Report Form*).

The data dictionary contains:

- the description of the key variables (i.e. subject states, visit types and visit states)
- the visit form schedule
- the eCRF forms and variables including label, internal variable name, type (e.g. date, datetime, number, text, single choice, boolean) and settings, and
- the monitoring report and event forms and variables including label, internal variable name, type (e.g. date, datetime, number, text, single choice, boolean) and settings

2 Key Variables

2.1 Subject States

Participants being enrolled in a study have a well-defined state at a certain point in time. Within the data export these states are called *subject state*. The subject state identifies the progress of the participant in the study.

The subject states are:

Label	Internal Value	Category	Description
screening	screening	active	Participant is in screening
screen failure	excluded	cancelled	Participant does not meet the in-/exclusion criteria and is excluded from the study
enrolled	enrolled	active	Participant meets the in-/exclusion criteria and is enrolled to the study
dropout	dropout	cancelled	Participant leaves the study prematurely
completed	completed	complete	Participant has completed the study
quarantined	locked	isolated	Participant is locked, e.g. due to missing ICF
deleted	deleted	isolated	Participant is deleted

Table 1: Key Variables - Subject States

2.2 Visit Types

Form entities are organized in visits and cycles (Year 0 - Year 3), i.e. Screening Y0-Y3, (Partial) Sampling Y0-Y3, (Partial) Repeat Sampling Y0, Phone Contact Y0-Y3, Events and Premature End visits.

A visit can either be a regular visit (i.e. Screening Y0-Y3, (Partial) Sampling Y0-Y3, (Partial) Repeat Sampling Y0, Phone Contact Y0-Y3, and Events), occurring within predefined time windows, or a non-regular visit (i.e. Premature End), occurring outside the scheduled visit windows.

The visit types are:

Screening Y0	The first scheduled regular visit during or after enrolment into the study. If the participant was participating in HDClarity 2.0/3.0, the visit is ready for data entry within the scheduled visit frame of 11 months after the last Screening Visit in HDClarity 2.0/3.0.

Screening Y1-Y3	Annual Screening visit scheduled **after** Screening Y0 visit. An annual Screening visit is ready for data entry within the scheduled visit frame of 1 year ±2 months after the Screening Y0 visit (i.e. Screening Y1 visit is scheduled at "Screening Y0 plus 1 year ±2 months", Screening Y2 is scheduled at "Screening Y0 plus 2 years ±2 months", and Screening Y3 is scheduled at "Screening Y0 plus 3 years ±2 months").
(Partial) Sampling Y0-Y3	Sampling visit scheduled 1-30 days **after** the Screening Y0-Y3 visits; if the cycle Y1-Y3 is cancelled due to failed screening, no Sampling visit is scheduled. For each cycle up to 3 Sampling visits can be scheduled if the previous Sampling visit is partial (i.e. failed eligibility check or total volume of usable CSF is 0ml). The optional second and third Sampling visits are scheduled 1-30 days **after** the previous Sampling visit.
(Partial) Repeat Sampling Y0	Repeat Sampling visit scheduled 28-56 days after the first complete Sampling Y0 visit. If the participant was participating in HDClarity 2.0/3.0 and already had a complete Repeat Sampling visit, no Repeat Sampling visit is scheduled for HDClarity 4.0.
Phone Contact Y0-Y3	Phone Contact visit scheduled at the earliest 1 day after each (Partial) Sampling visit Y0-Y3. if the previous Sampling visit is partial due to failed eligibility check (no sampling done), no Phone Contact visit is scheduled.
Repeat Phone Contact Y0	Repeat Phone Contact visit scheduled at the earliest 1 day after the (Partial) Repeat Sampling visit Y0. if the previous Repeat Sampling visit is partial due to failed eligibility check (no sampling done), no Repeat Phone Contact visit is scheduled.
Events	This is an ongoing visit where continuously updated information (reporting of Adverse Events and Serious Adverse Events) is stored. The visit is generated automatically when the participant is enrolled into the study (i.e. s/he meets the in-/exclusion criteria), and the date of the Events visit is automatically set to the date the participant is enrolled.
Premature End	A visit **during/after** the Screening Y0 visit occurs at any time outside the scheduled visit frames. It has to be created manually when a participant leaves the study prematurely.

Table 2: Key Variables - Visit Types

2.3 Visit States

The progress of a visit in terms of completion is identified by its so-called *visit state*. The visit states are:

editing	Visits that are not marked as signed. Visits being in state editing still contain forms with flagged errors that need to be corrected or empty forms that have not been deactivated.
plausible	Visits that are completely entered but not marked as signed yet. Visits being in state plausible contain entered forms without any flagged errors or empty forms that have been deactivated.
signed	Visits that are marked as signed. All entered forms must be complete, without errors and be signed. Empty forms must have been deactivated.
reviewing	Visits that are ready for review or in the process of being reviewed by a monitor.
completed	Visits that have undergone full monitoring review have the state completed or cancelled. All queries raised by the monitor must have been completed. Since monitoring is done not for 100% of the entered, the reviews might have been incompletely reviewed or bypassed.

Table 3: Key Variables - Visit States

3 Visit Form Schedule

The visit form schedule defines the assignment of forms to visit types:

eCRF Form	Screening Y0	Screening Y1-Y3	(Partial) Sampling Y0-Y3	(Partial) Repeat Sampling Y0	Phone Contact Y0-Y3	Repeat Phone Contact Y0-Y3	Events	End
Enrollment (Enrollment into HDClarity)	✓							
Eligibility Check (Eligibility Check)		✓	✓	✓				
Safety Lab Exam (Safety Laboratory Examination)	✓	✓						
Checklist (Visit Checklist)	✓	✓	✓	✓				
Motor (UHDRS®'99 Motor/Diagnostic Confidence)			✓	✓				
CSF (CSF Collection)			(✓)	(✓)				
CSF Quality (CSF Quality)			(✓)	(✓)				

eCRF Form	Screening Y0	Screening Y1-Y3	(Partial) Sampling Y0-Y3	(Partial) Repeat Sampling Y0	Phone Contact Y0-Y3	Repeat Phone Contact Y0-Y3	Events	End
Blood Processing (Blood Processing)			(✓)	(✓)				
Phone Contact (Phone Contact Sampling)					✓	✓		
AE Log (Adverse Event Log)							✓	
SAE (Serious Adverse Event)							(✓)	
End (Premature End)								✓
Monitoring SCR (Monitoring Screening Visit)	✓	✓						
Monitoring SPL (Monitoring Sampling Visit)			✓	✓				
Monitoring (S)AE (Monitoring Serious and Adverse Events)							✓	

eCRF Form	Screening Y0	Screening Y1-Y3	(Partial) Sampling Y0-Y3	(Partial) Repeat Sampling Y0	Phone Contact Y0-Y3	Repeat Phone Contact Y0-Y3	Events	End
Monitoring Event (Monitoring Event Form)	✓	✓	✓	✓	✓	✓	✓	

Table 4: Key Variables - Visit Assessment Schedule

Note: Forms represented in brackets are either optional or supplemental.

4 eCRF Forms

4.1 Enrollment (Enrollment into HDClarity)

Label	Variable	Type	Settings	Coding	Unit
Module: General varitems1 0.0					
Date of visit	svstdtc	date	mandatory readonly passive		
Module: Local Participant Classification lpc2 0.0					
Report:					
Disease burden score at time of screening visit	dbs	number	readonly		
HDClarity classification at time of screening visit	hdcat	single choice	readonly	1 = early pre-manifest HD 2 = late pre-manifest HD 3 = early HD 4 = moderate HD 5 = advanced HD 6 = healthy control 7 = juvenile manifest HD 8 = incomplete penetrance HD 9 = uncategorized	
Module: Enrollment into HDClarity enrl5 0.0					

Label	Variable	Type	Settings	Coding	Unit
Version of study protocol	protocol	single choice	mandatory readonly	4 = Version 4.0	
Participant is capable of providing informed consent or has a legal representative	ics1	boolean	mandatory	1 = yes 0 = no →	
IC procedures were completed and documented	ics2	boolean	mandatory	1 = yes → 0 = no →	
Group: *(→ ics2_1)*					
Date of informed consent	rfstdtc	date	mandatory		
Signed by	sgntr	single choice	mandatory	1 = participant 2 = legal representative 3 = parent/guardian	
Is there a local CAG report available that specifies exact allele repeat lengths	ics3	single choice	readonly	1 = yes 0 = no 2 = not required	
Enroll-HD core assessment completed within 90 days from screening	ics4	boolean	mandatory readonly passive	1 = yes 0 = no	
Report:					
Module: icec12 0.0					
Group: Inclusion Criteria *(→ ics2_1)*					

Label	Variable	Type	Settings	Coding	Unit
Either 21-75 years of age (manifest), or 18-75 years of age (incomplete penetrance, premanifest and controls), or ≥11 years of age (JHD), inclusive, at the time of consent	ic1	boolean	mandatory	1 = yes 0 = no	
Capable of complying with study procedures, including fasting, blood sampling and lumbar puncture	ic2	boolean	mandatory	1 = yes 0 = no	
Results of the safety laboratory examinations within 10% of the normal limits	ic3	boolean	mandatory	1 = yes 0 = no	
C-reactive protein (CRP) screening blood test results within >2X of upper limit of normal	ic4	boolean	mandatory	1 = yes 0 = no	
Negative urine pregnancy test available *(→ ic5_f)*	ic5	boolean	mandatory	1 = yes 0 = no →	
Group: *(→ ic5_0)*					
Has the PI confirmed that the participant is post-menopausal or is not sexually active	ic5_1	boolean	mandatory	1 = yes 0 = no	
Group: Exclusion Criteria *(→ ics2_1)*					
Use of investigational drugs or participation in a clinical drug trial within 30 days prior to annual Sampling Visit	ec1	boolean	mandatory	1 = yes 0 = no	
Current intoxication, drug or alcohol abuse or dependence	ec2	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
If using medications or nutraceuticals, the use of inappropriate (e.g., non-prescribed) dosages within 30 days prior to the annual Sampling visit	ec3	boolean	mandatory	1 = yes 0 = no	
Significant medical, neurological or psychiatric co-morbidity likely, in the judgment of the Investigator, to impair participant's ability to complete study procedures, or likely to reduce the utility of the sample and data for the study of HD	ec4	boolean	mandatory	1 = yes 0 = no	
Needle phobia	ec5	boolean	mandatory	1 = yes 0 = no	
Frequent headache	ec6	boolean	mandatory	1 = yes 0 = no	
Significant lower spinal deformity or major surgery at lumbar spine	ec7	boolean	mandatory	1 = yes 0 = no	
Antiplatelet or anticoagulant therapy within the past 14 days prior to annual Sampling Visit, including but not limited to: aspirin (>81mg), clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban and apixaban	ec8	boolean	mandatory	1 = yes 0 = no	
Clotting or bruising disorder	ec9	boolean	mandatory	1 = yes 0 = no	
Predictable non-compliance as assessed by investigator	ec10	boolean	mandatory	1 = yes 0 = no	
Inability or unwillingness to undertake any experimental procedure	ec11	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Any other reason that, in the clinical judgment of the Site Principal Investigator, it is felt that lumbar puncture performed per this protocol and associated manuals is unsafe without brain imaging	ec12	boolean	mandatory	1 = yes 0 = no	
General physical examination discloses any reason to suspect spinal deformity or abnormal bleeding tendency, e.g. easy bruising, petechial rash	ec13	boolean	mandatory	1 = yes 0 = no	
History or physical examination reveals any reason to suspect new focal neurological lesion, e.g. new headache, optic disc swelling, asymmetric focal long tract signs	ec17	boolean	mandatory	1 = yes 0 = no	
Lumbar puncture procedure performed for any reason in the previous 30 days	ec14	boolean	mandatory	1 = yes 0 = no	
Any SAE deemed related to the LP procedure or blood patch necessitated after LP	ec15	boolean	mandatory	1 = yes 0 = no	
Any other complication or experience during or after any previous lumbar puncture that, in the clinical judgement of the Site Principal Investigator, is likely to pose an unacceptable risk for future lumbar puncture	ec16	boolean	mandatory	1 = yes 0 = no	
Group: Eligibility *(→ ics2_1 ics1_0 ics2_0)*					
Did the participant pass the eligibility criteria?	elgbl	boolean	readonly	1 = yes 0 = no	
Group: Waiver *(→ elgbl_0)*					

Label	Variable	Type	Settings	Coding	Unit
Has the CI granted a waiver for all unmet criteria?	wvr	boolean	mandatory	1 = yes → 0 = no	
Group: *(→ wvr_1)*					
Please comment	wvr_cmt	text	mandatory		

4.2 Eligibility Check (Eligibility Check Screening Y1-Y3)

Label	Variable	Type	Settings	Coding	Unit
Module: General varitems1 0.0					
Date of visit	svstdtc	date	mandatory readonly passive		
Module: icec13 0.0					
Group: Eligibility Check					
Report:					
Confirmation of consent	ics	boolean	mandatory	1 = yes → 0 = no →	
Group: Confirmation of Inclusion Criteria *(→ ics_1)*					

Label	Variable	Type	Settings	Coding	Unit
Either 21-75 years of age (manifest), or 18-75 years of age (incomplete penetrance, premanifest and controls), or ≥11 years of age (JHD), inclusive, at the time of consent	ic1	boolean	mandatory	1 = yes 0 = no	
Capable of complying with study procedures, including fasting, blood sampling and lumbar puncture	ic2	boolean	mandatory	1 = yes 0 = no	
Results of the safety laboratory examinations within 10% of the normal limits *(→ scr_annual)*	ic3	boolean	mandatory	1 = yes 0 = no	
C-reactive protein (CRP) screening blood test results within >2X of upper limit of normal *(→ scr_annual)*	ic4	boolean	mandatory	1 = yes 0 = no	
Negative urine pregnancy test available? *(→ ic5_f)*	ic5	boolean	mandatory	1 = yes 0 = no →	
Group: *(→ ic5_0)*					
Has the PI confirmed that the participant is post-menopausal or is not sexually active	ic5_1	boolean	mandatory	1 = yes 0 = no	
Compliance with instructions to fast	ic6	boolean	mandatory	1 = yes 0 = no	
Group: Confirmation of Exclusion Criteria *(→ ics_1)*					
Current use of investigational drugs or participation in a clinical drug trial within 30 days prior to annual Sampling Visit	ec1	boolean	mandatory	1 = yes 0 = no	
Current intoxication, drug or alcohol abuse or dependence	ec2	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
If using medications or nutraceuticals, the use of inappropriate (e.g., non-prescribed) dosages within 30 days prior to the annual Sampling Visit	ec3	boolean	mandatory	1 = yes 0 = no	
Significant medical, neurological or psychiatric co-morbidity likely, in the judgment of the Investigator, to impair participant's ability to complete study procedures, or likely to reduce the utility of the sample and data for the study of HD	ec4	boolean	mandatory	1 = yes 0 = no	
Needle phobia	ec5	boolean	mandatory	1 = yes 0 = no	
Frequent headache	ec6	boolean	mandatory	1 = yes 0 = no	
Significant lower spinal deformity or major surgery at lumbar spine	ec7	boolean	mandatory	1 = yes 0 = no	
Antiplatelet or anticoagulant therapy within the past 14 days prior to annual Sampling Visit, including but not limited to: aspirin (>81mg), clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban and apixaban	ec8	boolean	mandatory	1 = yes 0 = no	
Clotting or bruising disorder	ec9	boolean	mandatory	1 = yes 0 = no	
Predictable non-compliance as assessed by investigator	ec10	boolean	mandatory	1 = yes 0 = no	
Inability or unwillingness to undertake any experimental procedure	ec11	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Any other reason that, in the clinical judgment of the Site Principal Investigator, it is felt that lumbar puncture performed per this protocol and associated manuals is unsafe without brain imaging	ec12	boolean	mandatory	1 = yes 0 = no	
General physical examination discloses any reason to suspect spinal deformity or abnormal bleeding tendency, e.g. easy bruising, petechial rash	ec13	boolean	mandatory	1 = yes 0 = no	
History or physical examination reveals any reason to suspect new focal neurological lesion, e.g. new headache, optic disc swelling, asymmetric focal long tract signs	ec17	boolean	mandatory	1 = yes 0 = no	
Lumbar puncture procedure performed for any reason in the previous 30 days	ec14	boolean	mandatory	1 = yes 0 = no	
Any SAE deemed related to the LP procedure or blood patch necessitated after LP	ec15	boolean	mandatory	1 = yes 0 = no	
Any other complication or experience during or after any previous lumbar puncture that, in the clinical judgement of the Site Principal Investigator, is likely to pose an unacceptable risk for future lumbar puncture	ec16	boolean	mandatory	1 = yes 0 = no	
Group: Additional Information *(→ ics_1)*					
Use of any anti-inflammatory medication within the past 14 days	ainf1	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Use of any dietary supplements containing tryptophan, leucine, niacin or niacinamide in the past 14 days	ainf2	boolean	mandatory	1 = yes 0 = no	
Use of any antidepressant medication within the past 30 days	ainf3	boolean	mandatory	1 = yes 0 = no	
Use of any antipsychotic medication within the past 30 days	ainf4	boolean	mandatory	1 = yes 0 = no	
Group: Eligibility *(→ ics_1 ics_0)*					
Did the participant pass the eligibility criteria?	elgbl	boolean	readonly	1 = yes 0 = no	
Has the CI granted a waiver for all unmet criteria? *(→ elgbl_0)*	wvr	boolean	mandatory	1 = yes → 0 = no	
Group: *(→ wvr_1)*					
Please comment	wvr_cmt	text	mandatory		
Group: Options *(→ ics_0 wvr_0)*					
Please select one of the following options	wvrno	single choice	mandatory	2 = cancel this annual cycle but keep participant enrolled 3 = cancel this annual cycle and end participation	

4.3 Eligibility Check (Eligibility Check Sampling Y0-Y3/Repeat Sampling Y0)

Label	Variable	Type	Settings	Coding	Unit
Module: General varitems1 0.0					
Date of visit	svstdtc	date	mandatory readonly passive		
Module: icec13 0.0					
Group: Eligibility Check					
Report:					
Confirmation of consent	ics	boolean	mandatory	1 = yes → 0 = no →	
Group: Confirmation of Inclusion Criteria *(→ ics_1)*					
Either 21-75 years of age (manifest), or 18-75 years of age (incomplete penetrance, premanifest and controls), or ≥11 years of age (JHD), inclusive, at the time of consent	ic1	boolean	mandatory	1 = yes 0 = no	
Capable of complying with study procedures, including fasting, blood sampling and lumbar puncture	ic2	boolean	mandatory	1 = yes 0 = no	
Negative urine pregnancy test available? *(→ ic5_f)*	ic5	boolean	mandatory	1 = yes 0 = no →	
Group: *(→ ic5_0)*					

Label	Variable	Type	Settings	Coding	Unit
Has the PI confirmed that the participant is post-menopausal or is not sexually active	ic5_1	boolean	mandatory	1 = yes 0 = no	
Compliance with instructions to fast	ic6	boolean	mandatory	1 = yes 0 = no	
Group: Confirmation of Exclusion Criteria *(→ ics_1)*					
Current use of investigational drugs or participation in a clinical drug trial within 30 days prior to annual Sampling Visit	ec1	boolean	mandatory	1 = yes 0 = no	
Current intoxication, drug or alcohol abuse or dependence	ec2	boolean	mandatory	1 = yes 0 = no	
If using medications or nutraceuticals, the use of inappropriate (e.g., non-prescribed) dosages within 30 days prior to the annual Sampling Visit	ec3	boolean	mandatory	1 = yes 0 = no	
Significant medical, neurological or psychiatric co-morbidity likely, in the judgment of the Investigator, to impair participant's ability to complete study procedures, or likely to reduce the utility of the sample and data for the study of HD	ec4	boolean	mandatory	1 = yes 0 = no	
Needle phobia	ec5	boolean	mandatory	1 = yes 0 = no	
Frequent headache	ec6	boolean	mandatory	1 = yes 0 = no	
Significant lower spinal deformity or major surgery at lumbar spine	ec7	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Antiplatelet or anticoagulant therapy within the past 14 days prior to annual Sampling Visit, including but not limited to: aspirin (>81mg), clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban and apixaban	ec8	boolean	mandatory	1 = yes 0 = no	
Clotting or bruising disorder	ec9	boolean	mandatory	1 = yes 0 = no	
Predictable non-compliance as assessed by investigator	ec10	boolean	mandatory	1 = yes 0 = no	
Inability or unwillingness to undertake any experimental procedure	ec11	boolean	mandatory	1 = yes 0 = no	
Any other reason that, in the clinical judgment of the Site Principal Investigator, it is felt that lumbar puncture performed per this protocol and associated manuals is unsafe without brain imaging	ec12	boolean	mandatory	1 = yes 0 = no	
General physical examination discloses any reason to suspect spinal deformity or abnormal bleeding tendency, e.g. easy bruising, petechial rash	ec13	boolean	mandatory	1 = yes 0 = no	
History or physical examination reveals any reason to suspect new focal neurological lesion, e.g. new headache, optic disc swelling, asymmetric focal long tract signs	ec17	boolean	mandatory	1 = yes 0 = no	
Lumbar puncture procedure performed for any reason in the previous 30 days	ec14	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Any SAE deemed related to the LP procedure or blood patch necessitated after LP	ec15	boolean	mandatory	1 = yes 0 = no	
Any other complication or experience during or after any previous lumbar puncture that, in the clinical judgement of the Site Principal Investigator, is likely to pose an unacceptable risk for future lumbar puncture	ec16	boolean	mandatory	1 = yes 0 = no	
Group: Additional Information *(→ ics_1)*					
Use of any anti-inflammatory medication within the past 14 days	ainf1	boolean	mandatory	1 = yes 0 = no	
Use of any dietary supplements containing tryptophan, leucine, niacin or niacinamide in the past 14 days	ainf2	boolean	mandatory	1 = yes 0 = no	
Use of any antidepressant medication within the past 30 days	ainf3	boolean	mandatory	1 = yes 0 = no	
Use of any antipsychotic medication within the past 30 days	ainf4	boolean	mandatory	1 = yes 0 = no	
Group: Eligibility *(→ ics_1 ics_0)*					
Did the participant pass the eligibility criteria?	elgbl	boolean	readonly	1 = yes 0 = no	
Has the CI granted a waiver for all unmet criteria? *(→ elgbl_0)*	wvr	boolean	mandatory	1 = yes → 0 = no	
Group: *(→ wvr_1)*					

Label	Variable	Type	Settings	Coding	Unit
Please comment	wvr_cmt	text	mandatory		
Group: Options *(→ ics_0 wvr_0)*					
Please select one of the following options	wvrno	single choice	mandatory	1 = cancel visit and reschedule a new Sampling Visit 2 = cancel this annual cycle but keep participant enrolled 3 = cancel this annual cycle and end participation	

4.4 Safety Lab Exam (Safety Laboratory Examination)

Label	Variable	Type	Settings	Coding	Unit
Module: les1 0.0					
Group: Laboratory Examinations for Safety - Screening					
15 ml of venous blood drawn for evaluation by the local laboratory	lbsmpl1	boolean	mandatory	1 = yes → 0 = no	
Group: *(→ lbsmpl1_1)*					
Date of blood draw	lbdat1	date	mandatory		
Table: Results of laboratory examinations for safety *(→ lbsmpl1_1)*					
Row: White Cell Count					

Label	Variable	Type	Settings	Coding	Unit
Actual	wbcres1	number	mandatory		
Lower limit	wbclo1	number	mandatory		
Upper limit	wbchi1	number	mandatory		
Unit	wbcu1	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	
Row: Neutrophil Count					
Actual	ncres1	number	mandatory		
Lower limit	nclo1	number	mandatory		
Upper limit	nchi1	number	mandatory		
Unit	ncu1	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	
Row: Lymphocyte Count					

Label	Variable	Type	Settings	Coding	Unit
Actual	lcres1	number	mandatory		
Lower limit	lclo1	number	mandatory		
Upper limit	lchi1	number	mandatory		
Unit	lcu1	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	
Row: Hemoglobin (Hb)					
Actual	hbres1	number	mandatory		
Lower limit	hblo1	number	mandatory		
Upper limit	hbhi1	number	mandatory		
Unit	hbu1	single choice	mandatory	2 = g/dl 3 = g/l 88 = other	
Row: Platelets					
Actual	pltres1	number	mandatory		

Label	Variable	Type	Settings	Coding	Unit
Lower limit	pltlo1	number	mandatory		
Upper limit	plthi1	number	mandatory		
Unit	pltu1	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	
Row: Prothrombin Time (PT)					
Actual	ptres1	number	mandatory		
Lower limit	ptlo1	number	mandatory		
Upper limit	pthi1	number	mandatory		
Unit	ptu1	single choice	mandatory	9 = seconds 88 = other	
Row: Activated Partial Thromboplastin time (APTT)					
Actual	apttres1	number	mandatory		
Lower limit	apttlo1	number	mandatory		
Upper limit	aptthi1	number	mandatory		

Label	Variable	Type	Settings	Coding	Unit
Unit	apttu1	single choice	mandatory	9 = seconds 88 = other	
Row: CRP					
Actual	crpres1	number	mandatory		
Lower limit	crplo1	number	mandatory		
Upper limit	crphi1	number	mandatory		
Unit	crpu1	single choice	mandatory	6 = mg/dl 7 = mg/l 8 = nmol/l 88 = other	
Group: *(→ lbsmpl1_1)*					
Safety lab result	lbres1	single choice	readonly	1 = passed 2 = failed *(lbres1_0 →)*	
Group: Laboratory Examinations for Safety - Rescreening *(→ lbres1_0)*					
Second blood draw for rescreening	lbsmpl2	boolean	mandatory	1 = yes → 0 = no	
Group: *(→ lbsmpl2_1)*					
Date of blood draw	lbdat2	date	mandatory		
Table: Results of laboratory examinations for safety *(→ lbsmpl2_1)*					

Label	Variable	Type	Settings	Coding	Unit
Row: White Cell Count					
Actual	wbcres2	number	mandatory		
Lower limit	wbclo2	number	mandatory		
Upper limit	wbchi2	number	mandatory		
Unit	wbcu2	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	
Row: Neutrophil Count					
Actual	ncres2	number	mandatory		
Lower limit	nclo2	number	mandatory		
Upper limit	nchi2	number	mandatory		
Unit	ncu2	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	

Label	Variable	Type	Settings	Coding	Unit
Row: Lymphocyte Count					
Actual	lcres2	number	mandatory		
Lower limit	lclo2	number	mandatory		
Upper limit	lchi2	number	mandatory		
Unit	lcu2	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	
Row: Hemoglobin (Hb)					
Actual	hbres2	number	mandatory		
Lower limit	hblo2	number	mandatory		
Upper limit	hbhi2	number	mandatory		
Unit	hbu2	single choice	mandatory	2 = g/dl 3 = g/l 88 = other	
Row: Platelets					

Label	Variable	Type	Settings	Coding	Unit
Actual	pltres2	number	mandatory		
Lower limit	pltlo2	number	mandatory		
Upper limit	plthi2	number	mandatory		
Unit	pltu2	single choice	mandatory	1 = µl 4 = K/cu mm 5 = L 10 = 10E3/µl 11 = 10E9/l 88 = other	
Row: Prothrombin Time (PT)					
Actual	ptres2	number	mandatory		
Lower limit	ptlo2	number	mandatory		
Upper limit	pthi2	number	mandatory		
Unit	ptu2	single choice	mandatory	9 = seconds 88 = other	
Row: Activated Partial Thromboplastin time (APTT)					
Actual	apttres2	number	mandatory		
Lower limit	apttlo2	number	mandatory		

Label	Variable	Type	Settings	Coding	Unit
Upper limit	aptthi2	number	mandatory		
Unit	apttu2	single choice	mandatory	9 = seconds 88 = other	
Row: CRP					
Actual	crpres2	number	mandatory		
Lower limit	crplo2	number	mandatory		
Upper limit	crphi2	number	mandatory		
Unit	crpu2	single choice	mandatory	6 = mg/dl 7 = mg/l 8 = nmol/l 88 = other	
Group: *(→ lbsmpl2_1)*					
Safety lab result	lbres2	single choice	readonly	1 = passed 2 = failed	

4.5 Checklist (Visit Checklist)

Label	Variable	Type	Settings	Coding	Unit
Module: Have the following forms been completed for this visit? vcheck5 0.0					
Comorbid	vc2	boolean	mandatory	1 = yes	

Label	Variable	Type	Settings	Coding	Unit
				0 = no	
Pharmacotherapy	vc3	boolean	mandatory	1 = yes 0 = no	
Nutritional Supplements	vc4	boolean	mandatory	1 = yes 0 = no	
Non-Pharmacotherapy	vc5	boolean	mandatory	1 = yes 0 = no	
Module: varitems18 0.0					
Group: Weight at last Enroll-HD visit					
Weight	weight_enr	number	readonly		kg
	weightenr_2	number	readonly		lbs
Is there a weight difference of ±3 kg or 6.5 lbs since the last Enroll-HD visit	weightupd	boolean	mandatory	1 = yes → 0 = no	
Group: *(→ weightupd_1)*					
Weight	weight	number			kg
	weight_2	number			lbs

4.6 Motor (UHDRS®'99 Motor/Diagnostic Confidence)

Label	Variable	Type	Settings	Coding	Unit
Module: Motor Assessment motor2 0.0					
Group: General					
Module: motor1 1.0					
Assessment date	qsdtc	date	mandatory		
Module: motor4 0.0					
Rater code	raterid	number	mandatory		
Motor score (TMS)	motscore	number	readonly		
Motor score (TMS) incomplete	miscore	number	readonly		
Group: Motor Assessment					
Table: Ocular pursuit					
Column: Horizontal					
Horizontal	ocularh	single choice	mandatory	0 = complete (normal) 1 = jerky movement 2 = interrupted pursuits/full range 3 = incomplete range 4 = cannot pursue	

Label	Variable	Type	Settings	Coding	Unit
Column: Vertical					
Vertical	ocularv	single choice	mandatory	0 = complete (normal) 1 = jerky movement 2 = interrupted pursuits/full range 3 = incomplete range 4 = cannot pursue	
Table: Saccade initiation					
Column: Horizontal					
Horizontal	sacinith	single choice	mandatory	0 = normal 1 = increased latency only 2 = suppressible blinks or head movements to initiate 3 = unsuppressible head movements 4 = cannot initiate saccades	
Column: Vertical					
Vertical	sacinitv	single choice	mandatory	0 = normal 1 = increased latency only 2 = suppressible blinks or head movements to initiate 3 = unsuppressible head movements 4 = cannot initiate saccades	
Table: Saccade velocity					

Label	Variable	Type	Settings	Coding	Unit
Column: Horizontal					
Horizontal	sacvelh	single choice	mandatory	0 = normal 1 = mild slowing 2 = moderate slowing 3 = severely slow, full range 4 = incomplete range	
Column: Vertical					
Vertical	sacvelv	single choice	mandatory	0 = normal 1 = mild slowing 2 = moderate slowing 3 = severely slow, full range 4 = incomplete range	
Dysarthria	dysarth	single choice	mandatory	0 = normal 1 = unclear, no need to repeat 2 = must repeat to be understood 3 = mostly incomprehensible 4 = anarthria	
Tongue protrusion	tongue	single choice	mandatory	0 = can hold tongue fully protruded for 10 sec 1 = cannot keep fully protruded for 10 sec 2 = cannot keep fully protruded for 5 sec 3 = cannot fully protrude tongue 4 = cannot protrude tongue beyond lips	

Label	Variable	Type	Settings	Coding	Unit
Table: Finger taps					
Column: Right					
Right	fingtapr	single choice	mandatory	0 = normal (≥15/5 sec.) 1 = mild slowing, reduction in amplitude (11-14/5 sec.) 2 = moderately impaired (7-10/5 sec.) 3 = severely impaired (3-6/5 sec.) 4 = can barely perform task (0-2/5 sec.)	
Column: Left					
Left	fingtapl	single choice	mandatory	0 = normal (≥15/5 sec.) 1 = mild slowing, reduction in amplitude (11-14/5 sec.) 2 = moderately impaired (7-10/5 sec.) 3 = severely impaired (3-6/5 sec.) 4 = can barely perform task (0-2/5 sec.)	
Table: Pronate/supinate-hands					
Column: Right					
Right	prosupr	single choice	mandatory	0 = normal 1 = mild slowing and/or irregular 2 = moderate slowing and irregular 3 = severe slowing and irregular 4 = cannot perform	

Label	Variable	Type	Settings	Coding	Unit
Column: Left					
Left	prosupl	single choice	mandatory	0 = normal 1 = mild slowing and/or irregular 2 = moderate slowing and irregular 3 = severe slowing and irregular 4 = cannot perform	
Luria	luria	single choice	mandatory	0 = ≥4 in 10 sec, no cue 1 = <4 in 10 sec, no cue 2 = ≥4 in 10 sec with cues 3 = <4 in 10 sec with cues 4 = cannot perform	
Table: Rigidity-arms					
Column: Right					
Right	rigarmr	single choice	mandatory	0 = absent 1 = slight or present only with activation 2 = mild to moderate 3 = severe, full range of motion 4 = severe with limited range	
Column: Left					
Left	rigarml	single choice	mandatory	0 = absent 1 = slight or present only with activation 2 = mild to moderate	

Label	Variable	Type	Settings	Coding	Unit
				3 = severe, full range of motion 4 = severe with limited range	
Bradykinesia-body	brady	single choice	mandatory	0 = normal 1 = minimally slow (?normal) 2 = mildly but clearly slow 3 = moderately slow, some hesitation 4 = markedly slow, long delays in initiation	
Table: Maximal dystonia					
Column: Trunk					
Trunk	dysttrnk	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: RUE					
RUE	dystrue	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	

Label	Variable	Type	Settings	Coding	Unit
Column: LUE					
LUE	dystlue	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: RLE					
RLE	dystrle	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: LLE					
LLE	dystlle	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Table: Maximal chorea					

Label	Variable	Type	Settings	Coding	Unit
Column: Face					
Face	chorface	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: BOL					
BOL	chorbol	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: Trunk					
Trunk	chortrnk	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: RUE					

Label	Variable	Type	Settings	Coding	Unit
RUE	chorrue	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: LUE					
LUE	chorlue	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: RLE					
RLE	chorrle	single choice	mandatory	0 = absent 1 = slight/intermittent 2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Column: LLE					
LLE	chorlle	single choice	mandatory	0 = absent 1 = slight/intermittent	

Label	Variable	Type	Settings	Coding	Unit
				2 = mild/common or moderate/intermittent 3 = moderate/common 4 = marked/prolonged	
Gait	gait	single choice	mandatory	0 = normal gait, narrow base 1 = wide base and/or slow 2 = wide base and walks with difficulty 3 = walks only with assistance 4 = cannot attempt	
Tandem walking	tandem	single choice	mandatory	0 = normal for 10 steps 1 = 1 to 3 deviations from straight line 2 = >3 deviations 3 = cannot complete 4 = cannot attempt	
Retropulsion pull test	retropls	single choice	mandatory	0 = normal 1 = recovers spontaneously 2 = would fall if not caught 3 = tends to fall spontaneously 4 = cannot stand	
	maxdychorea	button	passive		
	maxdyscheck	button	passive		
Module: Diagnostic Confidence motor3 1.0					

Label	Variable	Type	Settings	Coding	Unit
Diagnostic confidence level (DCL)	diagconf	single choice	mandatory	0 = normal (no abnormalities) 1 = non-specific motor abnormalities (less than 50 % confidence) 2 = motor abnormalities that may be signs of HD (50 - 89 % confidence) 3 = motor abnormalities that are likely signs of HD (90 - 98 % confidence) 4 = motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence)	
Group: *(→ diagconf_x)*					
Reason for discrepancy between DCL/Total Motor Score	dclrfi	text			

4.7 CSF (CSF Collection and Processing)

Label	Variable	Type	Settings	Coding	Unit
Module: Vital Signs varitems19 0.0					
Vital signs satisfactory	secsf3	boolean	mandatory	1 = yes 0 = no	
Module: clrlab1 0.0					
Group: CSF Collection					
LAB-ID	labid	text	passive		

Label	Variable	Type	Settings	Coding	Unit
Kit ID	kitid	text	mandatory		
Date and time CSF collection procedure is started	csfpdtc	datetime	mandatory		
Total volume of CSF obtained	lblpvol	number	mandatory		ml
Total volume of usable CSF obtained	lblpvolu	number	mandatory		ml
Is this a partial sampling visit? *(→ lblpvolu_0)*	csfpartial	boolean	mandatory	1 = yes → 0 = no	
Time CSF collection procedure is completed	lblpetim	time	mandatory		
Number of LP attempts	lblpcnt	single choice	mandatory	1 = 1 *(lp1 →)* 2 = 2 *(lp1 lp2 →)* 3 = 3 *(lp1 lp2 lp3 →)*	
Group: LP Attempt #1 *(→ lp1)*					
Investigator ID	invid1	number	mandatory		
Lumbar space used for lumbar puncture (LP)	lpsp1	single choice	mandatory	1 = L4/5 space 2 = L3/4 space 3 = other →	
Group: *(→ lpsp1_3)*					
Please enter used lumbar space	lpsp1spc	text	mandatory		
Group: Initial participant posture					

Label	Variable	Type	Settings	Coding	Unit
Lateral decubitus	ipp1ld	boolean	mandatory	1 = yes 0 = no	
Upright	ipp1up	boolean	mandatory	1 = yes *(ipp1up_yes →)* 0 = no	
Group: *(→ ipp1up_yes)*					
Was patient transferred to lateral decubitus position before CSF collection	ipp1upt	boolean	mandatory	1 = yes 0 = no	
Local anaesthesia (2% lidocaine) used	lplca1	boolean	mandatory	1 = yes *(lplca1_yes →)* 0 = no *(lplca1_no →)*	
Group: *(→ lplca1_yes)*					
Volume of lidocaine used	lplca1v	number	mandatory		ml
Group: *(→ lplca1_no)*					
Why lidocaine was not used	lplca1r	single choice	mandatory	1 = Allergy 2 = Other Contraindications 3 = Patient Request 4 = Investigator Preference 5 = Other	
Number of needle passes to obtain CSF	lpnnp1	single choice	mandatory	1 = 1 2 = 2 3 = 3 4 = 4 5 = 5	

Label	Variable	Type	Settings	Coding	Unit
Was the first ml of CSF blood contaminated?	lp1bc1	boolean	mandatory	1 = yes *(lp1bc1_yes →)* 0 = no	
Group: *(→ lp1bc1_yes)*					
Was the second ml of CSF blood contaminated?	lp1bc2	boolean	mandatory	1 = yes *(lp1bc2_yes →)* 0 = no	
Group: *(→ lp1bc2_yes)*					
Was the third ml of CSF blood contaminated?	lp1bc3	boolean	mandatory	1 = yes 0 = no	
Group: LP Attempt #2 *(→ lp2)*					
Investigator ID	invid2	number	mandatory		
Lumbar space used for lumbar puncture (LP)	lpsp2	single choice	mandatory	1 = L4/5 space 2 = L3/4 space 3 = other →	
Group: *(→ lpsp2_3)*					
Please enter used lumbar space	lpsp2spc	text	mandatory		
Group: Initial participant posture					
Lateral decubitus	ipp2ld	boolean	mandatory	1 = yes 0 = no	
Upright	ipp2up	boolean	mandatory	1 = yes *(ipp2up_yes →)* 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Group: *(→ ipp2up_yes)*					
Was patient transferred to lateral decubitus position before CSF collection	ipp2upt	boolean	mandatory	1 = yes 0 = no	
Local anaesthesia (2% lidocaine) used	lplca2	boolean	mandatory	1 = yes *(lplca2_yes →)* 0 = no *(lplca2_no →)*	
Group: *(→ lplca2_yes)*					
Volume of lidocaine used	lplca2v	number	mandatory		ml
Group: *(→ lplca2_no)*					
Why lidocaine was not used	lplca2r	single choice	mandatory	1 = Allergy 2 = Other Contraindications 3 = Patient Request 4 = Investigator Preference 5 = Other	
Number of needle passes to obtain CSF	lpnnp2	single choice	mandatory	1 = 1 2 = 2 3 = 3 4 = 4 5 = 5	
Was the first ml of CSF blood contaminated?	lp2bc1	boolean	mandatory	1 = yes *(lp2bc1_yes →)* 0 = no	
Group: *(→ lp2bc1_yes)*					

Label	Variable	Type	Settings	Coding	Unit
Was the second ml of CSF blood contaminated?	lp2bc2	boolean	mandatory	1 = yes *(lp2bc2_yes →)* 0 = no	
Group: *(→ lp2bc2_yes)*					
Was the third ml of CSF blood contaminated?	lp2bc3	boolean	mandatory	1 = yes 0 = no	
Group: LP Attempt #3 *(→ lp3)*					
Investigator ID	invid3	number	mandatory		
Lumbar space used for lumbar puncture (LP)	lpsp3	single choice	mandatory	1 = L4/5 space 2 = L3/4 space 3 = other →	
Group: *(→ lpsp3_3)*					
Please enter used lumbar space	lpsp3spc	text	mandatory		
Group: Initial participant posture					
Lateral decubitus	ipp3ld	boolean	mandatory	1 = yes 0 = no	
Upright	ipp3up	boolean	mandatory	1 = yes *(ipp3up_yes →)* 0 = no	
Group: *(→ ipp3up_yes)*					
Was patient transferred to lateral decubitus position before CSF collection	ipp3upt	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Local anaesthesia (2% lidocaine) used	lplca3	boolean	mandatory	1 = yes *(lplca3_yes →)* 0 = no *(lplca3_no →)*	
Group: *(→ lplca3_yes)*					
Volume of lidocaine used	lplca3v	number	mandatory		ml
Group: *(→ lplca3_no)*					
Why lidocaine was not used	lplca3r	single choice	mandatory	1 = Allergy 2 = Other Contraindications 3 = Patient Request 4 = Investigator Preference 5 = Other	
Number of needle passes to obtain CSF	lpnnp3	single choice	mandatory	1 = 1 2 = 2 3 = 3 4 = 4 5 = 5	
Was the first ml of CSF blood contaminated?	lp3bc1	boolean	mandatory	1 = yes *(lp3bc1_yes →)* 0 = no	
Group: *(→ lp3bc1_yes)*					
Was the second ml of CSF blood contaminated?	lp3bc2	boolean	mandatory	1 = yes *(lp3bc2_yes →)* 0 = no	
Group: *(→ lp3bc2_yes)*					

Label	Variable	Type	Settings	Coding	Unit
Was the third ml of CSF blood contaminated?	lp3bc3	boolean	mandatory	1 = yes 0 = no	
Group: CSF Processing *(→ csfpartial_1)*					
Time CSF processing is started	csfstim	time	mandatory		
Time CSF processing is completed	csfctim	time	mandatory		
CSF Tube Rack ID	csfrkid	text	mandatory		
Group: CSF aliquot					
Tube ID	csfaid	text	mandatory		
Quantity	csfaqty	number	mandatory		
Group: Cells from CSF					
Tube ID	csfcid	text	mandatory		
Quantity	csfcqty	number	mandatory		
Module: clrlab6 0.0					
Comments/Notable deviations for CSF collection/processing	csfcmt	text			

4.8 CSF Quality (CSF Quality)

Label	Variable	Type	Settings	Coding	Unit
Module: clrlab2 0.0					
Group: Onsite CSF Sample Quality control					
Group: Microscopic erythrocyte count in CSF in triplicate					
1. Count	erycnt1	number	mandatory		erys/µl
2. Count	erycnt2	number	mandatory		erys/µl
3. Count	erycnt3	number	mandatory		erys/µl
Flag	eryflag	boolean	readonly	1 = yes 0 = no	
Group: Microscopic leukocyte count in CSF in triplicate					
1. Count	leukcnt1	number	mandatory		cells/µl
2. Count	leukcnt2	number	mandatory		cells/µl
3. Count	leukcnt3	number	mandatory		cells/µl
Flag	leukflag	boolean	readonly	1 = yes 0 = no	

4.9 Blood Processing (Blood Processing)

Label	Variable	Type	Settings	Coding	Unit
Module: clrlab3 1.0					
Group: General					
LAB-ID	labid	text	passive		
Kit ID	kitid	text	mandatory		
When did the participant last eat or drink anything (except water)?	fastdtc	datetime	mandatory		
Date and time of blood draw	lbdtc	datetime	mandatory		
Group: Lithium Heparin Collection Tube					
Tube ID	lhtid	text	mandatory		
Quantity	lhqty	number	mandatory		
Group: Serum Collection Tube					
Tube ID	sstid	text	mandatory		
Quantity	sstqty	number	mandatory		
Group: Blood Processing					
Group: Serum					

Label	Variable	Type	Settings	Coding	Unit
Tube ID	sertid	text	mandatory		
Quantity of aliquots	seraqty	number	mandatory		
Tube rack ID	sertrid	text	mandatory		
Time serum processing is started	serstim	time	mandatory		
Time serum processing is completed	serctim	time	mandatory		
Group: Plasma					
Total volume (ml) of plasma transferred to 50 ml tube	plsmtotvol	number	mandatory		ml
Tube ID	plsmtid	text	mandatory		
Quantity of aliquots	plsmaqty	number	mandatory		
Tube rack ID	plsmtrid	text	mandatory		
Time plasma processing is started	plsmstim	time	mandatory		
Time plasma processing is completed	plsmctim	time	mandatory		
Module: clrlab7 0.0					
Comments/Notable deviations for blood collection/processing	plsmcmt	text			
Group: On site Sample Storage					

Label	Variable	Type	Settings	Coding	Unit
Date and time CSF samples are stored on site	cstrgdtc	datetime	mandatory		
Date and time blood-derived samples are stored on site	bstrgdtc	datetime	mandatory		

4.10 Phone Contact (Phone Contact (Sampling))

Label	Variable	Type	Settings	Coding	Unit
Module: Phone Contact pc1 0.0					
Did the participant receive phone contact from the site after the sampling visit?	pc1	boolean	mandatory	1 = yes → 0 = no →	
Group: *(→ pc1_1)*					
Date of contact	pc11	date	readonly passive		
Time of contact	pc12	time	mandatory		
Group: *(→ pc1_0)*					
Reason	pc10	single choice	mandatory	1 = unable to contact participant after multiple attempts 2 = participant withdrew consent to be contacted 3 = contact was not attempted	
Were there any adverse events?	pc2	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Module: Repeat Sampling Visit pc2 0.0 *(→ cycle0rpt_1)*					
Is this participant interested in attending a repeat sampling visit? *(→ csfpartial_0)*	pc3	boolean	mandatory	1 = yes 0 = no	

4.11 AE Log (Adverse Event Log)

Label	Variable	Type	Settings	Coding	Unit
Module: ae1 0.0					
Group: General Information					
Has the participant had any Adverse Events during this study	aeyn	boolean	mandatory	1 = yes → 0 = no	
Table: Details *(→ aeyn_1)*					
Dynamic Row, infinite times:					
Date of report	aedat	date	mandatory		
AE verbatim term	aeterm	text	mandatory	MedDRA-2015	
Start date	aestdat	date	mandatory		
Ongoing?	aeongo	boolean		1 = yes 0 = no	
End date *(→ aeongo_0)*	aeendat	date	mandatory		

Label	Variable	Type	Settings	Coding	Unit
Severity	aesev	single choice	mandatory	1 = mild 2 = moderate 3 = severe 4 = life-threatening 5 = death	
Relationship to study procedure	aerel	single choice	mandatory	1 = probably related *(aerel_x →)* 2 = possibly related *(aerel_x →)* 3 = unrelated	
Which study procedure *(→ aerel_x)*	aerelnst	single choice	mandatory	1 = lumbar puncture (low pressure syndrome) 2 = lumbar puncture (other complication) 4 = blood collection 5 = semen collection 3 = other study procedure	
Outcome	aeout	single choice	mandatory	1 = resolved; no sequelae 2 = ongoing; no treatment 3 = ongoing; undergoing treatment 4 = residual effects present; no treatment 5 = residual effects present; undergoing treatment 6 = death 7 = unknown 8 = stabilised	

Label	Variable	Type	Settings	Coding	Unit
Expected	aeexp	boolean	mandatory	1 = yes 0 = no	
SAE	aeser	boolean	mandatory	1 = yes 0 = no	

4.12 SAE (Serious Adverse Event)

Label	Variable	Type	Settings	Coding	Unit
Module: sae1 0.0					
Group: General					
Date of serious adverse event report	aedat	date	mandatory		
Group: Serious Adverse Event					
Report:					
AE number	aenum	number	mandatory		
Start date of serious adverse event	aestdat	date	mandatory		
Is the serious adverse event ongoing	aeongo	boolean	mandatory	1 = yes 0 = no →	
Group: *(→ aeongo_0)*					
Stop date of serious adverse event	aeendat	date	mandatory		

Label	Variable	Type	Settings	Coding	Unit
Was this an expected serious adverse event	aeexp	boolean	mandatory	1 = yes 0 = no	
Group: Brief description of participant					
Sex	sex	single choice	mandatory readonly	f = female m = male	
Age	age	number	mandatory readonly		
SAE verbatim term	aeterm	text		MedDRA-2015	
Brief description of the nature of the serious adverse event	aetermbd	text	mandatory		
Group: Category (outcome) of the serious adverse event					
Death	aesdth	boolean	mandatory	1 = yes 0 = no	
Disability/incapacity	aesdisab	boolean	mandatory	1 = yes 0 = no	
Life-threatening	aeslife	boolean	mandatory	1 = yes 0 = no	
Congenital anomaly/birth defect	aescong	boolean	mandatory	1 = yes 0 = no	
Hospitalization-initial or prolonged	aeshosp	boolean	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
Required intervention to prevent permanent impairment	aesinter	boolean	mandatory	1 = yes 0 = no	
None of the above	aesnone	boolean	mandatory	1 = yes 0 = no	
Outcome	aeout	single choice	mandatory	1 = resolved; no sequelae 2 = ongoing; no treatment 3 = ongoing; undergoing treatment 4 = residual effects present; no treatment 5 = residual effects present; undergoing treatment 6 = death 7 = unknown	
Describe any medical, behavioral, or other interventions taken as a result of this SAE	aerelnst	text	mandatory		
Group: Status of this report					
Final report	aerver	boolean		1 = yes 0 = no	
Was the participant withdrawn from the research due to this SAE	aedis	boolean	mandatory	1 = yes 0 = no	
Group: SAE Notification					
Date of notification	aenotdat	date	readonly		

4.13 End (Premature End of Study)

Label	Variable	Type	Settings	Coding	Unit
Module: end1 4.0					
Group: General					
Assessment date	dsdtc	date	mandatory readonly passive		
Group: End of Study					
Specify primary reason for participant's premature discontinuation from study	dsterm	single choice	mandatory	1 = event or intercurrent illness of a nature requiring withdrawal 2 = request of primary care physician, site investigator 3 = participant's request (includes carer/spouse/authorized representative's request) → 4 = lost to follow up 5 = institutionalized (will not be followed further) 7 = specific adverse event → 6 = other →	
Group: *(→ dsterm_3)*					
Please specify the reason for the participant's request	dsreas	single choice	mandatory	1 = unable to travel 2 = participant unwilling to continue	

Label	Variable	Type	Settings	Coding	Unit
				3 = participant moved away from the study site	
Group: *(→ dsterm_6)*					
Please specify	termoth	text	mandatory		
Group: *(→ dsterm_7)*					
Report:					
AE number	aenum	number	mandatory		
Did the participant request the removal of data	dsrdt	boolean	mandatory	1 = yes 0 = no	

5 Monitoring Report Forms

5.1 Monitoring SCR (Monitoring Screening Visit)

Label	Variable	Type	Settings	Coding	Unit
Module: mf1 0.0					
Group: Monitoring Form					
Monitoring visit date	mvdtc	date			
Group: Informed Consent					
Table: Participant					
Dynamic Row, infinite times: ICF					
Version No.	icfversion	text			
Dated	icfdtc	date			
Informed consent	mvic	single choice		1 = accurate 2 = not accurate 3 = missing	
Reason	mvic1	single choice		1 = incorrect 2 = incomplete 3 = optional components incorrect	
Group:					

Label	Variable	Type	Settings	Coding	Unit
Comment	mvcmt	text			
Group: Eligibility Check					
Is participant eligible (meets all criteria)	mvec	boolean		1 = yes 0 = no *(mvec_no →)*	
Group: *(→ mvec_no)*					
Was a waiver granted	mvecn	boolean		1 = yes *(mvecn_yes →)* 0 = no	
Group: *(→ mvecn_yes)*					
Is Waiver filed and signed	mvecw	boolean		1 = yes 0 = no	
Table: Visit Forms					
Dynamic Row, infinite times:					
Form	mvform	unknown		1 = Enrollment 4 = Eligibility Check 2 = Safety Lab Exam 3 = Checklist	
State	mvfstate	single choice		1 = accurate 2 = not accurate	
Comment	mvfcmt	text			

5.2 Monitoring SPL (Monitoring Sampling Visit)

Label	Variable	Type	Settings	Coding	Unit
Module: mf2 0.0					
Group: Monitoring Form					
Monitoring visit date	mvdtc	date			
Group: Eligibility Check					
Is participant eligible (meets all criteria)	mvec	boolean		1 = yes 0 = no *(mvec_no →)*	
Group: *(→ mvec_no)*					
Was a waiver granted	mvecn	boolean		1 = yes *(mvecn_yes →)* 0 = no	
Group: *(→ mvecn_yes)*					
Is Waiver filed and signed	mvecw	boolean		1 = yes 0 = no	
Comment	mvcmt	text			
Table: Visit Forms					
Dynamic Row, infinite times:					
Form	mvform	unknown		4 = Eligibility Check 3 = Checklist 5 = Motor	

Label	Variable	Type	Settings	Coding	Unit
				6 = CSF 7 = CSF Quality 8 = Blood Processing	
State	mvfstate	single choice		1 = accurate 2 = not accurate	
Comment	mvfcmt	text			

5.3 Monitoring (S)AE (Monitoring Serious and Adverse Events)

Label	Variable	Type	Settings	Coding	Unit
Module: mf3 0.0					
Group: Monitoring Form					
Monitoring visit date	mvdtc	date			
Is the AE log complete, up to date and accurate	mvaecmp	boolean		1 = yes 0 = no	
Were all AEs reported within 24hrs	mvaerep	boolean		1 = yes 0 = no	
Are any AEs classified as SAEs	mvsae	boolean		1 = yes 0 = no	
Comment	mvcmt	text			

6 Monitoring Event Forms

6.1 Monitoring Event (Monitoring Event Form)

Label	Variable	Type	Settings	Coding	Unit
Module: mv9 0.0					
Group: Monitoring Event					
PI name	me_pi	text	mandatory		
Date reported	me_dtc	date	mandatory		
Type	me_type	single choice	mandatory	1 = PV → 2 = issue →	
Group: Issues *(→ me_type_2)*					
Issues	me_issues	unknown	mandatory	bs = Biosamples sp = Study procedures icf = ICF it = IT Issues sdm = Source Documents Missing ntf = NTF Missing 88 = Other	
Group: Protocol Violations *(→ me_type_1)*					
Category	pv_cat	unknown	mandatory	pv_picf = Informed consent form - participant → pv_safe = Safety *(pv_cat_pv_cicf →)*	

Label	Variable	Type	Settings	Coding	Unit
				pv_dp = Data Protection *(pv_cat_pv_safe →)* pv_ie = Inclusion/Exclusion *(pv_cat_pv_dp →)* pv_bsp = Biosamples *(pv_cat_pv_ie →)* pv_oth = Other *(pv_cat_pv_bsp →)*	
Group: *(→ pv_cat_pv_oth)*					
Please specify	pv_oth	text	mandatory		
Group: *(→ pv_cat_pv_picf)*					
PV Informed consent form - participant	pv_picf	unknown	mandatory	6 = Missing consent form 15 = Missing pages of ICF 7 = Missing core study components box 21 = Signature for participant missing 31 = Incorrectly dated or undated by participant with no supporting documentation of date of consent 4 = Incorrectly dated or undated by participant but supporting documents document correct date 29 = Missing/incomplete printed name by participant and no supporting docs onsite 30 = Missing/incomplete printed name by participant with supporting docs onsite 3 = Incorrectly dated/signed (or missing date/signature) ICF by site personnel	

Label	Variable	Type	Settings	Coding	Unit
				28 = Missing or incomplete printed name by site personnel 5 = Legal Representative printed incorrect name on ICF 32 = Legal Representative missing, incomplete or incorrect date on ICF 33 = Legal Representative signature missing (only if Legal Representative is required) 34 = Legal Representative missing relationship or other specified information 40 = Inappropriate use of legal representative consent (participant able to consent on their own behalf) 35 = Missing statement from independent witness (only if witness is required) 41 = Participant/legal representative date different to date on site personnel signature line 38 = Participant/legal representative/witness failed to sign/date correction to ICF 22 = Site failed to sign/date correction to ICF 39 = Site staff completed checkboxes on behalf of participant 1 = Consent form completed after data collected	

Label	Variable	Type	Settings	Coding	Unit
				20 = Sections of ICF crossed out 24 = Whiteout used 23 = Site specific info missing from consent form 18 = Local ICF procedures not adhered to (e.g. time missing) 19 = Only photocopy of ICF onsite 16 = No copy of ICF given to participant 25 = Wrong person consented 26 = Wrong type of consent used 27 = Wrong version of consent used 2 = HIPAA form missing or not signed 42 = Wrong version of HIPAA used 88 = Other	
Group: *(→ pv_picf_88)*					
Please specify	pv_picf_oth	text	mandatory		
Group: *(→ pv_cat_pv_cicf)*					
PV Informed consent form - caregiver	pv_cicf	unknown	mandatory	k2 = v2	
Group: *(→ pv_cicf_88)*					
Please specify	pv_cicf_oth	text	mandatory		
Group: *(→ pv_cat_pv_safe)*					

Label	Variable	Type	Settings	Coding	Unit
PV Safety	pv_safe	unknown	mandatory	29 = No Reportable Event filled in/submitted within 48 hrs 30 = No Serious Adverse Event form filled in/submitted within 24hrs 31 = Lumbar puncture when safety blood out of range without waiver 88 = Other	
Group: *(→ pv_safe_88)*					
Please specify	pv_safe_oth	text	mandatory		
Group: *(→ pv_cat_pv_dp)*					
PV Data Protection	pv_dp	unknown	mandatory	31 = Vulnerable data stored incorrectly (electronic) 32 = Vulnerable data stored incorrectly (paper) 33 = Specific participant's study data shared outside of study site personnel 34 = Identifying information specific to one participant shared outside of study site personnel 88 = Other	
Group: *(→ pv_dp_88)*					
Please specify	pv_dp_oth	text	mandatory		

Label	Variable	Type	Settings	Coding	Unit
Group: *(→ pv_cat_pv_ie)*					
PV Inclusion/exclusion	pv_ie	unknown	mandatory	33 = Criteria not met for enrollment 88 = Other →	
Group: *(→ pv_ie_88)*					
Please specify	pv_ie_oth	text	mandatory		
Group: *(→ pv_cat_pv_bsp)*					
PV Biosamples	pv_bsp	unknown	mandatory	2 = CSF volume out of range (>25mls) 3 = Samples not stored in accordance with protocol and unusable 4 = Blood volume out of range 88 = Other	
Group: *(→ pv_bsp_88)*					
Please specify	pv_bsp_oth	text	mandatory		
All data to be quarantined	pv_dq	boolean	mandatory	1 = yes 0 = no	
Biosamples affected	pv_bs	boolean	mandatory	1 = yes *(bs_dq_1 →)* 0 = no	
Group: *(→ bs_dq_1 pv_x)*					
Sample quarantine request submitted	bs_dq	single choice	mandatory	1 = yes 0 = no	

Label	Variable	Type	Settings	Coding	Unit
				2 = no samples available	
Group: Monitoring Event					
Description	me_desc	text	mandatory		
Action taken/to be taken	me_act	text	mandatory		
Note to file available	me_ntf	single choice	mandatory	1 = yes 0 = no 2 = n/a	
Status	me_stat	single choice	mandatory	1 = open 2 = resolved →	
Group: *(→ me_stat_2)*					
Resolution date	me_rdtc	date	mandatory		
Resolution notes	me_rnote	text	mandatory		
Group: *(→ me_stat_x)*					
Sample quarantine release	qrel	boolean		1 = yes 0 = no	

References

[1]	CHDI Foundation Inc., *HDClarity 4.0 Data Management Requirements*, CLR4-REQ-0001-EN, Version 1.0, 19-Nov-2021
[2]	CHDI Foundation Inc., *HDClarity 4.0 CRF Requirements*, CLR4-REQ-0002-EN, Version 1.0, 19-Nov-2021
[3]	CHDI Foundation Inc., *HDClarity 4.0 Annotated CRF*, CLR4-DOC-0001-EN, Version 1.0, 23-Nov-2021

Approval

Document Title	HDClarity 4.0 Data Dictionary		
Document ID	CLR4-SPC-0001-EN-1.0		
Document Type	Specification		
Status	Final		
Version	1.0	**Release Date**	11-Nov-2021
Replaces Version	---		
Valid from	Approval		
Owner	CHDI Foundation, Inc.		

	Name	**Date**	**Signature**
Author	Gunter Antoneag	21-Oct-2021	
Review	Torsten Illmann	09-Nov-2021	
Approval	Nicole Piller	11-Nov-2021	

Revision Index

Date	Version	Chapter	Summary of Change(s) and if applicable Reason for Change(s)
11-Nov-2021	1.0	---	Initial Version