DATA DICTIONARY

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1   Overview

This Data Dictionary is designed to accompany HDClarity dataset releases, including periodic datasets (PDS) and specified datasets (SPS).

This document denotes each variable, including variable data availability in different types of dataset releases.

The HDClarity visit plan is also provided, as well as a brief overview of dataset structure, variable structure, representation of special values, and HD category classification. We strongly encourage data users to thoroughly read the accompanying data support documentation for detailed descriptions of dataset structure, data quality control procedures and participant identification risk management, and coding systems.

2 Visit Plan

Forms are organized by visit type, that is, Enroll-HD (Baseline/BL orFollow Up/FUP), HDClarity Screening (Screening/SCR), HDClarity Sampling (Sampling/BS), HDClarity Phone Contact, HDClarity Repeat Sampling (RPT Sampling/BS2), HDClarity Repeat Phone Contact, HDClarity Events, and HDClarity Premature End.

Participants may enroll in HDClarity multiples times (allowing a minimum of 11 months between HDClarity Screening Visits*), but within each enrollment the cycle of visits and assessments are the same and are shown in the table below. If participants enroll into HDClarity more than 2 months after their last Enroll-HD visit (BL/FUP), then the Enroll-HD assessment forms Variable, Motor, TFC, Function, Cognitive, and PBA-s must be carried out at the HDClarity screening visit (indicated by check marks in parentheses in Table); in other instances these data are leveraged from the Enroll-HD visit to minimize participant burden

Only data collected at the Enroll-HD (Baseline/BL; Follow Up/FUP), HDClarity screening (Screening/SCR), HDClarity sampling (Sampling/BS) and HDClarity Repeat Sampling (RPT Sampling/BS2) visits are included in the HDClarity periodic dataset.

Form Name	Enroll-HD (BL/FUP)	HDClarity Screening	HDClarity Sampling	HDClarity Phone Contact	HDClarity Repeat Sampling	HDClarity Repeat Sampling Phone Contact	HDClarity Events	HDClarity End
Demog	✓							
CAG	✓							
Comorbid[1]	✓	✓	✓		✓			
PharmacoTx[1]	✓	✓	✓		✓			

Non-PharmacoTx[1]	✓	✓	✓		✓			
NutSuppl[1]	✓	✓	✓		✓			
Mortality	✓							
Enrollment CLR		✓						
Eligibility Check (1)			✓					
Eligibility Check (2)					✓			
Checklist		✓						
Checklist SMP			✓		✓			
Safety Lab Exam		✓						

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

Repeated enrollments are shown by a numerical suffix (#1, #2, #3 etc.) at the end of the recoded HDID. [1]These are log forms which are updated on a continuous basis at each visit.

3 Entity Relation Diagram

The HDClarity PDS entity relation diagram (Figure 1) provides an overview of the constituent data files, and their relationship, in this dataset. Key variables ("primary keys (PK)" and "foreign keys (FK)") are required to combine the data files. Primary keys are the set of attributes that uniquely identify a data record. Foreign keys are a set of attributes within a data record that clearly correspond to another dataset, the primary key of the other dataset. This way, a relationship between two data records is defined.

Further information on dataset structure is provided in the accompanying document "*Understanding Dataset Structure*", which we encourage all data users to review.
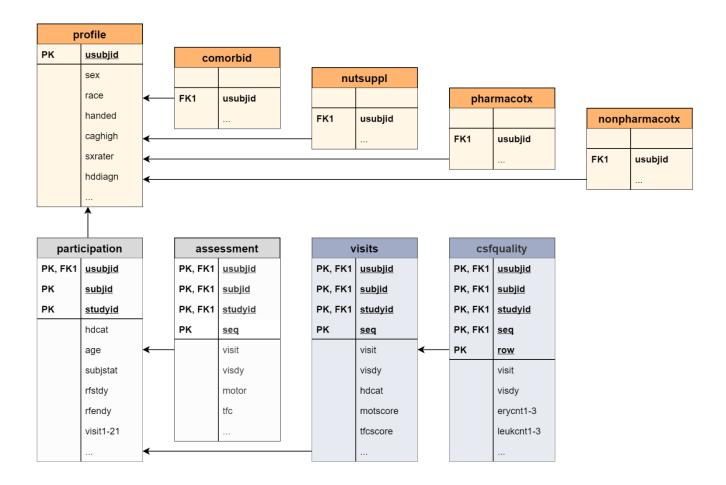

Figure 1. HDClarity PDS entity relationship diagram.

4   Structure of Variables

Each HDClarity data file contains variables. This Data Dictionary lists all variables by form, alongside several attributes (see Table 1).

Table 1. Data dictionary column fields.

Attribute	Description
Label	Description of variable
Domain	Variable domain abbreviation (CDISC SDTM compliant). Refer to Table 2 for definitions.
Category	Category (optional)
Variable	Internal variable name. Variable is defined in CDISC SDTM compliant naming convention or as close as possible.
Data Type	*Boolean:* Represents the values 1 (yes) and 0 (no). *Number:* Represents integer or floating-point data values. *Text:* Represents alphanumeric string data values. *Date:* The date type is represented as the number of days relative to the date of the participant's very first HDClarity screening visit date. Note that dates that have been specified in the original data as "incomplete" (e.g. without entry of a day) have been automatically completed by the following rule: use "15" as day if day is missing and use "1" as day and "7" as month if day and month is missing. After this completion, the number of days relating to the very first HDClarity screening visit date is calculated and provided in the data. The information about whether a date has been automatically completed is not included in the PDS but can be obtained via SPS request. *Single choice:* Variable with assigned coding list where one item can be selected. The value within an export is taken from the underlying coding list which is defined as a parameter in the data dictionary tables.
Parameter	Parameter value of coded variables (optional).
Coding	Internal parameter value of coded variables (optional).
Unit	Unit of input field (optional).
Transformation	One important objective of the periodic dataset is to de-identify the HDClarity data in order to minimize the possibility to identify a participant. Therefore, some variables are transformed, recoded or outliers removed/cut. These transformations are described on a variable to variable basis. Details on variable transformations or calculations are also provided here.
Availability	All variables in the HDClarity dataset are listed in the Data Dictionary. This column allows the researcher to identify which variables are available in the PDS ("PDS"), which are available via special request ("available upon Scientific Review Committee approval"), and which are restricted ("not available").

Table 2: Variable domain definitions.

Domain Abbreviation	Domain	Description of the domain
AE	Adverse Events	An event domain that contains data describing untoward medical occurrences in a participant which may not necessarily have a causal relationship with the study.
CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.
CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.
DM	Demographics	A special-purpose domain that includes a set of essential standard variables that describe each subject in the study.
DS	Disposition	An events domain that contains information encompassing and representing data related to subject disposition.
IE	Inclusion/Exclusion Criteria	A findings domain that contains those criteria that cause the subject to be in violation of the inclusion/exclusion criteria.
LB	Laboratory Test Results	A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.
MH	Medical History	An events domain that contains data that includes the subject's prior medical history at the start of the study
QS	Questionnaires	A findings domain that contains data for named, stand-alone instruments designed to provide an assessment of a concept. Questionnaires have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and have documented methods for administration and analysis.
SAE	Serious adverse event	An event domain that contains data describing serious untoward medical occurrences in a participant which may not necessarily have a causal relationship with the study.
SC	Subject Characteristics	A findings domain that contains subject-related data not collected in other domains.
SUPPAE	Supplemental Qualifiers for Adverse Events	A dataset used to represent non-standard variables and their association to parent records in the Adverse Events domain.
SUPPCM	Supplemental Qualifiers for Concomitant/Prior Medications	A dataset used to represent non-standard variables and their association to parent records in the Concomitant/Prior Medications domain.
SUPPLB	Supplemental Qualifiers for Laboratory Test Results	A dataset used to represent non-standard variables and their association to parent records in the Laboratory Test Results domain.
SUPPMH	Supplemental Qualifiers for Medical History	A dataset used to represent non-standard variables and their association to parent records in the Medical History domain.

SUPPQS	Supplemental Qualifiers for Questionnaires	A dataset used to represent non-standard variables and their association to parent records in the Questionnaires domain.
SUPPSC	Supplemental Qualifiers for Subject Characteristics	A dataset used to represent non-standard variables and their association to parent records in the Subject Characteristics domain.
SUPPVS	Supplemental Qualifiers for Vital Signs	A dataset used to represent non-standard variables and their association to parent records in the Vital Signs domain.
SV	Subject Visits	A special-purpose domain that contains the actual start and end data/time for each visit of each individual subject.
VS	Vital Signs	A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index, height and weight.

5   Representation of Special Values

Date Values

Transformation of date values

To minimize participant identification risk, the HD Clarity PDS does not contain date values. Date values referring to visit dates are transformed to a numeric value, reflective of the number of days since the **first HDClarity screening visit** and the date of interest. Date values that refer to date of birth or symptom onset are transformed into age values.

Further information is provided in the accompanying "*Understanding Dataset Structure*" document.

Imputation of date values/Autocompletion

Incomplete date values were **imputed** according to the following rules:

Day is missing: YYYY-MM-*DD* (missing): YYYY-MM-15

Month and day are missing: YYYY-*MM* (missing)-*DD* (missing): YYYY-07-01

Note that because of these imputation rules, events with clear temporal definition sometimes appear **out of sequence** or have the **same date** values. For example, end dates may appear prior to, or on the same day as, start dates for comorbidities and pharmacotherapies.

Missing Values

There are two overarching categories of missing data in the dataset: **system-defined** missing data (indicated by blank variable 'entries'), and **user-defined** missing data (indicated by specific codes, which indicate reason why they are missing).

System defined missing data occurs where the electronic data capture (EDC) system dictates a missing variable field. These missing data values are indicated by **blank entries** in the dataset, this can be observed for variables indicating symptom onset as well as variables such as weight or height.

User defined missing data occur where a mandatory variable field, as determined by the EDC system, is **not completed**, or where the value entered into the EDC is **incorrect**. In these instances, data entry users are prompted to indicate why the value is missing, or why the value entered is not correct. These user-defined labels - 'exceptional values' – are listed below. Each is represented in the dataset by a **specific code**:

- **Unknown** (entered by the site, only available for specific fields): 9999 (numeric); UNKNOWN (text)

  Refers to mandatory values which are **occasionally unknown**. This exceptional value code may be selected as a response to the question, "Is/was your Mother affected by HD? (response: yes/no/unknown)", where a participant did not know their mother.

- **Missing** (value expected, but not entered): 9998 (numeric); MISSING (text); 9998-09-09 (date)

  Refers to mandatory values which could not be completed because **data collection was not performed**. This code may be used if a participant refuses to provide a response, if the collection of data was accidentally omitted, or if a value could not be obtained because required instrumentation was not available.

- **Not applicable** (value expected, but not entered): 9997 (numeric); NOTAPPL (text); 9997-09-09 (date)

  Refers to mandatory values which could not be completed because they **do not apply to the participant due to certain circumstances or characteristics**. For example, the question "Age at onset of symptoms in mother" for the mother who is still premanifest and does not have symptoms yet shall be answered as not applicable. The variable value is **purposefully** not entered. **Note the distinction between this value and system-defined missing values is that the** *user*, **as opposed to the EDC** *system*, **marks them as non-applicable**.

- **Wrong** (value was entered, but declared as wrong by the site. Entered value excluded from dataset): 9996 (numeric); WRONG (text); 9996-09-09 (date)

   Refers to mandatory values which are entered into the EDC and then identified **to be wrong or highly questionable**. This may be because data were collected by the wrong person (e.g., assessment performed by untrained site member), faulty instrumentation (e.g., uncalibrated weighing scales), etc. Although these data are not technically missing, they are recoded as wrong using the codes indicated above for PDS releases.

Artificial Values for Aggregated Data

To minimize participant identification risk, **data aggregation techniques** are applied to specific variables for PDS releases. These variables, and the criteria/thresholds used for aggregation in PDS releases, are described in Table 3. Where values fall outside of aggregation thresholds, they are ubiquitously replaced by one artificial value (e.g., ">28")

Note that aggregation **thresholds differ between PDS releases**. Changes in the HDClarity cohort size and profile allow for such aggregation threshold adjustments while maintaining low identification risk thresholds.

Table 3 . Aggregated variables and aggregation thresholds.

Data file	Variable	Variable label	Criteria for aggregation
profile	caglow	Research smaller CAG allele determined from DNA	>28
profile	race	Ethnicity	Fewer than 30 participants per category (such categories are aggregated into other)

6   HD Category Classification

Included in the data is a specific variable that allows the user to distinguish between the different HD categories of participants included in the study (*hdcat*). Participants are assigned to a specific HD category depending on their CAG length alone, or on their CAG length and disease burden score (DBS) computed as (CAG − 35.5) × age, as well as on the Total Functional Capacity (TFC) score. DBS computation is based on age (to 2 decimal points) and research CAG.

Slight changes were made to the HDClarity study protocol pursuant to the previous PDS release. These concern the criteria used to assign participants HD categories. In the current PDS, the following criteria were applied uniformly to all participants:

- Early pre-manifest: diagnostic confidence <4 and CAG ≥40 and DBS<250;

- Late pre-manifest: diagnostic confidence <4 and CAG ≥40 and DBS≥250;

- Early Manifest: diagnostic confidence =4 and CAG ≥36 and TFC score of 7 to 13;

- Moderate Manifest HD: diagnostic confidence =4 and CAG≥36 and TFC score of 3 to 6;

- Advanced Manifest HD: diagnostic confidence =4 and CAG≥36 and TFC score of 0 to 2.

7   Legend for the Data Dictionary

This Data Dictionary details *all* variables collected in HDClarity.

Periodic datasets (PDS), prepared from the HDClarity electronic data capture (EDC) database every 6 months, include the *majority of variables* collected. Variables included in the PDS are highlighted in green. Each HDClarity PDS goes through stringent quality control and de-identification procedures prior to release. To this end, certain variables are transformed, aggregated, or suppressed (excluded) in each PDS to minimize participant identification.

Access to non-transformed, de-aggregated, or suppressed data may be obtained via **specified dataset** (**SPS**) request, pursuant to review and approval by the Enroll-HD Scientific Review Committee (SRC). These variables are highlighted in orange.

Finally, certain variables are restricted, typically due to their highly identifying nature. These variables, highlighted in red, and not available via PDS or SPS request, but are included here for completeness.

The variable column 'Availability' indicates these three classes of variables using the color-coding shown below.

Availability	Meaning
PDS	Included in the PDS.
Available upon SRC approval	Not included in the PDS but available via SPS request contingent on SRC approval.
Not available	Restricted variables which are not available in the PDS or via SPS request.

8 Key Variables of a Visit

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded subject identifier (HDID) #enrollment number[1]	---	---	subjid	text					PDS
Recoded HDID (i.e., recoded subject identifier)			usubjid	Text					PDS
Study ID			studyid	Text	- CLR - ENR				PDS
Sequence number			seq	text					PDS
Creation date		---	ctime	date					Not available
Site name	---	---	site	text					Not available
Visit name[2]			visit		- Screening - Sampling - RPT Sampling - Baseline - Follow Up				PDS
Visit name[2]			visit		- Screening - Sampling - Phone Contact - RPT Sampling - RPT Phone Contact - Event - End - Baseline				Available upon SRC approval

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[1] All visits belonging to the same visit package for any given participant have the same subjid – a string variable consisting of the participant ID followed by a # and a number indicating the visit package (please refer to "Understanding Dataset Structure").

[2] Screening, Sampling, RPT Sampling visits are part of the HDClarity study. Baseline and Follow Up visits belong to Enroll-HD.

					- Follow Up				
Visit date	SV	---	visdat	date					Not available
Visit day (i.e., number of days since first HD Clarity screening visit date, unique to each individual participant)	SV		visdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Visit status			visstat		- plausible - reviewing - completed				PDS
Number of visits	---	---	visitcnt	number					PDS
Row Number	---	---	row	number				Unique row index number. Only for datafile "csfquality"	PDS
Form Number	---	---	nr	number					Not available

9 Data File "Profile"

Key variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)	---	ENR CLR	---	usubjid	text				One-way transformation from HDID to HDID (recoded).	PDS

Form "Demographics (Demog)"

This form is part of the General visit.

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded Region ID		ENR		region	text	- Europe - Northern America				PDS
Gender	DM	ENR		sex	single choice	- female - male	- f - m			PDS
Aggregated HD Clarity ethnicity	DM	ENR		race	single choice	- Caucasian - other	- 1 - 6			PDS
Aggregated Enroll-HD ethnicity	DM	ENR		race	single choice	- Caucasian - American - Black - Hispano or Latino Origin - Native Hawaiian or Other Pacific Islander - Alaska Native/Inuit - other - American Indian/Native American/Amerindian - African - South - African - North - Asian - West - Asian - East	- 1 - 2 - 3 - 4 - 5 - 6 - 8 - 11 - 12 - 13 - 14		Aggregated into Caucasian vs other ethnicity	Available upon SRC approval

						- mixed	- 15			
Handedness	DM	ENR		handed	single choice	- right - left - mixed	- 1 - 2 - 3			PDS

Form "CAG Report (CAG)"

This form is part of the General visit.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date and time of collection	LB			lbdtc	date					Not available

Section: CAG Analysis

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Specimen type	LB			lbspec	single choice	- blood - brain (postmortem)	- 1 - 2			Available upon SRC approval
Were the exact repeat lengths given?	SUPPLB			lbrpt	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Smaller allele - CAG repeat length (local CAG)	LB			allele1l	number					Not available
Smaller research CAG allele determined from DNA (aggregated research CAG for values<27)	LB			caglow	number				CAG high (biorep)	PDS
Larger allele - CAG repeat length (local CAG)	LB			allele2l	number					Not available
Larger research CAG allele determined from DNA (aggregated research CAG for values <36 and >70)	LB			caghigh	number				CAG low (biorep)	PDS

Analyzing laboratory	LB			lbnam	text					Not available
Comments	SUPPLB			cmt	boolean	- yes - no		- 1 - 0		Not available
Enter comment	CO		Local CAG	coval	text					Not available

Form "Enrollment into HD Clarity (Enrollment CLR)"

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Consented to Family History at visit	SC	ENR		fhx	boolean	- yes - no	- 1 - 0			PDS

Form "HD Clinical Characteristics (HD CC)"

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Mother affected	MH	ENR		momhd	single choice	- yes - no	- 1 - 0			PDS
Age at onset of symptoms in mother	MH	ENR		momagesx	number			years		PDS
Father affected	MH	ENR		dadhd	single choice	- yes - no	- 1 - 0			PDS
Age at onset of symptoms in father	MH	ENR		dadagesx	number			years		PDS
Previous suicidal ideation or attempts?	MH	ENR		hxsid	boolean	- yes '- no	- 1 - 0			PDS

Section History of Motor Symptoms

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Have motor symptoms compatible with HD ever been a part of the participant's medical history?	MH	ENR		ccmtr	boolean	- yes - no	- 1 - 0			PDS

Group At what age did the participant's motor symptoms begin?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Motor symptoms - age (years)	SUPPMH	ENR		ccmtrage	number					PDS
Motor symptoms - year of onset	MH	ENR		ccmtryr	number					Not available

Section HD History – Participant and Family

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Symptoms first noted by participant (age)	MH	ENR		sxsubj	number				Convert to age, e.g. "41"	PDS
Initial major symptom noted by participant	MH	ENR		sxsubjm	single choice	- motor - cognitive - psychiatric - oculomotor - other - mixed	- 1 - 2 - 3 - 4 - 5 - 6			PDS

Group Mixed symptoms

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Major symptom noted by participant – motor	MH	ENR		sxs_m	boolean	- yes	- 1			PDS
Major symptom noted by participant - cognitive	MH	ENR		sxs_c	boolean	- yes	- 1			PDS
Major symptom noted by participant - psychiatric	MH	ENR		sxs_p	boolean	- yes	- 1			PDS
Major symptom noted by participant - oculomotor	MH	ENR		sxs_o	boolean	- yes	- 1			PDS

Symptoms first noted by family (age)	MH	ENR		sxfam	number					Convert to age, e.g. "41"	PDS
Initial major symptom noted by family	MH	ENR		sxfamm	single choice	- motor - cognitive - psychiatric - oculomotor - other - mixed	- 1 - 2 - 3 - 4 - 5 - 6				PDS

Group Mixed symptoms

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Major symptom noted by family - motor	MH	ENR		sxf_m	boolean	- yes	- 1			PDS
Major symptom noted by family - cognitive	MH	ENR		sxf_c	boolean	- yes	- 1			PDS
Major symptom noted by family - psychiatric	MH	ENR		sxf_p	boolean	- yes	- 1			PDS
Major symptom noted by family - oculomotor	MH	ENR		sxf_o	boolean	- yes	- 1			PDS

Section HD History - Rater

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Age of clinical HD diagnosis	MH	ENR		hddiagn	number				Convert to age, e.g. "41"	PDS
Can you, as a rater, estimate the time of symptom onset	MH	ENR		sxest	boolean	- yes - no	- 1 - 0			PDS

Rater's estimate of symptom onset (age)	MH	ENR		sxrater	number				Convert to age, e.g. "41"	PDS
Confidence with which this estimation is made	MH	ENR		sxestcfd	single choice	- high - low	- 1 - 2			PDS
Please specify why you, as a rater, cannot estimate symptom onset (without additional external information) at the moment	MH	ENR		sxreas	single choice	- participant cannot provide information (mute, or cognitively too impaired) - information provided deemed unreliable	- 1 - 2			PDS
What is your best guess of how many years ago symptom onset took place	MH	ENR		sxgs	single choice	- < 5 - < 10 - < 15 - < 20 - > 20	- 1 - 2 - 3 - 4 - 5			PDS
Date of data entry	MH	ENR		sxgsdtc	date					Not available
Day of data entry (ref. to 1st CLR Screening visit)	MH	ENR		sxgsdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS

Group What are these symptoms?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
	MH	ENR		sxraterm	single choice	- motor - cognitive	- 1 - 2			PDS

						- psychiatric	- 3			
Rater's judgement of initial major symptom						- oculomotor	- 4			
						- other	- 5			
						- mixed	- 6			

Group Mixed symptoms

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Rater's judgement of initial major symptom - motor	MH	ENR		sxr_m	boolean	- yes	- 1			PDS
Rater's judgement of initial major symptom - cognitive	MH	ENR		sxr_c	boolean	- yes	- 1			PDS
Rater's judgement of initial major symptom - psychiatric	MH	ENR		sxr_p	boolean	- yes	- 1			PDS
Rater's judgement of initial major symptom - oculomotor	MH	ENR		sxr_o	boolean	- yes	- 1			PDS

Section HD Clinical Characteristics and Age-of-Onset

Each estimate of symptom onset should be based on ALL available sources of information including reports of participant, companions, case notes and clinical rating scales.

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Has depression (includes treatment with antidepressants with or without a formally-stated diagnosis of depression) ever been a part of the	MH	ENR		ccdep	boolean	- yes - no	- 1 - 0			PDS

participant's medical history?										

Group At what age did the depression begin?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Depression - age (years)	SUPPMH	ENR		ccdepage	number					PDS
Depression - year of onset	SUPPMH	ENR		ccdepyr	number					Not available
Has irritability ever been a part of the participant's medical history?	MH	ENR		ccirb	boolean	- yes - no	- 1 - 0			PDS

Group At what age did the irritability begin?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Irritability - age (years)	SUPPMH	ENR		ccirbage	number					PDS
Irritability - year of onset	SUPPMH	ENR		ccirbyr	number					Not available
Has violent or aggressive behaviour ever been a part of the participant's medical history?	MH	ENR		ccvab	boolean	- yes - no	- 1 - 0			PDS

Group At what age did violent or aggressive behaviour begin?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
age (years)	SUPPMH	ENR		ccvabage	number					PDS
years of onset	SUPPMH	ENR		ccvabyr	number					Not available
Has apathy ever been a part of the participant's medical history	MH	ENR		ccapt	boolean	- yes - no	- 1 - 0			PDS

Group At what age did apathy begin?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
age (years)	SUPPMH	ENR		ccaptage	number					PDS
years of onset	MH	ENR		ccaptyr	number					Not available
Has perseverative obsessive behaviours ever been a part of the participant's medical history	MH	ENR		ccpob	boolean	- yes - no	- 1 - 0			PDS

Group At what age did perseverative obsessive behaviour begin?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Perseverative/obsessive behaviors - age (years)	SUPPMH	ENR		ccpobage	number					PDS

years of onset	MH	ENR		ccpobyr	number						Not available
Has psychosis (hallucinations or delusions) ever been a part of the participant's medical history	MH	ENR		ccpsy	boolean	- yes - no		- 1 - 0			PDS

Group At what age did psychosis (hallucinations or delusions) begin?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Psychosis - age (years)	SUPPMH	ENR		ccpsyage	number					PDS
Psychosis - year of onset	MH	ENR		ccpsyyr	number					Not available
Does the participant have a family history of a psychotic illness in a first degree relative	MH	ENR		ccpsyfh	boolean	- yes - no	- 1 - 0			PDS
Has significant cognitive impairment (severe enough to impact on work or activities of daily living) or dementia ever been a part of the participant's medical history	MH	ENR		cccog	boolean	- yes - no	- 1 - 0			PDS

Group At what age did cognitive impairment first start to have an impact on daily life?

Label	Domain	Study	Cat	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
age (years)	SUPPMH	ENR		cccogage	number					PDS
years of onset	MH	ENR		cccogyr	number					Not available

10 Data File "visits" (HDClarity and Enroll-HD visits)

Key variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)	---	ENR CLR	---	usubjid	text					PDS
Recoded subject identifier #enrollment number	---	CLR	---	subjid	text					PDS
Study name	---	ENR CLR	---	study		- HDClarity - Enroll-HD				PDS
Study ID	---	ENR CLR	---	studyid	text	- CLR - ENR				PDS
Participant status	SUPPSC	ENR CLR	---	subjstat	text	- enrolled - completed - excluded - withdrawn - violator				PDS
Visit name[2]	---	ENR CLR	---	visit	text	- Screening - Sampling - RPT Sampling - Baseline - Follow Up				PDS
Visit day of the Enroll visit	---	ENR CLR	---	visdy_ENR						Available upon SRC approval
Visit day (i.e., number of days since first HD Clarity screening visit date, unique to each	SV	ENR CLR		visdy	number				Transformed into days relative to date of first HD	PDS

individual participant)						Clarity screening visit.				
Sequence number	---	ENR CLR	---	seq	text					PDS
Visit status	---	ENR CLR	---	visstat	text	- plausible - reviewing - completed				PDS

General Visits

Label	Domain	Study	Cat.	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of birth	DM	ENR		brthdtc	date					Not available
Recoded age at enrollment (aggregated if <18)	DM	ENR CLR		age_0	number				Birth date is transformed into age at time of enrollment into HD Clarity (rounded to a whole number).	Available upon SRC approval
Recoded age at visit (aggregated if <18)	DM	ENR CLR		age	number					PDS
HD Clarity classification at time of screening visit	SC	CLR		hdcat[3]	single choice	- early pre-manifest HD - late pre-manifest HD - early HD - moderate HD - advanced HD - healthy control	-1 -2 -3 -4 -5 -6			PDS
Disease burden score at time of screening visit	SC	CLR		dbs[4]	number					PDS

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[3]

- Early pre-manifest: diagnostic confidence <4 and CAG ≥40 and DBS<250;
- Late pre-manifest: diagnostic confidence <4 and CAG ≥40 and DBS≥250;
- Early Manifest: diagnostic confidence =4 and CAG ≥36 and TFC score of 7 to 13;
- Moderate Manifest HD: CAG≥36 and TFC score of 3 to 6;
- Advanced Manifest HD: CAG≥36 and TFC score of 0 to 2.

[4] DBS = (research CAG – 35.5) × age with two decimal points

Form "Enrollment into HD Clarity (Enrollment CLR)"

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of visit	SV	CLR		visdat	date					Not available

Section: Enrollment into HD Clarity

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Participant is capable of providing informed consent or has a legal representative	SC	CLR		ics1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
IC procedures were completed and documented	SC	CLR		ics2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Date of informed consent	DM	CLR		rfstdtc	date					Not available
Study reference start day (ref. to 1st CLR Screening visit)	DM	CLR		rfstdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Signed by	SC	CLR		sgntr	single choice	- participant - legal representative	- 1 - 2			Available upon SRC approval
Is there a local CAG report available that specifies exact allele repeat lengths?	SC	CLR		ics5	single choice	- yes - no - not required	- 1 - 2 - 3			Not available
Has eligibility been	SC	CLR		ics6	boolean	- yes	- 1			Available

confirmed with Central Coordination?						- no	- 0		upon SRC approval
If the participant is premanifest how is then their DBS?	SC	CLR		ics7	single choice	- DBS < 250 (early premanifest) - DBS ≥ 250 (late premanifest) - not applicable	- 1 - 2 - 3		Available upon SRC approval
Enroll-HD core assessment completed within 60 days from screening	SC	CLR		ics3	boolean	- yes - no	- 1 - 0		Available upon SRC approval
If not Enroll-HD core assessment completed within 60 days from screening, have you received approval from the Chief Investigator to repeat the core assessments at this visit	SC	CLR		ics3a	boolean	- yes - no	- 1 - 0		Available upon SRC approval
Was this participant recruited into Enroll-HD because of participation in HD Clarity	SC	CLR		ics4	boolean	- yes - no	- 1 - 0		Available upon SRC approval

Form "Eligibility Check – Sampling and Repeat Sampling (Eligibility Check)"

This form is part of the Sampling visit.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of visit	SV	CLR		visdat	date					Not available

Section: Eligibility Check - Sampling and Repeat Sampling (Eligibility Check)

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Subject Reference Start Date	IE	CLR		rfsdtc	date					Not available
Date of Sampling visit	IE	CLR		smpl_visit	date					Not available
Day of Sampling visit	IE	CLR		smpl_visitdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Sampling visit within 30 days of the Screening visit	IE	CLR		svtf_bs	boolean	- yes - no	- 1 - 0			PDS
Repeat Sampling visit within 28-56 days of the Baseline Sampling visit	IE	CLR		svtf_bs2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Confirmation of consent	IE	CLR		ics	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Section: Confirmation of Inclusion Criteria

	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
21-75 years of age, inclusive	IE	CLR		ic1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Capable of complying with study procedures, including fasting, blood sampling and lumbar puncture	IE	CLR		ic2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Results of the safety laboratory examinations within 10% of the normal limits	IE	CLR		ic3_3	boolean	- yes - no	- 1 - 0			PDS
C-reactive protein (CRP) screening blood test results within >2X of upper limit of normal	IE	CLR		Ic4_3	boolean	- yes - no	- 1 - 0			PDS
Compliance with instructions to fast	IE	CLR		ic3	boolean	- yes - no	- 1 - 0			PDS

Section: Confirmation of Exclusion Criteria

Label	Domain	Study	Cat.	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Current use of investigational drugs or participation in a clinical drug trial	IE	CLR		ec1	boolean	- yes - no	- 1 - 0			PDS
Current	IE	CLR		ec2	boolean	- yes	- 1			PDS

intoxication, drug or alcohol abuse or dependence						- no	- 0			
Use of inappropriate (e.g., non-therapeutically high) dosages of HD Rx	IE	CLR		ec3	boolean	- yes - no	- 1 - 0			PDS
If using medications or nutraceuticals, the use of inappropriate (e.g., non-prescribed) or unstable doseages within 30 days prior to the Sampling visit	IE	CLR		ec3_3	boolean	- yes - no	- 1 - 0			PDS
Change of dosages of HD Rx over the past 30 days from sampling	IE	CLR		ec4	boolean	- yes - no	- 1 - 0			PDS
Significant medical, neurological or psychiatric co-morbidity likely, in the judgment of the Investigator, to impair participant's ability to complete study procedures	IE	CLR		ec5	boolean	- yes - no	- 1 - 0			PDS
Needle phobia	IE	CLR		ec6	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Frequent headache	IE	CLR		ec7	boolean	- yes	- 1			

						- no	- 0			Available upon SRC approval
Significant lower spinal deformity or major surgery at lumbar spine	IE	CLR		ec8	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Antiplatelet or anticoagulant therapy within the past 14 days, including but not limited to: aspirin, clopidogrel, dipyridamole, warfarin, dabigatran, rivaroxaban and apixaban	IE	CLR		ec9	boolean	- yes - no	- 1 - 0			PDS
Clotting or bruising disorder	IE	CLR		ec10	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Predictable non-compliance as assessed by investigator	IE	CLR		ec11	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Inability or unwillingness to undertake any experimental procedure	IE	CLR		ec12	boolean	- yes - no	- 1 - 0			Available upon SRC approval

History or physical examination discloses any reason to suspect abnormal bleeding tendency, e.g. easy bruising, petechial rash	IE	CLR		ec13	boolean	- yes - no	- 1 - 0			Available upon SRC approval
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	CLR		ec14	boolean	- yes - no	- 1 - 0			PDS
Standard neurological examination discloses any reason to suspect raised intracranial pressure or a focal neurological lesion/neurological signs not readily explained by HD	IE	CLR		ec15	boolean	- yes - no	- 1 - 0			PDS
General physical examination discloses any reason to suspect spinal deformity or abnormal bleeding	IE	CLR		ec16	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
tendency, e.g. easy bruising, petechial rash										
History or physical examination discloses any other reason that, in the clinical judgment of the Site PI, it is felt that the LP performed per this protocol and associated manuals is unsafe without brain imaging	IE	CLR		ec17_3		- yes - no	- 1 - 0			PDS

Section: Additional Information

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

medication within the past 30 days?										PDS
Use of any antipsychotic medication within the past 30 days?	IE	CLR		ainf4	boolean	- yes - no	- 1 - 0			PDS

Section: Eligibility

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Did the participant pass the eligibility criteria?	IE	CLR		elgbl	single choice	- yes - no	- 1 - 2			PDS

Section: Waiver

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Has the CI granted a waiver for all unmet criteria?	IE	CLR		smpl_wvr	boolean	- yes - no	- 1 - 0			PDS
Other inclusion/exclusion criteria[5]	IE	CLR		Icecoth[5]	boolean	- yes - no	- 1 - 0			PDS
Please comment	IE	CLR		wvr_cmt	text					Not available

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[5] Aggregated value for all inclusion and exclusion criteria not included in the PDS release. Yes indicates individual did not meet at least one inclusion criterion marked as 'available upon SRC approval', or did meet at least one exclusion criterion marked as 'available upon SRC approval', but is included in the dataset given completion of a waiver.

Form "Safety Laboratory Examinations (Safety Lab Exam)"

This form is part of the Screening visit.

Section: Laboratory Examinations for Safety - Screening

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
15 ml of venous blood drawn for evaluation by the local laboratory	LB	CLR		lbsmpl1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Date of blood draw	LB	CLR		lbdat1	date					Not available
Day of blood draw	LB	CLR		lbdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Age at time of plasma collection				plsmsage	number					PDS
White Cell Count - Actual	LB	CLR		wbcres1	number					Available upon SRC approval
White Cell Count - Unit	LB	CLR		wbcu1	single choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88			Available upon SRC approval
White Cell Count - Categorical value of the test value	LB	CLR		wbcres1c	single choice	- high - low			Transformed[6]	PDS
White Cell Count - Lower	LB	CLR		wbclo1	number					Available

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[6] High = higher than the reference range, Low = lower than the reference range; Blank entry = within the reference range.

limit									Available upon SRC approval
White Cell Count - Upper limit	LB	CLR		wbchi1	number				Available upon SRC approval
Neutrophil Count - Actual	LB	CLR		ncres1	number				Available upon SRC approval
Neutrophil Count - Unit	LB	CLR		ncu1	single choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88		Available upon SRC approval
Neutrophil Count - Categorical value of the test value	LB	CLR		ncres1c	single choice	- high - low		Transformed[5]	PDS
Neutrophil Count - Lower limit	LB	CLR		nclo1	number				Available upon SRC approval
Neutrophil Count - Upper limit	LB	CLR		nchi1	number				Available upon SRC approval
Lymphocyte Count - Actual	LB	CLR		lcres1	number				Available upon SRC approval
Lymphocyte Count - Unit	LB	CLR		lcu1	single-choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88		Available upon SRC approval
Lymphocyte Count - Categorical value of the test value	LB	CLR		lcres1c	single choice	- high - low	- 1 - 0	Transformed[6]	PDS

Lymphocyte Count - Lower limit	LB	CLR		lclo1	number				Available upon SRC approval
Lymphocyte Count - Upper limit	LB	CLR		lchi1	number				Available upon SRC approval
Hemoglobin (Hb) – Actual	LB	CLR		hbres1	number				Available upon SRC approval
Hemoglobin (Hb) - Unit	LB	CLR		hbu1	single-choice	- g/dl - g/l - other	- 2 - 3 - 88		Available upon SRC approval
Hemoglobin (Hb) - Categorical value of the test value	LB	CLR		hbres1c	single choice	- high - low		Transformed[6]	PDS
Hemoglobin (Hb) - Lower limit	LB	CLR		hblo1	number				Available upon SRC approval
Hemoglobin (Hb) - Upper limit	LB	CLR		hbhi1	number				Available upon SRC approval
Platelets – Actual	LB	CLR		pltres1	number				Available upon SRC approval
Platelets – Unit	LB	CLR		pltu1	single-choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88		Available upon SRC approval
Platelets - Categorical value of the test value	LB	CLR		pltres1c	single choice	- high - low		Transformed[6]	PDS
Platelets - Lower limit	LB	CLR		pltlo1	number				Available upon SRC

									approval
Platelets - Upper limit	LB	CLR		plthi1	number				Available upon SRC approval
Prothrombin Time (PT) - Actual	LB	CLR		ptres1	number				Available upon SRC approval
Prothrombin Time (PT) – Unit	LB	CLR		ptu1	single choice	- other - seconds	- 88 - 9		Available upon SRC approval
Prothrombin Time (PT) - Categorical value of the test value	LB	CLR		ptres1c	single choice	- high - low		Transformed[6]	PDS
Prothrombin Time (PT) - Lower limit	LB	CLR		ptlo1	number				Available upon SRC approval
Prothrombin Time (PT) - Upper limit	LB	CLR		pthi1	number				Available upon SRC approval
Activated Partial Thromboplastin time (APTT) - Actual	LB	CLR		apttres1	number				Available upon SRC approval
Activated Partial Thromboplastin time (APTT) - Unit	LB	CLR		apttu1	single choice	- other - seconds	- 88 - 9		Available upon SRC approval
Activated Partial Thromboplastin time (APTT) - Categorical value of the test value	LB	CLR		apttres1c	single choice	- high - low		Transformed[6]	PDS
Activated Partial Thromboplastin time (APTT) - Lower limit	LB	CLR		apttlo1	number				Available upon SRC approval
Activated Partial Thromboplastin time (APTT)	LB	CLR		apttthi1	number				Available upon SRC

- Upper limit										approval
CRP – Actual	LB	CLR		crpres1	number					Available upon SRC approval
CRP – Unit	LB	CLR		crpu1	single-choice	- mg/dl - mg/l - nmol/l - other	- 6 - 7 - 8 - 88			Available upon SRC approval
CRP - Categorical value of the test value	LB	CLR		crpres1c	single choice	- high - low			Transformed[6]	PDS
CRP - Lower limit	LB	CLR		crplo1	number					Available upon SRC approval
CRP - Upper limit	LB	CLR		crphi1	number					Available upon SRC approval
Safety lab result	LB	CLR		lbres1	single choice	- passed - failed	- 1 - 2			PDS

Section: Laboratory Examinations for Safety - Rescreening

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Second blood draw for rescreening	LB	CLR		lbsmpl2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Date of blood draw	LB	CLR		lbdat2	date					Not available
Day of blood draw	LB	CLR		lbdy2	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Age at time of plasma collection	LB	CLR		plsmsage	number					PDS
White Cell Count - Actual	LB	CLR		wbcres2	number					Available upon SRC approval
White Cell Count – Unit	LB	CLR		wbcu2	single-choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88			Available upon SRC approval
White Cell Count - Categorical value of the test value	LB	CLR		wbcres2c	single choice	- high - low			Transformed[6]	PDS
White Cell Count - Lower limit	LB	CLR		wbclo2	number					Available upon SRC approval
White Cell Count - Upper	LB	CLR		wbchi2	number					Available upon SRC

limit									
Neutrophil Count - Actual	LB	CLR		ncres2	number				Available upon SRC approval
Neutrophil Count - Unit	LB	CLR		ncu2	single-choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88		Available upon SRC approval
Neutrophil Count - Categorical value of the test value	LB	CLR		ncres2c	single choice	- high - low		Transformed[6]	PDS
Neutrophil Count - Lower limit	LB	CLR		nclo2	number				Available upon SRC approval
Neutrophil Count - Upper limit	LB	CLR		nchi2	number				Available upon SRC approval
Lymphocyte Count - Actual	LB	CLR		lcres2	number				Available upon SRC approval
Lymphocyte Count - Unit	LB	CLR		lcu2	single-choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88		Available upon SRC approval
Lymphocyte Count - Categorical value of the test value	LB	CLR		lcres2c	single choice	- high - low		Transformed[6]	PDS
Lymphocyte Count - Lower limit	LB	CLR		lclo2	number				Available upon SRC approval

Lymphocyte Count - Upper limit	LB	CLR		lchi2	number					Available upon SRC approval
Hemoglobin (Hb) - Actual	LB	CLR		hbres2	number					Available upon SRC approval
Hemoglobin (Hb) - Unit	LB	CLR		hbu2	single-choice	- g/dl - g/l - other	- 2 - 3 - 88			Available upon SRC approval
Hemoglobin (Hb) - Categorical value of the test value	LB	CLR		hbres2c	single choice	- high - low			Transformed[6]	PDS
Hemoglobin (Hb) - Lower limit	LB	CLR		hblo2	number					Available upon SRC approval
Hemoglobin (Hb) - Upper limit	LB	CLR		hbhi2	number					Available upon SRC approval
Platelets – Actual	LB	CLR		pltres2	number					Available upon SRC approval
Platelets - Unit	LB	CLR		pltu2	single-choice	- µl - K/cu mm - L - 10E3/µl - 10E9/l - other	- 1 - 4 - 5 - 10 - 11 - 88			Available upon SRC approval
Platelets - Categorical value of the test value	LB	CLR		pltres2c	single choice	- high - low			Transformed[6]	PDS
Platelets - Lower limit	LB	CLR		pltlo2	number					Available upon SRC approval
Platelets - Upper limit	LB	CLR		plthi2	number					Available upon SRC

										approval
Prothrombin Time (PT) - Actual	LB	CLR		ptres2	number					Available upon SRC approval
Prothrombin Time (PT) - Unit	LB	CLR		ptu2	single-choice	- other - seconds	- 88 - 9			Available upon SRC approval
Prothrombin Time (PT) - Categorical value of the test value	LB	CLR		ptres2c	single choice	- high - low			Transformed[6]	PDS
Prothrombin Time (PT) - Lower limit	LB	CLR		ptlo2	number					Available upon SRC approval
Prothrombin Time (PT) - Upper limit	LB	CLR		pthi2	number					Available upon SRC approval
Activated Partial Thromboplastin time (APTT) - Actual	LB	CLR		apttres2	number					Available upon SRC approval
Activated Partial Thromboplastin time (APTT) - Unit	LB	CLR		apttu2	single-choice	- other - seconds	- 88 - 9			Available upon SRC approval
Activated Partial Thromboplastin time (APTT) - Categorical value of the test value	LB	CLR		apttres2c	single choice	- high - low			Transformed[6]	PDS
Activated Partial Thromboplastin time (APTT) - Lower limit	LB	CLR		apttlo2	number					Available upon SRC approval
Activated Partial Thromboplastin time (APTT) - Upper limit	LB	CLR		aptthi2	number					Available upon SRC approval
CRP – Actual	LB	CLR		crpres2	number					Available upon SRC

									approval
CRP - Unit	LB	CLR		crpu2	single-choice	- mg/dl - mg/l - nmol/l - other	- 6 - 7 - 8 - 88		Available upon SRC approval
CRP - Categorical value of the test value	LB	CLR		crpres2c	single choice	- high - low	- 1 - 0	Transformed[6]	PDS
CRP - Lower limit	LB	CLR		crplo2	number				Available upon SRC approval
CRP - Upper limit	LB	CLR		crphi2	number				Available upon SRC approval
Safety lab result	LB	CLR		lbres2	single choice	- passed - failed	- 1 - 2		PDS

Form "CSF Collection and Processing (CSF)"

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

Section: CSF Collection

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
LAB-ID	LB	CLR	LB	labid	Text					Not available
Kit ID	SUPPLB	CLR	LB	kitid	Text					Not available
Date and time CSF collection procedure is started	SUPPLB	CLR	LB	csfpdtc	datetime					Not available
Day when CSF collection procedure started	SUPPLB	CLR	LB	csfpdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Time when CSF collection procedure started taken from the "csfpdtc" variable	SUPPLB	CLR	LB	csfpt	number					Available upon SRC approval
Age at time of CSF draw	SUPPLB	CLR	LB	csfpage	number					PDS
Total volume of CSF obtained	LB	CLR		lblpvol	number			ml		Available upon SRC approval
Total volume of usable CSF obtained	SUPPLB	CLR	LB	lblpvolu	number			ml		Available upon SRC approval
Time CSF collection procedure is completed	SUPPLB	CLR	LB	lblpetim	Time					Available upon SRC approval

Number of LP attempts	SUPPLB	CLR	LB	lblpcnt	single choice	- 1 - 2 - 3	- 1 - 2 - 3			Available upon SRC approval

Section: LP Attempt #1

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
LP Attempt 1 - Investigator ID	LB	CLR		invid1	number					Not available
LP Attempt 1 - Lumbar space used for lumbar puncture (LP)	SUPP	CLR	LB	lpsp1	single choice	- L4/5 space - L3/4 space - other	- 1 - 2 - 3			Available upon SRC approval
LP Attempt 1 - Please enter used lumbar space	SUPP	CLR	LB	lpsp1spc	text					Not available
Initial participant posture										
LP Attempt 1 - Lateral decubitus	LB	CLR		ipp1ld	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 1 - Upright	LB	CLR		ipp1up	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 1 - Was patient transferred to lateral decubitus position before CSF collection	SUPPLB	CLR	LB	ipp1upt	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 1 - Local anaesthesia (2% lidocaine) used	SUPP	CLR	LB	lplca1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 1 - Volume of lidocaine used	LB	CLR		lplca1v	number			ml		Available upon SRC approval
LP Attempt 1 - Why lidocaine was not used	SUPP	CLR	LB	lplca1r	single choice	- Allergy - Other Contraindications - Patient Request	- 1 - 2 - 3			Available upon SRC approval

						- Investigator Preference - Other	- 4 - 5			
LP Attempt 1 - Number of needle passes to obtain CSF	SUPPLB	CLR	LB	lpnnp1	single choice	- 1 - 2 - 3 - 4 - 5	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval
LP Attempt 1 - Was the first ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp1bc1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 1 - Was the second ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp1bc2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 1 - Was the third ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp1bc3	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Section: LP Attempt #2

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

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
						- Other	- 5			
LP Attempt 2 - Number of needle passes to obtain CSF	SUPPLB	CLR	LB	lpnnp2	single choice	- 1 - 2 - 3 - 4 - 5	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval
LP Attempt 2 - Was the first ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp2bc1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 2 - Was the second ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp2bc2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 2 - Was the third ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp2bc3	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Section: LP Attempt #3

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
LP Attempt 3 - Investigator ID	LB	CLR		invid3	number					Not available
LP Attempt 3 - Lumbar space used for lumbar puncture (LP)	SUPP	CLR	LB	lpsp3	single choice	- L4/5 space - L3/4 space - other	- 1 - 2 - 3			Available upon SRC approval
LP Attempt 3 - Please enter used lumbar space	SUPP	CLR	LB	lpsp3spc	text					Not available
Initial participant posture										
LP Attempt 3 - Lateral decubitus	LB	CLR		ipp3ld	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 3 - Upright	LB	CLR		ipp3up	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 3 - Was patient transferred to	SUPPLB	CLR	LB	ipp3upt	boolean	- yes - no	- 1 - 0			Available upon SRC

lateral decubitus position before CSF collection										approval
LP Attempt 3 - Local anaesthesia (2% lidocaine) used	SUPP	CLR	LB	lplca3	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 3 - Volume of lidocaine used	LB	CLR	LB	lplca3v	number			ml		Available upon SRC approval
LP Attempt 3 - Why lidocaine was not used	SUPP	CLR	LB	lplca3r	single choice	- Allergy - Other Contraindications - Patient Request - Investigator Preference - Other	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval
LP Attempt 3 - Number of needle passes to obtain CSF	SUPPLB	CLR	LB	lpnnp3	single choice	- 1 - 2 - 3 - 4 - 5	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval
LP Attempt 3 - Was the first ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp3bc1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 3 - Was the second ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp3bc2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
LP Attempt 3 - Was the third ml of CSF blood contaminated?	SUPPLB	CLR	LB	lp3bc3	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Section: CSF Processing

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Time CSF processing is started	SUPPLB	CLR	LB	csfstim	time					Available upon SRC approval
Time CSF processing is completed	SUPPLB	CLR	LB	csfctim	time					Available upon SRC approval
CSF Tube Rack ID	SUPPLB	CLR	LB	csfrkid	text					Not available
CSF aliquot - Tube ID	SUPPLB	CLR	LB	csfaid	text					Not available
CSF aliquot - Quantity	SUPPLB	CLR	LB	csfaqty	number					Available upon SRC approval
Cells from CSF - Tube ID	SUPPLB	CLR	LB	csfcid	text					Not available
Cells from CSF - Quantity	SUPPLB	CLR	LB	csfcqty	number					Available upon SRC approval

Form "Variable Items (Variable)"

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

Section: Vital Signs

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Height (cm)	VS	ENR CLR		height	number			cm		PDS
Height (inches)	VS	ENR CLR		height_2	number			inches		Available upon SRC approval
Weight (kg)	VS	ENR CLR		weight	number			kg		PDS
Weight (lbs)	VS	ENR CLR		weight_2	number			Lbs		Available upon SRC approval
BMI	VS	ENR CLR		bmi	number					PDS

Form "Core Cognitive Assessment (Cognitive)"

This form is part of the Screening visit.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Assessment date	QS	ENR CLR	Cognitive	cogn_qsdtc	date					**Not available**
Assessment day	QS	ENR CLR	Cognitive	cogn_qsdy	number				Transformed into days relative to date of first HD Clarity screening visit.	**Available upon SRC approval**

Section: Core Cognitive Assessment

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Symbol Digit Modality Test completed	QS	ENR CLR	SDMT	sdmt	boolean	- yes - no	- 1 - 0			PDS
Symbol Digit Modality Test - Total correct	QS	ENR CLR	SDMT	sdmt1	number					PDS
Symbol Digit Modality Test - Total errors	QS	ENR CLR	SDMT	sdmt2	number					PDS
Symbol Digit Modality Test - Reason for not completion	QS	ENR CLR	SDMT	sdmtnd	single choice	- cognitive impairment - motor impairment - mental state - physical health - visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10			PDs

Verbal Fluency Test (Category) completed	QS	ENR CLR	Categoric al Verbal Fluency	verfct	boolean	- yes - no	- 1 - 0			PDS
Verbal Fluency Test - Category	QS	ENR CLR	Categoric al Verbal Fluency	verfctd	single choice	- animals - other	- 1 - 2			PDS
Verbal Fluency Test - Please specify category (if other)	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfctds	text					Not available
Verbal Fluency Test - Total correct 0-15 seconds	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfct1	number					Available upon SRC approval
Verbal Fluency Test - Total correct 16-30 seconds	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfct2	number					Available upon SRC approval
Verbal Fluency Test - Total correct 31-45 seconds	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfct3	number					Available upon SRC approval
Verbal Fluency Test - Total correct 46-60 seconds	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfct4	number					Available upon SRC approval
Verbal Fluency Test - Total correct (1 min)	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfct5	number					PDS
Verbal Fluency Test - Total intrusion errors	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfct6	number					PDS
Verbal Fluency Test - Total perseverative errors	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfct7	number					PDS
Verbal Fluency Test - Reason for not completion	SUPPQS	ENR CLR	Categoric al Verbal Fluency	verfctnd	single choice	- cognitive impairment - motor impairment - mental state - physical health	- 1 - 2 - 3 - 4			PDS

						- visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	- 5 - 6 - 7 - 8 - 9 - 10			
Stroop Color Naming Test completed	QS	ENR CLR	Stroop Color Naming	scnt	boolean	- yes - no	- 1 - 0			PDS
Stroop Color Naming Test - Total correct	QS	ENR CLR	Stroop Color Naming	scnt1	number					PDS
Stroop Color Naming Test - Total errors	QS	ENR CLR	Stroop Color Naming	scnt2	number					PDS
Stroop Color Naming Test - Total self-corrected errors	QS	ENR CLR	Stroop Color Naming	scnt3	number					PDS
Stroop Color Naming Test - Reason for not completion	QS	ENR CLR	Stroop Color Naming	scntnd	single choice	- cognitive impairment - motor impairment - mental state - physical health - visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10			PDS
Stroop Word Reading Test completed	QS	ENR CLR	Stroop Word Reading	swrt	boolean	- yes - no	- 1 - 0			PDS
Stroop Word Reading Test - Total correct	QS	ENR CLR	Stroop Word Reading	swrt1	number					PDS

Stroop Word Reading Test - Total errors	QS	ENR CLR	Stroop Word Reading	swrt2	number					PDS
Stroop Word Reading Test - Total self-corrected errors	QS	ENR CLR	Stroop Word Reading	swrt3	number					PDS
Stroop Word Reading Test - Reason	QS	ENR CLR	Stroop Color Naming	swrtnd	single choice	- cognitive impairment - motor impairment - mental state - physical health - visual impairment - language barrier - refusal - study conflict - scheduling issue - site error	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10			PDS

Form "Problem Behaviours Assessment – Short (PBA-s)"

This form is part of the Screening visits.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Assessment date	QS	ENR CLR	PBA-s	pbas_qsdtc	date					Not available
Assessment day	QS	ENR CLR	PBA-s	pbas_qsdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval

Section: Domain scores

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Depression	QS	ENR CLR		depscore	number					PDS
Irritability/aggression	QS	ENR CLR		irascore	number					PDS
Psychosis	QS	ENR CLR		psyscore	number					PDS
Apathy	QS	ENR CLR		aptscore	number					PDS
Executive function	QS	ENR CLR		exfscore	number					PDS

Section: Problem Behaviours Assessment for HD

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
1. Depressed mood										
Depressed mood -	QS	ENR	PBA-s	pbas1sv	single	- absent	- 0			PDS

Severity		CLR			choice	- slight, questionable	- 1			
						- mild (present, not a problem)	- 2			
						- moderate (symptom causing problem)	- 3			
						- severe (almost intolerable for career)	- 4			
Depressed mood - Frequency of use	QS	ENR CLR	PBA-s	pbas1fr	single choice	- never/almost never	- 0			PDS
						- seldom (less than once/week)	- 1			
						- sometimes (up to four times a week)	- 2			
						- frequently (most days/5, 6 or 7 times a week)	- 3			
						- daily/almost daily for most (or all) of day	- 4			
Depressed mood – Worst	QS	ENR CLR	PBA-s	pbas1wo	single choice	- absent	- 0			PDS
						- slight, questionable	- 1			
						- mild (present, not a problem)	- 2			
						- moderate (symptom causing problem)	- 3			
						- severe (almost intolerable for career)	- 4			
2. Suicidal ideation										
Suicidal ideation - Severity	QS	ENR CLR	PBA-s	pbas2sv	single choice	- absent	- 0			PDS
						- slight, questionable	- 1			
						- mild (present, not a problem)	- 2			
						- moderate (symptom causing problem)	- 3			
						- severe (almost intolerable for career)	- 4			

Suicidal ideation - Frequency of use	QS	ENR CLR	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			PDS
Suicidal ideation – Worst	QS	ENR CLR	PBA-s	pbas2wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS
3. Anxiety										
Anxiety - Severity	QS	ENR CLR	PBA-s	pbas3sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS
Anxiety - Frequency of use	QS	ENR CLR	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)	- 0 - 1 - 2 - 3			PDS

						- daily/almost daily for most (or all) of day	- 4			
Anxiety – Worst	QS	ENR CLR	PBA-s	pbas3wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS
4. Irritability										
Irritability - Severity	QS	ENR CLR	PBA-s	pbas4sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS
Irritability - Frequency of use	QS	ENR CLR	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			PDS
Irritability – Worst	QS	ENR CLR	PBA-s	pbas4wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom	- 0 - 1 - 2 - 3			PDS

						causing problem)				
						- severe (almost intolerable for career)	- 4			

5. Angry or aggressive behavior

Angry or aggressive behavior - Severity	QS	ENR CLR	PBA-s	pbas5sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS
Angry or aggressive behavior - Frequency of use	QS	ENR CLR	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			PDS
Angry or aggressive behavior - Worst	QS	ENR CLR	PBA-s	pbas5wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS

6. Lack of initiative (apathy)

Lack of initiative (apathy) - Severity	QS	ENR CLR	PBA-s	pbas6sv	single choice	- absent - slight, questionable - mild (present, not a problem)	- 0 - 1 - 2			PDS

						- moderate (symptom causing problem)	- 3		
						- severe (almost intolerable for career)	- 4		
Lack of initiative (apathy) - Frequency of use	QS	ENR CLR	PBA-s	pbas6fr	single choice	- never/almost never	- 0		PDS
						- seldom (less than once/week)	- 1		
						- sometimes (up to four times a week)	- 2		
						- frequently (most days/5, 6 or 7 times a week)	- 3		
						- daily/almost daily for most (or all) of day	- 4		
Lack of initiative (apathy) – Worst	QS	ENR CLR	PBA-s	pbas6wo	single choice	- absent	- 0		PDS
						- slight, questionable	- 1		
						- mild (present, not a problem)	- 2		
						- moderate (symptom causing problem)	- 3		
						- severe (almost intolerable for career)	- 4		
7. Perseverative thinking or behavior									
Perseverative thinking or behavior - Severity	QS	ENR CLR	PBA-s	pbas7sv	single choice	- absent	- 0		PDS
						- slight, questionable	- 1		
						- mild (present, not a problem)	- 2		
						- moderate (symptom causing problem)	- 3		
						- severe (almost intolerable for career)	- 4		
Perseverative thinking or behavior - Frequency of use	QS	ENR CLR	PBA-s	pbas7fr	single choice	- never/almost never	- 0		PDS
						- seldom (less than once/week)	- 1		
						- sometimes (up to four	- 2		

						times a week)				
						- frequently (most days/5, 6 or 7 times a week)	- 3			
						- daily/almost daily for most (or all) of day	- 4			
Perseverative thinking or behavior – Worst	QS	ENR CLR	PBA-s	pbas7wo	single choice	- absent	- 0			PDS
						- slight, questionable	- 1			
						- mild (present, not a problem)	- 2			
						- moderate (symptom causing problem)	- 3			
						- severe (almost intolerable for career)	- 4			
8. Obsessive-Compulsive Behaviours										
Obsessive-Compulsive Behaviours - Severity	QS	ENR CLR	PBA-s	pbas8sv	single choice	- absent	- 0			PDS
						- slight, questionable	- 1			
						- mild (present, not a problem)	- 2			
						- moderate (symptom causing problem)	- 3			
						- severe (almost intolerable for career)	- 4			
Obsessive-Compulsive Behaviours - Frequency of use	QS	ENR CLR	PBA-s	pbas8fr	single choice	- never/almost never	- 0			PDS
						- seldom (less than once/week)	- 1			
						- sometimes (up to four times a week)	- 2			
						- frequently (most days/5, 6 or 7 times a week)	- 3			
						- daily/almost daily for most (or all) of day	- 4			
Obsessive-Compulsive Behaviours – Worst	QS	ENR	PBA-s	pbas8wo	single choice	- absent	- 0			PDS
						- slight, questionable	- 1			

		CLR					- mild (present, not a problem)	- 2			
							- moderate (symptom causing problem)	- 3			
							- severe (almost intolerable for career)	- 4			

9. Delusions / paranoid thinking

Delusions / paranoid thinking - Severity	QS	ENR CLR	PBA-s	pbas9sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4		PDS
Delusions / paranoid thinking - Frequency of use	QS	ENR CLR	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		PDS
Delusions / paranoid thinking – Worst	QS	ENR CLR	PBA-s	pbas9wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4		PDS

10. Hallucinations

						- absent	- 0		PDS

Hallucinations - Severity	QS	ENR CLR	PBA-s	pbas10sv	single choice	- slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 1 - 2 - 3 - 4			
Modality of hallucinations	QS	ENR CLR	PBA-s	pbas10sm	multiple choice	- auditory - visual - tactile - olfactory - gustatory	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval
Hallucinations - Frequency of use	QS	ENR CLR	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			PDS
Hallucinations - Worst	QS	ENR CLR	PBA-s	pbas10wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS
Modality of hallucinations	QS	ENR CLR	PBA-s	pbas10wm	multiple choice	- auditory - visual - tactile - olfactory - gustatory	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval

11. Disoriented Behaviour

Disoriented Behaviour - Severity	QS	ENR CLR	PBA-s	pbas11sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS
Disoriented Behaviour - Frequency of use	QS	ENR CLR	PBA-s	pbas11fr	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			PDS
Disoriented Behaviour – Worst	QS	ENR CLR	PBA-s	pbas11wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for career)	- 0 - 1 - 2 - 3 - 4			PDS

Section: Information

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
i) Is informant a relative?	QS	ENR CLR	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			PDS
ii) Is informant a household member?	QS	ENR CLR	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 - 5 - 6			Available upon SRC approval
General comments	CO	ENR CLR	PBA	coval	text					Not available

Form "UHDRS Motor/Diagnostic Confidence (Motor)"

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

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Assessment date	QS	ENR CLR	Motor	motor_qsdtc	date					Not available
Assessment day	QS	ENR CLR	Motor	motor_qsdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Motor score	QS	ENR CLR	Motor	motscore	number					PDS
Motor score incomplete	QS	ENR CLR	Motor	miscore	number					PDS

Section: Motor Assessment

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Ocular pursuit – Horizontal	QS	ENR CLR	Motor	ocularh	single choice	-complete (normal) -jerky movement -interrupted pursuits/full range -incomplete range -cannot pursue	- 0 - 1 - 2 - 3 - 4			PDS
Ocular pursuit - Vertical	QS	ENR CLR	Motor	ocularv	single choice	-complete (normal) -jerky movement -interrupted pursuits/full range -incomplete range -cannot pursue	- 0 - 1 - 2 - 3 - 4			PDS

Saccade initiation - Horizontal	QS	ENR CLR	Motor	sacinith	single choice	- normal	- 0			PDS
						- increased latency only	- 1			
						-suppressible blinks or head movements to initiate	- 2			
						-unsuppressible head movements	- 3			
						-cannot initiate saccades	- 4			
Saccade initiation - Vertical	QS	ENR CLR	Motor	sacinitv	single choice	-normal	- 0			PDS
						-increased latency only	- 1			
						-suppressible blinks or head movements to initiate	- 2			
						-unsuppressible head movements	- 3			
						-cannot initiate saccades	- 4			
Saccade velocity - Horizontal	QS	ENR CLR	Motor	sacvelh	single choice	- normal	- 0			PDS
						- mild slowing	- 1			
						- moderate slowing	- 2			
						- severely slow, full range	- 3			
						- incomplete range	- 4			
Saccade velocity - Vertical	QS	ENR CLR	Motor	sacvelv	single choice	- normal	- 0			PDS
						- mild slowing	- 1			
						- moderate slowing	- 2			
						- severely slow, full range	- 3			
						- incomplete range	- 4			
	QS		Motor	dysarth		-normal	- 0			PDS

Saccade velocity - Dysarthria		ENR CLR			single choice	-unclear, no need to repeat	- 1			
						-must repeat to be understood	- 2			
						-mostly incomprehensible	- 3			
						-anarthria	- 4			
Saccade velocity - Tongue protrusion	QS	ENR CLR	Motor	tongue	single choice	-can hold tongue fully protruded	- 0			PDS
						-cannot keep fully protruded for 10 sec	- 1			
						-cannot keep fully protruded for 5 sec	- 2			
						-cannot fully protrude tongue	- 3			
						- cannot protrude tongue beyond lips	- 4			
Finger taps - Right	QS	ENR CLR	Motor	fingtapr	single choice	-normal (≥15/5 sec.)	- 0			PDS
						-mild slowing, reduction in amplitude (11-14/5 sec.)	- 1			
						-moderately impaired (7-10/5 sec.)	- 2			
						-severely impaired (3-6/5 sec.)	- 3			
						-can barely perform task (0-2/5 sec.)	- 4			
Finger taps - Left	QS	ENR CLR	Motor	fingtapl	single choice	-normal (≥15/5 sec.)	- 0			PDS
						-mild slowing, reduction in amplitude (11-14/5 sec.)	- 1			

						-moderately impaired (7-10/5 sec.)	- 2			
						-severely impaired (3-6/5 sec.)	- 3			
						-can barely perform task (0-2/5 sec.)	- 4			
Pronate/supinate-hands: Right	QS	ENR CLR	Motor	prosupr	single choice	- normal	- 0			PDS
						- mild slowing and/or irregular	- 1			
						- moderate slowing and irregular	- 2			
						- severe slowing and irregular	- 3			
						- cannot perform	- 4			
Pronate/supinate-hands: Left	QS	ENR CLR	Motor	prosupl	single choice	- normal	- 0			PDS
						- mild slowing and/or irregular	- 1			
						- moderate slowing and irregular	- 2			
						- severe slowing and irregular	- 3			
						- cannot perform	- 4			
Pronate/supinate-hands: Luria	QS	ENR CLR	Motor	luria	single choice	-≥4 in 10 sec, no cue	- 0			PDS
						-<4 in 10 sec, no cue	- 1			
						-≥4 in 10 sec with cues	- 2			
						-<4 in 10 sec with cues	- 3			
						-cannot perform	- 4			
Rigidity-arms: Right	QS	ENR CLR	Motor	rigarmr	single choice	- absent	- 0			PDS
						- slight or present only with activation	- 1			
						- mild to moderate	- 2			
						- severe, full range of motion	- 3			

						- severe with limited range	- 4			
Rigidity-arms: Left	QS	ENR CLR	Motor	rigarml	single choice	- absent	- 0			PDS
						- slight or present only with activation	- 1			
						- mild to moderate	- 2			
						- severe, full range of motion	- 3			
						- severe with limited range	- 4			
Rigidity-arms: Bradykinesia-body	QS	ENR CLR	Motor	brady	single choice	- normal	- 0			PDS
						- minimally slow (?normal)	- 1			
						- mildly but clearly slow	- 2			
						- moderately slow, some hesitation	- 3			
						- markedly slow, long delays in initiation	- 4			
Maximal dystonia – Trunk	QS	ENR CLR	Motor	dysttrnk	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal dystonia – RUE	QS	ENR CLR	Motor	dystrue	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			

Maximal dystonia – LUE	QS	ENR CLR	Motor	dystlue	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal dystonia – RLE	QS	ENR CLR	Motor	dystrle	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal dystonia – LLE	QS	ENR CLR	Motor	dystlle	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal chorea - Face	QS	ENR CLR	Motor	chorface	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal chorea - BOL	QS	ENR CLR	Motor	chorbol	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
	QS		Motor	chortrnk		- absent	- 0			PDS

Maximal chorea – Trunk		ENR CLR			single choice	- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal chorea – RUE	QS	ENR CLR	Motor	chorrue	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal chorea – LUE	QS	ENR CLR	Motor	chorlue	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal chorea – RLE	QS	ENR CLR	Motor	chorrle	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal chorea – LLE	QS	ENR CLR	Motor	chorlle	single choice	- absent	- 0			PDS
						- slight/intermittent	- 1			
						- mild/common or moderate/intermittent	- 2			
						- moderate/common	- 3			
						- marked/prolonged	- 4			
Maximal chorea - Gait	QS	ENR CLR	Motor	gait	single choice	- normal gait, narrow base	- 0			PDS

						- wide base and/or slow	- 1			
						- wide base and walks with difficulty	- 2			
						- walks only with assistance	- 3			
						- cannot attempt	- 4			
Maximal chorea - Tandem walking	QS	ENR CLR	Motor	tandem	single choice	- normal for 10 steps	- 0			PDS
						- 1 to 3 deviations from straight line	- 1			
						- >3 deviations	- 2			
						- cannot complete	- 3			
						- cannot attempt	- 4			
Maximal chorea - Retropulsion pull test	QS	ENR CLR	Motor	retropls	single choice	- normal	- 0			PDS
						- recovers spontaneously	- 1			
						- would fall if not caugh	- 2			
						- tends to fall spontaneously	- 3			
						- cannot stand	- 4			

Section: Diagnostic Confidence

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

Form "UHDRS Total Functional Capacity (TFC)"

This form is part of the Screening visit.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Assessment date	QS	ENR CLR	TFC	tfc_qsdtc	date					Not available
Assessment day	QS	ENR CLR	TFC	tfc_qsdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Functional score	QS	ENR CLR	TFC	tfcscore	number					PDS

Section: Functional Capacity

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

Label	Domain	Study	Category	Variable	Type		Coding			Availability
						- normal	- 3			
Care level	QS	ENR CLR	TFC	carelevl	single choice	- full time skilled nursing	- 0			PDS
						- home or chronic care	- 1			
						- home	- 2			

Information Sources

Label	Domain	Study	Category	Variable	Type		Coding			Availability
Was the information obtained from	QS	ENR CLR	TFC	tfcsrc	single choice	- participant only - participant and family/companion	- 1 - 2			Available upon SRC approval

Form "UHDRS Functional Assessment/Independence Scale (Function)"

This form is part of the Screening visit.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Assessment date	QS	ENR CLR	Function	function_qsdtc	date					Not available
Assessment day	QS	ENR CLR	Function	function_qsdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Functional assessment score	QS	ENR CLR	Function	fascore	number					PDS
Functional score incomplete	QS	ENR CLR	Function	fiscore	number					PDS

Section: Functional Assessment

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Could subject engage in gainful employment in his/her accustomed work	QS	ENR CLR	Function	emplusl	boolean	- yes - no	- 1 - 0			PDS
Could subject engage in any kind of gainful employment?	QS	ENR CLR	Function	emplany	boolean	- yes - no	- 1 - 0			PDS
Could subject engage in any kind of volunteer or non-gainful work?	QS	ENR CLR	Function	volunt	boolean	- yes - no	- 1 - 0			PDS
Could subject manage his/her finances (monthly) without any help?	QS	ENR CLR	Function	fafinan	boolean	- yes - no	- 1 - 0			PDS
Could subject shop for groceries without help?	QS	ENR CLR	Function	grocery	boolean	- yes - no	- 1 - 0			PDS
Could subject handle money as a purchaser in a simple cash (shop) transaction?	QS	ENR CLR	Function	cash	boolean	- yes - no	- 1 - 0			PDS
Could subject supervise children without help?	QS	ENR CLR	Function	supchild	boolean	- yes - no	- 1 - 0			PDS
Could subject operate an automobile safely and independently?	QS	ENR CLR	Function	drive	boolean	- yes - no	- 1 - 0			PDS
Could subject do his/her own housework without help?	QS	ENR CLR	Function	housewrk	boolean	- yes - no	- 1 - 0			PDS
Could subject do his/her own laundry (wash/dry) without help?	QS	ENR CLR	Function	laundry	boolean	- yes - no	- 1 - 0			PDS
Could participant prepare his/her own meals without help?	QS	ENR CLR	Function	prepmeal	boolean	- yes - no	- 1 - 0			PDS

Could subject use the telephone without help?	QS	ENR CLR	Function	telephon	boolean	- yes - no	- 1 - 0			PDS
Could subject take his/her own medications without help?	QS	ENR CLR	Function	ownmeds	boolean	- yes - no	- 1 - 0			PDS
Could subject feed himself/herself without help?	QS	ENR CLR	Function	feedself	boolean	- yes - no	- 1 - 0			PDS
Could subject dress himself/herself without help?	QS	ENR CLR	Function	dress	boolean	- yes - no	- 1 - 0			PDS
Could subject bathe himself/herself without help?	QS	ENR CLR	Function	bathe	boolean	- yes - no	- 1 - 0			PDS
Could subject use public transport to get to places without help?	QS	ENR CLR	Function	pubtrans	boolean	- yes - no	- 1 - 0			PDS
Could subject walk to places in his/her neighbourhood without help?	QS	ENR CLR	Function	walknbr	boolean	- yes - no	- 1 - 0			PDS
Could subject walk without falling?	QS	ENR CLR	Function	walkfall	boolean	- yes - no	- 1 - 0			PDS
Could subject walk without help?	QS	ENR CLR	Function	walkhelp	boolean	- yes - no	- 1 - 0			PDS
Could subject comb hair without help?	QS	ENR CLR	Function	comb	boolean	- yes - no	- 1 - 0			PDS
Could subject transfer between chairs without help?	QS	ENR CLR	Function	trnchair	boolean	- yes - no	- 1 - 0			PDS
Could subject get in and out of bed without help?	QS	ENR CLR	Function	bed	boolean	- yes - no	- 1 - 0			PDS
Could subject use	QS	ENR	Function	toilet	boolean	- yes	- 1			PDS

toilet/commode without help?		CLR				- no	- 0			
Could subject's care still be provided at home?	QS	ENR CLR	Function	carehome	boolean	- yes - no	- 1 - 0			PDS
Information sources										
Was the functional assessment information obtained from	QS	ENR CLR	Function	fasrc	single choice	- subject only - subject and family/companion	- 1 - 2			Available upon SRC approval

Section: Independence Scale

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Subject's independence in %	QS	ENR CLR	Independence	indepscl	single choice	- no special care needed	- 100			PDS
						-	- 95			
						- no physical care needed if difficult tasks are avoided	- 90			
						-	- 85			
						- pre-disease level of employment changes or ends; cannot perform household chores to pre-disease level, may need help with finances	- 80			
						-	- 75			
						- self-care maintained for bathing, limited household duties, e.g. cooking and use of knives, driving terminates; unable to manage finances	- 70			
						-	- 65			
						- needs minor assistance in dressing, toileting, bathing; food must be cut for subject	- 60			

					-	- 55		
					- 24-hour supervision appropriate; assistance required for bathing, eating, toileting	- 50		
					-	- 45		
					- chronic care facility needed; limited self feeding, liquified diet	- 40		
					-	- 35		
					- subject provides minimal assistance in own feeding, bathing, toileting	- 30		
					-	- 25		
					- no speech, must be fed	- 20		
					-	- 15		
					- tube fed, total bed care	- 10		
					-	- 5		

11 Data File "Participation"

Key Variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)	---	ENR CLR	---	usubjid	text					PDS
Recoded subject identifier #enrollment number	---	CLR	---	subjid	text					PDS
Study ID	---	CLR	---	studyid	text	- CLR				PDS
Study	---	CLR	---	study		- HDClarity				PDS

General Visits

Label	Domain	Study	Cat.	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
HD Clarity classification at time of screening visit	SC	CLR		hdcat[7]	single choice	- early pre-manifest HD - late pre-manifest HD - early HD - moderate HD - advanced HD - healthy control	-1 -2 -3 -4 -5 -6			PDS

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[7]

- Early pre-manifest: diagnostic confidence <4 and CAG ≥40 and DBS<250;
- Late pre-manifest: diagnostic confidence <4 and CAG ≥40 and DBS≥250;
- Early Manifest: diagnostic confidence =4 and CAG ≥36 and TFC score of 7 to 13;
- Moderate Manifest HD: diagnostic confidence =4 and CAG≥36 and TFC score of 3 to 6;
- Advanced Manifest HD: diagnostic confidence =4 and CAG≥36 and TFC score of 0 to 2

Date of birth	DM	ENR		brthdtc	date						Not available
Recoded age at enrollment (aggregated if <18)	DM	ENR CLR		age_0	number					Birth date is transformed into age at time of enrollment of HD Clarity (rounded to a whole number).	Available upon SRC approval
Recoded age at visit (aggregated if <18)	DM	ENR CLR		age	number						PDS

Form "Enrollment into HD Clarity (Enrollment CLR)"

This form is part of the Screening visit.

Section: Local Participant Classification

Label	Domain	Study	Cat.	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Subject Reference Start Date	IE	CLR		rfsdtc	date					Not available
Study reference start day (ref. to 1st CLR Screening visit)	IE	CLR		rfstdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Day of informed consent	IE	CLR		rficdy	number				Transformed into days relative to date of first HD Clarity	PDS

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
									screening visit.	PDS
Study reference end day (ref. to 1st CLR Screening visit)	IE	CLR		rfendy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Participant status	SUPPSC	ENR CLR	---	subjstat	text	- enrolled - completed - excluded - withdrawn - violator				PDS

These variables are created specifically for the **Participation File**

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Number of events	SV	ENR		evtnum	number				Number of event forms entered.	PDS
Number of visits	SV	CLR	---	visitcnt	number					PDS
Visit type[1]	SV	ENR CLR	---	visit1, visit2, ... visit21	text	- Baseline - Follow Up - Screening - Biosample - Repeat Biosample	- BL - FUP - SCR - BS - BS2			PDS
Day of visit (sequence is ordered by visit days)[8]	SV	ENR CLR	---	vis1dy, vis2dy, ..., vis21dy,	number				Transformed into days relative to date of first HD Clarity	PDS

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[8] If ENR and CLR visit happened on the same day, then the ENR visit will get the lowest sequence number

									screening visit.	
Samples collected at each visit	SV	ENR CLR		vis1smpl, ... vis21smpl	text					PDS

12 Data File "Assessment"

Please note that the variables included in the assessment file indicate that the assessment was collected in the study, but may or may not be included in the PDS release.

Key Variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)	---	ENR CLR	---	usubjid						PDS
Recoded subject identifier #enrollment number	---	CLR	---	subjid						PDS
Study ID	---	ENR CLR	---	studyid	text	- CLR -ENR				PDS
Sequence number	---	ENR CLR	---	seq						PDS
Visit name[2]	---	ENR CLR	---	visit	text	- Screening - Sampling - RPT Sampling - Baseline - Follow Up				PDS
Visit day (i.e., number of days since first HD Clarity screening visit date, unique to each individual participant)	---	ENR CLR	---	visdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS

These variables are created specifically for the **Assessment File**

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Enrollment CLR	SUPPSV	ENR CLR		enrollmentclr	boolean	- 1 (available)				PDS

Eligibility Check	SUPPSV	ENR CLR		eligibilitycheck	boolean	- 1 (available)				PDS
Safety Lab Exam	SUPPSV	ENR CLR		safetylabexam	boolean	- 1 (available)				PDS
CSF	SUPPSV	ENR CLR		csf	boolean	- 1 (available)				PDS
CSF Quality	SUPPSV	ENR CLR		csfquality	boolean	- 1 (available)				PDS
Variable	SUPPSV	ENR CLR		variable	boolean	- 1 (available)				PDS
UHDRS Motor/Diagnostic Confidence	SUPPSV	ENR CLR		motor	boolean	- 1 (available)				PDS
UHDRS Total Functional Capacity	SUPPSV	ENR CLR		tfc	boolean	- 1 (available)				PDS
UHDRS Function Assessment/ Independence Scale	SUPPSV	ENR CLR		function	boolean	- 1 (available)				PDS
Cognitive Assessments	SUPPSV	ENR CLR		cognitive	boolean	- 1 (available)				PDS
Problem Behaviours Assessment - Short	SUPPSV	ENR CLR		pbas	boolean	- 1 (available)				PDS

13 Data File "Comorbid Conditions (Comorbid)"

This form is part of the General visit.

Key Variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)		ENR CLR		usubjid						PDS

Section: Past Disorders and Comorbidities

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Comorbid condition (Entered by the site)	MH	ENR		mhterm__term	text array					Not available
Comorbid condition - Modified Term (recoded to all English terms)	MH	ENR		mhterm__modify	text				ICD10	PDS
Comorbid condition - Code (ICD-10 codes and Enroll-HD specific codes, instead of MedDRA)[9]	MH	ENR		mhterm__decod	text				ICD-10-2014	PDS
Condition – Certainty	MH	ENR		mhterm__certainty	text					Not available
Body system code	MH	ENR		mhbodsys	single choice	- cardiovascular - pulmonary - neurologic - ENT - gynecologic/urologic - reproductive - gastrointestinal - metabolic/endocrine - hemato/lymphatic	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9			PDS

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[9] The MedDRA codes can be requested via a specified dataset request if you have a MedDRA license available.

					- dermatological - psychiatric - musculoskelatal - allergy/immunologic - ophthalmological - hepatobiliary - renal - other	- 10 - 11 - 12 - 13 - 14 - 15 - 16 - 17			
Comorbid condition - Start date	MH	ENR		mhstdtc	date				Not available
Comorbid condition - Start day (ref. to 1st CLR Screening visit)	MH	ENR		mhstdy	number			Transformed into days relative to date of first HD Clarity screening visit.	PDS
Comorbid condition - Ongoing	MH	ENR		mhenrf	boolean	- yes - no	- 1 - 0		PDS
Comorbid condition - End date	MH	ENR		mhendtc	date				Not available
Comorbid condition - End day (ref. to 1st CLR Screening visit)	MH	ENR		mhendy	number			Transformed into days relative to date of first HD Clarity screening visit.	PDS

99

14 Data File "Pharmacotherapy (PharmacoTx)"

This form is part of the General visit.

Key Variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)		ENR		usubjid						PDS

Section: Medications (Pharmacotherapy)

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Drug name	CM	ENR		cmtrt__term						Not available
Drug name (Modified Term)	CM	ENR		cmtrt__modify	text				coded with ICD10	PDS
Drug name (Coded Value)	CM	ENR		cmtrt__decod	text				ICD10[7]	PDS
Drug name – Certainty	CM	ENR		cmtrt__certainty	text					Not available
Drug ingredient – Modified Term	CM	ENR		cmtrt__ing	text					PDS
Drug ingredient – Code (coded by ATC)	CM	ENR		cmtrt__atc	text					PDS
Indication	CM	ENR		cmindc__term	text array					Not available
Indication – Modified Term (recoded to all english terms)	CM	ENR		cmindc__modify	text				ICD10	PDS
Indication - Code (Enroll-HD specific)	CM	ENR		cmindc__decod	text				ICD10[7]	PDS

Indication (Certainty)	CM	ENR		cmindc__certainty	text					Not available
Dose of drug (only valid entries)	CM	ENR		cmdose__ cmdostxt	text					Available upon SRC approval
Dose of drug's unit	CM	ENR		cmdose__cmdosu	text					PDS
Daily intake	CM	ENR		cmfrq	number array	- in the morning - at noon - in the evening - at night	- 1 - 2 - 3 - 4			Available upon SRC approval
Frequency of administration	CM	ENR		cmdosfrq	single choice	- daily - every 2nd day - every 3rd day - weekly - every 2nd week - monthly - every 2nd month - every 3rd month - annually - as needed	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10			PDS
Route of administration	CM	ENR		cmroute	single choice	- p.o. - p.r. - s.c. - i.m. - i.v. - nasal - td - sl	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8			PDS

						- inh - other	- 9 - 10			
Start date of administration	CM	ENR		cmstdtc	date					Not available
Start day of administration (ref. to 1st CLR Screening visit)	CM	ENR		cmstdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Ongoing	CM	ENR		cmenrf	boolean	- yes - no	- 1 - 0			PDS
Stop date of administration	CM	ENR		cmendtc	date					Not available
End day of administration (ref. to 1st CLR Screening visit)	CM	ENR		cmendy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS

15 Data File "Non-Pharmacologic Therapies (NonPharmacoTx)"

This form is part of the General visit.

Key Variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)		ENR		usubjid						PDS

Section: Non-Pharmacologic Therapies

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Therapy	CM	ENR	Non-Pharmacologic Therapies	cmtrt_term	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			PDS
Number of times is administered	SUPPCM	ENR	Non-Pharmacologic Therapies	cmfrq	number					PDS
Frequency of administration	CM	ENR	Non-Pharmacologic Therapi	cmdosfrq	single choice	- daily - weekly - monthly - as needed	- 1 - 2 - 3 - 4			PDS

			es							
Start date of administration	CM	ENR	Non-Pharmacologic Therapies	cmstdtc	date					Not available
Start day of administration (ref. to 1st CLR Screening visit)	CM	ENR	Non-Pharmacologic Therapies	cmstdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Administration Ongoing	CM	ENR	Non-Pharmacologic Therapies	cmenrf	boolean	- yes - no	- 1 - 0			PDS
Stop date of administration	CM	ENR	Non-Pharmacologic Therapies	cmendtc	date					Not available
Stop day of administration (ref. to 1st CLR Screening visit)	CM	ENR	Non-Pharmacologic Therapies	cmendy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS

16 Data File "Nutritional Supplements (NutSuppl)"

This form is part of the General visit.

Key Variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)		ENR		usubjid						PDS

Section: Nutritional Supplements

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Type of nutritional supplement	CM	ENR	NutSuppl	cmcat	single choice	- vitamin & supplements - herbs (extracts) - herbs (teas) - other natural remedies - aromatherapies homeopathic remedies - homepathic remedies - high calorie diet	- 1 - 2 - 3 - 4 - 5 - 6 - 7			PDS
Supplement - Modified Term (recoded to all english terms)	CM	ENR	NutSuppl	cmtrt_modify	text					PDS
Supplement – Code	CM	ENR	NutSuppl	cmtrt_decod	text					PDS
Supplement - ATC Code(s)	CM	ENR	NutSuppl	cmtrt__atc	text					PDS
Supplement - Ingredient(s)	CM	ENR	NutSuppl	cmtrt__ing	text					PDS
Dose of Supplement	CM	ENR	NutSuppl	cmdostxt	number					Available upon SRC approval
Total daily dose of Supplement	CM	ENR	NutSuppl	cmdostot	number					PDS

Unit of Supplement's dose	CM	ENR	NutSuppl	cmdosunit	single choice	- g - mg - IU - spoons - tablets - drops - capsule - other	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8			PDS
Daily intake	SUPPCM	ENR	NutSuppl	cmfrq	number array	- in the morning - at noon - in the evening - at night	- 1 - 2 - 3 - 4			Available upon SRC approval
Frequency of administration	CM	ENR	NutSuppl	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			PDS
Start date of supplement administration	CM	ENR	NutSuppl	cmstdtc	date					Not available
Start day of supplement administration (ref. to 1st CLR Screening visit)	CM	ENR	NutSuppl	cmstdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Supplement administration ongoing	CM	ENR	NutSuppl	cmenrf	boolean	- yes - no	- 1 - 0			PDS

Stop date of supplement administration	CM	ENR	NutSuppl	cmendtc	date					Not available
End day of supplement administration (ref. to 1st CLR Screening visit)	CM	ENR	NutSuppl	cmendy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS

17 Data File "CSF Quality"

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

Key Variables of a Visit

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Recoded HDID (i.e., recoded subject identifier)	---	CLR	---	usubjid						PDS
Recoded subject identifier #enrollment number	---	CLR	---	subjid						PDS
Study ID	---	CLR	---	studyid	text	- CLR - ENR				PDS
Visit name[2]	---	ENR CLR	---	visit	text	- Screening - Sampling - RPT Sampling - Baseline - Follow Up				PDS
Visit day (i.e., number of days since first HD Clarity screening visit date, unique to each individual participant)	---	CLR	---	visdy	number				Transformed into days relative to date of first HD Clarity screening visit.	PDS
Visit status		ENR CLR	---	visstat	text	- plausible - reviewing - completed				PDS
Row Index (Number)	---	CLR	---	row	number				Unique row index number. Only for datafile "csfquality"	PDS

Section: Onsite CSF Sample Quality control

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Microscopic erythrocyte count in CSF in triplicate										
1. Erythrocyte Count	LB	CLR	LB	erycnt1	number			erys/µl		PDS
2. Erythrocyte Count	LB	CLR	LB	erycnt2	number			erys/µl		PDS
3. Erythrocyte Count	LB	CLR	LB	erycnt3	number			erys/µl		PDS
Erythrocyte Flag depending on erythrocytes count	SUPPLB	CLR	LB	eryflag	boolean	- yes - no	- 1 - 0			PDS
Microscopic leukocyte count in CSF in triplicate										
1. Leukocyte Count	SUPPLB	CLR	LB	leukcnt1	number			cells/µl		PDS
2. Leukocyte Count	SUPPLB	CLR	LB	leukcnt2	number			cells/µl		PDS
3. Leukocyte Count	SUPPLB	CLR	LB	leukcnt3	number			cells/µl		PDS
Leukocyte flag depending on leukocytes count	SUPPLB	CLR	LB	leukflag	boolean	- yes - no	- 1 - 0			PDS

Section: CSF Quality Control on Hemoglobin

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Results										
HbA conc 1	LB	CLR		hbac1	number			ng/ml		PDS
HbA conc 2	LB	CLR		hbac2	number			ng/ml		PDS
HbA conc 3	LB	CLR		hbac3	number			ng/ml		PDS
Mean HbA conc	LB	CLR		hbacm	number			ng/ml		PDS
SD	LB	CLR		sd	number					PDS
CV%	LB	CLR		cv	number					PDS

Comments	LB	CLR		cmt	text						Not available
Analysis lab	LB	CLR		lab	text						Not available
Assay type	LB	CLR		assay	text						Not available
Assay date	LB	CLR		assaydtc	date						Not available
Days when assay (external qc) has been done	LB	CLR		assaydy	number					Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Report#	LB	CLR		rptno	text						Not available

Additional assessments (not provided in regular PDS)

Form "Mortality"

This form is part of the General visit.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Assessment date	DS	ENR		dsdtc	date					Not available
Assessment day	DS	ENR		dsdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval

Section: Death Report Form

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of death	DS	ENR		dssdtc	date					Not available
Age of death	DS	ENR		dssage	number				Transformed from date of death.	Available upon SRC approval
Place of death	DS	ENR		dsplace	single choice	- home - hospital - nursing home - hospice care - unknown	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval
Cause of death	DS	ENR		dsend	single choice	- pneumonia - other infection - cancer	- 1 - 2 - 3			Available upon SRC approval

					- stroke - trauma - suicide - other	- 4 - 5 - 6 - 7			Not available
If other cause of death, please specify	DS	ENR		dsendoth	text					Not available
Was an autopsy performed?	DS	ENR		dsautop	single choice	- no - yes - Unknown	- 0 - 1 - 9999			Available upon SRC approval
Result of autopsy	DS	ENR		dsautopr	text	-	-			Not available
Information obtained primarily from	DS	ENR		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			Available upon SRC approval
Please specify from information were obtained	DS	ENR		infooth	text					Not available
Comments?	DS	ENR		dscom	boolean	- yes - no	- 1 - 0			Not available
Comment	CO	ENR		coval	text	-	-			Not available

Form "Premature End of Study (End)"

This form is part of the Premature End visit.

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of end of study report	DS	ENR CLR		dsdtc	Date					Not available
Day of end of study report	DS	CLR		dsdy	Number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval

Section: End of Study

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Specify primary reason for participant's premature discontinuation from study	DS	ENR CLR		dsterm	single choice	- event or intercurrent illness of a nature requiring withdrawal - request of primary care physician, site investigator - participant's request (includes career/spouse/authorized Representative's request) - lost to follow up - institutionalized (will not be followed further) - other - specific adverse event	- 1 - 2 - 3 - 4 - 5 - 6 - 7			Available upon SRC approval

Please specify the reason for the participant's request	DS	ENR CLR		dsreas	single choice	- unable to travel - participant unwilling to continue - participant moved away from the study site	- 1 - 2 - 3			Available upon SRC approval
If primary reason for participant's premature discontinuation, please specify	DS	ENR CLR		termoth	text					Not available
AE number	DS	ENR CLR		aenum	number					Available upon SRC approval
Did the participant request the removal of data	DS	ENR CLR		dsrdt	boolean	- yes - no	- 1 - 0			Not available

Form "Visit Checklist (Checklist)"

This form is part of the Screening visit.

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

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
General Variable	SV	ENR		vc1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Comorbid	SV	ENR		vc2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Pharmacotherapy	SV	ENR		vc3	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Nutritional Supplements	SV	ENR		vc4	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Non-Pharmacotherapy	SV	ENR		vc5	boolean	- yes - no	- 1 - 0			Available upon SRC approval

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	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Comorbid	SV	ENR		vc2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Pharmacotherapy	SV	ENR		vc3	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Nutritional Supplements	SV	ENR		vc4	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Non-Pharmacotherapy	SV	ENR		vc5	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Have you repeated the UHDRS motor exam	SV	ENR		v8	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Section: Safety Evaluation prior to CSF Collection

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Did your repeat physical examination conducted today reveal any reason to suspect abnormal bleeding tendency, e.g. easy bruising, petechial rash?	IE	CLR		secsf1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Did your repeat neurological examination conducted today reveal any reason to suspect new focal neurological lesion, e.g. new	IE	CLR		secsf2	boolean	- yes - no	- 1 - 0			Available upon SRC approval

headache, optic disc swelling, asymmetric focal long tract signs?										
Vital signs satisfactory	IE	CLR		secsf3	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Form "Blood Processing"

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

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
LAB-ID	LB	CLR		labid	text					Not available
Kit ID	SUPPLB	CLR	LB	kitid	text					Not available
Date and time of blood draw	LB	CLR		lbdtc	datetime					Not available
Lithium Heparin Collection Tube										
Lithium Heparin Collection Tube - Tube ID	LB	CLR		lhtid	text					Not available
Lithium Heparin Collection Tube - Quantity	SUPPLB	CLR	LB	lhqty	number					Available upon SRC approval
Serum Collection Tube										
Serum Collection Tube - Tube ID	LB	CLR		sstid	text					Not available
Serum Collection Tube - Quantity	SUPPLB	CLR	LB	sstqty	number					Available upon SRC approval

Section: Blood Processing

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Serum										
Serum - Tubes ID	LB	CLR		sertid	text					Not available
Serum - Quantity	SUPPLB	CLR	LB	seraqty	number					Available upon SRC

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
										approval
Serum - Tube rack ID	LB	CLR		sertrid	text					Not available
Time serum processing is started	SUPPLB	CLR	LB	serstim	datetime					Available upon SRC approval
Time serum processing is completed	SUPPLB	CLR	LB	serctim	datetime					Available upon SRC approval
Plasma										
Plasma - Tubes ID	LB	CLR		plsmtid	text					Not available
Plasma - Quantity	SUPPLB	CLR	LB	plsmaqty	number					Available upon SRC approval
Plasma - Tube rack ID	LB	CLR		plsmtrid	text					Not available
Time plasma processing is started	SUPPLB	CLR	LB	plsmstim	time					Available upon SRC approval
Time plasma processing is completed	SUPPLB	CLR	LB	plsmctim	time					Available upon SRC approval
Age at time of plasma collection		CLR		plsmsage	number					Available upon SRC approval

Section: On site Sample Storage

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date and time CSF samples are stored on site	SUPPLB	CLR	LB	cstrgdtc	datetime					Not available
Date and time blood-derived samples are stored on site	SUPPLB	CLR	LB	bstrgdtc	datetime					Not available

Form "Adverse Events Log (AE)"

This form is part of the Events visit.

Section: General Information

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Has the participant had any Adverse Events during this study	AE	CLR		aeyn	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Section: Details

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of report	AE	CLR		aedat	date					Not available
AE verbatim term	AE	CLR		aeterm__term	text array					Available upon SRC approval
AE verbatim term (Modified Term)	AE	CLR		aeterm__modify	text array					Available upon SRC approval
AE verbatim term (Coded Value)	AE	CLR		aeterm__code	text array					Available upon SRC approval
AE verbatim term – Certainty	AE	CLR		aeterm__certainty	text array					Not available
AE Start date	AE	CLR		aestdat	date					Not available
Start day of adverse event	AE	CLR		aestdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval

AE End date	AE	CLR		aeendat	date					Not available
End Day of adverse event	AE	CLR		aeendy	number				Transformed into days relative to date of first HD Clarity screening visit..	Available upon SRC approval
AE Ongoing?	AE	CLR		aeongo	boolean	- yes - no	- 1 - 0			Available upon SRC approval
AE Severity	AE	CLR		aesev	single choice	- mild - moderate - severe - life-threatening - death	- 1 - 2 - 3 - 4 - 5			Available upon SRC approval
AE relationship to study procedure	AE	CLR		aerel	single choice	- probably related - possibly related - unrelated	- 1 - 2 - 3			Available upon SRC approval
AE related to which study procedure?	AE	CLR		aerelnst	single choice	- lumbar puncture (low pressure syndrome) - lumbar puncture (other complication) - other study	- 1 - 2 - 3			Available upon SRC approval

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						procedure				
AE Outcome	AE	CLR		aeout	single choice	- resolved; no sequelae	- 1			Available upon SRC approval
						- ongoing; no treatment	- 2			
						- ongoing; undergoing treatment	- 3			
						- residual effects present; no treatment	- 4			
						- residual effects present; undergoing treatment	- 5			
						- death	- 6			
						- unknown	- 7			
Was this an expected adverse event	SUPPAE	CLR		aeexp	boolean	- yes - no	- 1 - 0			Available upon SRC approval
SAE	AE	CLR		aeser	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Form "Serious Adverse Event (SAE)"

This form is part of the Events visit. **This form will only be made available when there is enough sample size.**

Section: General

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of serious adverse event report	SAE	CLR		saedat	date					Not available
Day of serious adverse event report	SAE	CLR		saedy	number					Available upon SRC approval

Section: Serious Adverse Event

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
SAE number (reference to AE)	AE	CLR		aenum	number					Available upon SRC approval
Start date of serious adverse event	AE	CLR		aestdat	date					Not available
Start day of serious adverse event	AE	CLR		aestdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Is the serious adverse event ongoing	AE	CLR		saeongo	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Stop date of serious adverse event	AE	CLR		saeendat	date					Not available
Stop day of serious adverse event	AE	CLR		saendy	number				Transformed into days relative to date of first HD Clarity	Available upon SRC approval

											screening visit.	
Was this an expected serious adverse event	AE	CLR		saeexp	boolean	- yes - no	- 1 - 0					Available upon SRC approval
Gender	AE	CLR		sex	single choice	- female - male	- f - m					Available upon SRC approval
Age	AE	CLR		age	number							Available upon SRC approval
SAE verbatim term	AE	CLR		saeterm__term	text							Available upon SRC approval
SAE verbatim term (Modified Term)	AE	CLR		saeterm__modify	text							Available upon SRC approval
SAE verbatim term (Coded Value)	AE	CLR		saeterm__decod	text							Available upon SRC approval
SAE verbatim term - Certainty	AE	CLR		saeterm__certainty	text							Not available
Brief description of the nature of the serious adverse event	SUPPAE	CLR		aetermbd	text							Not available
Nature of the serious adverse event - death	AE	CLR		aesdth	boolean	- yes - no	- 1 - 0					Available upon SRC approval
Nature of the serious adverse event - Disability/incapacity	AE	CLR		aesdisab	boolean	- yes - no	- 1 - 0					Available upon SRC approval

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Nature of the serious adverse event - Life-theatening	AE	CLR		aeslife	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Nature of the serious adverse event - Congenital anomaly/birth defect	AE	CLR		aescong	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Nature of the serious adverse event - Hospitalization-initial or prolonged	AE	CLR		aeshosp	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Nature of the serious adverse event - Required intervention to prevent permanent impairment	AE	CLR		aesinter	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Nature of the serious adverse event - None of the above	AE	CLR		aesnone	boolean	- yes - no	- 1 - 0			Available upon SRC approval
SAE Outcome	AE	CLR		saeout	single choice	- resolved; no sequelae - ongoing; no treatment - ongoing; undergoing treatment - residual effects present; no treatment - residual effects present; undergoing treatment - death	- 1 - 2 - 3 - 4 - 5 - 6			Available upon SRC approval

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
						- unknown	- 7			
Describe any medical, behavioral, or other interventions taken as a result of this SAE	SUPPAE	CLR		aerelnst	text					Not available

Status of this report

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Is this the final SAE report	AE	CLR		aerver	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Was the participant withdrawn from the research due to this SAE	AE	CLR		aedis	boolean	- yes - no	- 1 - 0			Available upon SRC approval

Section: SAE Notification

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Date of notification	AE	CLR		aenotdat	date					Not available
Day of notification	AE	CLR		aenotdy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval

Form "Phone Contact - Sampling (Phone Contact)"

This form is part of the Phone Contact visit.

Section: Phone Contact

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Did the participant receive phone contact from the site after the sampling visit?	SV	CLR		pc1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Date of contact	SV	CLR		pc11	date					Not available
Day of contact	SV	CLR		pc11dy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Time of contact	SV	CLR		pc12	time					Not available
Reason of phone contact not performed	SV	CLR		pc10	single choice	- unable to contact participant after multiple attempts - participant withdrew consent to be contacted - contact was not attempted	- 1 - 2 - 3			Available upon SRC approval
Were there any adverse events?	SV	CLR		pc2	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Is this participant interested in attending a repeat sampling visit?	SV	CLR		pc3	boolean	- yes - no	- 1 - 0			Available upon SRC approval

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Form "Phone Contact – Repeat Sampling (Phone Contact)"

This form is part of the Repeat Phone Contact visit.

Section: Phone Contact

Label	Domain	Study	Category	Variable	Type	Parameter	Coding	Unit	Transformation	Availability
Did the participant receive phone contact from the site after the sampling visit?	SV	CLR		pc1	boolean	- yes - no	- 1 - 0			Available upon SRC approval
Date of contact	SV	CLR		pc11	date					Not available
Day of contact	SV	CLR		pc11dy	number				Transformed into days relative to date of first HD Clarity screening visit.	Available upon SRC approval
Time of contact	SV	CLR		pc12	time					Not available
Reason of phone contact not performed	SV	CLR		pc10	single choice	- unable to contact participant after multiple attempts - participant withdrew consent to be contacted - contact was not attempted	- 1 - 2 - 3			Available upon SRC approval
Were there any adverse events?	SV	CLR		pc2	boolean	- yes - no	- 1 - 0			Available upon SRC approval

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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*, 19 December 2018 (Version No. 003): https://enroll-hd.org/enrollhd_documents/2020-10-R1/HDClarity-Protocol-2020-10-R1.pdf