Data Dictionary of Enroll-HD Plus Periodic Dataset

Version 2016-10-R1

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1 Purpose of this Document

The purpose of this document is to provide a data dictionary of the Enroll-HD Periodic Dataset that is available for the public research community. The dataset includes data from the studies ENROLL, REGISTRY and Adhoc Data. The dataset represents a data extract of the database of the Enroll-HD multistudy system at a certain point in time.

Studies description

Enroll-HD (ENR) is a global, longitudinal observational study of HD. It includes participants from North America, Europe, Australasia and Latin America. The study started in 2011.

Registry is a European, longitudinal observational study of HD. Participants are from Europe. The study started in 2004. As Enroll-HD began, Registry sites and participants began to transition into Enroll-HD. This dataset includes a subset of participants who initially joined Registry but who have since consented to Enroll-HD and have agreed to have their Registry data migrated into the Enroll-HD study. Registry data included in this dataset were either obtained under the Registry Protocol version 2 (R2) or Registry Protocol version 3 (R3). The assessment protocol changed between protocols and therefore specific forms and associated variables differ depending on which protocol was used at the time of data capture. Fields have been annotated with R2 or R3 as appropriate.

Ad Hoc (RET) is a subset of assessment data (e.g. UHDRS Motor) collected at routine clinical visits that pre-date a participant's enrolment into Registry.

Data quality

Enroll-HD and Registry data included in the dataset were monitored in accordance with the respective study monitoring plans [5] [6]. Adhoc Data were not monitored.

In addition, the data has been verified using various electronic plausibility checks [7] [8].

To obtain a copy of the documents, please contact IT Support.

De-identification policies

Data that is potentially identifying for a participant has been removed or de-identified within this dataset. The policies for de-identification use methods supported by the HIPAA Privacy Rule, namely "Expert Determination" [2].

The data dictionary describes all data files and its variables used within the combined periodic dataset.

2 Structure of the Dataset

The dataset consists of several data files. These contain data items defined by variables. Variables are taken from the eCRFs from the Enroll-HD study, REGISTRY study, and Adhoc data. Specific data items have been transformed or obscured due to de-identification reasons.

2.1 Studies of the Combined Dataset

Data files are associated with one or several studies. The studies have been collected by different sponsors.

Study acronym	Study name	Sponsor	Chronological order
ENR	Enroll-HD	CHDI	Enroll-HD is the most recent study participation of a participant. This participation is mandatory.
R3	REGISTRY V3	EHDN	REGISTRY V3 participation is optional and has been taken place before Enroll-HD.
R2	REGISTRY V2	EHDN	REGISTRY V2 participation is optional and has been taken place before Enroll-HD and REGSITRY V3 (if available).
RET	Ad Hoc	(any)	The existence Ad Hoc data is optional and has been collected before Enroll-HD and REGISTRY V3 (if available) and REGISTRY V2 (if available) .

2.2 Data Files of the Combined Dataset

There are three types of data files:

- The participant-based data files "profile", "pharmacotx", "nonpharmacotx", "nutsuppl", and "comorbid" contain general study-independent information about the participant. This information can be used for all studies.
- The participant-based data files "participation", "assessment" and "events" contain study specific information about a participant within a study. The data file "events" is a special data file for Enroll-HD containing all the reportable events of a participant.
- The visit-based data files contain information about concrete visits within a study. The data file "enroll" contains visit-depending information about the Enroll-HD study combined in one data file. The file "registry" contains visit-dependent information about all REGISTRY studies and visits combined in one data file, and the file "adhoc" contains the information about Ad Hoc data.

Data File	Type	Studies	Description
profile	participant-based	ENR R3 R2 RET	General and annually updated information including the forms: Demog, HDCC, CAG, Mortality
pharmacotx	participant-based	ENR R3 R2 RET	Information about pharmacologic therapies
nutsuppl	participant-based	ENR R3 R2 RET	Information about nutritional supplements
nonpharmacotx	participant-based	ENR R3 R2 RET	Information about non pharmacologic therapies
comorbid	participant-based	ENR R3 R2 RET	Information about comorbid conditions
participation	study-based	ENR R3 R2 RET	Study-specific information about participant taken part in the study. Start, end, reasons, visits, etc. are stored within a general way.
assessment	study-based	ENR R3 R2 RET	Study-specific information about existing regular visits performed in any study. Provides overview about number, type and sequence of visits.
event	study-based	ENR	Information about reportable events happened within Enroll-HD
enroll	visit-based	ENR	Enroll data contains forms from Enroll-HD study
registry	visit-based	R3 R2	REGISTRY visits contains combined forms from REGISTRY3 and REGISTRY2.
adhoc	visit-based	RET	Ad Hoc data containing forms: Variable, Motor, Function, TFC, MMSE, Cognitive

2.3 Entity Relation Diagram

The following diagram gives an overview about the data files in this dataset, shows the relations between them and their key variables ("primary keys") which are required to combine the data files.
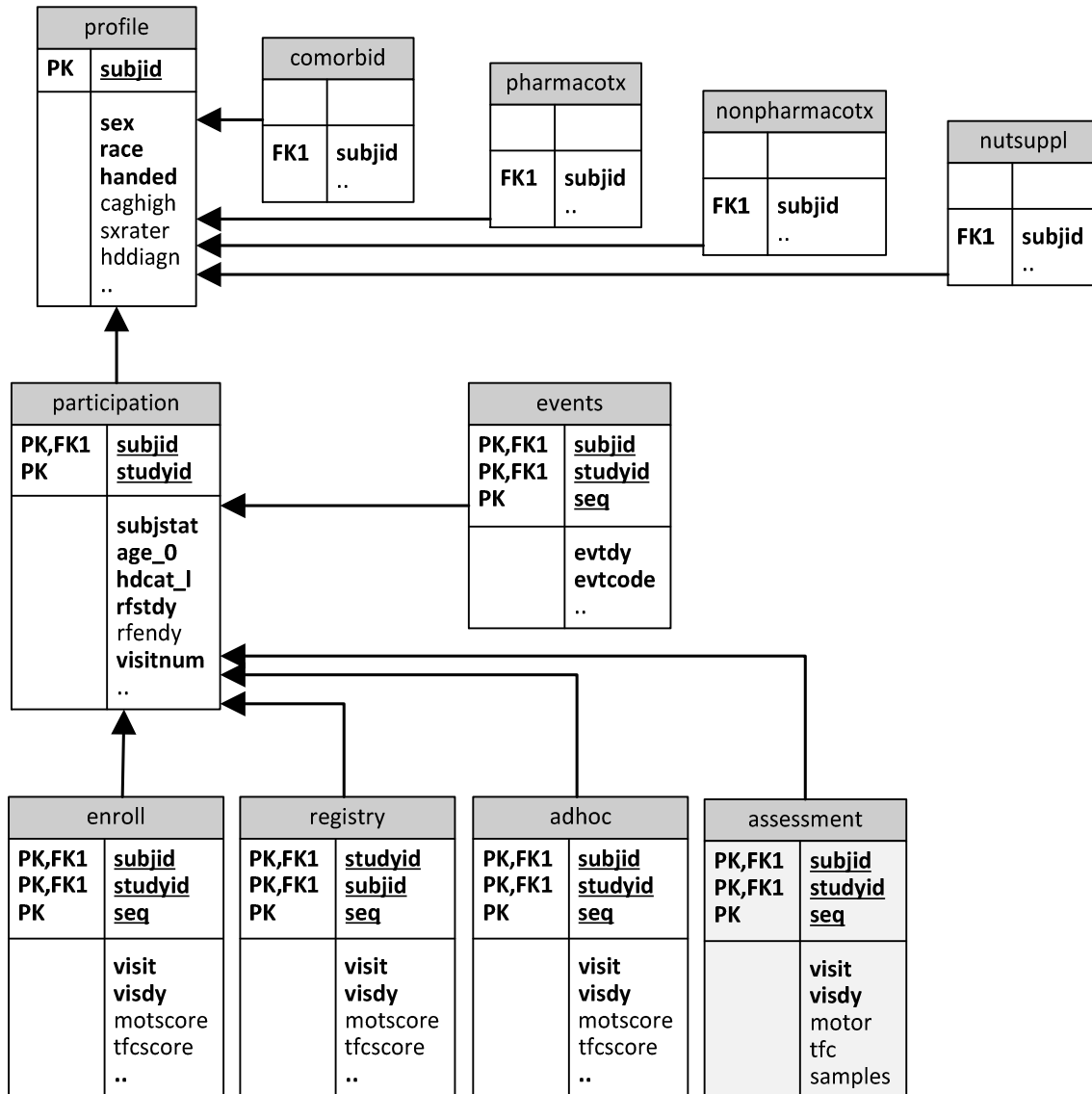
Figure 1: Entity Relationship Diagram

2.4 Structure of Variables

Each data file contains variables. The data dictionary of each data file lists its variables with the following attributes:

Attribute	Description
Label	Variable label (CDISC SDTM compliant)
Domain	Assigned CDSIC SDTM Domain
Category	Assigned CDSIC SDTM Category (optional)
Variable	Internal variable name. Variable is defined in CDSIC SDTM compliant naming convention as far as possible.
Type	Data types of input fields: boolean — The boolean type represents the values: 1 (yes) and 0 (no). number — The number type represents integer or floating point data values. text — The text type represents alphanumeric string data values. date — The date type is represented as the number of days relating to the date of the participant's Enroll-HD baseline visit. 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 enrollment date is calculated and provided in the data. The information about whether a date has been automatically completed or not is not included in the dataset. 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 parameter in the data dictionary tables.
Parameter	Textparameter 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 Enroll-HD data in order to minimize the possibility to identify a

Attribute	Description
	participant. Therefore many variables are transformed, recoded or outliers removed/cut. These transformations are described on a variable to variable basis.

2.5   Representation of Special Values

Date Values

Date values are represented as relative number of days since date of Enroll–HD baseline visit. The studies REGISTRY2, REGISTRY3 and Ad Hoc are also referenced to the baseline visit of Enroll-HD. Note that days can be negative (in case the date refers to a point in time before enrollment). Date values that have been entered as incomplete date have been automatically completed including the following rule.: value been entered as "YYYY-MM" to "YYYY-MM-15", values entered as "YYYY", as "YYYY-07-01".

Examples:

Baseline date: 11/01/2014 (MM/DD/YYYY)

Entered Date Value	Completed Date	Representation Dataset
11/01/2014	11/01/2014	0
11/12/2014	11/12/2014	11
11/2014	11/15/2014	15
2014	07/01/2014	-123

Missing Values

Values that are explicitly defined as missing, not applicable or wrong are represented as "NA".

Artificial Values for Aggregated Data

For specific variables, certain values are regarded as too identifying (e.g. very low or very high CAG repeat lengths). These values are "aggregated" meaning that all values within that range are represented by one artificial value.

The following variables are aggregated:

Variable	Domain	Data Files	Aggregation	Representation
caghigh	SC	profile	greater than 55	">70"
caglow	SC	profile	greater than 31	">28"
age	SC	profile	lower than 18	"<18"

The data handling manual [3] describes how to handle aggregated values.

3 Participant-Based Data Files

Participant-based data files are directly related to a participant independent of a study, i.e. the data is not assessed during a specific study visit. The data is either captured once only or in an periodically (e.g. annually) updated manner.

There are the following participant-based data files:

- profile
- pharmacotx
- nonpharmacotx
- nutsuppl
- comorbid

In general, these data files contain more than one entry per participant. Different entries are characterized by an index (variable "seq").

3.1 Data File "profile" (Participant Profile)

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				one-way transformation from HDID to recoded HDID .
Region (latest)	---	---	region	text	- Europe - Latin America - Northern America - Australasia			
Gender	DM		sex	single choice	- female - male	- f - m		
Ethnicity	DM		race	single choice	- Caucasian - American Black - Hispanic or Latino Origin - American Indian Native American Amerindian - Asian - Mixed - Other	- 1 - 2 - 3 - 8 - 16 - 15 - 6		Original values from eCRF are aggregated for de-identification reasons.
Handedness	SC		handed	single choice	- right - left - mixed	- 1 - 2 - 3		
Previous suicidal ideation or attempts?	MH		hxsid	boolean	- yes - no	- 1 - 0		

Age of death	SUPPDS	Mortality	dssage	number			Years	Age at death, e.g. "75"
Place of death	SUPPDS	Mortality	dsplace	single choice	- home - hospital - nursing home - hospice care - unknown	- 1 - 2 - 3 - 4 - 5		
Cause of death	SUPPDS	Mortality	dsend	single choice	- pneumonia - other infection - cancer - stroke - trauma - suicide - other	- 1 - 2 - 3 - 4 - 5 - 6 - 7		
Larger research CAG allele determined from DNA	SC	---	caghigh	text				Aggregation: Values greater than 70 are represented as ">70" ,
Smaller research CAG allele determined from DNA	SC	----	caglow	text				Aggregation: Values greater than 28 are represented as ">28", others as numbers.
Mother affected	MH		momhd	boolean	- yes - no	- 1 - 0		
Age at onset of symptoms in mother	MH		momagesx	number			years	
Father affected	MH		dadhd	boolean	- yes - no	- 1 - 0		
Age at onset of symptoms in father	MH		dadagesx	number			years	

Family History	SC		fhx	boolean	- yes - no	- 1 - 0	
Have motor symptoms compatible with HD ever been a part of the participant's medical history?	MH		ccmtr	boolean	- yes - no	- 1 - 0	
Group At what age did the participant's motor symptoms begin?							
age (years)	SUPPMH		ccmtrage	number			
Symptoms first noted by participant	MH		sxsubj	number			Convert to age, e.g. "41"
Symptoms first noted by family	MH		sxfam	number			Convert to age
Date of clinical HD diagnosis	MH		hddiagn	number			Convert to age
Can you, as a rater, estimate the time of symptom onset	MH		sxest	boolean	- yes - no	- 1 - 0	
Rater's estimate of symptom onset	MH		sxrater	number			Convert to age
Confidence with which this estimation is made	MH		sxestcfd	single choice	- high - low	- 1 - 2	
Group What are these symptoms?							
Initial major symptom noted by participant	MH		sxsubjm	single choice	- motor - cognitive - psychiatric - oculomotor - other	- 1 - 2 - 3 - 4 - 5	

					- mixed	- 6		
Initial major symptom noted by family	MH		sxfamm	single choice	- motor - cognitive - psychiatric - oculomotor - other - mixed	- 1 - 2 - 3 - 4 - 5 - 6		
Rater's judgement of initial major symptom	MH		sxraterm	single choice	- motor - cognitive - psychiatric - oculomotor - other - mixed	- 1 - 2 - 3 - 4 - 5 - 6		
Has depression (includes treatment with antidepressants with or without a formally-stated diagnosis of depression) ever been a part of the participant's medical history?	MH		ccdep	boolean	- yes - no	- 1 - 0		
Group At what age did the depression begin?								
age (years)	SUPPMH		ccdepage	number				
Has irritability ever been a part of the participant's medical history?	MH		ccirb	boolean	- yes - no	- 1 - 0		
Group At what age did the irritability begin?								
age (years)	SUPPMH		ccirbage	number				
Has violent or aggressive	MH		ccvab	boolean	- yes	- 1		

					- no	- 0		
behaviour ever been a part of the participant's medical history?								
Group At what age did violent or aggressive behaviour begin?								
age (years)	SUPPMH		ccvabage	number				
Has apathy ever been a part of the participant's medical history	MH		ccapt	boolean	- yes - no	- 1 - 0		
Group At what age did apathy begin?								
age (years)	SUPPMH		ccaptage	number				
Has perseverative obsessive behaviours ever been a part of the participant's medical history	MH		ccpob	boolean	- yes - no	- 1 - 0		
Group At what age did perseverative obsessive behaviour begin?								
age (years)	SUPPMH		ccpobage	number				
Has psychosis (hallucinations or delusions) ever been a part of the participant's medical history	MH		ccpsy	boolean	- yes - no	- 1 - 0		
Group At what age did psychosis (hallucinations or delusions) begin?								
age (years)	SUPPMH		ccpsyage	number				
Does the participant have a	MH		ccpsyfh	boolean	- yes	- 1		

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
family history of a psychotic illness in a first degree relative					- no	- 0		
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		cccog	boolean	- yes - no	- 1 - 0		
Group At what age did cognitive impairment first start to have an impact on daily life?								
age (years)	SUPPMH		cccogage	number				

3.2 Data File "pharmacotx" (Pharmacotherapy)

The data file pharmacotx contains information about medications taken by the participant. Drug name and drug code are coded with the WHO-Drug Dictionary. In addition to the drug name and code the ingredients and ATC codes are listed.
The Indication is coded with the MedDRA code to ease the analysis.

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				One-way transformation from HDID to recoded HDID.
Drug name – Modified Term (coded by WHO-DD)	CM		cmtrt__modify	text				Modified term contains coded term from WHO Drug Dictionary.
Drug name - Code (coded by WHO-DD)	CM		cmtrt__decod	text				

Ingredient – Modified Term	CM		cmtrt__ing	text				comma "," separated list
Ingredient – Code (coded by ATC)	CM		cmtrt__atc	text				comma "," separated list
Indication – Modified Term (coded by MedDRA)	CM		cmindc__modify	text				Modified term in English.
Indication - Code (coded by MedDRA)	CM		cmindc__decod	text				
Total daily dose	CM		cmdostot	text				
Unit (unit of one intake)	CM		cmdose__cmdosu	text				
Frequency	CM		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		
Route	CM		cmroute	single choice	- p.o. - p.r. - s.c. - i.m. - i.v. - nasal - td	- 1 - 2 - 3 - 4 - 5 - 6 - 7		

					- sl - inh - other	- 8 - 9 - 10		
Start day	CM		cmstdy	date				Transformed into days relative to baseline date of Enroll-HD.
Ongoing	CM		cmenrf	boolean	- yes - no	- 1 - 0		
End day	CM		cmendy	date				Transformed into days relative to baseline date of Enroll-HD.

3.3 Data File "nonpharmacotx" (Non-Pharmacologic Therapies)

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				One-way transformation from HDID to recoded HDID.
Therapy	CM		cmtrt	single choice	- Physical therapy - Occupational therapy - Psychotherapy - Counseling - Speech Language therapy - Swallowing therapy - Music therapy - Relaxation therapy (meditation, massage, yoga, etc.) - Acupuncture	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9		
Number of times	SUPPCM		cmfrq	number				
Frequency	CM		cmdosfrq	single choice	- daily - weekly - monthly - as needed	- 1 - 2 - 3 - 4		
Start day	CM		cmstdy	date				Transformed into days relative to baseline date of Enroll-HD.
Ongoing	CM		cmenrf	boolean	- yes - no	- 1 - 0		
End day	CM		cmendy	date				Transformed into days relative to baseline date of Enroll-HD.

3.4 Data File "nutsuppl" (Nutritional Supplements)

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				One-way transformation from HDID to recoded HDID.
Type	CM		cmcat	single choice	- vitamin & supplements - herbs (extracts) - herbs (teas) - other natural remedies - aromatherapies - homepathic remedies	- 1 - 2 - 3 - 4 - 5 - 6		
NutSuppl Supplement – Modified Term	CM		cmtrt__modify	text				
NutSuppl Supplement – Code	CM		cmtrt__decod	text				
NutSuppl Supplement - ATC Code(s)	CM		cmtrt__atc	text				
NutSuppl Supplement - ingredient(s)	CM		cmtrt__ing	text				
Total daily dose	CM		cmdostot	number				
Unit	CM		cmdosunit	single choice	- g - mg - IU - spoons - tablets - drops	- 1 - 2 - 3 - 4 - 5 - 6		

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
					- capsule - other	- 7 - 8		
Frequency	CM		cmdosfrq	single choice	- daily - weekly - monthly - as needed	- 1 - 2 - 3 - 4		
Start day	CM		cmstdy	date				Transformed into days relative to baseline date of Enroll-HD.
Ongoing	CM		cmenrf	boolean	- yes - no	- 1 - 0		
End day	CM		cmendy	date				Transformed into days relative to baseline date of Enroll-HD.

3.5 Data File "comorbid" (Comorbid Conditions)

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				One-way transformation from HDID to recoded HDID.
Condition – Modified Term (coded with ICD10)	MH	mhx	mhterm_ _modify	text				Modified term provided in English.
Condition – Code (coded with ICD10 + MedDRA)	MH	mhx	mhterm_ _decod	text				
Body system code	MH	mhx	mhbodsys	single choice	- cardiovascular - pulmonary	- 1 - 2		

					- neurologic - ENT - gynecologic urologic - reproductive - gastrointestinal - metabolic endocrine - hemato lymphatic - dermatological - psychiatric - musculoskelatal - allergy immunologic - ophthalmological - hepatobiliary - renal - other	- 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 - 11 - 12 - 13 - 14 - 15 - 16 - 17		
Start day	MH	mhx	mhstdy	date				Transformed into days relative to baseline date of Enroll-HD.
Ongoing	MH	mhx	mhenrf	boolean	- yes - no	- 1 - 0		
End day	MH	mhx	mhendy	date				Transformed into days relative to baseline date of Enroll-HD.

4 Study-Based Data Files

Study-based data files are directly related to a study participant, i.e. the data is not assessed during a specific visit. The data files contain data collected at different visits.

There are the following participant-based data files:

- participation
  Provides information about the study participation like participant identifier, participant status, study start, end day, and visits completed. It provides an overview about the participation as a whole.

- assessment
  Provides information about the assessments completed at regular visits.

- event (Enroll-HD only)
  Provides information about reportable events in Enroll-HD study.

In general, these data files contain more than one entry per participant. Different entries are characterized by an index (variable "seq").

4.1 Participants' Statuses

A participant that is enrolled in the Enroll-HD study has a well-defined status at a certain point in time. A participant's status decribes the progress of the participant in the study:

Participant Status	Description
enrolled	Participant is currently participating in the study.
completed	Completion of the study. Currently, the only possible completion is the death of the participant.
excluded	Screen failure, i.e. violation of an in- or exclusion criteria. Currently there are no inclusion criterias and only one exclusion criteria for "community controls".
withdrawn	Premature end of study (dependent on specifc termination reasons given within the *End* form (data file *Prematue End* or *Phone Contact*).
violator	Premature end of study (dependent on specifc termination reasons given within the *End* form (data file *Prematue End* or *Phone Contact*).

4.2 Data File "participation"

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				one-way transformation from HDID to recoded HDID .
Study ID	---	---	studyid	text	- ENR - R3 - R2 - RET			
Study	---	---	study	text	- Enroll-HD - REGISTRY3 - REGISTRY2 - Adhoc			
Participant status (latest)	SUPPSC	---	subjstat	text	- enrolled - completed - excluded - withdrawn - violator			See chapter 4.1 for details.
Participant category (at enrollment)	SUPPSC	---	hdcat_0	single choice	- pre-manifest/pre-motor-manifest HD - manifest/motor-manifest HD - genotype negative - family control	- 2 - 3 - 4 - 5		Community controls are not included, genotype unknown are automatically mapped to another category.
Participant category (latest)	SUPPSC	---	hdcat_l	single choice	- pre-manifest/pre-motor-manifest HD - manifest/motor-manifest HD - genotype negative - family control	- 2 - 3 - 4 - 5		Community controls are not included, genotype unknown are automatically mapped to another category.

Age at enrollment	DM	---	age_0	number				Birth date is transformed into age at time of enrollment (rounded to a whole number).
Study reference start day (baseline)	DM	---	rfstdy	number				Number of days before/since enrollment for Enroll-HD.
Day of informed consent	DM	---	rficdy	number				Number of days before/after enrollment/baseline for Enroll-HD
Day of end of study	DM	---	rfendy					Contains date of death if participant died or date of withdrawal/violation if participant discontinued the study prematurely
Specify primary reason for participant's premature discontinuation from study (lost to follow up hint: failure of participant to return to follow-up visit and failure to be located by investigator)	DS	---	dsterm	single choice	- event or intercurrent illness of a nature requiring withdrawal - request of primary care physician, site investigator - participant's request (includes carer spouse authorized represent-tative's request) - lost to follow up - institutionalized (will not be followed further) - other	- 1 - 2 - 3 - 4 - 5 - 6		An entry of "request of primary care physician [..]" (Code 2) or "participant's request [..]"(Code 3), involves the participant status to be "withdrawn", for any other reasons, it should be categorized as "violator".
Number of events	SV	---	evtnum	number				Number how many event forms are entered.
Number of serious events	SV	---	saenum	number				Number how many SAE forms are entered.
Number of visits	SV	---	visitnum	Number				

| Visit type | SV | --- | visit1, visit2, ... visit21 | text | - BL (Baseline)
- FUP (Follow Up)
- PC (Phone Contact)
- U (Unscheduled)
- R (Ad Hoc)
- E (Premature End) | | | Sequence of visits ordered by visit date |
| Day of visit | SV | --- | vis1dy, vis2dy, …, vis21dy, | number | | | | Ordered sequence of visit days (in dependency to Enroll-HD Baseline) |

4.3   Data File "assessment"

The "assesment" file contains an overview about all available (entered) assessments/ forms for normal visits of all studies. Assessemtents with the same name in different studies are represented within the same column regardless of whether the assessments contain a different set of variables in the assessment form, e.g. "Enrollment", "Variable". The differences are defined in chapter 5.

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				one-way transformation from HDID to recoded HDID .
Study ID	---	---	studyid	text	- ENR - R3 - R2 - RET			
Visit name	SV	----	visit	text	- Baseline - Follow-Up - Phone Contact - Unscheduled - Retro Visit			
Visit Index	---	---	seq	number				Unique row number to identify

							several entries.
Visit day	SV	----	visdy	date		Days	Transformed into days relative to baseline date of Enroll-HD.
Enrollment	SUPPSV	---	enrollment	text	- 1 (available)		The clinical data of this assessment is not included in the dataset. Certain variables are included in the participant data file.
Variable	SUPPSV	---	variable		- 1 (available)		
Medical History	SUPPSV	---	mhx		- 1 (available)		
Samples	SUPPSV	---	samples		- 1 (available)		The clinical data of this assessment is not included in the dataset.
UHDRS Motor/Diagnostic Confidence	SUPPSV	---	motor		- 1 (available)		
UHDRS Total Functional Capacity	SUPPSV	---	tfc		- 1 (available)		
UHDRS Function Assessment/Independence Scale	SUPPSV	---	funct		- 1 (available)		
Cognitive Assessments	SUPPSV	---	cognitive		- 1 (available)		Checked if any cognitive assessment has been done during the study visit
Mini Mental State Examination	SUPPSV	---	mmse		- 1 (available)		
Physiotherapy Outcome Measures	SUPPSV	---	physio		- 1 (available)		
Problem Behaviours Assessment - Short	SUPPSV	---	pbas		- 1 (available)		
Client Service Receipt Inventory	SUPPSV	---	csri		- 1 (available)		The clinical data of this assessment is not included in the dataset.

Caregivers Quality of Life Questionnaire	SUPPSV	---	careqol		- 1 (available)		The clinical data of this assessment is not included in the dataset.
Short Form Health Survey – 12v2	SUPPSV	---	sf12		- 1 (available)		
Hospital Anxiety and Depression Scale - Snaith Irritability Scale	SUPPSV	---	hadssis		- 1 (available)		
Columbia-Suicide Severity Rating Scale - Annual	SUPPSV	---	cssrsfup		- 1 (available)		
Columbia-Suicide Severity Rating Scale - Baseline	SUPPSV	---	cssrsbl		- 1 (available)		
WPAI-SHP	SUPPSV	---	wpaishp		- 1 (available)		
Missed Visit	SUPPSV	---	missedvisit		- 1 (available)		
UHDRS Behavioral Assessment	SUPPSV	---	behaviour		- 1 (available)		
Summary	SUPPSV	---	summary		- 1 (available)		The clinical data of this assessment is not included in the dataset.
Global Clinical Impression Scale	SUPPSV	---	gci		- 1 (available)		
Care Giver Questionnaire	SUPPSV	---	care		- 1 (available)		The clinical data of this assessment is not included in the dataset.
Problem Behaviours Assessment for HD	SUPPSV	---	pbahd		- 1 (available)		The clinical data of this assessment is not included in the dataset.
SF-36v2 Health Survey	SUPPSV	---	Sf36v2		- 1 (available)		
Becks Depression Scale	SUPPSV	---	bdi		- 1 (available)		
Hamilton Rating Scale for Depression	SUPPSV	---	hamilton		- 1 (available)		
SF-36v1 Health Survey	SUPPSV	---	sf36v1		- 1 (available)		

4.4 Data File "event" (Reportable Event Monitoring)

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	ENR	---	---	subjid	text				One-way transformation from HDID to recoded HDID.
Study ID	ENR	---	---	studyid	text	- ENR			
Index	ENR	---	---	seq	number				Unique row number to identify several entries.
Day of report	ENR	SUPPAE		evtdy	date				Transformed into days relative to baseline date of Enroll-HD.
Reportable event codes	ENR	SUPPAE		evtcode	single choice	- suicide attempts - completed suicide - mental health event requiring hospitalization - death (other than suicide, any cause)	- 1 - 2 - 3 - 4		
Event term – Modified Term (coded with MedDRA)	ENR	SUPPAE		evtterm_ _modify	text				Modified term provided in English. (only filled if event code (evtcode) is 2).
Event term – Code (coded with MedDRA)	ENR	SUPPAE		evtterm_ _decod	text				MEDRA code provided in English. (only filled if event code (evtcode) is 2).
Onset day	ENR	SUPPAE		evtstdy	date				Transformed into days relative to baseline date of Enroll-HD.

Date estimated	ENR	SUPPAE		stdtcest	boolean	- yes - no	- 1 - 0	
Resolved	ENR	SUPPAE		evtongo	boolean	- yes - no	- 1 - 0	
End Day	ENR	SUPPAE		evtendy	date			Transformed into days relative to baseline date of Enroll-HD.
Status of DSMC review	ENR	SUPPAE		evtdsmc	single choice	- closed completed review	- 3	Only closed events are included.

5 Visit-Based Data Files

All study visits are represented by a separate data file per study. One study visit is represented on one line and identical variables among visits are represented in the same column. The visit schedules are described in chapters 5.3, 5.4, 5.5, and 5.6.

- enroll
- registry
- adhoc

Chapter 5.1 describes all existing visits for the studies, chapter 5.2 the possible progress states of a visit and chapter 5.3 to 5.6 available forms being assessed within each visit. Chapter 5.7 describes common key variables that are identical for each visit-based data file. The visit-specific variables are described on a form by form basis from chapter 5.7 to chapter 5.27. Note, some forms are used in several visits.

5.1 Study Visits

Form entities are organized in visits, i.e. General, Baseline, Follow Up, Unscheduled, and Premature End visits.

A visit can either be a regular visit (i.e. General, Baseline, Follow Up), occurring within predefined time frames, or a non-regular visit (i.e. Unscheduled, Phone Contact, Premature End), occurring outside the scheduled visit frames

The study visits are:

Visit	Studies	Description
Baseline	ENR R3 R2	The first scheduled regular visit during or after enrollment into the study.
Follow Up	ENR R3 R2	Annual visit scheduled **after** Baseline visit. Follow Up visits should be done in annual cycles.
Phone Contact	ENR	A visit that occurred at any time **after** the Baseline visit and **instead** of an annual Follow Up visit. It is created manually to document the reason for a missed Follow Up visit. It is handled as special visit by the system.

Visit	Studies	Description
Unscheduled	ENR R3	An irregular visit **after** the Baseline visit occurs at any time outside the scheduled visit frames. It can be created manually whenever a visit takes place in-between regular visits. It is handled as a special visit by the system.
Ad Hoc	RET	An visit that has occurred **before** the Baseline visit of Enroll-HD and REGISTRY. Data is obtained from previous studies.

5.2 Study Visit States

Data included in the dataset were monitored in accordance with the respective study monitoring plan. The progress of the visit in terms of completion is identified by its so-called *visit state*. Possible visit states are:

Visit State	Description
signed	Visits that are marked as *signed*. All entered forms must be complete, without errors and be signed. Empty forms must have been deactivated.
reviewing	Visits that are ready for review or in the process of being reviewed by a monitor.
completed	Visits that have undergone full monitoring review have the state completed or canceled. All queries raised by monitors must have been completed. Since monitoring is done not for 100% of the entered data, the visits may might have been incompletely reviewed or bypassed.

5.3   Form Schedules of Visits for Study Enroll-HD

Form Name	Baseline	Follow Up	Un-scheduled	Phone Contact
MHx	✓			
Variable (BL)	✓			
Variable (FU)		✓	✓	
Motor	✓	✓	✓	
TFC	✓	✓	✓	
Function	✓	✓	✓	
Cognitive	✓	✓	✓	
MMSE	✓	✓		
Physiotherapy	✓	✓		
PBA-s	✓	✓	✓	
SF-12	✓	✓		
HADS-SIS	✓	✓		
WPAI-SHP	✓	✓		
C-SSRS BL[1]	✓	✓	✓	
C-SSRS FUP	✓	✓	✓	
Missed Visit				✓

5.4   Form Schedules of Visits for Study Registry3

Form Name	Baseline	Follow Up	Unscheduled
Variable (BL)	✓		
Variable (FU)		✓	✓
Motor	✓	✓	✓
TFC	✓	✓	✓

---

[1] C-SSRS BL is the first assessment occurring on any visit. On subsequent visits is FUP version is used.

Form Name	Baseline	Follow Up	Unscheduled
Function	✓	✓	✓
Cognitive	✓	✓	✓
PBA-s	✓	✓	✓
SF-36v2	✓	✓	✓
HADS-SIS	✓	✓	✓
C-SSRS BL	✓		
C-SSRS FUP		✓	✓
Behaviour	✓	✓	✓

5.5 Form Schedules of Visits for Study Registry2

Form Name	Baseline	Follow Up
Variable	✓	✓
Motor	✓	✓
TFC	✓	✓
Function	✓	✓
Cognitive	✓	✓
BDI	✓	✓
Behaviour	✓	✓
Hamilton	✓	✓
SF-36v1	✓	✓

5.6 Form Schedules of Visits for Study Ad Hoc

Form Name	Adhoc
Variable	✓
Motor	✓
Function	✓

Form Name	Adhoc
TFC	✓
MMSE	✓
Cognitive	✓

5.7 Key Variables of a Visit

Label	Domain	Cat.	Variable	Type	Parameter	Coding	Unit	Transformation
HDID (recoded)	---	---	subjid	text				One-way transformation from HDID to recoded HDID.
Study ID	---	---	studyid		- ENR - R3 - R2 - RET			
Visit index	---	---	seq					Unique visit index number
Visit name	SV	---	visit	text	- Baseline - Follow-Up - Phone Contact - Unscheduled - Retro Visit			
Visit day	SV	---	visdy	date			Days	Transformed into days relative to baseline date of Enroll-HD.
Visit status	SV	---	visstat	text	- plausible - reviewing - completed			
Age at visit	DM	---	age	number				

5.8   Form "Medical History (MHx)"

This form is part of the Baseline visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Has the participant had alcohol problems in the past	ENR	MH		hxalcab	boolean	- yes - no	- 1 - 0		
Has the participant ever smoked	ENR	MH		hxtobab	boolean	- yes - no	- 1 - 0		
Packyears	ENR	MH		hxpacky					
Has the participant ever abused drugs	ENR	MH		hxdrugab	boolean	- yes - no	- 1 - 0		
Group Drug use for non-medical reasons									
Group Marijuana									
Abuse	ENR	SUPPSU		hxmar	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxmarfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Heroin									
Abuse	ENR	SUPPSU		hxher	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxherfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Cocaine									

Abuse	ENR	SUPPSU		hxcoc	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxcocfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Club drugs (Ecstacy, GHB, Roofies)									
Abuse	ENR	SUPPSU		hxclb	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxclbfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Amphetamines									
Abuse	ENR	SUPPSU		hxamp	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxampfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Ritalin									
Abuse	ENR	SUPPSU		hxrit	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SC		hxritfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Hallucinogens									
Abuse	ENR	SUPPSU		hxhal	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxhalfrq	single choice	- seldom - occasionally	- 1 - 2		

					- frequently	- 3		
Group Inhalants								
Abuse	ENR	SUPPSU		hxinh	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxinhfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Opium								
Abuse	ENR	SUPPSU		hxopi	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxopifrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Painkillers								
Abuse	ENR	SUPPSU		hxpak	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxpakfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Barbiturates sedatives								
Abuse	ENR	SUPPSU		hxbar	boolean	- yes - no	- 1 - 0		
Frequency	ENR	SU		hxbarfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Tranquilizers								
Abuse	ENR	SUPPSU		hxtrq	boolean	- yes	- 1		

						- no	- 0		
Frequency	ENR	SU		hxtrqfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

5.9   Form "Variable Items" (Baseline Visit)

This form is part of the Baseline visit.

Section General Variable Items I

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Participant category	ENR R3	SC		hdcat	single choice	- pre-manifest pre-motor-manifest HD - manifest motor-manifest HD - genotype negative - family control	- 2 - 3 - 4 - 5		Community controls are not included, genotype unknown are automatically mapped to another category.
Group Vital Signs									
Height (cm)	ENR R3 R2 RET	VS		height	number				No cut-off values (due to data overdispersion)
Weight (kg)	ENR R3 R2 RET	VS		weight	number				No cut-off values (due to data overdispersion)
BMI	ENR R3 R2 RET	VS		bmi	number				
Does the participant currently drink alcohol?	ENR R3	MH	mhx	alcab	boolean	- yes - no	- 1 - 0		

Units per week	ENR R3	SU	mhx	alcunits	number				
Does the participant currently smoke?	ENR R3	MH	mhx	tobab	boolean	- yes - no	- 1 - 0		
Packyears	ENR R3	MH	mhx	packy					(tobcpd 20) * tobyos correct to three decimal places
Current caffeine use?	ENR	MH	mhx	cafab	boolean	- yes - no	- 1 - 0		
Do you drink more than 3 cups of coffee, tea and cola drinks combined per day?	ENR	SU	mhx	cafpd	boolean	- yes - no	- 1 - 0		
Does the participant currently use drugs?	ENR R3	MH	mhx	drugab	boolean	- yes - no	- 1 - 0		
Group Drug use for non-medical reasons?									
Group Marijuana									
Abuse	ENR R3	SUPPSU	mhx	mar	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	marfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Heroin									
Abuse	ENR R3	SUPPSU	mhx	her	boolean	- yes - no	- 1 - 0		

Frequency	ENR R3	SU	mhx	herfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Cocaine									
Abuse	ENR R3	SUPPSU	mhx	coc	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	cocfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Club drugs (Ecstacy, GHB, Roofies)									
Abuse	ENR R3	SUPPSU	mhx	clb	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	clbfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Amphetamines									
Abuse	ENR R3	SUPPSU	mhx	amp	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	ampfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Ritalin									
Abuse	ENR R3	SUPPSU	mhx	rit	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	ritfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Hallucinogens

Abuse	ENR R3	SUPPSU	mhx	hal	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	halfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Inhalants

Abuse	ENR R3	SUPPSU	mhx	inh	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	inhfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Opium

Abuse	ENR R3	SUPPSU	mhx	opi	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	opifrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Painkillers

Abuse	ENR R3	SUPPSU	mhx	pak	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	pakfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Barbiturates sedatives

Abuse	ENR R3	SUPPSU	mhx	bar	boolean	- yes - no	- 1 - 0		

Frequency	ENR R3	SU	mhx	barfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Tranquilizers									
Abuse	ENR R3	SUPPSU	mhx	trq	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	trqfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Section General Variable Items II

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Marital status	ENR R3 R2	SC		maristat	single choice	- single - married - partnership - divorced - widowed - legally separated	- 1 - 3 - 2 - 4 - 5 - 6		Coding 5 and 6 are not available for studies R2 and R3
Residence	ENR R3 R2	SC		res	single choice	- rural - village - town - city	- 1 - 2 - 3 - 4		
ISCED education level	ENR R3	SC		isced	single choice	- ISCED 0 - ISCED 1 - ISCED 2 - ISCED 3 - ISCED 4 - ISCED 5 - ISCED 6	- 0 - 1 - 2 - 3 - 4 - 5 - 6		Details about the ISCED education level can be found in the supporting documents for the ISCED [4]
Employment	ENR	SC		jobclas	single	- full-time employed	- 1		

					choice	- part-time employed	- 2		
						- self employed	- 3		
						- not employed	- 4		
Status (if employed)	ENR	SC		jobpaid	single choice	- paid	- 1		
						- unpaid	- 2		
Have you had to stop or reduce work due to your health?	ENR	SC		rdcwk	boolean	- yes	- 1		
						- no	- 0		
How many days in the last 6 months have you been off work because of HD?	ENR	SC		rdcwkd	number			days	
How many fewer hours per week have you worked because of HD?	ENR	SC		rdcwkhw	number			hours week	
Reason (if not employed)	ENR	SC		emplnrsn	single choice	- sick leave	- 1		
						- retirement	- 2		
						- working in the home (e.g. caring for children)	- 3		
							- 4		
						- unemployed	- 5		
						- training college			
Retired due to (if retired)	ENR	SC		emplnrd	single choice	- ill health	- 1		
						- age	- 2		
Group If retired or unemployed									
Do you receive social security or disability benefit?	ENR	SC		ssdb	boolean	- yes	- 1		
						- no	- 0		
Do you intend to return to work?	ENR	SC		rtrnwk	boolean	- yes	- 1		
						- no	- 0		

Since when have you been unemployed retired?	ENR	SC		rtrddur	number			Years	Age at retirement

5.10 Form "Variable Items" (Follow-Up Visit)

This form is part of the Follow Up and Unscheduled visit.

Section General Variable Items I

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Group Vital Signs									
Height (cm)	ENR R3 R2	VS		height	number				No cut-off values (due to data overdispersion)
Weight (kg)	ENR R3 R2	VS		weight	number				No cut-off values (due to data overdispersion)
BMI	ENR R3 R2	VS		bmi	number				
Does the participant currently drink alcohol?	ENR R3	MH	mhx	alcab	boolean	- yes - no	- 1 - 0		
Units per week	ENR R3	SU	mhx	alcunits	number				
Does the participant currently smoke?	ENR R3	MH	mhx	tobab	boolean	- yes - no	- 1 - 0		
Packyears	ENR R3	MH	mhx	packy					(tobcpd 20) * tobyos correct to three decimal places
Current caffeine	ENR	MH	mhx	cafab	boolean	- yes	- 1		

use?						- no	- 0		
Do you drink more than 3 cups of coffee, tea and cola drinks combined per day?	ENR	SU	mhx	cafpd	boolean	- yes - no	- 1 - 0		
Does the participant currently use drugs?	ENR R3	MH	mhx	drugab	boolean	- yes - no	- 1 - 0		
Group Drug use for non-medical reasons?									
Group Marijuana									
Abuse	ENR R3	SUPPSU	mhx	mar	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	marfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Heroin									
Abuse	ENR R3	SUPPSU	mhx	her	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	herfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Cocaine									
Abuse	ENR R3	SUPPSU	mhx	coc	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	cocfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Club drugs (Ecstacy, GHB, Roofies)									
Abuse	ENR R3	SUPPSU	mhx	clb	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	clbfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Amphetamines									
Abuse	ENR R3	SUPPSU	mhx	amp	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	ampfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Ritalin									
Abuse	ENR R3	SUPPSU	mhx	rit	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	ritfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Hallucinogens									
Abuse	ENR R3	SUPPSU	mhx	hal	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	halfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Group Inhalants									
Abuse	ENR R3	SUPPSU	mhx	inh	boolean	- yes - no	- 1 - 0		

Frequency	ENR R3	SU	mhx	inhfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Opium									
Abuse	ENR R3	SUPPSU	mhx	opi	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	opifrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Painkillers									
Abuse	ENR R3	SUPPSU	mhx	pak	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	pakfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Barbiturates sedatives									
Abuse	ENR R3	SUPPSU	mhx	bar	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	barfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		
Group Tranquilizers									
Abuse	ENR R3	SUPPSU	mhx	trq	boolean	- yes - no	- 1 - 0		
Frequency	ENR R3	SU	mhx	trqfrq	single choice	- seldom - occasionally - frequently	- 1 - 2 - 3		

Section General Variable Items II

Label	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Any changes to the following General Variable Items	ENR R3	MH		updsc	boolean	- yes - no	- 1 - 0		
Participant category	ENR R3	SC		hdcat	single choice	- pre-manifest pre-motor-manifest HD - manifest motor-manifest HD - genotype negative - family control	- 2 - 3 - 4 - 5		Community controls are not included, genotype unknown are automatically mapped to another category.
Marital status	ENR R3	SC		maristat	single choice	- Single - married - partnership - divorced - widowed - legally separated	- 1 - 3 - 2 - 4 - 5 - 6		
Residence	ENR R3	SC		res	single choice	- rural - village - town - city	- 1 - 2 - 3 - 4		
ISCED education level	ENR R3	SC		isced	single choice	- ISCED 0 - ISCED 1 - ISCED 2 - ISCED 3 - ISCED 4 - ISCED 5 - ISCED 6	- 0 - 1 - 2 - 3 - 4 - 5 - 6		
Employment	ENR	SC		jobclas	single choice	- full-time employed - part-time employed - self employed	- 1 - 2 - 3		

					- not employed	- 4		
Status (if employed)	ENR	SC		jobpaid	single choice	- paid - unpaid	- 1 - 2		
Reason (if not employed)	ENR	SC		emplnrsn	single choice	- sick leave - retirement - working in the home (e.g. caring for children) - unemployed - training college	- 1 - 2 - 3 - 4 - 5		
Retired due to (if retired)	ENR	SC		emplnrd	single choice	- ill health - age	- 1 - 2		
Group If retired or unemployed									
Do you receive social security or disability benefit?	ENR	SC		ssdb	boolean	- yes - no	- 1 - 0		
Do you intend to return to work?	ENR	SC		rtrnwk	boolean	- yes - no	- 1 - 0		
Since when have you been unemployed retired?	ENR	SC		rtrddur	number			Years	Age at retirement, e.g. ("65")

Section Additional Employment Section (if employed):

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Have you had to stop or reduce work due to your health?	ENR	SC		rdcwk	boolean	- yes - no	- 1 - 0		
How many days in the last 6 months have you been off work because of HD?	ENR	SC		rdcwkd	number				

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
How many fewer hours per week have you worked because of HD?	ENR	SC		rdcwkhw	number				

Section Since the last visit have there been:

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Any changes to participant's medication?	ENR R3	SV		updmed	boolean	- yes - no	- 1 - 0		
Any changes to participant's comorbid conditions?	ENR R3	SV		updmh	boolean	- yes - no	- 1 - 0		
Any updates to the clinical characteristics and or onset of HD?	ENR R3	SV		updhdh	boolean	- yes - no	- 1 - 0		

5.11 Form "UHDRS Motor Diagnostic Confidence (Motor)"

This form is part of the Baseline, Follow Up, Unscheduled visit, and Retrospective visit.

Section General

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Motor score (TMS)	ENR R3 R2 RET	QS	Motor	motscore	text				Score is calculated when every item on the TMS has been scored
Motor score (TMS) incomplete	ENR R3 R2 RET	QS	Motor	miscore	text				The Motor score (incomplete) is calculated when there is at least one item on the TMS that has not been score (e.g. unable to assess left hand finger-tapping due to amputation).

Section Motor Assessment

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Group Ocular pursuit									
Horizontal	ENR R3 R2 RET	QS	Motor	ocularh	single choice	- complete (normal) - jerky movement - interrupted pursuits full range - incomplete range - cannot pursue	- 0 - 1 - 2 - 3 - 4		
Vertical	ENR R3 R2 RET	QS	Motor	ocularv	single choice	- complete (normal) - jerky movement - interrupted pursuits full range - incomplete range	- 0 - 1 - 2 - 3		

						- cannot pursue	- 4		
Group Saccade initiation									
Horizontal	ENR R3 R2 RET	QS	Motor	sacinith	single choice	- normal - increased latency only - suppressible blinks or head movements to initiate - unsuppressible head movements - cannot initiate saccades	- 0 - 1 - 2 - 3 - 4		
Vertical	ENR R3 R2 RET	QS	Motor	sacinitv	single choice	- normal - increased latency only - suppressible blinks or head movements to initiate - unsuppressible head movements - cannot initiate saccades	- 0 - 1 - 2 - 3 - 4		
Group Saccade velocity									
Horizontal	ENR R3 R2 RET	QS	Motor	sacvelh	single choice	- normal - mild slowing - moderate slowing - severely slow, full range - incomplete range	- 0 - 1 - 2 - 3 - 4		
Vertical	ENR R3 R2 RET	QS	Motor	sacvelv	single choice	- normal - mild slowing - moderate slowing - severely slow, full range - incomplete range	- 0 - 1 - 2 - 3 - 4		
Dysarthria	ENR R3 R2 RET	QS	Motor	dysarth	single choice	- normal - unclear, no need to repeat - must repeat to be understood	- 0 - 1 - 2		

						- mostly incomprehensible	- 3		
						- anarthria	- 4		
Tongue protrusion	ENR R3 R2 RET	QS	Motor	tongue	single choice	- can hold tongue fully protruded for 10 sec - cannot keep fully protruded for 10 sec - cannot keep fully protruded for 5 sec - cannot fully protrude tongue - cannot protrude tongue beyond lips	- 0 - 1 - 2 - 3 - 4		
Group Finger taps									
Right	ENR R3 R2 RET	QS	Motor	fingtapr	single choice	- normal (≥15 5 sec.) - mild slowing, reduction in amplitude (11-14 5 sec.) - moderately impaired (7-10 5 sec.) - severely impaired (3-6 5 sec.) - can barely perform task (0-2 5 sec.)	- 0 - 1 - 2 - 3 - 4		
Left	ENR R3 R2 RET	QS	Motor	fingtapl	single choice	- normal (≥15 5 sec.) - mild slowing, reduction in amplitude (11-14 5 sec.) - moderately impaired (7-10 5 sec.) - severely impaired (3-6 5 sec.) - can barely perform task (0-2 5 sec.)	- 0 - 1 - 2 - 3 - 4		
Group Pronate supinate-hands									
Right	ENR R3 R2 RET	QS	Motor	prosupr	single choice	- normal - mild slowing and or irregular	- 0 - 1		

						- moderate slowing and irregular - severe slowing and irregular - cannot perform	- 2 - 3 - 4		
Left	ENR R3 R2 RET	QS	Motor	prosupl	single choice	- normal - mild slowing and or irregular - moderate slowing and irregular - severe slowing and irregular - cannot perform	- 0 - 1 - 2 - 3 - 4		
Luria	ENR R3 R2 RET	QS	Motor	luria	single choice	- ≥4 in 10 sec, no cue - <4 in 10 sec, no cue - ≥4 in 10 sec with cues - <4 in 10 sec with cues - cannot perform	- 0 - 1 - 2 - 3 - 4		
Group Rigidity-arms									
Right	ENR R3 R2 RET	QS	Motor	rigarmr	single choice	- absent - slight or present only with activation - mild to moderate - severe, full range of motion - severe with limited range	- 0 - 1 - 2 - 3 - 4		
Left	ENR R3 R2 RET	QS	Motor	rigarml	single choice	- absent - slight or present only with activation - mild to moderate - severe, full range of motion - severe with limited range	- 0 - 1 - 2 - 3 - 4		
Bradykinesia-body	ENR R3 R2 RET	QS	Motor	brady	single choice	- normal - minimally slow (?normal) - mildly but clearly slow	- 0 - 1 - 2		

| | | | | | | | - moderately slow, some hesitation | - 3 | | |
| | | | | | | | - markedly slow, long delays in initiation | - 4 | | |

Group Maximal dystonia

Trunk	ENR R3 R2 RET	QS	Motor	dysttrnk	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
RUE	ENR R3 R2 RET	QS	Motor	dystrue	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
LUE	ENR R3 R2 RET	QS	Motor	dystlue	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
RLE	ENR R3 R2 RET	QS	Motor	dystrle	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
LLE	ENR R3 R2 RET	QS	Motor	dystlle	single choice	- absent - slight intermittent	- 0 - 1		

						- mild common or moderate intermittent	- 2		
						- moderate common	- 3		
						- marked prolonged	- 4		
Group Maximal chorea									
Face	ENR R3 R2 RET	QS	Motor	chorface	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
BOL	ENR R3 R2 RET	QS	Motor	chorbol	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
Trunk	ENR R3 R2 RET	QS	Motor	chortrnk	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
RUE	ENR R3 R2 RET	QS	Motor	chorrue	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
LUE	ENR R3 R2 RET	QS	Motor	chorlue	single choice	- absent - slight intermittent	- 0 - 1		

						- mild common or moderate intermittent - moderate common - marked prolonged	- 2 - 3 - 4		
RLE	ENR R3 R2 RET	QS	Motor	chorrle	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
LLE	ENR R3 R2 RET	QS	Motor	chorlle	single choice	- absent - slight intermittent - mild common or moderate intermittent - moderate common - marked prolonged	- 0 - 1 - 2 - 3 - 4		
Gait	ENR R3 R2 RET	QS	Motor	gait	single choice	- normal gait, narrow base - wide base and or slow - wide base and walks with difficulty - walks only with assistance - cannot attempt	- 0 - 1 - 2 - 3 - 4		
Tandem walking	ENR R3 R2 RET	QS	Motor	tandem	single choice	- normal for 10 steps - 1 to 3 deviations from straight line - >3 deviations - cannot complete - cannot attempt	- 0 - 1 - 2 - 3 - 4		
Retropulsion pull test	ENR R3 R2 RET	QS	Motor	retropls	single choice	- normal - recovers spontaneously - would fall if not caught - tends to fall spontaneously	- 0 - 1 - 2 - 3		

					- cannot stand	- 4		

Section Diagnostic Confidence

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Diagnostic confidence level (DCL)	ENR R3 R2 RET	QS	Motor	diagconf	single choice	- normal (no abnormalities) - non-specific motor abnormalities (less than 50 % confidence) - motor abnormalities that may be signs of HD (50 - 89 % confidence) - motor abnormalities that are likely signs of HD (90 - 98 % confidence) - motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence)	- 0 - 1 - 2 - 3 - 4		

5.12 Form "UHDRS Total Functional Capacity (TFC)"

This form is part of the Baseline, Follow Up, Retrospective, and Unscheduled visit.

Section General

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Functional score	ENR R3 R2 RET	QS	TFC	tfcscore	number				
Occupation	ENR R3 R2 RET	QS	TFC	occupatn	single choice	- unable - marginal work only - reduced capacity for	- 0 - 1 - 2		

						usual job - normal	- 3		
Finances	ENR R3 R2 RET	QS	TFC	finances	single choice	- unable - major assistance - slight assistance - normal	- 0 - 1 - 2 - 3		
Domestic chores	ENR R3 R2 RET	QS	TFC	chores	single choice	- unable - impaired - normal	- 0 - 1 - 2		
ADL	ENR R3 R2 RET	QS	TFC	adl	single choice	- total care - gross tasks only - minimal impairment - normal	- 0 - 1 - 2 - 3		
Care level	ENR R3 R2 RET	QS	TFC	carelevl	single choice	- full time skilled nursing - home or chronic care - home	- 0 - 1 - 2		

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

This form is part of the Baseline, Follow Up, Unscheduled visit, and Retrospective visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Functional assessment score	ENR R3 R2 RET	QS		Function	fascore	number			
Functional score incomplete	ENR R3 R2 RET	QS		Function	fiscore	number			
Could subject engage in gainful employment in	ENR R3 R2 RET	QS		Function	emplusl	boolean	- yes - no	- 1 - 0		

his/her accustomed work?									
Could subject engage in any kind of gainful employment?	ENR R3 R2 RET	QS	Function	emplany	boolean	- yes - no	- 1 - 0		
Could subject engage in any kind of volunteer or non-gainful work?	ENR R3 R2 RET	QS	Function	volunt	boolean	- yes - no	- 1 - 0		
Could subject manage his/her finances (monthly) without any help?	ENR R3 R2 RET	QS	Function	fafinan	boolean	- yes - no	- 1 - 0		
Could subject shop for groceries without help?	ENR R3 R2 RET	QS	Function	grocery	boolean	- yes - no	- 1 - 0		
Could subject handle money as a purchaser in a simple cash (shop) transaction?	ENR R3 R2 RET	QS	Function	cash	boolean	- yes - no	- 1 - 0		
Could subject supervise children without help?	ENR R3 R2 RET	QS	Function	supchild	boolean	- yes - no	- 1 - 0		
Could subject operate an automobile safely and independently?	ENR R3 R2 RET	QS	Function	drive	boolean	- yes - no	- 1 - 0		
Could subject do his/her own housework without help?	ENR R3 R2 RET	QS	Function	housewrk	boolean	- yes - no	- 1 - 0		
Could subject do his/her own laundry (wash/dry) without help?	ENR R3 R2 RET	QS	Function	laundry	boolean	- yes - no	- 1 - 0		
Could participant prepare his/her own meals without help?	ENR R3 R2 RET	QS	Function	prepmeal	boolean	- yes - no	- 1 - 0		
Could subject use the telephone without help?	ENR R3 R2 RET	QS	Function	telephon	boolean	- yes - no	- 1 - 0		
Could subject take his/her	ENR R3	QS	Function	ownmed	boolean	- yes	- 1		

own medications without help?	R2 RET			s		- no	- 0		
Could subject feed himself/herself without help?	ENR R3 R2 RET	QS	Function	feedself	boolean	- yes - no	- 1 - 0		
Could subject dress himself/herself without help?	ENR R3 R2 RET	QS	Function	dress	boolean	- yes - no	- 1 - 0		
Could subject bathe himself/herself without help?	ENR R3 R2 RET	QS	Function	bathe	boolean	- yes - no	- 1 - 0		
Could subject use public transport to get to places without help?	ENR R3 R2 RET	QS	Function	pubtrans	boolean	- yes - no	- 1 - 0		
Could subject walk to places in his/her neighbourhood without help?	ENR R3 R2 RET	QS	Function	walknbr	boolean	- yes - no	- 1 - 0		
Could subject walk without falling?	ENR R3 R2 RET	QS	Function	walkfall	boolean	- yes - no	- 1 - 0		
Could subject walk without help?	ENR R3 R2 RET	QS	Function	walkhelp	boolean	- yes - no	- 1 - 0		
Could subject comb hair without help?	ENR R3 R2 RET	QS	Function	comb	boolean	- yes - no	- 1 - 0		
Could subject transfer between chairs without help?	ENR R3 R2 RET	QS	Function	trnchair	boolean	- yes - no	- 1 - 0		
Could subject get in and out of bed without help?	ENR R3 R2 RET	QS	Function	bed	boolean	- yes - no	- 1 - 0		
Could subject use toilet/commode without help?	ENR R3 R2 RET	QS	Function	toilet	boolean	- yes - no	- 1 - 0		
Could subject's care still be provided at home?	ENR R3 R2 RET	QS	Function	carehome	boolean	- yes - no	- 1 - 0		
Subject's independence in %	ENR R3	QS	Independ	indepscl	single	- no special care needed	- 100		

	R2 RET		ence		choice	-	- 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		

5.14 Form "Cognitive Assessments (Cognitive)"

This form is part of the Baseline, Follow Up, Unscheduled visit, and Ad Hoc visit. In Enroll-HD the forms is called "Core and Extended Cognitive Assessments", in REGISTRY 3 there are two separate forms "Cogntive – short" and "Cognitive– long" version, and in REGISTRY 2 and Ad Hoc there is just one "Cognitive" form. Within this dataset, all cognitive assessments are listed in one virtual cognitive form. Identical assessments use the same variables also for different studies.

Section Specifics

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Did the participant complete the assessment in their native language and with normal or corrected-to-normal vision and hearing?	ENR R3 RET	SUPPQS	Cognitive Assessment	gen1	boolean	- yes - no	- 1 - 0		
Did the participant complete the assessment in their native language?	ENR R3 RET	SUPPQS	Cognitive Assessment	gen2	boolean	- yes - no	- 1 - 0		
At what age did the participant learn the language used?	ENR R3 RET	SUPPQS	Cognitive Assessment	gen3	number			years	
Did the participant have normal corrected-to-normal hearing and vision?	ENR R3 RET	SUPPQS	Cognitive Assessment	gen4	boolean	- yes - no	- 1 - 0		
Was vision uncorrected (e.g. no glasses during visit)?	ENR R3 RET	SUPPQS	Cognitive Assessment	gen5	boolean	- yes - no	- 1 - 0		
Was hearing uncorrected (e.g. no hearing aid worn)?	ENR R3 RET	SUPPQS	Cognitive Assessment	gen6	boolean	- yes - no	- 1 - 0		

Section Core Cognitive Assessment

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Symbol Digit Modality Test completed	ENR R3 RET	QS	SDMT	sdmt	boolean	- yes - no	- 1 - 0		
Total correct	ENR R3 R2 RET	QS	SDMT	sdmt1	number				
Total errors	ENR R3 RET	QS	SDMT	sdmt2	number				
Verbal Fluency Test (Category) completed	ENR R3 RET	QS	Categorical Verbal Fluency	verfct	boolean	- yes - no	- 1 - 0		
Category	ENR R3 RET	QS	Categorical Verbal Fluency	verfctd	single choice	- animals - other	- 1 - 2		
Total correct (1min)	ENR R3 RET	QS	Categorical Verbal Fluency	verfct5	number				
Total intrusion errors	ENR R3 RET	QS	Categorical Verbal Fluency	verfct6	number				
Total perseverative errors	ENR R3 RET	QS	Categorical Verbal Fluency	verfct7	number				
Stroop Colour Naming Test completed	ENR R3 RET	QS	Stroop Color Naming	scnt	boolean	- yes - no	- 1 - 0		
Total correct	ENR R3 R2 RET	QS	Stroop Color Naming	scnt1	number				
Total errors	ENR R3 RET	QS	Stroop Color Naming	scnt2	number				
Total self-corrected errors	ENR R3 RET	QS	Stroop Color Naming	scnt3	number				
Stroop Word Reading Test completed	ENR R3 RET	QS	Stroop Word Reading	swrt	boolean	- yes - no	- 1 - 0		
Total correct	ENR R3 R2 RET	QS	Stroop Word Reading	swrt1	number				

| Total errors | ENR R3 RET | QS | Stroop Word Reading | swrt2 | number | | | | |
| Total self-corrected errors | ENR R3 RET | QS | Stroop Word Reading | swrt3 | number | | | | |

Section Extended Cognitive Assessments

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Stroop Interference Test completed	ENR R3 RET	QS	Stroop Interference	sit	boolean	- yes - no	- 1 - 0		
Total correct	ENR R3 R2 RET	QS	Stroop Interference	sit1	number				
Total errors	ENR R3 RET	QS	Stroop Interference	sit2	number				
Total self-corrected errors	ENR R3 RET	QS	Stroop Interference	sit3	number				
Trailmaking Test completed	ENR R3	QS	Trail Making A&B	trl	boolean	- yes - no	- 1 - 0		
Part A: time to complete	ENR R3	QS	Trail Making A&B	trla1	number			sec	
Part A: total correct	ENR R3	QS	Trail Making A&B	trla2	number				
Part A: total errors	ENR R3	QS	Trail Making A&B	trla3	number				
Part B: time to complete	ENR R3	QS	Trail Making A&B	trlb1	number			sec	
Part B: total correct	ENR R3	QS	Trail Making A&B	trlb2	number				
Part B: total errors	ENR R3	QS	Trail Making A&B	trlb3	number				
Verbal Fluency Test (Letters) completed	ENR R3 RET	QS	Letter Verbal Fluency	verflt	boolean	- yes - no	- 1 - 0		
Total correct (3 min)	ENR R3 R2 RET	QS	Letter Verbal Fluency	verflt05	number				
Total intrusion errors	ENR R3	QS	Letter Verbal	verflt06	number				

	RET		Fluency						
Total perseverative errors	ENR R3 RET	QS	Letter Verbal Fluency	verflt07	number				
Hopkins Verbal Learning Test-R completed (optional)	R2 R3	QS	HVLT	hvlt	boolean	- yes - no	- 1 - 0		
Used form	R2 R3	QS	HVLT	hvltd	single choice	- form 1 - form 2 - form 3	- 1 - 2 - 3		
Trial 1: correct	R2 R3	QS	HVLT	hvltt11	number				
Trial 2: correct	R2 R3	QS	HVLT	hvltt21	number				
Trial3: correct	R2 R3	QS	HVLT	hvltt31	number				
Delayed recall correct	R2 R3	QS	HVLT	hvlt1	number				
Total repetitions (trials 1-3 & delayed)	R2 R3	QS	HVLT	hvlt2	number				
Total intrusions (trials 1-3 & delayed)	R2 R3	QS	HVLT	hvlt3	number				
Recognition: true positives	R2 R3	QS	HVLT	hvlt4	number				
Recognition: false positives	R2 R3	QS	HVLT	hvlt5	number				
Dementia Rating Scale-2 completed (optional)	R2 R3	QS	Mattis DRS	mdrs	boolean	- yes - no	- 1 - 0		
Attention	R2 R3	QS	Mattis DRS	mdrs1	number				
Initiation / perseveration	R2 R3	QS	Mattis DRS	mdrs2	number				
Construction	R2 R3	QS	Mattis DRS	mdrs3	number				
Conceptualization	R2 R3	QS	Mattis DRS	mdrs4	number				
Memory	R2 R3	QS	Mattis DRS	mdrs5	number				

5.15 Form "Mini Mental State Examination (MMSE)"

This form is part of the Baseline, Follow Up and Ad Hoc visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
MMSE score	ENR RET	QS	MMSE	mmsetotal	number				

5.16 Form "Physiotherapy Outcomes Measures (Physiotherapy)"

This form is part of the Baseline and Follow Up visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Timed "Up and Go" performed	ENR	QS	TUG	tug	boolean	- yes - no	- 1 - 0		
Total time	ENR	QS	TUG	tug1	number			sec	
30 second chair stand test performed	ENR	QS	30sec Chair Stand	scst	boolean	- yes - no	- 1 - 0		
Number of times the participant stands in 30 seconds	ENR	QS	30sec Chair Stand	scst1	number				

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

This form is part of the Baseline, Follow Up and Unscheduled visit.

Section General

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Group Domain scores									
Depression	ENR R3	QS	PBA-s	depscore	number				
Irritability aggression	ENR R3	QS	PBA-s	irascore	number				
Psychosis	ENR R3	QS	PBA-s	psyscore	number				
Apathy	ENR R3	QS	PBA-s	aptscore	number				

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformat.
Executive function	ENR R3	QS	PBA-s	exfscore	number				

Section Problem Behaviours Assessment for HD

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformat.
Group Depressed mood									
Severity	ENR R3	QS	PBA-s	pbas1sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas1fr	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		
Worst	ENR R3	QS	PBA-s	pbas1wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Group Suicidal ideation									
Severity	ENR R3	QS	PBA-s	pbas2sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas2fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 times a week)	- 0 - 1 - 2		

						- frequently (most days 5, 6 or 7 times a week) - daily almost daily for most (or all) of day	- 3 - 4		
Worst		QS	PBA-s	pbas2wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		

Group Anxiety

Severity	ENR R3	QS	PBA-s	pbas3sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas3fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst		QS	PBA-s	pbas3wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		

Group Irritability

Severity	ENR R3	QS	PBA-s	pbas4sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem)	- 0 - 1 - 2 - 3		

					- severe (almost intolerable for carer)	- 4		
Frequency	ENR R3	QS	PBA-s	pbas4fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst		QS	PBA-s	pbas4wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Group Angry or aggressive behaviour									
Severity	ENR R3	QS	PBA-s	pbas5sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas5fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst		QS	PBA-s	pbas5wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Group Lack of initiative (apathy)									

Severity	ENR R3	QS	PBA-s	pbas6sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas6fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst		QS	PBA-s	pbas6wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Group Perseverative thinking or behaviour									
Severity	ENR R3	QS	PBA-s	pbas7sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas7fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst		QS	PBA-s	pbas7wo	single choice	- absent - slight, questionable - mild (present, not a problem)	- 0 - 1 - 2		

| | | | | | - moderate (symptom causing problem) | - 3 | | |
| | | | | | - severe (almost intolerable for carer) | - 4 | | |

Group Obsessive-Compulsive Behaviours

Severity	ENR R3	QS	PBA-s	pbas8sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas8fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst		QS	PBA-s	pbas8wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		

Group Delusions   paranoid thinking

Severity	ENR R3	QS	PBA-s	pbas9sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas9fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 times a week) - frequently (most days 5, 6 or 7 times a week)	- 0 - 1 - 2 - 3 - 4		

						- daily almost daily for most (or all) of day			
Worst	ENR R3	QS	PBA-s	pbas9wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Group Hallucinations									
Severity	ENR R3	QS	PBA-s	pbas10sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Group Please specify									
Modality of hallucinations - auditory	ENR R3	QS	PBA-s	pbas10sm__1	boolean	- auditory	- 1		
Modality of hallucinations - visual	ENR R3	QS	PBA-s	pbas10sm__2	boolean	- visual	- 1		
Modality of hallucinations - tactile	ENR R3	QS	PBA-s	pbas10sm__3	boolean	- tactile	- 1		
Modality of hallucinations - olfactory	ENR R3	QS	PBA-s	pbas10sm__4	boolean	- olfactory	- 1		
Modality of hallucinations - gustatory	ENR R3	QS	PBA-s	pbas10sm__5	boolean	- gustatory	- 1		

Frequency	ENR R3	QS	PBA-s	pbas10fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst	ENR R3	QS	PBA-s	pbas10wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Group Disoriented Behaviour									
Severity	ENR R3	QS	PBA-s	pbas11sv	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		
Frequency	ENR R3	QS	PBA-s	pbas11fr	single choice	- never almost never - seldom (less than once week) - sometimes (up to 4 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		
Worst	ENR R3	QS	PBA-s	pbas11wo	single choice	- absent - slight, questionable - mild (present, not a problem) - moderate (symptom causing problem) - severe (almost intolerable for carer)	- 0 - 1 - 2 - 3 - 4		

Section Information

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformat.
Is informant a relative?	ENR R3	QS	PBA	pbainfo	single choice	- spouse or partner - parent - sibling - child - other relative - friend or neighbour - professional care worker - other - no informant - participant came alone	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9		
Is informant a household member?	ENR R3	QS	PBA	pbahshd	single choice	- household member (i.e. relative or friend who lives with participant) - not a household member but has frequent contact with participant (most days) - not a household member and sees participant less than three or four times a week - staff of residential care home or hospital	- 1 - 2 - 3 - 4		

5.18 Form "Short Form Health Survey – 12v2 (SF-12)"

This form is part of the Baseline, Follow Up and Unscheduled visit.

Section Scoring

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Online scoring	ENR	QS	QS	scoring	single choice	- pending - succeeded - failed	- 0 - 1 - 2		

						- failed (2)	- 3		
						- error	- 4		
Physical Functioning (PF)	ENR		QS	pf	number				
Role-Physical (RP)	ENR		QS	rp	number				
Bodily Pain (BP)	ENR		QS	bp	number				
General Health (GH)	ENR		QS	gh	number				
Vitality (VT)	ENR		QS	vt	number				
Social Functioning (SF)	ENR		QS	sf	number				
Role-Emotional (RE)	ENR		QS	re	number				
Mental Health (MH)	ENR		QS	mh	number				
Physical Component (PCS)	ENR		QS	pcs	number				
Mental Component (PCS)	ENR		QS	mcs	number				

5.19 Form "Short Form Health Survey – 36v2 (SF-36v2)"

This form is part of the Baseline, Follow Up and Unscheduled visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
SF-36 v.2 score	R3	QS		sfscore_v2	number				

5.20 Form "Short Form Health Survey – 36v1 (SF-36v1)"

This form is part of the Baseline, Follow Up and Unscheduled visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
SF-36 score	R2	QS		sfscore_v1	number				

5.21 Form "Hospital Anxiety and Depression Scale Snaith Irritability Scale (HADS-SIS)"

This form is part of the Baseline, Follow Up and Unscheduled visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Anxiety subscore	ENR R3	QS	HADS-SIS	anxscore	number				
Depression subscore	ENR R3	QS	HADS-SIS	hads_depscore	number				
Irritability subscore	ENR R3	QS	HADS-SIS	irrscore	number				
Outward irritability subscore	ENR R3	QS	HADS-SIS	outscore	number				
Inward irritability subscore	ENR R3	QS	HADS-SIS	inwscore	number				

5.22 Form "Work Productivity and Activity Impairment-Specific Health Problem Questionnaire (WPAI-SHP)"

This form is part of the Baseline, Follow Up and Unscheduled visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Work time missed due to HD	ENR	QS	WPAI-SHP	wpaiscr1	number			%	
Impairment while working due to HD	ENR	QS	WPAI-SHP	wpaiscr2	number			%	
Overall work impairment due to HD	ENR	QS	WPAI-SHP	wpaiscr3	number			%	
Activity impairment due to HD	ENR	QS	WPAI-SHP	wpaiscr4	number			%	

5.23 Form "Beck - Depression Inventory (BDI)"

This form is part of the Baseline and Follow Up visit.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Becks Score	R2	QS	QS	bdiscore	number				

5.24 Form "Behaviour"

This form is part of the Baseline, Follow Up and Unscheduled visit.

Section General

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Behavioral score	R3 R2	QS		behscore	number				

Behavioral score incomplete	R3 R2	QS		biscore	number				
Group Sub-scores									
Depression	R3	QS		behaviour_depscore	number				
Drive/executive function	R3	QS		defscore	number				
Irritability/aggression	R3	QS		behaviour_irascore	number				
Psychosis	R3	QS		behaviour_psyscore	number				

Section Behavioral Assessment

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Group Depressed mood									
Frequency	R3 R2	QS		deprfr	single choice	- never or almost never - seldom, less than once a week - sometimes, at least once a week - frequently, several times a week - very frequently, most of the time	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		deprsv	single choice	- no mood disturbance	- 0 - 1		

						- questionable or equivalent	- 2		
						equivocal	- 3		
						- mild, responds to redirection and reassurance	- 4		
						- moderately depressed, expresses distress			
						- severe, significant suffering and loss of functioning			
Group Low self-esteem/guilt									
Frequency	R3 R2	QS		guiltfr	single choice	- never or almost never	- 0		
						- seldom, less than once a week	- 1		
						- sometimes, at least once a week	- 2		
						- frequently, several times a week	- 3		
						- very frequently, most of the time	- 4		
Severity	R3 R2	QS		guiltsv	single choice	- no evidence	- 0		
						- questionable or	- 1		

						equivocal - mild, definitely present - moderate, some distress - severe	- 2 - 3 - 4		
Group Anxiety									
Frequency	R3 R2	QS		anxifr	single choice	- never or almost never - seldom, less than once a week - sometimes, at least once a week - frequently, several times a week - very frequently, most of the time	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		anxisv	single choice	- no evidence - questionable or equivocal - mild, responds to reassurance - moderate, impacts on everyday life - severe, causing a profound restriction of	- 0 - 1 - 2 - 3 - 4		

						activities			

Group Suicidal thoughts									
Frequency	R3 R2	QS		suicfr	single choice	- not thinking about suicide or self harm - seldom thinking about suicide - less than once a month - sometimes thinking about suicide - at least once a month - frequently thinking about suicide - at least once a week - often thinks about suicide - sometimes for days and weeks on end	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		suicsv	single choice	- no suicidal thoughts - no thoughts at current time, but person talks about suicide as a potential option - fleeting thoughts about	- 0 - 1 - 2 - 3 - 4		

						it - seriously considered suicide but has no plan - has a plan and is actively preparing			
Group Disruptive or aggressive behavior									
Frequency	R3 R2	QS		aggrfr	single choice	- never or almost never - seldom, less than once a month - sometimes, at least once a month - frequently, at least once a week - very frequently, everyday	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		aggrsv	single choice	- behavior well-controlled - verbal threats or intimidating behavior - mild physically or verbally threatening behavior - clear physical	- 0 - 1 - 2 - 3 - 4		

						threat (moderately aggressive), bumping, shoving, verbal outburst - clear physical threat (severe aggression) striking/hitting, or definite intention to cause injury			
Group Irritable behavior									
Frequency	R3 R2	QS		irritfr	single choice	- never or almost never - seldom, less than once a week - sometimes, at least once a week - frequently, several times a week - very frequently, most of the time	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		irritsv	single choice	- behavior well-controlled - questionable or equivocal	- 0 - 1 - 2 - 3		

						- definite but mild - moderate, others change their behavior to avoid irritating subject - severe irritability	- 4		
Group Perseverative/obsessional thinking									
Frequency	R3 R2	QS		obsessfr	single choice	- never or almost never - seldom, less than once a week - sometimes, at least once a week - frequently, several times a week - very frequently, most of the time	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		obsesssv	single choice	- thinking is always flexible - questionable or equivocal - gets stuck on certain ideas but can be	- 0 - 1 - 2 - 3 - 4		

						easily redirected - moderate - gets stuck on certain ideas, difficult to redirect - severe - gets stuck on certain ideas, and does not respond to redirection			
Group Compulsive behavior									
Frequency	R3 R2	QS		compulfr	single choice	- never or almost never - seldom, less than once a week - sometimes, at least once a week - frequently, several times a week - very frequently, most of the time	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		compulsv	single choice	- behavior always well-controlled - equivocal - has a mild impulse not sufficient to act on	- 0 - 1 - 2 - 3 - 4		

						- mild - has impulse, acts on impulse, but can stop - moderate - has impulse, acts on it and sometimes cannot stop - severe - has impulse, acts on it and cannot stop				
Group Delusions										
Frequency	R3 R2	QS		delusfr	single choice	- no evidence - seldom, less than once a month - sometimes, at least once a month - frequently, at least once a week - very frequently, sometimes for days on end	- 0 - 1 - 2 - 3 - 4			
Severity	R3 R2	QS		delussv	single choice	- no evidence - has delusional idea(s), not sure it is true - convinced of	- 0 - 1 - 2 - 3 - 4			

						idea(s) but allows that the idea is not true - utterly convinced of the idea(s) - utterly convinced of the idea(s), behavior is determined by the delusion(s)			
Group Hallucinations									
Frequency	R3 R2	QS		hallucfr	single choice	- no evidence of hallucinations - seldom, less than once a month - sometimes, at least once a month - frequently, at least once a week - often, sometimes for days on end	- 0 - 1 - 2 - 3 - 4		
Severity	R3 R2	QS		hallucsv	single choice	- no evidence - has hallucinations, but doubts they are real	- 0 - 1 - 2 - 3 - 4		

						- convinced of the reality of the hallucinations, but allows that it is possible that they are not real - utterly convinced of the hallucinations being real, but not acting on them - severe - has hallucinations that are vivid, subject is utterly convinced they are real and the hallucinations severely disrupt behavior			
Group Apathy									
Frequency	R3 R2	QS		apathfr	single choice	- never - seldom apathetic, less than once a week - sometimes, at	- 0 - 1 - 2 - 3 - 4		

						least once a week - frequently, several times a week - very frequently, most of the time			
Severity	R3 R2	QS		apathsv	single choice	- no evidence - equivocal - mild apathy - subject not initiating conversation or activity but is responsive - moderate apathy - sometimes responds to efforts to get involved in conversation/activities - severe apathy - generally unresponsive to attempts to involve subject in activities or conversation	- 0 - 1 - 2 - 3 - 4		
Group Behavioral Milestones									

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Does the examiner believe the participant is confused?	R3 R2	QS		confus	boolean	- yes - no	- 1 - 0		
Does the examiner believe the participant is demented?	R3 R2	QS		dement	boolean	- yes - no	- 1 - 0		
Does the examiner believe the participant is depressed?	R3 R2	QS		deprexam	boolean	- yes - no	- 1 - 0		
Does the participant require pharmacotherapy for depression?	R3 R2	QS		deprrfr	boolean	- yes - no	- 1 - 0		
Does the participant require pharmacotherapy for irritability?	R3 R2	QS		irritrfr	boolean	- yes - no	- 1 - 0		
Group Information sources									
Was the behavioral assessment information obtained from:	R3 R2	QS		isobt	single choice	- participant only - participant and family/companion	- 1 - 2		

5.25 Form "Hamilton"

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Hamilton Score	R2	QS		hamscore	number				

5.26 Form "GCI"

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Based upon my review of the information, I feel the severity of illness is	R3 R2	QS		svrtyll	single choice	- normal, not at all ill - borderline ill - mildly ill - moderately ill - markedly ill - severely ill - among the most extremely ill patients - not assessed	- 1 - 2 - 3 - 4 - 5 - 6 - 7 - 0		

5.27 Form "C-SSRS BL"

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Group Suicidal Ideation – For Lifetime, rate the period when the participant felt the most suicidal.									
Have you wished you were dead or wished you could go to sleep and not wake up?	ENR R3			sid1	boolean	- yes - no	- 1 - 0		
Have you actually had any thoughts of killing yourself?	ENR R3			sid2	boolean	- yes - no	- 1 - 0		

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Group Suicidal Ideation (continued)									
Have you been thinking about how you might do this?	ENR R3			sid3	boolean	- yes - no	- 1 - 0		
Have you had these thoughts and had some intention of acting on them?	ENR R3			sid4	boolean	- yes - no	- 1 - 0		
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?	ENR R3			sid5	boolean	- yes - no	- 1 - 0		
Group Intensity of Ideation – Most Severe									
Type	ENR R3			int1	single choice	- Wish to be dead - Non-Specific Active Suicidal Thoughts - Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act - Active Suicidal Ideation with Some Intent to Act, without Specific Plan - Actve Suicidal Ideation with Specific Plan and Intent	- 1 - 2 - 3 - 4 - 5		
How many times have you had these thoughts?	ENR R3			int2	single choice	- Less than once a week - Once a week - 2-5 times in week - Daily or almost daily - Many times each day	- 1 - 2 - 3 - 4 - 5		

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
When you have the thoughts, how long do they last?	ENR R3			int3	single choice	- Fleeting – few seconds or minutes - Less than 1 hour/some of the time - 1-4 hours/a lot of time - 4-8 hours/most of day - More than 8 hours/persistent or continuous	- 1 - 2 - 3 - 4 - 5		
Could/can you stop thinking about killing yourself or wanting to die if you want do?	ENR R3			int4	single choice	- Easily able to control thoughts - Can control thoughts with little difficulty - Can control thoughts with some difficulty - Can control thoughts with a lot of difficulty - Unable to control thoughts - Does not attempt to control thoughts	- 1 - 2 - 3 - 4 - 5 - 0		
Are there things – anyone or anything (e.g. family, religion, pain of death) – that stopped you from wanting to die or acting on thoughts of committing suicide?	ENR R3			int5	single choice	- Deterrents definitely stopped you - Deterrents probably stopped you - Uncertain that deterrents stopped you - Deterrents most likely did not stop you from attempting suicide - Deterrents definitely did not stop you - Does not apply; wish to die only	- 1 - 2 - 3 - 4 - 5 - 0		

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
What sort of reasons did you have for thinking about wanting to die or killing yourself?	ENR R3			int6	single choice	- Completely to get attention, revenge or a reaction from others - Mostly to get attention, revenge or reaction from others - Equally to get attention, revenge or a reaction from others - Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling - Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) - Does not apply	- 1 - 2 - 3 - 4 - 5 - 0		
Group Suicidal Behavior									
Actual attempt	ENR R3			sbh1	boolean	- yes - no	- 1 - 0		
Total # of attempts	ENR R3			sbh1n	number				
Has subject engaged in Non-Suicidal Self-Injurious Behavior?	ENR R3			sbh2	boolean	- yes - no	- 1 - 0		

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?	ENR R3			sbh3	boolean	- yes - no	- 1 - 0		
Total # of interrupted	ENR R3			sbh3n	number				
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?	ENR R3			sbh4	boolean	- yes - no	- 1 - 0		
Total # of aborted	ENR R3			sbh4n	number				
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?	ENR R3			sbh5	boolean	- yes - no	- 1 - 0		
Suicidal behaviour was present during the assessment period?	ENR R3			sbh6	boolean	- yes - no	- 1 - 0		
Group Answer for Actual Attempts Only									

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Day of most recent attempt	ENR R3			attmpt1 dy	date				Transformed into days relative to baseline date of Enroll-HD.
Actual Lethality/Medical Damage	ENR R3			attmpt1 1	single choice	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	- 0 - 1 - 2 - 3 - 4 - 5		
Potential Lethality	ENR R3			attmpt1 2	single choice	- not likely to result in injury - likely to result in injury - likely to result in death	- 0 - 1 - 2		
Day of most lethal attempt	ENR R3			attmpt2 dy	date				Transformed into days relative to baseline date of Enroll-HD.
Actual Lethalit/Medical Damage	ENR R3			attmpt2 1	single choice	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	- 0 - 1 - 2 - 3 - 4 - 5		
Potential Lethality	ENR R3			attmpt2 2	single choice	- not likely to result in injury - likely to result in injury - likely to result in death	- 0 - 1 - 2		
Day of Initial/First attempt	ENR R3			attmpt3 dy	date				Transformed into days relative to baseline date of Enroll-HD.

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Actual Lethality/Medical Damage	ENR R3			attmpt31	single choice	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	- 0 - 1 - 2 - 3 - 4 - 5		
Potential Lethality	ENR R3			attmpt32	single choice	- not likely to result in injury - likely to result in injury - likely to result in death	- 0 - 1 - 2		

5.28 Form "C-SSRS FUP"

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Group Suicidal Ideation – For Lifetime, rate the period when the participant felt the most suicidal.									
Have you wished you were dead or wished you could go to sleep and not wake up?	ENR R3			sid1	boolean	- yes - no	- 1 - 0		
Have you actually had any thoughts of killing yourself?	ENR R3			sid2	boolean	- yes - no	- 1 - 0		
Group Suicidal Ideation (continued)									
Have you been thinking about how you might do this?	ENR R3			sid3	boolean	- yes - no	- 1 - 0		

Have you had these thoughts and had some intention of acting on them?	ENR R3		sid4	boolean	- yes - no	- 1 - 0	
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?	ENR R3		sid5	boolean	- yes - no	- 1 - 0	
Group Intensity of Ideation – Most Severe							
Type	ENR R3		int1	single choice	- Wish to be dead - Non-Specific Active Suicidal Thoughts - Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act - Active Suicidal Ideation with Some Intent to Act, without Specific Plan - Actve Suicidal Ideation with Specific Plan and Intent	- 1 - 2 - 3 - 4 - 5	
How many times have you had these thoughts?	ENR R3		int2	single choice	- Less than once a week - Once a week - 2-5 times in week - Daily or almost daily - Many times each day	- 1 - 2 - 3 - 4 - 5	

When you have the thoughts, how long do they last?	ENR R3			int3	single choice	- Fleeting – few seconds or minutes - Less than 1 hour/some of the time - 1-4 hours/a lot of time - 4-8 hours/most of day - More than 8 hours/persistent or continuous	- 1 - 2 - 3 - 4 - 5		
Could/can you stop thinking about killing yourself or wanting to die if you want do?	ENR R3			int4	single choice	- Easily able to control thoughts - Can control thoughts with little difficulty - Can control thoughts with some difficulty - Can control thoughts with a lot of difficulty - Unable to control thoughts - Does not attempt to control thoughts	- 1 - 2 - 3 - 4 - 5 - 0		
Are there things – anyone or anything (e.g. family, religion, pain of death) – that stopped you from wanting to die or acting on thoughts of committing suicide?	ENR R3			int5	single choice	- Deterrents definitely stopped you - Deterrents probably stopped you - Uncertain that deterrents stopped you - Deterrents most likely did not stop you from attempting suicide - Deterrents definitely did not stop you - Does not apply; wish to die only	- 1 - 2 - 3 - 4 - 5 - 0		

What sort of reasons did you have for thinking about wanting to die or killing yourself?	ENR R3			int6	single choice	- Completely to get attention, revenge or a reaction from others - Mostly to get attention, revenge or reaction from others - Equally to get attention, revenge or a reaction from others - Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling - Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling) - Does not apply	- 1 - 2 - 3 - 4 - 5 - 0	
Group Suicidal Behavior								
Actual attempt	ENR R3			sbh1	boolean	- yes - no	- 1 - 0	
Total # of attempts	ENR R3			sbh1n	number			
Has subject engaged in Non-Suicidal Self-Injurious Behavior?	ENR R3			sbh2	boolean	- yes - no	- 1 - 0	
Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?	ENR R3			sbh3	boolean	- yes - no	- 1 - 0	

Total # of interrupted	ENR R3			sbh3n	number				
Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?	ENR R3			sbh4	boolean	- yes - no	- 1 - 0		
Total # of aborted	ENR R3			sbh4n	number				
Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?	ENR R3			sbh5	boolean	- yes - no	- 1 - 0		
Suicidal behaviour was present during the assessment period?	ENR R3			sbh6	boolean	- yes - no	- 1 - 0		
Completed Suicide was present during the assessment perion	ENR R3			sbh7	boolean	- yes - no	- 1 - 0		
Group Answer for Actual Attempts Only									
Day of most recent attempt	ENR R3			attmpt1dy	date				Transformed into days relative to baseline date of Enroll-HD.

Actual Lethality/Medical Damage	ENR R3			attmpt11	single choice	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	- 0 - 1 - 2 - 3 - 4 - 5	
Potential Lethality	ENR R3			attmpt12	single choice	- not likely to result in injury - likely to result in injury - likely to result in death	- 0 - 1 - 2	
Day of most lethal attempt	ENR R3			attmpt2dy	date			Transformed into days relative to baseline date of Enroll-HD.
Actual Lethalit/Medical Damage	ENR R3			attmpt21	single choice	- No physical damage - Minor physical damage - Moderate physical damage - Moderately severe physical damage - Severe physical damage - Death	- 0 - 1 - 2 - 3 - 4 - 5	
Potential Lethality	ENR R3			attmpt22	single choice	- not likely to result in injury - likely to result in injury - likely to result in death	- 0 - 1 - 2	
Day of Initial/First attempt	ENR R3			attmpt3dy	date			Transformed into days relative to baseline date of Enroll-HD.

| Actual Lethality/Medical Damage | ENR R3 | | | attmpt31 | single choice | - No physical damage
- Minor physical damage
- Moderate physical damage
- Moderately severe physical damage
- Severe physical damage
- Death | - 0
- 1
- 2
- 3
- 4
- 5 | | |
| Potential Lethality | ENR R3 | | | attmpt32 | single choice | - not likely to result in injury
- likely to result in injury
- likely to result in death | - 0
- 1
- 2 | | |

5.29 Form "Missed Visit"

This form is part of the Phone Contact visit.

Section Documentation of Missed Follow-Up

Label	Study	Domain	Category	Variable	Type	Parameter	Coding	Unit	Transformation
Source of information	ENR			mvsrc	single choice	- participant - spouse partner - next of kin (family or friends) - physician - nurse - other (e.g. hearsay, obituary in newspaper, death certificate)	- 1 - 2 - 3 - 4 - 5 - 6		
Reason for missed follow-up visit	ENR			mvrsn	single choice	- participant alive, unable to attend FUP, open to future FUPs - participant alive, objects to further FUP visits, open to	- 1 - 2 - 3 - 4 - 5		

					- further phone contacts - participant alive, objects to further FUP visits and to further phone contacts - participant alive, lost to FUP - participant dead - status unclear	- 6		
Group If participant is alive								
Level of care required	ENR			crlvl	single choice	- The participant does not require any help or help for basic activities of daily living (un dressing, washing bathing, getting up going to bed). - The participant requires some help to manage basic activities of daily living (typically < 4 h support per day), but no full-time supervision. - The participant requires extensive help to manage basic activities of daily living (typically ≥ 4 h support per day), and full-time supervision with additional help as required.	- 0 - 1 - 2		
Days since full-time dependency	ENR			dpdy	date				Transformed into days relative to baseline date of Enroll-HD.

References

[1]   CHDI Foundation Inc., *Description of Monitoring*, Version 1.0, 2015

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