Annotated Case Report Form (CRF) for Enroll-HD Periodic Dataset

[document updated Dec 16, 2020]

Enroll-HD

A worldwide observational study for Huntington's disease families

A CHDI Foundation Project

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1 Purpose of this Document

The purpose of this document is to provide an annotated view of the Enroll-HD eCRF (electronic Case Report Form). It shows the source of the variable names provided in the Enroll-HD periodic dataset, which is available to the HD research community at large. The periodic dataset represents a data extract of the Enroll-HD Electronic Data Capture (EDC) database at a defined point in time. Information that could potentially identify a participant has been removed or de-identified within this dataset. When available, CDISC SDMT naming conventions were used.

The annotated view shows all forms, variables, and variable names used within the periodic dataset. Forms and variables that are not provided in the dataset are not shown in the annotated forms. Variables that have been transformed for de-identification reasons are shown in the transformed manner (e.g. day of informed consent in the PDS, not date of informed consent as entered in the EDC) in the annotated view.

The variables and data files of the dataset are described in detail within the data dictionary for the Enroll-HD periodic dataset.

2   Forms and Data Files

Forms are CRF entry screens that are displayed to data entry personnel and show how data is entered in the eCRF. Data files are sets of variables that define how the data are represented in the periodic dataset.. The following table defines how forms and data files are related.

Form / Data File	Profile	Partici-pation	Pharmaco Tx	NutSuppl	NonPhar-macoTx	Comorbid	Event	Enroll
Enrollment		✓						
Demog	✓							
MHx								✓
HD CC	✓							
PharmacoTx			✓					
NutSuppl				✓				
NonPharmacoTx					✓			
Comorbid						✓		
Mortality	✓							
Variable BL								✓
Variable FUP								✓
Motor								✓
TFC								✓
Function								✓

Form / Data File	Profile	Partici-pation	Pharmaco Tx	NutSuppl	NonPhar-macoTx	Comorbid	Event	Enroll
PBA-s BL								✓
Cognitive								✓
HADS-SIS								✓
MMSE								✓
Physio								✓
SF12								✓
WPAI-SHP								✓
CSSRS BL								✓
CSSRS FUP								✓
Event							✓	
End		✓						
Missed Visit								✓

The data files "Profile" and "Participation" are not displayed on an entry form but consist of variables of various forms. It contains key information like subject, study and region identifers and some visit-independent subject information, e.g. the subject's latest HD classification. Please refer to the data dictionary for detailed information.

2.1 Legend of the EDC field types:

Data entry fields displayed in white: Data entered by the site. In the periodic data set, the data could be used as is, or is transformed into another value (e.g. date of informed consent is transformed to day of informed consent in relation to the day of the baseline visit which is considered day "0")

Day of informed consent:

Data entry fields displayed in green (background color): Value is autocalculated in the EDC, based on other values entered.

BMI:

Data entry fields single choice:
Dropdown list: List of values is displayed beneath the field to show the possible selections. One value can be selected.

Marijuana   ---- ▾ hxmar   ---- ▾ hxmarfrq
           yes 1   seldom 1
           no 0   occasionally 2
                   frequently 3

Radio buttons: One value can be selected.

Handedness: 🔴   ○ right 1
                   ○ left 2
                   ○ mixed 3

Data entry field with multiple choices: one or more options can be selected

Mixed symptoms: [6959] 6959_1   motor: ☐ 1

                                     cognitive: ☐ 1

                                     psychiatric: ☐ 1

                                     oculomotor: ☐ 1

3   Form "Enrollment"

4   Form "Demographics (Demog)"

Demographics (invariable) [dm1] 116_1

Age at enrollment: [   ]   age

Gender: ○ female F ○ male m   sex

[dm2]

Ethnicity: ○ Caucasian 1   race
                        ○ American - Black 2
                        ○ Hispano or Latino Origin 3
                        ○ American Indian/Native American/Amerindian 8
                        ○ Asian 16
                        ○ mixed 15
                        ○ other 6

[dm4]

Handedness: 🔲   ○ right 1   handed
                        ○ left 2
                        ○ mixed 3

5   Form "Medical History (MHx)"

Past Medical History [mhx4] 376_1

Has the participant had alcohol problems in the past?	○ yes 1 ○ no 0	hxalcab
Has the participant ever smoked?	○ yes 1 ○ no 0	hxtobab
Cigarettes per day:		hxtobcpd
Years of smoking:		hxtobyos
Packyears:		packy
Has the participant ever abused drugs?	○ yes 1 ○ no 0	hxdrugab

Drug use for non-medical reasons? [384] 384_1

	Abuse		Frequency	
Marijuana	---- ⌄ hxmar yes 1 no 0		---- ⌄ hxmarfrq seldom 1 occasionally 2 frequently 3	
Heroin	---- ⌄ hxher yes 1 no 0		---- ⌄ hxherfrq seldom 1 occasionally 2 frequently 3	
Cocaine	---- ⌄ hxcoc yes 1 no 0		---- ⌄ hxcocfrq seldom 1 occasionally 2 frequently 3	

Club drugs (Ecstacy, GHB, Roofies)	---- ⌄ hxclb	---- ⌄ hxclbfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Amphetamines	---- ⌄ hxamp	---- ⌄ hxampfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Ritalin	---- ⌄ hxrit	---- ⌄ hxritfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Hallucinogens	---- ⌄ hxhal	---- ⌄ hxhalfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Inhalants	---- ⌄ hxinh	---- ⌄ hxinhfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Opium	---- ⌄ hxopi	---- ⌄ hxopifrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Painkillers	---- ⌄ hxpak	---- ⌄ hxpakfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Barbiturates/sedatives	---- ⌄ hxbar	---- ⌄ hxbarfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		
Tranquilizers	---- ⌄ hxtrq	---- ⌄ hxtrqfrq		
	yes 1 no 0	seldom 1 occasionally 2 frequently 3		

6 Form "HD Clinical Characteristics (HD CC)"

Family History [hdcc6] 594_1

Mother affected:	○ yes 1 ○ no 0 ○ unknown 9999	momhd
	Age at onset of symptoms in mother: [____] years	momagesx
Father affected:	○ yes 1 ○ no 0 ○ unknown 9999	dadhd
	Age at onset of symptoms in father: [____] years	dadagesx

[hdcc2]
Each estimate of symptom onset should be based on ALL available sources of information including reports of participant, companions, case notes and clinical rating scales.

HD Clinical Characteristics and Age-of-Onset 📄 [6895] 6895_1

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?　　○ yes 1 ○ no 0　　　　ccdep

At what age did the depression begin? [6897] 6897_1

age (years)

[____] ccdepage

Has irritability ever been a part of the participant's medical history?　　○ yes 1 ○ no 0　　　　ccirb

At what age did the irritability begin? [6903] 6903_1

age (years)

[____] ccirbage

Has violent or aggressive behavior ever been a part of the participant's medical history?　　○ yes 1 ○ no 0　　　　ccvab

At what age did violent or aggressive behaviour begin? [6909] 6909_1

age (years)

[____] ccvabage

Has apathy ever been a part of the participant's medical history: ○ yes 1 ○ no 0   ccapt

At what age did apathy begin? [6915] 6915_1

age (years)

[____] ccaptyr

Has perseverative/obsessive behaviors ever been a part of the participant's medical history: ○ yes 1 ○ no 0   ccpob

At what age did perseverative/obsessive behaviour begin? [6921] 6921_1

age (years)

[____] ccpobage

Has psychosis (hallucinations or delusions) ever been a part of the participant's medical history: ○ yes 1 ○ no 0   ccpsy

At what age did psychosis (hallucinations or delusions) begin? [6927] 6927_1

age (years)

[____] ccpsyage

Does the participant have a family history of a psychotic illness in a first degree relative: ○ yes 1 ○ no 0   ccpsyfh

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: ○ yes 1 ○ no 0   cccog

At what age did cognitive impairment first start to have an impact on daily life? [6934] 6934_1

age (years)

[____] cccogage

History of HD Motor Symptoms [6940] 6940_1

Have motor symptoms compatible with HD ever been a part of the participant's medical history?

○ yes 1 ○ no 0   ccmtr

At what age did the participant's motor symptoms begin? [6942] 6942_1

age (years)

[____] ccmtrage

[hdcc4]

HD History - Participant and Family [6947] 6947_1

Symptoms first noted by participant: [____]   sxsubj

Initial major symptom noted by participant: ○ motor 1 ○ cognitive 2 ○ psychiatric 3 ○ oculomotor 4 ○ other 5 ○ mixed 6   sxsubjm

Mixed symptoms: [6951] 6951_1

motor:	☐ 1	sxs_m
cognitive:	☐ 1	sxs_c
psychiatric:	☐ 1	sxs_p
oculomotor:	☐ 1	sxs_o

Symptoms first noted by family: [____]   sxfam

Initial major symptom noted by family: ○ motor 1 ○ cognitive 2 ○ psychiatric 3 ○ oculomotor 4 ○ other 5 ○ mixed 6   sxfamm

Mixed symptoms: [6959] 6959_1

motor:	☐ 1	sxf_m
cognitive:	☐ 1	sxf_c
psychiatric:	☐ 1	sxf_p
oculomotor:	☐ 1	sxf_o

HD History - Rater [6964] 6964_1

Date of clinical HD diagnosis:	☐	hddiagn
Can you, as a rater, estimate the time of symptom onset:	○ yes 1 ○ no 0	sxest

Rater's estimate of symptom onset: ☐   sxrater

Confidence with which this estimation is made: ○ high 1 ○ low 2   sxestcfd

Please specify why you, as a rater, can not estimate symptom onset (without additional external information) at the moment:
- ○ participant can not provide information (mute, or cognitively too impaired) 1
- ○ information provided deemed unreliable 2   sxreas

What is your best guess of how many years ago symptom onset took place: sxgs
- ○ < 5 1
- ○ < 10 2
- ○ < 15 3
- ○ < 20 4
- ○ > 20 5

Day of data entry: ☐   sxgsdy

Rater's judgement of initial major symptom: ○ motor 1 ○ cognitive 2 ○ psychiatric 3 ○ oculomotor 4 ○ other 5 ○ mixed 6   sxraterm

Mixed symptoms: [6976] 6976_1

motor:	☐ 1	sxr_m
cognitive:	☐ 1	sxr_c
psychiatric:	☐ 1	sxr_p
oculomotor:	☐ 1	sxr_o

Suicidal Behavior [hdcc7] 3918_1

Previous suicidal ideation or attempts?	○ yes 1 ○ no 0	hxsid

NOTE: This form is part of the "profile" dataset

7   Form "Pharmacotherapy (PharmacoTx)"

[cm1]

Medications (Pharmacotherapy) [med] 222_1

	Drug name		Indication		Total Daily Dose / Unit		Frequency		Route		Start day		Ongoing		End day	
1.		modify decod cmtrt		modify decod cmindc		cmdostot	---- ⌄ cmdosfrq		---- ⌄ cmroute		cmstdy		☐ 1 cmenrf		cmendy
					cmdosu cmdose		daily 1		p.o. 1							
							every 2nd day 2		p.r. 2							
							every 3rd day 3		s.c. 3							
							weekly 4		i.m. 4							
							every 2nd week 5		i.v. 5							
							monthly 6		nasal 6							
							every 2nd month 7		td 7							
							every 3rd month 8		sl 8							
							annually 9		inh 9							
							as needed 10		other 10							
2.		modify decod cmtrt		modify decod cmindc		cmdostot	cmdosu cmdose	---- ⌄ cmdosfrq		---- ⌄ cmroute		cmstdy		☐ 1 cmenrf		cmendy
3.		modify decod cmtrt		modify decod cmindc		cmdostot	cmdosu cmdose	---- ⌄ cmdosfrq		---- ⌄ cmroute		cmstdy		☐ 1 cmenrf		cmendy

Total Daily Dose is a calculated value.

8   Form "Nutritional Supplements (NutSuppl)"

Nutritional Supplements [3905] .Nutritional Supplements 3905_1

	Type		Total Daily Dose		Unit		Frequency		Start day		Ongoing	End day	
1.	---- ⌄	cmcat		cmdostot	---- ⌄	cmdosunit	---- ⌄	cmdosfrq		cmstdy	☐ 1 cmenrf		cmendy

Type options:
- vitamin & supplements 1
- herbs (extracts) 2
- herbs (teas) 3
- other natural remedies 4
- aromatherapies 5
- homepathic remedies 6
- high calorie diet 7

Unit options:
- g 1
- mg 2
- IU 3
- spoons 4
- tablets 5
- drops 6
- capsule 7
- other 8

Frequency options:
- daily 1
- every 2nd day 2
- every 3rd day 3
- weekly 4
- every 2nd week 5
- monthly 6
- every 2nd month 7
- every 3rd month 8
- annually 9
- as needed 10

	Type		Total Daily Dose		Unit		Frequency		Start day		Ongoing	End day	
2.	---- ⌄	cmcat		cmdostot	---- ⌄	cmdosunit	---- ⌄	cmdosfrq		cmstdy	☐ 1 cmenrf		cmendy
3.	---- ⌄	cmcat		cmdostot	---- ⌄	cmdosunit	---- ⌄	cmdosfrq		cmstdy	☐ 1 cmenrf		cmendy

Total Daily Dose is a calculated value.

9   Form "Non-Pharmacologic Therapies (NonPharmaTx)"

Non-Pharmacologic Therapies [3894] .Non-Pharmacologic Therapies 3894_1

Therapy		Number of times	Frequency		Start day	Ongoing	End day	
1.	---- ▼ cmtrt	cmfrq	---- ▼	cmdosfrq	cmstdy	☐ 1 cmenrf		cmendy

Physical therapy 1
Occupational therapy 2
Psychotherapy 3
Counseling 4
Speech/Language therapy 5
Swallowing therapy 6
Music therapy 7
Relaxation therapy (meditation, massage, yoga, etc.) 8
Acupuncture 9

daily 1
weekly 2
monthly 3
as needed 4

| 2. | ---- ▼ cmtrt | cmfrq | ---- ▼ | cmdosfrq | cmstdy | ☐ 1 cmenrf | | cmendy |
| 3. | ---- ▼ cmtrt | cmfrq | ---- ▼ | cmdosfrq | cmstdy | ☐ 1 cmenrf | | cmendy |

10 Form "Comorbid Conditions (Comorbid)"

Past Disorders and Comorbidities [group] MH 251_1

	Condition				Body system code		Start day		Ongoing	End day	
1.		modify		decod ⇨mhterm	---- ⌄	mhbodsys		mhstdy	☐ 1 mhenrf		mhendy

cardiovascular 1
pulmonary 2
neurologic 3
ENT 4
gynecologic/urologic 5
reproductive 6
gastrointestinal 7
metabolic/endocrine 8
hemato/lymphatic 9
dermatological 10
psychiatric 11
musculoskelatal 12
allergy/immunologic 13
ophthalmological 14
hepatobiliary 15
renal 16
other 17

	Condition				Body system code		Start day		Ongoing	End day	
2.		modify		decod ⇨mhterm	---- ⌄	mhbodsys		mhstdy	☐ 1 mhenrf		mhendy
3.		modify		decod ⇨mhterm	---- ⌄	mhbodsys		mhstdy	☐ 1 mhenrf		mhendy
4.		modify		decod ⇨mhterm	---- ⌄	mhbodsys		mhstdy	☐ 1 mhenrf		mhendy
5.		modify		decod ⇨mhterm	---- ⌄	mhbodsys		mhstdy	☐ 1 mhenrf		mhendy
6.		modify		decod ⇨mhterm	---- ⌄	mhbodsys		mhstdy	☐ 1 mhenrf		mhendy

Annotated Case Report Form (CRF) for Enroll-HD Periodic Dataset
Updated 2020-12-16

11 Form "Reportable Event Monitoring (Event)"

General [3007] 3007_1

Day of report: [   ]   evtdy

Reportable Event [3009] 3009_1

Reportable event codes:
                                                                              evtcode
- ⚪ suicide attempts 01
- ⚪ completed suicide 2
- ⚪ mental health event requiring hospitalization 3
- ⚪ death (other than suicide, any cause) 4

Event term: [   ]   modify decod   evtterm

Details of Reportable Event [3014] 3014_1

Onset day: [   ]   evtstdy

Date estimated: ⚪ yes 1   ⚪ no 0   stdtcest

Resolved: ⚪ yes 1   ⚪ no 0   evtongo

End day: [   ]   evtendy

DSMC Review [4750] 4750_1

Status of DSMC review:
                                                                              evtdsmc
- ⚪ pending review 1
- ⚪ ongoing review 2
- ⚪ closed/completed review 3

Annotated Case Report Form (CRF) for Enroll-HD Periodic Dataset
Updated 2020-12-16

12   Form "Mortality"

Death Report Form [mortrpt] 2848_1

Age of death:	☐ years	dssage
Place of death:	○ home 1	dsplace
	○ hospital 2	
	○ nursing home 3	
	○ hospice care 4	
	○ unknown 5	
Cause of death:	○ pneumonia 1	dsend
	○ other infection 2	
	○ cancer 3	
	○ stroke 4	
	○ trauma 5	
	○ suicide 6	
	○ other 7	

Annotated Case Report Form (CRF) for Enroll-HD Periodic Dataset
Updated 2020-12-16

13 Form "Variable Items - Baseline Visit (Variable BL)"

General Variable Items I [often] 649_1

[varitems2]

Weight (kg)

[   ] weight

Height (cm)

[   ] height

BMI: [   ]   bmi

[varitems3]

Does the participant currently drink alcohol?	○ yes 1 ○ no 0		alcab
	Units per week:	[ ]	alcunits
Does the participant currently smoke?	○ yes 1 ○ no 0		tobab
	Cigarettes per day:	[ ]	tobcpd
	Years of smoking:	[ ]	tobyos
	Packyears:	[ ]	packy
Current caffeine use?	○ yes 1 ○ no 0		cafab
	Do you drink more than 3 cups of coffee, tea and cola drinks combined per day?	○ yes 1 ○ no 0	cafpd
Does the participant currently use drugs?	○ yes 1 ○ no 0		drugab

Drug use for non-medical reasons? [787] 787_1

	Abuse		Frequency	
Marijuana	[---- ▾]	mar	[---- ▾]	marfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Heroin	[---- ▾]	her	[---- ▾]	herfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Cocaine	[---- ▾]	coc	[---- ▾]	cocfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	

Club drugs (Ecstacy, GHB, Roofies)	---- ⌄ clb	---- ⌄ clbfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Amphetamines	---- ⌄ amp	---- ⌄ ampfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Ritalin	---- ⌄ rit	---- ⌄ ritfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Hallucinogens	---- ⌄ hal	---- ⌄ halfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Inhalants	---- ⌄ inh	---- ⌄ inhfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Opium	---- ⌄ opi	---- ⌄ opifrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Painkillers	---- ⌄ pak	---- ⌄ pakfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Barbiturates/sedatives	---- ⌄ bar	---- ⌄ barfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	
Tranquilizers	---- ⌄ trq	---- ⌄ trqfrq	
	yes 1	seldom 1	
	no 0	occasionally 2	
		frequently 3	

General Variable Items II [rarely] 650_1

[varitems7]

Marital status:
- ○ single 1
- ○ married 3
- ○ partnership 2
- ○ divorced 4
- ○ widowed 5
- ○ legally separated 6

maristat

[varitems8]

Residence:
- ○ rural 1
- ○ village 2
- ○ town 3
- ○ city 4

res

[varitems10]

ISCED education level: 📄
- ○ ISCED 0 0
- ○ ISCED 1 1
- ○ ISCED 2 2
- ○ ISCED 3 3
- ○ ISCED 4 4
- ○ ISCED 5 5
- ○ ISCED 6 6

isced

[varitems13]

Employment:
- ○ full-time employed 1
- ○ part-time employed 2
- ○ self employed 3
- ○ not employed 4

jobclas

Status: ○ paid 1 ○ unpaid 2   jobpaid

Reason:
- ○ sick leave 1
- ○ retirement 2
- ○ working in the home (e.g. caring for children) 3
- ○ unemployed 4
- ○ training/college 5

emplnrsn

Retired due to: ○ ill health 1
                ○ age 2

emplnrd

[varitems15]

Do you receive incapacity benefit/social security or disability benefit?   ○ yes 1 ○ no 0   ssdb

Do you intend to return to work?   ○ yes 1 ○ no 0   rtrnwk

Since when have you been unemployed/retired?   [____] YYYY   rtrddur

Additional Employment Section [varitems14] SC 3920_1

Have you had to stop or reduce work due to your health?   ○ yes 1 ○ no 0   rdcwk

How many days in the last 6 months have you had off work because of HD?   [____] days   rdcwkd

How many fewer hours per week have you worked because of HD?   [____] hours/week   rdcwkhw

14 Form "Variable Items - Follow-Up Visit (Variable FUP)"

General Variable Items I [often] 657_1

[varitems2]

Weight (kg)

[_____] weight

Height (cm)

[_____] height

BMI: [_____] bmi

[varitems3]

Does the participant currently drink alcohol?	○ yes 1 ○ no 0		alcab
Units per week:		[_____]	alcunits
Does the participant currently smoke?	○ yes 1 ○ no 0		tobab
Cigarettes per day:		[_____]	tobcpd
Years of smoking:		[_____]	tobyos
Packyears:		[_____]	packy
Current caffeine use?	○ yes 1 ○ no 0		cafab
Do you drink more than 3 cups of coffee, tea and cola drinks combined per day?		○ yes 1 ○ no 0	cafpd
Does the participant currently use drugs?	○ yes 1 ○ no 0		drugab

Drug use for non-medical reasons? [787] 787_1

	Abuse		Frequency	
Marijuana	[---- ▼]	mar	[---- ▼]	marfrq
	yes 1 no 0		seldom 1 occasionally 2 frequently 3	
Heroin	[---- ▼]	her	[---- ▼]	herfrq
	yes 1 no 0		seldom 1 occasionally 2 frequently 3	
Cocaine	[---- ▼]	coc	[---- ▼]	cocfrq
	yes 1 no 0		seldom 1 occasionally 2 frequently 3	

Club drugs (Ecstacy, GHB, Roofies)	---- ⌄	clb	---- ⌄	clbfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Amphetamines	---- ⌄	amp	---- ⌄	ampfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Ritalin	---- ⌄	rit	---- ⌄	ritfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Hallucinogens	---- ⌄	hal	---- ⌄	halfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Inhalants	---- ⌄	inh	---- ⌄	inhfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Opium	---- ⌄	opi	---- ⌄	opifrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Painkillers	---- ⌄	pak	---- ⌄	pakfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Barbiturates/sedatives	---- ⌄	bar	---- ⌄	barfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	
Tranquilizers	---- ⌄	trq	---- ⌄	trqfrq
	yes 1		seldom 1	
	no 0		occasionally 2	
			frequently 3	

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Updated 2020-12-16

General Variable Items II [rarely] 658_1

General Variable items of previous visits:

Participant category	----	(invalid)
Occupation		(invalid)
Employment		(invalid)
Marital status	----	(invalid)
Residence	----	(invalid)
ISCED education level	----	(invalid)
Years of education		(invalid)

html

Any changes to the rarely changing
General Variable Items above:

⦿ yes 1 ⦿ no 0   updsc

[varitems12]

Participant category: ⦿ genotype unknown 1   hdcat
                                     ⦿ pre-manifest/pre-motor-manifest HD 2
                                     ⦿ manifest/motor-manifest HD 3
                                     ⦿ genotype negative 4
                                     ⦿ family control 5
                                     ⦿ community control 6

[varitems7]

Marital status: ⦿ single 1   maristat
                                     ⦿ married 3
                                     ⦿ partnership 2
                                     ⦿ divorced 4
                                     ⦿ widowed 5
                                     ⦿ legally separated 6

[varitems8]

Residence: ⦿ rural 1   res
                                     ⦿ village 2
                                     ⦿ town 3
                                     ⦿ city 4

[varitems10]

ISCED education level: 📄   ⦿ ISCED 0 0   isced
                                     ⦿ ISCED 1 1
                                     ⦿ ISCED 2 2
                                     ⦿ ISCED 3 3
                                     ⦿ ISCED 4 4
                                     ⦿ ISCED 5 5
                                     ⦿ ISCED 6 6

This table contains information about value of "Participant Category", "Occupation", etc.

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Employment:
- ○ full-time employed 1
- ○ part-time employed 2
- ○ self employed 3
- ○ not employed 4

jobclas

Status:
- ○ paid 1
- ○ unpaid 2

jobpaid

Reason:
- ○ sick leave 1
- ○ retirement 2
- ○ working in the home (e.g. caring for children) 3
- ○ unemployed 4
- ○ training/college 5

emplnrsn

Retired due to:
- ○ ill health 1
- ○ age 2

emplnrd

[varitems15]

Do you receive incapacity benefit/social security or disability benefit?	○ yes 1 ○ no 0	ssdb
Do you intend to return to work?	○ yes 1 ○ no 0	rtrnwk
Since when have you been unemployed/retired?	[____] YYYY	rtrddur

Additional Employment Section [varitems14] SC 3920_1

Have you had to stop or reduce work due to your health?	○ yes 1 ○ no 0	rdcwk
How many days in the last 6 months have you had off work because of HD?	[____] days	rdcwkd
How many fewer hours per week have you worked because of HD?	[____] hours/week	rdcwkhw

[varitems11]

Since the last visit have there been [chklist] 836_1

Any changes to participant's medication?	○ yes 1 ○ no 0	updmed
Any changes to participant's comorbid conditions?	○ yes 1 ○ no 0	updmh
Any updates to the clinical characteristics and/or onset of HD?	○ yes 1 ○ no 0	updhdh
Any updates to family history?	○ yes 1 ○ no 0	updfh

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15 Form "UHDRS Motor/Diagnostic Confidence (Motor)"

[motor2]

General [motor] 132_1

Motor score (TMS): [   ]   motscore

Motor score (TMS) incomplete: [   ]   miscore

Motor Assessment [135] 135_1

Ocular pursuit: [136] 136_1

Horizontal	Vertical	
○ 0	○ 0	0 = complete (normal)
○ 1	○ 1	1 = jerky movement
○ 2	○ 2	2 = interrupted pursuits/full range
○ 3	○ 3	3 = incomplete range
○ 4 ocularh	○ 4 ocularv	4 = cannot pursue

Saccade initiation: [140] 140_1

Horizontal	Vertical	
○ 0	○ 0	0 = normal
○ 1	○ 1	1 = increased latency only
○ 2	○ 2	2 = suppressible blinks or head movements to initiate
○ 3	○ 3	3 = unsuppressible head movements
○ 4 sacinith	○ 4 sacinitv	4 = cannot initiate saccades

Saccade velocity: [144] 144_1

Horizontal	Vertical	
○ 0	○ 0	0 = normal
○ 1	○ 1	1 = mild slowing
○ 2	○ 2	2 = moderate slowing
○ 3	○ 3	3 = severely slow, full range
○ 4 sacvelh	○ 4 sacvelv	4 = incomplete range

Dysarthria:

dysarth

- ○ 0 = normal 0
- ○ 1 = unclear, no need to repeat 1
- ○ 2 = must repeat to be understood 2
- ○ 3 = mostly incomprehensible 3
- ○ 4 = anarthria 4

Tongue protrusion:

tongue

- ○ 0 = can hold tongue fully protruded for 10 sec 0
- ○ 1 = cannot keep fully protruded for 10 sec 1
- ○ 2 = cannot keep fully protruded for 5 sec 2
- ○ 3 = cannot fully protrude tongue 3
- ○ 4 = cannot protrude tongue beyond lips 4

Finger taps: [150] 150_1

Right	Left	
○ 0	○ 0	0 = normal (≥15/5 sec.)
○ 1	○ 1	1 = mild slowing, reduction in amplitude (11-14/5 sec.)
○ 2	○ 2	2 = moderately impaired (7-10/5 sec.)
○ 3	○ 3	3 = severely impaired (3-6/5 sec.)
○ 4 fingtapr	○ 4 fingtapl	4 = can barely perform task (0-2/5 sec.)

Pronate/supinate-hands: [154] 154_1

Right	Left	
○ 0	○ 0	0 = normal
○ 1	○ 1	1 = mild slowing and/or irregular
○ 2	○ 2	2 = moderate slowing and irregular
○ 3	○ 3	3 = severe slowing and irregular
○ 4 prosupr	○ 4 prosupl	4 = cannot perform

Luria:

○ 0 = ≥4 in 10 sec, no cue 0
○ 1 = <4 in 10 sec, no cue 1
○ 2 = ≥4 in 10 sec with cues 2
○ 3 = <4 in 10 sec with cues 3
○ 4 = cannot perform 4

luria

Rigidity-arms: [159] 159_1

Right	Left	
○ 0	○ 0	0 = absent
○ 1	○ 1	1 = slight or present only with activation
○ 2	○ 2	2 = mild to moderate
○ 3	○ 3	3 = severe, full range of motion
○ 4 rigarmr	○ 4 rigarml	4 = severe with limited range

Bradykinesia-body:

○ 0 = normal 0
○ 1 = minimally slow (?normal) 1
○ 2 = mildly but clearly slow 2
○ 3 = moderately slow, some hesitation 3
○ 4 = markedly slow, long delays in initiation 4

brady

Maximal dystonia: [164] 164_1

Trunk	RUE	LUE	RLE	LLE	
○ 0	○ 0	○ 0	○ 0	○ 0	0 = absent
○ 1	○ 1	○ 1	○ 1	○ 1	1 = slight/intermittent
○ 2	○ 2	○ 2	○ 2	○ 2	2 = mild/common or moderate/intermittent
○ 3	○ 3	○ 3	○ 3	○ 3	3 = moderate/common
○ 4 dysttrnk	○ 4 dystrue	○ 4 dystlue	○ 4 dystrle	○ 4 dystlle	4 = marked/prolonged

Maximal chorea: [171] 171_1

Face	BOL	Trunk	RUE	LUE	RLE	LLE	
○ 0	○ 0	○ 0	○ 0	○ 0	○ 0	○ 0	0 = absent
○ 1	○ 1	○ 1	○ 1	○ 1	○ 1	○ 1	1 = slight/intermittent
○ 2	○ 2	○ 2	○ 2	○ 2	○ 2	○ 2	2 = mild/common or moderate/intermittent
○ 3	○ 3	○ 3	○ 3	○ 3	○ 3	○ 3	3 = moderate/common
○ chorface 4	○ chorbol 4	○ chortrnk 4	○ chorrue 4	○ chorlue 4	○ chorrle 4	○ chorlle 4	4 = marked/prolonged

Gait:

○ 0 = normal gait, narrow base 0
○ 1 = wide base and/or slow 1
○ 2 = wide base and walks with difficulty 2
○ 3 = walks only with assistance 3
○ 4 = cannot attempt 4

gait

Tandem walking:
- ○ 0 = normal for 10 steps 0
- ○ 1 = 1 to 3 deviations from straight line 1
- ○ 2 = >3 deviations 2
- ○ 3 = cannot complete 3
- ○ 4 = cannot attempt 4

tandem

Retropulsion pull test:
- ○ 0 = normal 0
- ○ 1 = recovers spontaneously 1
- ○ 2 = would fall if not caught 2
- ○ 3 = tends to fall spontaneously 3
- ○ 4 = cannot stand 4

retropls

Diagnostic Confidence [motor3] .DCL 185_1

Diagnostic confidence level (DCL):
- ○ 0 = normal (no abnormalities) 0
- ○ 1 = non-specific motor abnormalities (less than 50 % confidence) 1
- ○ 2 = motor abnormalities that may be signs of HD (50 - 89 % confidence) 2
- ○ 3 = motor abnormalities that are likely signs of HD (90 - 98 % confidence) 3
- ○ 4 = motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence) 4

diagconf

16   Form "UHDRS Total Funtional Capacity (TFC)"

General [tfc] 893_1

Functional score: [   ]   tfcscore

Functional Capacity [functcap] 895_1

Occupation: occupatn
- ○ 0 = unable 0
- ○ 1 = marginal work only 1
- ○ 2 = reduced capacity for usual job 2
- ○ 3 = normal 3

Finances: finances
- ○ 0 = unable 0
- ○ 1 = major assistance 1
- ○ 2 = slight assistance 2
- ○ 3 = normal 3

Domestic chores: ○ 0 = unable 0 ○ 1 = impaired 1 ○ 2 = normal 2   chores

ADL: adl
- ○ 0 = total care 0
- ○ 1 = gross tasks only 1
- ○ 2 = minimal impairment 2
- ○ 3 = normal 3

Care level: carelevl
- ○ 0 = full time skilled nursing 0
- ○ 1 = home or chronic care 1
- ○ 2 = home 2

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

[function2]

General [function] 849_1

Functional assessment score:	☐	fascore
Functional score incomplete:	☐	fiscore

Functional Assessment [852] 852_1

	yes	no	
Could subject engage in gainful employment in his/her accustomed work	○ 1	○ 0	emplusl
Could subject engage in any kind of gainful employment?	○ 1	○ 0	emplany
Could subject engage in any kind of volunteer or non-gainful work?	○ 1	○ 0	volunt
Could subject manage his/her finances (monthly) without any help?	○ 1	○ 0	fafinan
Could subject shop for groceries without help?	○ 1	○ 0	grocery
Could subject handle money as a purchaser in a simple cash (shop) transaction?	○ 1	○ 0	cash
Could subject supervise children without help?	○ 1	○ 0	supchild
Could subject operate an automobile safely and independently?	○ 1	○ 0	drive
Could subject do his/her own housework without help?	○ 1	○ 0	housewrk
Could subject do his/her own laundry (wash/dry) without help?	○ 1	○ 0	laundry
Could participant prepare his/her own meals without help?	○ 1	○ 0	prepmeal
Could subject use the telephone without help?	○ 1	○ 0	telephon
Could subject take his/her own medications without help?	○ 1	○ 0	ownmeds
Could subject feed himself/herself without help?	○ 1	○ 0	feedself
Could subject dress himself/herself without help?	○ 1	○ 0	dress
Could subject bathe himself/herself without help?	○ 1	○ 0	bathe

Could subject use public transport to get to places without help?	○ 1	○ 0	pubtrans
Could subject walk to places in his/her neighbourhood without help?	○ 1	○ 0	walknbr
Could subject walk without falling?	○ 1	○ 0	walkfall
Could subject walk without help?	○ 1	○ 0	walkhelp
Could subject comb hair without help?	○ 1	○ 0	comb
Could subject transfer between chairs without help?	○ 1	○ 0	trnchair
Could subject get in and out of bed without help?	○ 1	○ 0	bed
Could subject use toilet/commode without help?	○ 1	○ 0	toilet
Could subject's care still be provided at home?	○ 1	○ 0	carehome

Independence Scale [indep1] .Independence 883_1

Subject's independence in %:

indepscl

- ○ 100 = no special care needed 100
- ○ 95 95
- ○ 90 = no physical care needed if difficult tasks are avoided 90
- ○ 85 85
- ○ 80 = pre-disease level of employment changes or ends; cannot perform household chores to pre-disease level, may need help with finances 80
- ○ 75 75
- ○ 70 = self-care maintained for bathing, limited household duties, e.g. cooking and use of knives, driving terminates; unable to manage finances 70
- ○ 65 65
- ○ 60 = needs minor assistance in dressing, toileting, bathing; food must be cut for subject 60
- ○ 55 55
- ○ 50 = 24-hour supervision appropriate; assistance required for bathing, eating, toileting 50
- ○ 45 45
- ○ 40 = chronic care facility needed; limited self feeding, liquified diet 40
- ○ 35 35
- ○ 30 = subject provides minimal assistance in own feeding, bathing, toileting 30
- ○ 25 25
- ○ 20 = no speech, must be fed 20
- ○ 15 15
- ○ 10 = tube fed, total bed care 10
- ○ 5 5

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

General [general] 2623_1

[pbas1]

Domain scores: [2624] 2624_1

Depression:	☐	depscore
Irritability/aggression:	☐	irascore
Psychosis:	☐	psyscore
Apathy:	☐	aptscore
Executive function:	☐	exfscore

Problem Behaviours Assessment for HD 📄 [2630] .PBA-s 2630_1

1. Depressed mood: [2631] 2631_1

a. Severity: pbas1sv
- ⊙ 0 = absent 0
- ⊙ 1 = slight, questionable 1
- ⊙ 2 = mild (present, not a problem) 2
- ⊙ 3 = moderate (symptom causing problem) 3
- ⊙ 4 = severe (almost intolerable for carer) 4

b. Frequency: pbas1fr
- ⊙ 0 = never/almost never 0
- ⊙ 1 = seldom (less than once/week) 1
- ⊙ 2 = sometimes (up to four times a week) 2
- ⊙ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ⊙ 4 = daily/almost daily for most (or all) of day 4

c. Worst: pbas1wo
- ⊙ 0 = absent 0
- ⊙ 1 = slight, questionable 1
- ⊙ 2 = mild (present, not a problem) 2
- ⊙ 3 = moderate (symptom causing problem) 3
- ⊙ 4 = severe (almost intolerable for carer) 4

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2. Suicidal ideation: [2635] 2635_1

a. Severity:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas2sv

b. Frequency:
- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

pbas2fr

c. Worst:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas2wo

3. Anxiety: [2639] 2639_1

a. Severity:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas3sv

b. Frequency:
- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

pbas3fr

c. Worst:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas3wo

4. Irritability: [2643] 2643_1   a. Severity:

pbas4sv
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

b. Frequency:

pbas4fr
- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

c. Worst:

pbas4wo
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

5. Angry or aggressive behaviour: [2647] 2647_1   a. Severity:

pbas5sv
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

b. Frequency:

pbas5fr
- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

c. Worst:

pbas5wo
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

6. Lack of initiative (apathy): [2651] 2651_1

a. Severity:

○ 0 = absent 0
○ 1 = slight, questionable 1
○ 2 = mild (present, not a problem) 2
○ 3 = moderate (symptom causing problem) 3
○ 4 = severe (almost intolerable for carer) 4

pbas6sv

b. Frequency:

○ 0 = never/almost never 0
○ 1 = seldom (less than once/week) 1
○ 2 = sometimes (up to four times a week) 2
○ 3 = frequently (most days/5, 6 or 7 times a week) 3
○ 4 = daily/almost daily for most (or all) of day 4

pbas6fr

c. Worst:

○ 0 = absent 0
○ 1 = slight, questionable 1
○ 2 = mild (present, not a problem) 2
○ 3 = moderate (symptom causing problem) 3
○ 4 = severe (almost intolerable for carer) 4

pbas6wo

7. Perseverative thinking or behaviour: [2655] 2655_1

a. Severity:

○ 0 = absent 0
○ 1 = slight, questionable 1
○ 2 = mild (present, not a problem) 2
○ 3 = moderate (symptom causing problem) 3
○ 4 = severe (almost intolerable for carer) 4

pbas7sv

b. Frequency:

○ 0 = never/almost never 0
○ 1 = seldom (less than once/week) 1
○ 2 = sometimes (up to four times a week) 2
○ 3 = frequently (most days/5, 6 or 7 times a week) 3
○ 4 = daily/almost daily for most (or all) of day 4

pbas7fr

c. Worst:

○ 0 = absent 0
○ 1 = slight, questionable 1
○ 2 = mild (present, not a problem) 2
○ 3 = moderate (symptom causing problem) 3
○ 4 = severe (almost intolerable for carer) 4

pbas7wo

8. Obsessive-Compulsive Behaviours:
[2659] 2659_1

a. Severity:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas8sv

b. Frequency:
- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

pbas8fr

c. Worst:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas8wo

9. Delusions / paranoid thinking: [2663]
2663_1

a. Severity:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas9sv

b. Frequency:
- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

pbas9fr

c. Worst:
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

pbas9wo

10. Hallucinations: [2667] 2667_1

a. Severity:

- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

Please specify [modsv] 2669_1

Modality of hallucinations:
- ☐ auditory 1
- ☐ visual 2
- ☐ tactile 3
- ☐ olfactory 4
- ☐ gustatory 5

pbas10sv

pbas10sm

b. Frequency:

- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

pbas10fr

c. Worst:

- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
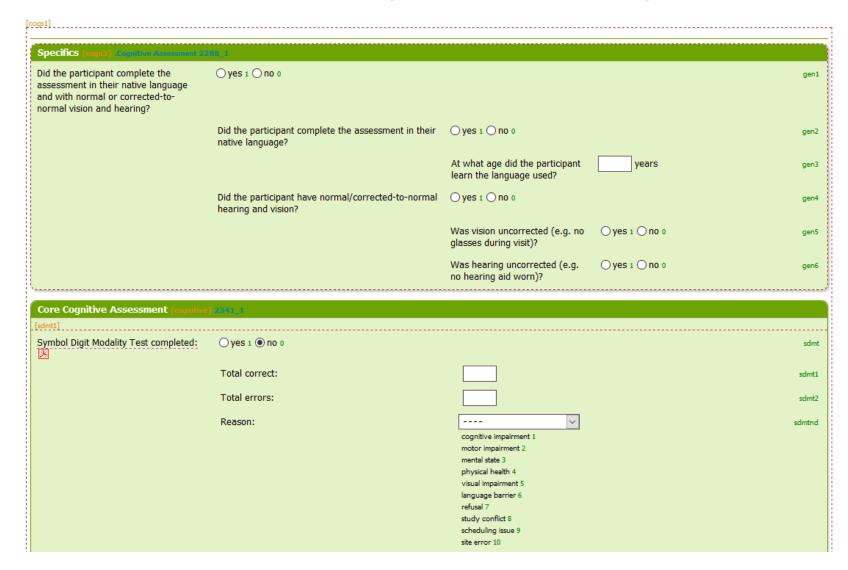- ○ 4 = severe (almost intolerable for carer) 4

Please specify [modwo] 2673_1

Modality of hallucinations:
- ☐ auditory 1
- ☐ visual 2
- ☐ tactile 3
- ☐ olfactory 4
- ☐ gustatory 5

pbas10wo

pbas10wm

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11. Disoriented Behaviour: [2675] 2675_1

a. Severity: *(pbas11sv)*
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

b. Frequency: *(pbas11fr)*
- ○ 0 = never/almost never 0
- ○ 1 = seldom (less than once/week) 1
- ○ 2 = sometimes (up to four times a week) 2
- ○ 3 = frequently (most days/5, 6 or 7 times a week) 3
- ○ 4 = daily/almost daily for most (or all) of day 4

c. Worst: *(pbas11wo)*
- ○ 0 = absent 0
- ○ 1 = slight, questionable 1
- ○ 2 = mild (present, not a problem) 2
- ○ 3 = moderate (symptom causing problem) 3
- ○ 4 = severe (almost intolerable for carer) 4

Information [pba1] .PBA 1006_1

i) Is informant a relative? *(pbainfo)*
- ○ spouse or partner 1
- ○ parent 2
- ○ sibling 3
- ○ child 4
- ○ other relative 5
- ○ friend or neighbor 6
- ○ professional care worker 7
- ○ other 8
- ○ no informant - participant came alone 9

ii) Is informant a household member? *(pbahshd)*
- ○ household member (i.e. relative or friend who lives with participant) 1
- ○ not a household member but has frequent contact with participant (most days) 2
- ○ not a household member and sees participant less than three or four times a week 3
- ○ staff of residential care home or hospital 4

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19 Form "Core and Extended Cognitive Assessment (Cognitive)"

[cogs1]

Specifics [cogn3] .Cognitive Assessment 2288_1

Did the participant complete the assessment in their native language and with normal or corrected-to-normal vision and hearing?	○ yes 1 ○ no 0	gen1
Did the participant complete the assessment in their native language?	○ yes 1 ○ no 0	gen2
At what age did the participant learn the language used?	[____] years	gen3
Did the participant have normal/corrected-to-normal hearing and vision?	○ yes 1 ○ no 0	gen4
Was vision uncorrected (e.g. no glasses during visit)?	○ yes 1 ○ no 0	gen5
Was hearing uncorrected (e.g. no hearing aid worn)?	○ yes 1 ○ no 0	gen6

Core Cognitive Assessment [cognitive] 2341_1

[sdmt1]

Symbol Digit Modality Test completed:	○ yes 1 ◉ no 0	sdmt
Total correct:	[____]	sdmt1
Total errors:	[____]	sdmt2
Reason:	[---- ▾]	sdmtnd

cognitive impairment 1
motor impairment 2
mental state 3
physical health 4
visual impairment 5
language barrier 6
refusal 7
study conflict 8
scheduling issue 9
site error 10

[verfct1]

Verbal Fluency Test (Category) completed: 🔗 ○ yes 1 ○ no 0   verfct

Category:
```
----  ▼
```
animals 1
other 2

verfctd

Total correct (1 min): [____] verfct5

Total intrusion errors: [____] verfct6

Total perseverative errors: [____] verfct7

Reason:
```
----  ▼
```
cognitive impairment 1
motor impairment 2
mental state 3
physical health 4
visual impairment 5
language barrier 6
refusal 7
study conflict 8
scheduling issue 9
site error 10

verfctnd

[scnt1]

Stroop Color Naming Test completed: 🔗 ○ yes 1 ○ no 0   scnt

Total correct: [____] scnt1

Total errors: [____] scnt2

Total self-corrected errors: [____] scnt3

Reason:
```
----  ▼
```
cognitive impairment 1
motor impairment 2
mental state 3
physical health 4
visual impairment 5
language barrier 6
refusal 7
study conflict 8
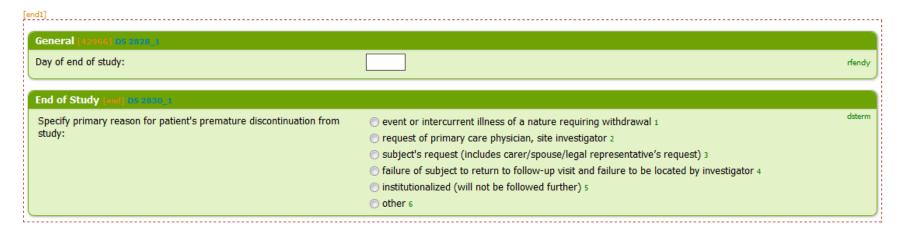scheduling issue 9
site error 10

scntnd

Annotated Case Report Form (CRF) for Enroll-HD Periodic Dataset
Updated 2020-12-16

[tm1]

Trailmaking Test completed: 📄   ○ yes 1 ○ no 0   trl

Trailmaking Test [6851] 6851_1

Part A: time to complete: [＿＿＿] sec   trla1

Part A: total correct: [＿＿＿]   trla2

Part A: total errors: [＿＿＿]   trla3

Part B: time to complete: [＿＿＿] sec   trlb1

Part B: total correct: [＿＿＿]   trlb2

Part B: total errors: [＿＿＿]   trlb3

[verflt1]

Verbal Fluency Test (Letters) completed: ○ yes 1 ○ no 0   verflt
📄

Subscores: [scores] 6879_1   Total correct (3 min):   [＿＿＿]   verflt05

                                     Total intrusion errors: [＿＿＿]   verflt06

                                     Total perseverative errors: [＿＿＿]   verflt07

Total errors: [＿＿＿]   sit2

Total self-corrected errors: [＿＿＿]   sit3

20 Form "Premature End of Study (End)"

[end1]

General [42966] DS 2828_1

Day of end of study: _____ rfendy

End of Study [end] DS 2830_1

Specify primary reason for patient's premature discontinuation from study:

dsterm

- ○ event or intercurrent illness of a nature requiring withdrawal 1
- ○ request of primary care physician, site investigator 2
- ○ subject's request (includes carer/spouse/legal representative's request) 3
- ○ failure of subject to return to follow-up visit and failure to be located by investigator 4
- ○ institutionalized (will not be followed further) 5
- ○ other 6

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

General [hads] .HADS 1972_1

Anxiety subscore:		anxscore
Depression subscore:		hads_depscore
Irritability subscore:		irrscore
Outward irritability subscore:		outscore
Inward irritability subscore:		inwscore

22   Form "Mini Mental State Examination (MMSE) (US)"

General [mmse] 3078_1

MMSE score: [   ]   mmsetotal

23   Form "Physiotherapy Outcomes Measures (Physio)"

Timed Up and Go Test [tug01] .TUG 3055_1

Timed "Up and Go" performed: 🗎   ○ yes 1 ○ no 0   tug

Total time: [   ] sec   tug1

30 Second Chair Stand Test [scst1] .30sec Chair Stand 3073_1

30 second chair stand test performed: 🗎   ○ yes 1 ○ no 0   scst

Number of times the participant stands in 30 seconds: [   ]   scst1

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

Scoring [3931] 3931_1

Online scoring: scoring

       pending 0
       succeeded 1
       failed 2
       failed (2) 3
       error 4

Domain scores	Physical Functioning (PF)	Role-Physical (RP)	Bodily Pain (BP)	General Health (GH)
Norm-based scores	pf	rp	bp	gh

Domain scores	Vitality (VT)	Social Functioning (SF)	Role-Emotional (RE)	Mental Health (MH)
Norm-based scores	vt	sf	re	mh

Summary Scale Measures Physical Component (PCS) Mental Component (PCS)

      pcs   mcs

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

General [general] 3146_1

Scores: [3147] 3147_1

Work time missed due to HD:	▢ %		wpaiscr1
Impairment while working due to HD:	▢ %		wpaiscr2
Overall work impairment due to HD:	▢ %		wpaiscr3
Activity impairment due to HD:	▢ %		wpaiscr4

26   Form "CSSRS BL"

[cssrs2]

Suicidal Ideation - For Lifetime, rate the period when the participant felt the most suicidal. 📄 [2092] 2092_1

1. Wish to be dead: [2093] 2093_1	Have you wished you were dead or wished you could go to sleep and not wake up?	○ yes 1 ○ no 0	sid1
2. Non-Specific Active Suicidal Thoughts: [2097] 2097_1	Have you actually had any thoughts of killing yourself?	○ yes 1 ○ no 0	sid2

Suicidal Ideation (continued) [2101] .C-SSRS 2101_1

3. Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act: [2102] 2102_1

Have you been thinking about how you might do this?	○ yes 1 ○ no 0	sid3

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan: [2106] 2106_1

Have you had these thoughts and had some intention of acting on them?	○ yes 1 ○ no 0	sid4

5. Active Suicidal Ideation with Specific Plan and Intent: [2110] 2110_1

Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?	○ yes 1 ○ no 0	sid5

Intensity of Ideation - Most Severe [2114] .C-SSRS 2114_1

Most Severe Ideation: [2115] 2115_1   Type # (l-5):   int1

Wish to be dead 1
Non-Specific Active Suicidal Thoughts 2
Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act 3
Active Suicidal Ideation with Some Intent to Act, without Specific Plan 4
Active Suicidal Ideation with Specific Plan and Intent 5

Frequency: [2118] 2118_1   How many times have you had these thoughts?   int2

○ Less than once a week 1
○ Once a week 2
○ 2-5 times in week 3
○ Daily or almost daily 4
○ Many times each day 5

Duration: [2120] 2120_1   When you have the thoughts, how long do they last?   int3

○ Fleeting - few seconds or minutes 1
○ Less than 1 hour/some of the time 2
○ 1-4 hours/a lot of time 3
○ 4-8 hours/most of day 4
○ More than 8 hours/persistent or continuous 5

Controllability: [2122] 2122_1   Could/can you stop thinking about killing yourself or wanting to die if you want to?   ○ Easily able to control thoughts 1   int4

○ Can control thoughts with little difficulty 2

Answer for Actual Attempts Only [2151] .C-SSRS 2151_1

Most recent attempt: [2152] 2152_1   Day of most recent attempt: [ ]   attmpt1dy

Actual Lethality/Medical Damage: [- - - - ▼]   attmpt11

No physical damage 0
Minor physical damage 1
Moderate physical damage 2
Moderately severe physical damage 3
Severe physical damage 4
Death 5

Potential Lethality: [- - - - ▼]   attmpt12

not likely to result in injury 0
likely to result in injury 1
likely to result in death 2

Most lethal attempt: [2157] 2157_1   Day of most lethal attempt: [ ]   attmpt2dy

Actual Lethality/Medical Damage: [- - - - ▼]   attmpt21

No physical damage 0
Minor physical damage 1
Moderate physical damage 2
Moderately severe physical damage 3
Severe physical damage 4
Death 5

Potential Lethality: [- - - - ▼]   attmpt22

not likely to result in injury 0
likely to result in injury 1
likely to result in death 2

Initial/First attempt: [2162] 2162_1   Day of Initial/First Attempt: [ ]   attmpt3dy

Actual Lethality/Medical Damage: [- - - - ▼]   attmpt31

No physical damage 0
Minor physical damage 1
Moderate physical damage 2
Moderately severe physical damage 3
Severe physical damage 4
Death 5

Potential Lethality: [- - - - ▼]   attmpt32

not likely to result in injury 0
likely to result in injury 1
likely to result in death 2

Suicidal behavior : [2145] 2145_1   Suicidal behaviour was present during the assessment period?   ○ yes 1 ○ no 0   sbh6

27 Form "CSSRS FUP"

[cssrs2]

Suicidal Ideation - Rate the period since last visit. 📄 [2168] 2168_1

1. Wish to be dead: [2169] 2169_1   Have you wished you were dead or wished you could go to sleep and not wake up?   ○ yes 1 ○ no 0   sid1

2. Non-Specific Active Suicidal Thoughts: [2173] 2173_1   Have you actually had any thoughts of killing yourself?   ○ yes 1 ○ no 0   sid2

Suicidal Ideation (continued) [2177] .C-SSRS 2177_1

3. Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act: [2178] 2178_1

     Have you been thinking about how you might do this?   ○ yes 1 ○ no 0   sid3

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan: [2182] 2182_1

     Have you had these thoughts and had some intention of acting on them?   ○ yes 1 ○ no 0   sid4

5. Active Suicidal Ideation with Specific Plan and Intent: [2186] 2186_1   Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?   ○ yes 1 ○ no 0   sid5

Intensity of Ideation - Most Severe [2190] .C-SSRS 2190_1

Most Severe Ideation: [2191] 2191_1   Type # (l-5):   int1

Wish to be dead 1
Non-Specific Active Suicidal Thoughts 2
Active Suicidal Ideation with Any Methods (not Plan) without Intent to Act 3
Active Suicidal Ideation with Some Intent to Act, without Specific Plan 4
Active Suicidal Ideation with Specific Plan and Intent 5

Frequency: [2194] 2194_1   How many times have you had these thoughts?   int2

○ Less than once a week 1
○ Once a week 2
○ 2-5 times in week 3
○ Daily or almost daily 4
○ Many times each day 5

Duration: [2196] 2196_1   When you have the thoughts, how long do they last?   int3

○ Fleeting - few seconds or minutes 1
○ Less than 1 hour/some of the time 2
○ 1-4 hours/a lot of time 3
○ 4-8 hours/most of day 4
○ More than 8 hours/persistent or continuous 5

Controllability: [2198] 2198_1   Could/can you stop thinking about killing yourself or wanting to die if you want to?

- ○ Easily able to control thoughts 1
- ○ Can control thoughts with little difficulty 2
- ○ Can control thoughts with some difficulty 3
- ○ Can control thoughts with a lot of difficulty 4
- ○ Unable to control thoughts 5
- ○ Does not attempt to control thoughts 0

int4

Deterrents: [2200] 2200_1   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?

- ○ Deterrents definitely stopped you 1
- ○ Deterrents probably stopped you 2
- ○ Uncertain that deterrents stopped you 3
- ○ Deterrents most likely did not stop you from attempting suicide 4
- ○ Deterrents definitely did not stop you 5
- ○ Does not apply; wish to die only 0

int5

Reasons for Ideation: [2202] 2202_1   What sort of reasons did you have for thinking about wanting to die or killing yourself?

- ○ Completely to get attention, revenge or a reaction from others 1
- ○ Mostly to get attention, revenge or a reaction from others. 2
- ○ Equally to get attention, revenge or a reaction from others 3
- ○ Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling). 4
- ○ Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling). 5
- ○ Does not apply 0

int6

Suicidal Behavior [2204] 2204_1

Actual Attempt: [2205] 2205_1   Actual attempt: ○ yes 1 ○ no 0   sbh1

Total # of attempts: [_____]   sbh1n

Has subject engaged in Non-Suicidal Self-Injurious Behavior?   ○ yes 1 ○ no 0   sbh2

Interrupted Attempt: [2211] 2211_1   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?   ○ yes 1 ○ no 0   sbh3

Total # of interrupted: [_____]   sbh3n

Aborted Attempt: [2216] 2216_1   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?   ○ yes 1 ○ no 0   sbh4

Total # of aborted: [_____]   sbh4n

Preparatory Acts or Behavior: [2221] 2221_1   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)?   ○ yes 1 ○ no 0   sbh5

Suicidal Behavior: [2225] 2225_1   Suicidal behaviour was present during the assessment period?   ○ yes 1 ○ no 0   sbh6

Completed Suicide: [2227] 2227_1   Completed suicide was present during the assessment period: ○ yes 1 ○ no 0   sbh7

28 Form "Missed Visit"

Documentation of Missed Follow-Up [mvfup] 4052_1

Source of information:

mvsrc

- ○ 1 = participant 1
- ○ 2 = spouse/partner 2
- ○ 3 = next of kin (family or friends) 3
- ○ 4 = physician 4
- ○ 5 = nurse 5
- ○ 6 = other (e.g. hearsay, obituary in newspaper, death certificate) 6

Reason for missed follow-up visit:

mvrsn

- ○ 0 = participant involved in a clinical trial, for which the suspension of Enroll-HD visits is requested 0
- ○ 1 = participant alive, unable to attend FUP, open to future FUPs 1
- ○ 2 = participant alive, objects to further FUP visits, open to further phone contacts 2
- ○ 3 = participant alive, objects to further FUP visits and to further phone contacts 3
- ○ 4 = participant alive, lost to FUP 4
- ○ 5 = participant dead 5
- ○ 6 = status unclear 6

If participant is alive [4056] 4056_1

Level of care required:

crlvl

- ○ 0 = The participant does not require any help for basic activities of daily living (un/dressing, washing/bathing, getting up/going to bed). 0
- ○ 1 = The participant requires some help to manage basic activities of daily living (typically < 4h support per day), but no full-time supervision. 1
- ○ 2 = The participant requires extensive help to manage basic activities of daily living (typically ≥ 4h support per day), and full-time supervision with additional help as required. 2

Days since full-time dependency: [   ]

dpdy

Revision History

Version	Summary of Changes
2020-12-16	Initial version of annotated CRF for Enroll-HD Periodic Dataset PDS5_R1.