

PDS4 | 2018-10-R1

Periodic Dataset 4

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

Version 2018-10-R1

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's 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 in the annotated view.

The variables and data files of the dataset are described in detail within the <u>data dictionary</u> for the Enroll-HD PDS.

2 Forms and Data Files

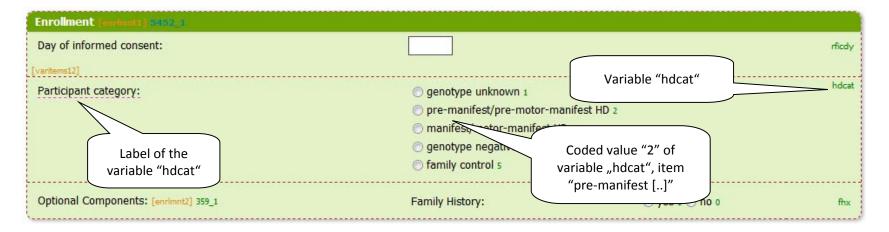
Forms are CRF entry screens that are displayed to data entry personnel and show how data is entered in the eCRF. Data files are sets of variables that define how the data are represented. The following table defines how forms and data files are related.

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								✓

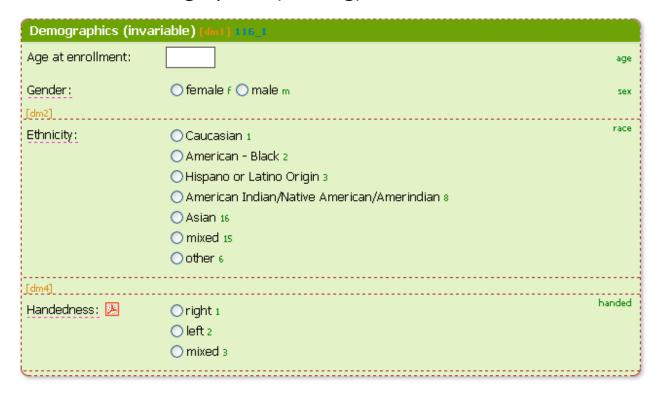
Form / Data File	Profile	Partici- pation	Pharmaco Tx	NutSuppl	NonPhar- macoTx	Comorbid	Event	Enroll
PBA-s BL								✓
Cognitive								\checkmark
HADS-SIS								\checkmark
MMSE								✓
Physio								\checkmark
SF12								\checkmark
WPAI-SHP								\checkmark
CSSRS BL								\checkmark
CSSRS FUP								\checkmark
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 <u>data dictionary</u> for detailed information.

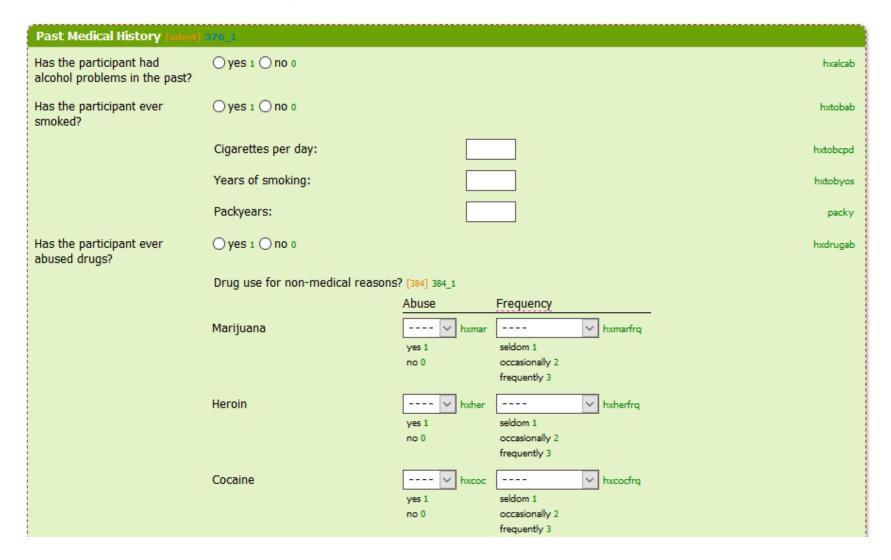
3 Form "Enrollment"

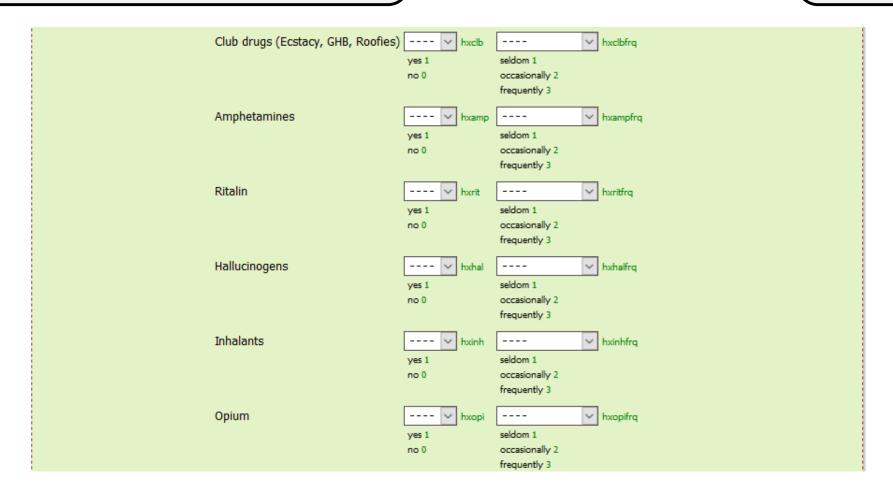


4 Form "Demographics (Demog)"



5 Form "Medical History (MHx)"





6 Form "HD Clinical Characteristics (HD CC)"

Family History [hdcc6] 594_1		
Mother affected:	○ yes ı ○ no o ○ unknown 9999	momhd
	Age at onset of symptoms in mother: years	momagesx
Father affected:	○ yes ı ○ no o ○ unknown 9999	dadhd
	Age at onset of symptoms in father: years	dadagesx
[hdcc2] Each estimate of symptom onset shoul scales.	ld be based on ALL available sources of information including reports of participant, companions, case notes and clinical ra	ting
HD Clinical Characteristics and Age-o	f-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	

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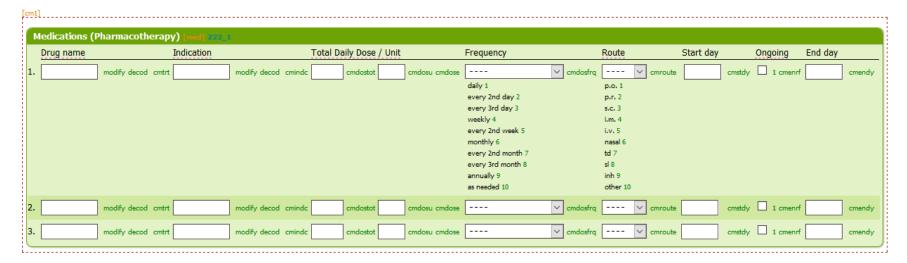
	Has apathy ever been a part of the participant's medical history:	○yes 1 ○ no 0	ccapt	
		At what age did apathy begin? [6915] 6915_1		١
		age (years)		ı
		ccaptyr		١
	Has perseverative/obsessive behaviors ever been a part of the participant's medical history:	○ yes 1 ○ no 0	ccpob	
		At what age did perseverative/obsessive behaviour begin? [6921] 6921_1		١
		age (years)		١
		ccpobage		١
	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		ı
		age (years)		١
		ccpsyage		١
		Does the participant have a family history of a	ccpsyfh	
	Has significant cognitive impairment	○yes 1 ○no 0	cccog	١
	(severe enough to impact on work or activities of daily living) or dementia ever			١
	been a part of the participant's medical			١
	history:			
		At what age did cognitive impairment first start to have an impact on daily life? [6934] 6934_1		
		age (years)		
		cccogage		
1				1

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 [6	59471 6947 1			
Symptoms first noted by participant:				sxsubj
Initial major symptom noted by participant:	O motor 1 O cognitive 2 O psychiatric 3 O oculomotor 4 (other 5 O mixed 6		sxsubjm
	Mixed symptoms: [6951] 6951_1	motor:	□ 1	sxs_m
		cognitive:	□ i	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 O mixed 6		sxfamm
	Mixed symptoms: [6959] 6959_1	motor:	□ i	sxf_m
		cognitive:	□ 1	sxf_c
		psychiatric:	□ 1	sxf_p
		oculomotor:	□ i	sxf_o

HD History - Rater [6964] 6964_1				
Date of clinical HD diagnosis:	. mm.yyyy			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	oparticipant can not pro	ovide information (mute, or cogniti	vely too impaired) sxreas
	information) at the moment:	information provided	deemed unreliable 2	
	What is your best guess of how many years ago symptom onset took place:	O < 5 1		sxgs
	symptom onset took place.	○ < 10 2 ○ < 15 3		
		O < 20 4		
		○ > 20 s		
	Day of data entry:			sxgsdy
Rater's judgement of initial major symptom:	○ motor 1 ○ cognitive 2 ○ psychiatric 3 ○ oculomotor	4 Oother 5 Omixed 6		sxraterm
	Mixed symptoms: [6976] 6976_1	motor:	□ 1	sxr_m
		cognitive:	□ i	sxr_c
		psychiatric:	□ 1	sxr_p
		oculomotor:	□ 1	sxr_o
Suicidal Behavior [hdoc7] 3918_1				
Previous suicidal ideation or attempts?	○ yes 1 ○ no 0			hxsid

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

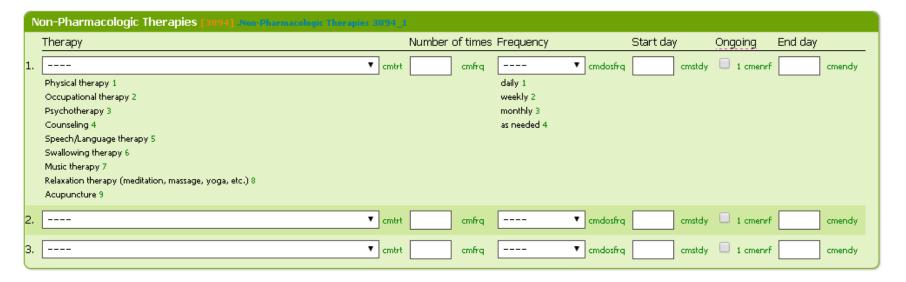
7 Form "Pharmacotherapy (PharmacoTx)"



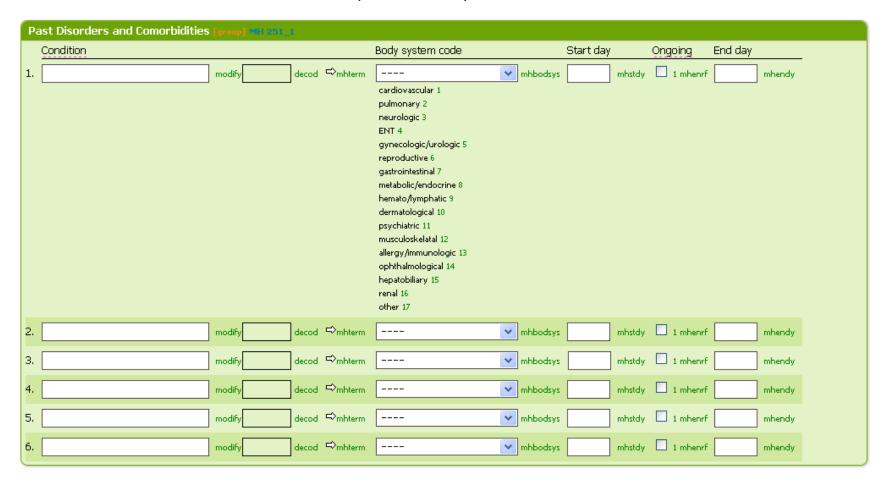
8 Form "Nutritional Supplements (NutSuppl)"



9 Form "Non-Pharmacologic Therapies (NonPharmaTx)"



10 Form "Comorbid Conditions (Comorbid)"



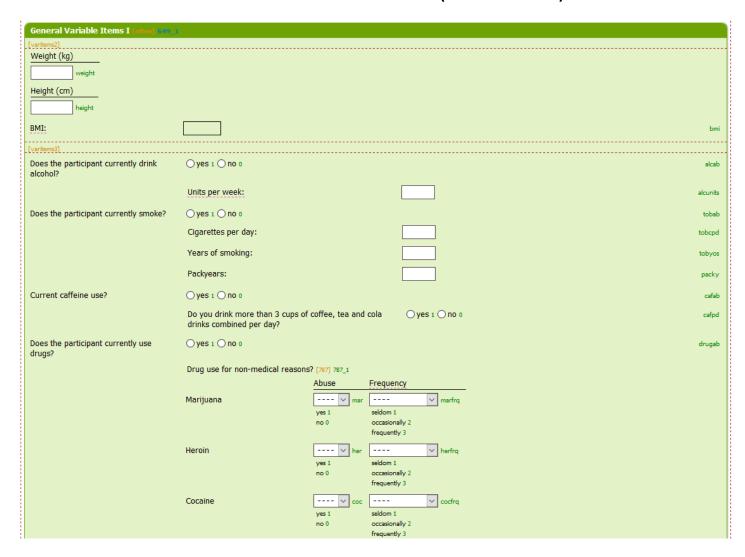
11 Form "Reportable Event Monitoring (Event)"

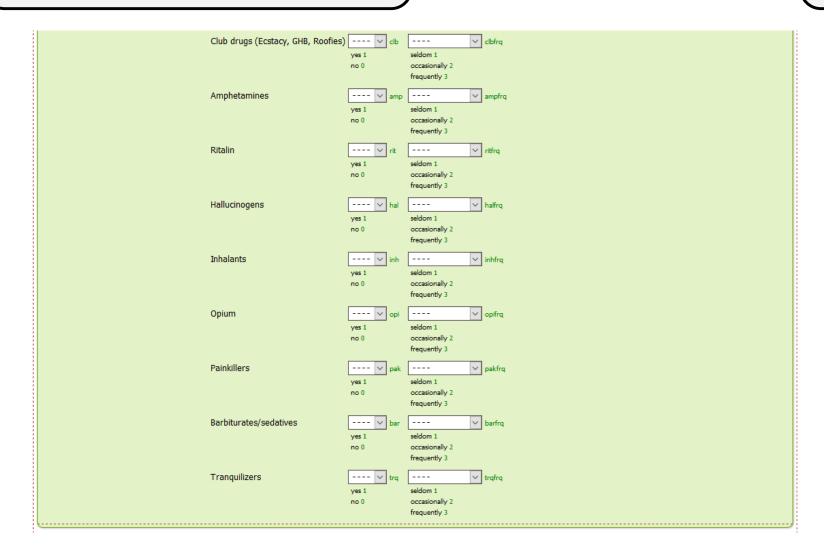
General [3007] 3007 _1	1	1
Day of report:		evtdy
Reportable Event [30	009] 3009_1	
Reportable event codes:	 suicide attempts 01 completed suicide 2 mental health event requiring hospitalization 3 	evtcode
	Odeath (other than suicide, any cause) 4	
	Event term: modify decod	evtterm
Details of Reportable	e Event [3014] 3014_1	
Onset day:		evtstdy
Date estimated:	○ yes 1 ○ no 0	stdtcest
Resolved:	○yesı ○no o	evtongo
	End day:	evtendy
DSMC Review [4750]	4750_1	
Status of DSMC review:	 pending review 1 ongoing review 2 closed/completed review 3 	evtdsmc

12 Form "Mortality"

Death Report Form [mor	trpt] 2848_1	
Age of death:	years	dssage
Place of death:	 home 1 hospital 2 nursing home 3 hospice care 4 unknown 5 	dsplace
Cause of death:	other infection 2 cancer 3 stroke 4 trauma 5 suicide 6 other 7	dsend

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

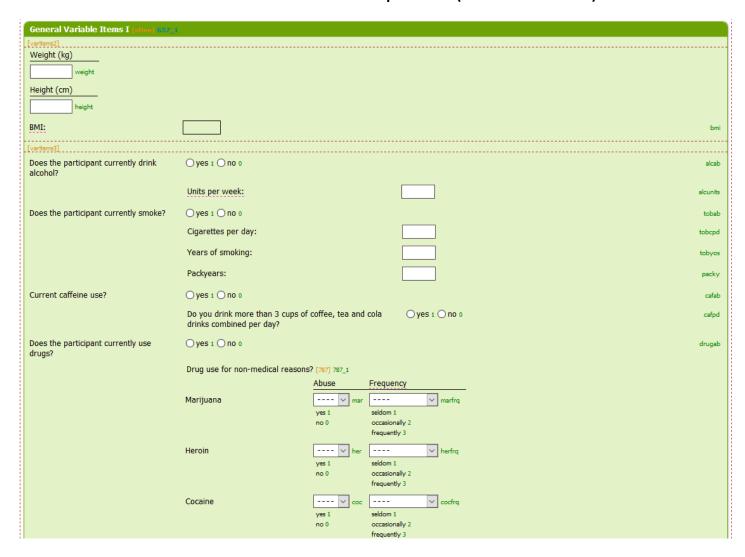




General Variable Items II [rarely] 650_1		
[varitems7]		
Marital status:	 Single 1 Married 3 Partnership 2 divorced 4 widowed 5 legally separated 6 	maristat
[varitems8]		
Residence:	 ○ rural 1 ○ village 2 ○ town 3 ○ city 4 	res
[varitems10]		
ISCED education level: 🔼	○ ISCED 0 0 ○ ISCED 1 1 ○ ISCED 2 2 ○ ISCED 3 3 ○ ISCED 4 4 ○ ISCED 5 5 ○ ISCED 6 6	isced

[varitems13]				
Employment:	O full-time employed 1			jobclas
	O part-time employed 2			
	○ self employed 3			
	O not employed 4			
	Status:	Opaid 1 Ounpaid 2		jobpaid
	Reason:	Osick leave 1		emplnrsn
		retirement 2		
		oworking in the home (e.g.	caring for children) 3	
		Ounemployed 4		
		O training/college 5		
		Retired due to:	ill health 1	emplnrd
			O age 2	
[varitems15]				
	Do you receive incapacity benefit/social security or disability benefit?	○ yes 1 ○ no 0		ssdb
	Do you intend to return to work?	○ yes ı ○ no o		rtrnwk
	Since when have you been unemployed/retired?			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)"



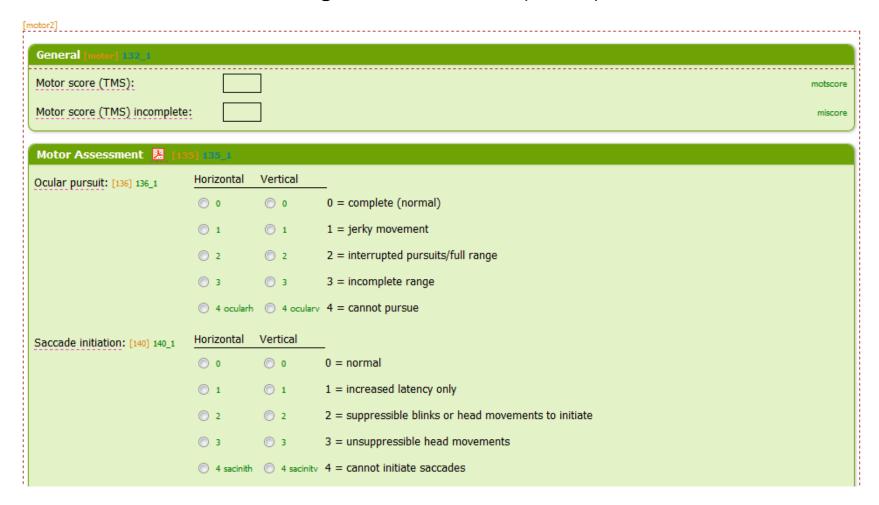


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General Variable Items II [rarely] 658	
General Variable items of previous visits:	
Participant category (invalid) Occupation (invalid) Employment (invalid) Marital status (invalid) Residence (invalid)	This table contains information about value of "Participant"
ISCED education level (invalid)	Category",
Years of education (invalid)	"Occupation", etc.
html	
Any changes to the rarely changing General Variable Items above:	○ yes 1 ○ no 0 updsc
	o genotype unknown 1 O pre-manifest/pre-motor-manifest HD 2
	O manifest/motor-manifest HD 3
	O genotype negative 4
	○ family control 5 ○ community control 6
	To and
	Marital status: Osingle 1
	O married 3
	O partnership 2
	O divorced 4
	O widowed 5
	O legally separated 6
	Residence: Orural 1 Ovillage 2
	O town 3
	O city 4
	[varitems10]
	ISCED education level: 🔼 O ISCED 0 o
	○ ISCED 1 1
	○ ISCED 2 2
	O ISCED 3 3
	○ ISCED 4 4 ○ ISCED 5 5
	O ISCED 6 6

	[varitems13]				
_	Employment:	○ full-time employed 1 ○ part-time employed 2 ○ self employed 3 ○ not employed 4			jobclas
		Status:	O paid 1 O unpaid 2		jobpaid
		Reason:	sick leave 1 retirement 2 working in the ho unemployed 4 training/college 5	me (e.g. caring for children)	emplnrsn
-			Retired due to:	ill health 1	emplnrd
	[varitems15]	Do you receive incapacity benefit/social security or disability benefit?	O yes 1 O no 0		ssdb
		Do you intend to return to work?	Oyes 1 Ono 0		rtrnwk
_		Since when have you been unemployed/retired?	YYYY		rtrddur
Additional Employment Section [varitem	is14] 9C 3920_1				
Have you had to stop or reduce work due to your health?	Oyes 1 Ono 0				rdcwk
	How many days in the last 6 months have you had work because of HD?	off 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] 636-1				
Any changes to participant's medication?	○yesı⊙no₀				updmed
Any changes to participant's comorbid conditions?	Oyes 1 Ono 0				updmh
Any updates to the clinical characteristics and/or onset of HD?	○yes ı ○no o				updhdh

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



Saccade velocity: [144] 144_1	Horizontal	Vertical					
	© 0	○ 0	0 = normal				
	1		1 = mild slowing				
			2 = moderate slowing				
			3 = severely slow, full range				
	4 sacvelh	4 sacvely	4 = incomplete range				
Dysarthria:	⊚ 0 = norm	nal o	dysar	th			
		ear, no need					
			e understood 2				
	3 = most4 = anari	:ly incompreh thria 4	lensible 3				
Tongue protrusion:	1 = cann2 = cann3 = cann	 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 = moderately impaired (7-10/5 sec.)				
		⊙ 3	3 = severely impaired (3-6/5 sec.)				
	4 fingtapr	6 4 fingtap	4 = can barely perform task (0-2/5 sec.)				

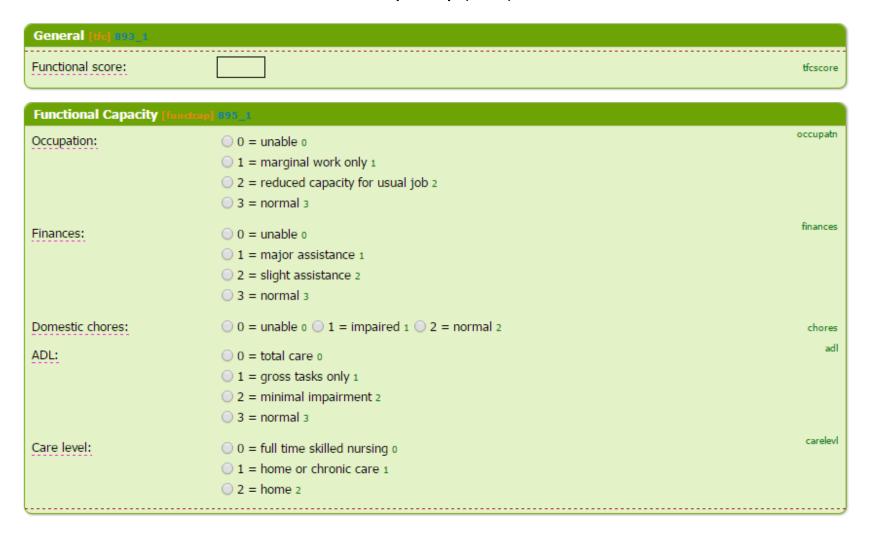
Right	Left	_			
⊙ 0	⊙ 0	0 = normal			
O 1	O 1	1 = mild slowing and/or irregular			
		2 = moderate slowing and irregular			
3		3 = severe slowing and irregular			
4 prosupr	0 4 prosup	4 = cannot perform			
0 = ≥4 in	10 sec, no	cue o	luria		
○ 1 = <4 in	10 sec, no o	cue 1			
② 2 = ≥4 in	10 sec with	cues 2			
∅ 4 = canno	ot perform 4				
Right	Left	_			
○ 0	○ 0	0 = absent			
© 1	○ 1	1 = slight or present only with activation			
2		2 = mild to moderate			
⊙ 3		3 = severe, full range of motion			
6 4 rigarmr	4 rigarml	4 = severe with limited range			
⊚ 0 = norm	nal o		brady		
	mally slow (?	normal) 1			
2 = mildly	y but clearly	slow 2			
3 = mode	erately slow,	some hesitation 3			
	edly slow. In	and delays in initiation 4			
	0 0 1 2 3 3	0 0 0 0 0 0 0 1 0 1 0 1 0 1 0 1 0 1 0 1	○ 0 ○ 0 0 = normal ○ 1 1 = mild slowing and/or irregular ○ 2 2 = moderate slowing and irregular ○ 3 ○ 3 3 = severe slowing and irregular ○ 4 prosupr ○ 4 prosupl 4 = cannot perform ○ 0 = ≥4 in 10 sec, no cue 0 ○ 1 = <4 in 10 sec, no cue 1		

Maximal dystonia: [164] 164_1	Trunk	RUE	LUE	RLE	LLE	_			
	⊙ o	⊙ 0	○ 0	○ 0	○ 0	0 = absent			
	O 1	O 1	O 1	1	O 1	1 = slight/inter	mittent		
						2 = mild/comm	non or mod	erate/intermittent	
	3	3	⊙ 3	⊙ 3		3 = moderate/	common		
	4 dysttrnk	4 dystrue	4 dystlue	4 dystrle	4 dystlle	4 = marked/pr	olonged		
Maximal chorea: [171] 171_1	Face	BOL	Trunk	RUE	LUE	RLE	LLE	_	
	© 0	0	0	© 0	0	© 0	© 0	0 = absent	
	© 1	⑤ 1	⑤ 1	(i) 1	(C)	© 1	© 1	1 = slight/intermittent	
	© 2	© 2	© 2	© 2	© 2	© 2	② 2	2 = mild/common or moderate/intermittent	
	© 3	© 3	© 3	⊚ 3		© 3	⊙ 3	3 = moderate/common	
	Chorface	Chorbol 4	chortrnk	chorrue	e	ue 🔘 chorrle 4	chorlle	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 							gai	t

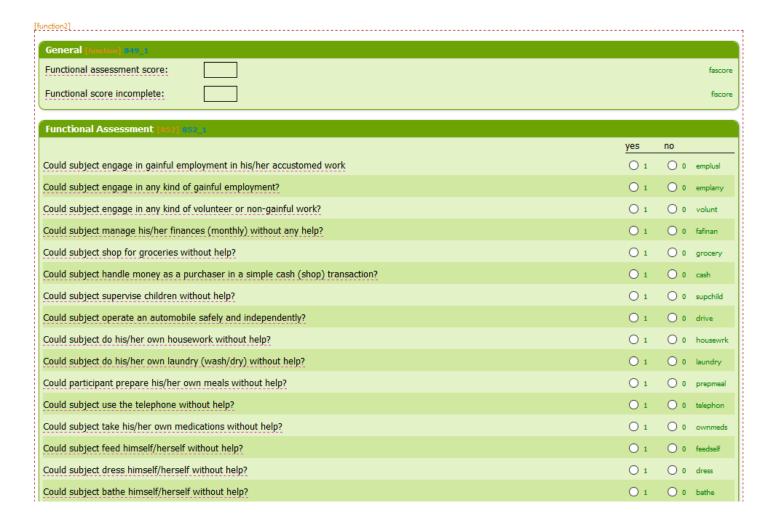
Version 1

	Tandem walking:	 0 = normal for 10 steps 0 1 = 1 to 3 deviations from straight line 1 2 = >3 deviations 2 	tandem				
		⊙ 3 = cannot complete 3					
		○ 4 = cannot attempt 4	retropls				
	Retropulsion pull test:	○ 0 = normal o ○ 1 = recovers spontaneously 1	retropis				
		2 = would fall if not caught 2					
		○ 3 = tends to fall spontaneously 3					
l		○ 4 = cannot stand 4					
	Diagnostic Confidence [motor3].DCL 185_1						

16 Form "UHDRS Total Funtional Capacity (TFC)"



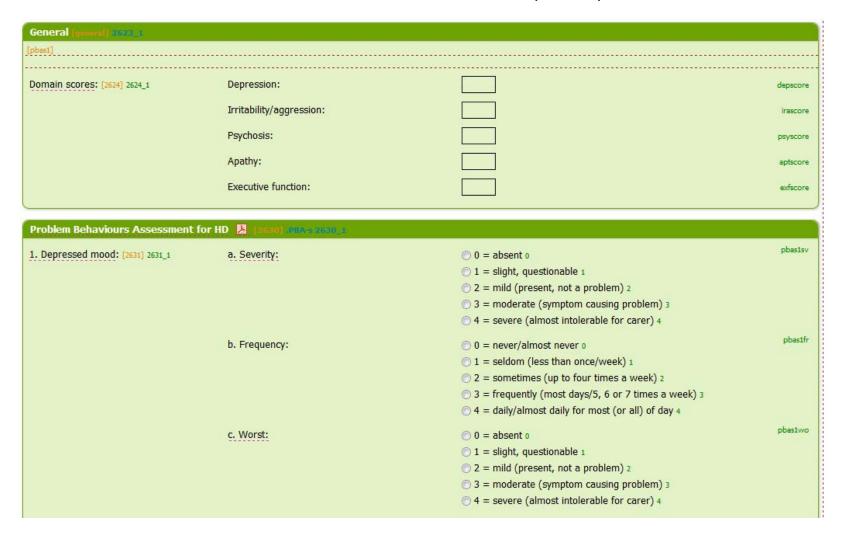
17 Form "UHDRS Functional Assessment/Independence Scale (Function)"



Version 1

Could subject use public transport	to get to places without help?	O 1	O 0	pubtrans
Could subject walk to places in his	/her neighbourhood without help?	O 1	O 0	walknbr
Could subject walk without falling?	O 1	O 0	walkfall	
Could subject walk without help?		O 1	O 0	walkhelp
Could subject comb hair without he	elp?	O 1	O 0	comb
Could subject transfer between ch	airs without help?	O 1	0 0	trnchair
Could subject get in and out of bed	d without help?	O 1	O 0	bed
Could subject use toilet/commode	without help?	O 1	O 0	toilet
Could subject's care still be provide	ed at home?	O 1	O 0	carehome
Indopondonco Scalo (intert)	h			
Independence Scale [indep1] .Im				indepscl
Subject's independence in %:	○ 100 = no special care needed 100			
	O 95 95			
	O 90 = no physical care needed if difficult tasks are avoided 90 O 95			
	0.85 85	4:	laural.	
	80 = pre-disease level of employment changes or ends; cannot perform household chores to parameter may need help with finances 80	pre-disease	ievei,	
	O 75 75			
	70 = self-care maintained for bathing, limited household duties, e.g. cooking and use of knives unable to manage finances 70	s, driving ter	minates	Ç
	○ 65 65			
	○ 60 = needs minor assistance in dressing, toileting, bathing; food must be cut for subject 60			
	○ 55 55			
	\bigcirc 50 = 24-hour supervision appropriate; assistance required for bathing, eating, toileting 50			
	O 45 45			
	0 40 = chronic care facility needed; limited self feeding, liquified diet 40			
	0 35 35			
	30 = subject provides minimal assistance in own feeding, bathing, toileting 30			
	O 25 25			
	○ 20 = no speech, must be fed 20○ 15 15			
	15 15 15 10 = tube fed, total bed care 10			
	0 10 = tube red, total bed care 10			

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



Version 1

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

a was taken as a			pbas4sv
4. Irritability: [2643] 2643_1	a. Severity:	0 = absent 0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
		1 = slight, questionable 1	
		② 2 = mild (present, not a problem) 2	
		(a) 3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
	b. Frequency:	0 = never/almost never 0	pbas4fr
		○ 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	
			pbas4wo
	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	
E Array on a consiste behaviour from	- Coursitus		pbas5sv
5. Angry or aggressive behaviour: [2647]	a. Severity:	0 = absent o	
_		1 = slight, questionable 1	
		② 2 = mild (present, not a problem) 2	
		(3 = moderate (symptom causing problem) 3	
		⊕ 4 = severe (almost intolerable for carer) 4	
	b. Frequency:	0 = never/almost never o	pbas5fr
		○ 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	
	a Maret	0	pbas5wo
	c. Worst:	0 = absent o	
		① 1 = slight, questionable 1	
		② 2 = mild (present, not a problem) 2	
		© 3 = moderate (symptom causing problem) 3	
		⊕ 4 = severe (almost intolerable for carer) 4	

			pbas6sv
6. Lack of initiative (apathy): [2651] 2651_1	a. Severity:	○ 0 = absent o	ppasesv
		\bigcirc 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:	○ 0 = never/almost never o	pbas6fr
	• •	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	
			pbas6wo
	c. Worst:	0 = absent o	,
		○ 1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		○ 3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
7. Perseverative thinking or behaviour:	a. Severity:	○ 0 = absent o	pbas7sv
[2655] 2655_1	d. Severity.	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:	○ 0 = never/almost never o	pbas7fr
		○ 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:	○ 0 = absent 0	pbas7wo
	5. 775.55.	1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
		4 - Severe (dilliost illustrable for caref) 4	

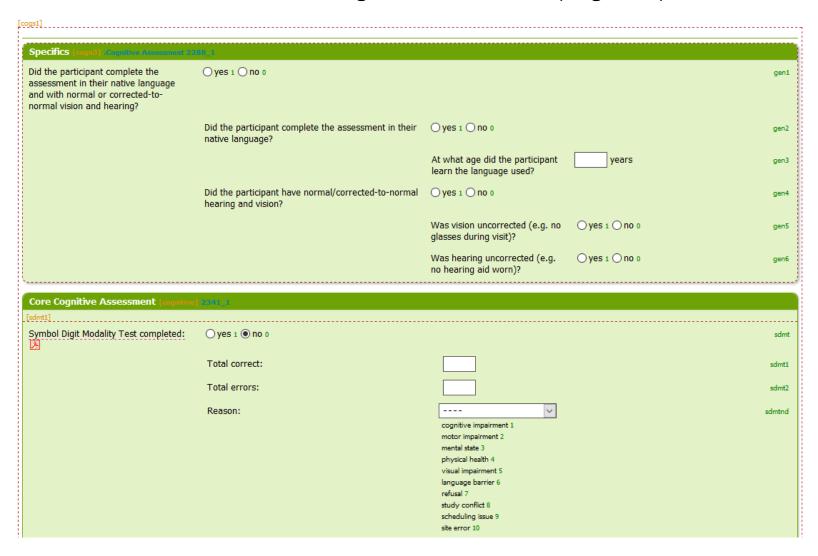
8. Obsessive-Compulsive Behaviours: [2659] 2659_1	a. Severity:	 0 = absent 0 1 = slight, questionable 1 2 = mild (present, not a problem) 2 3 = moderate (symptom causing problem) 3 4 = severe (almost intolerable for carer) 4 	pbas8sv
	b. Frequency:	 0 = never/almost never 0 1 = seldom (less than once/week) 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

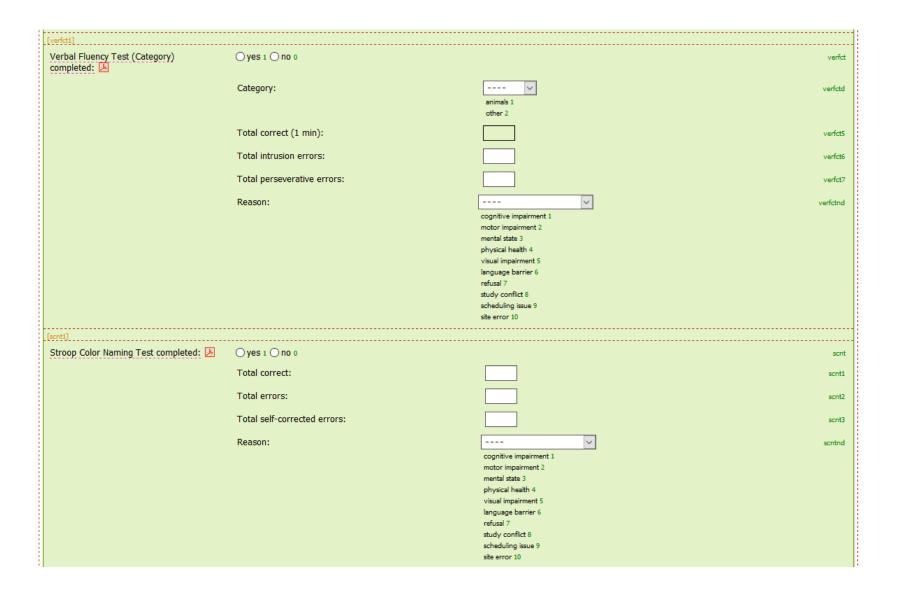
	10. Hallusinations, facest accord	2. Coveriby	@ 0 _ =hh		pbas10sv
	10. Hallucinations: [2667] 2667_1	a. Severity:	0 = absent o1 = slight, questionable 1		
			2 = mild (present, not a pro	blom) a	
			3 = moderate (symptom car	•	
			4 = severe (almost intoleral		
H				ne for carer) 4	
I			Please specify [modsv] 2669_1		
I			Modality of hallucinations:	auditory 1	pbas10sm
				visual 2	
I				tactile 3	
H				olfactory 4	
I				gustatory s	-1
H		b. Frequency:	0 = never/almost never 0		pbas10fr
			1 = seldom (less than once/		
			2 = sometimes (up to four t	The state of the s	
			3 = frequently (most days/5		
			4 = daily/almost daily for m	ost (or all) of day 4	
		c. Worst:	○ 0 = absent o		pbas10wo
I					
			2 = mild (present, not a pro	blem) 2	
I			3 = moderate (symptom car	using problem) 3	
H			4 = severe (almost intoleration)	ole for carer) 4	
			Please specify [modwo] 2673_1		
			Modality of hallucinations:	auditory 1	pbas10wm
			•	visual 2	
				tactile 3	
				olfactory 4	
				gustatory 5	

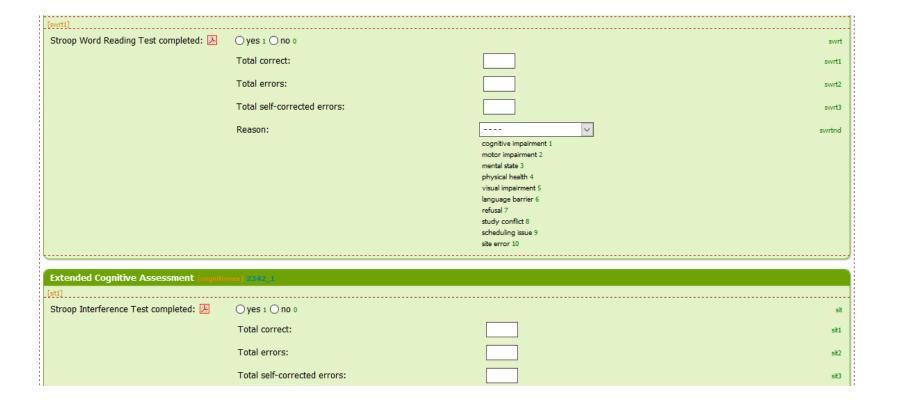
11			
11. Disoriented Behaviour: [2675]	2675_1 a. Severity:	○ 0 = absent o	pbas11sv
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
	h Francisco	© 0	pbas11fr
	b. Frequency:	© 0 = never/almost never o	·
		1 = seldom (less than once/week) 1	
		2 = sometimes (up to four times a week) 2	
		(a) 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:	○ 0 = absent o	pbas11wo
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
i			
Information [pba1] .PBA 1006_1			
i) Is informant a relative?	o spouse or partner 1		pbainfo
	o parent 2		
	isibling 3		
	Child 4		
	other relative s		
	friend or neighbor 6		
	professional care worker 7		
	other 8		
	o no informant - participant came alone 9		
	ii) Is informant a household member?	o household member (i.e. relative or friend who lives with partici	ipant) 1 pbahshd
		not a household member but has frequent contact with particip (most days) 2	
		 not a household member and sees participant less than three of times a week 3 	or four

o staff of residential care home or hospital 4

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

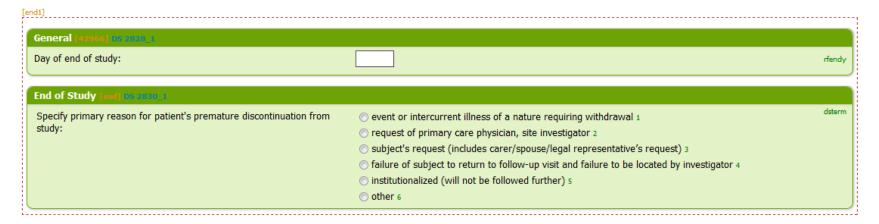




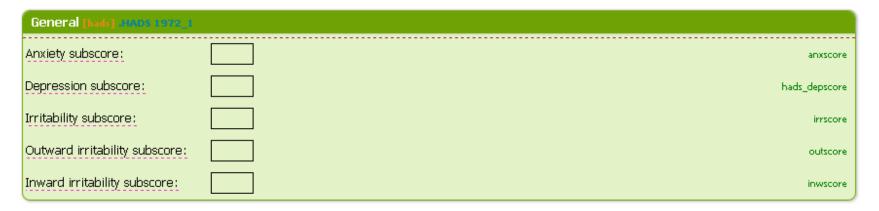


[tm1]				
Trailmaking Test completed: 😕	○ yes 1 ○ no 0		trl	ı
	Trailmaking Test [6851] 6851_1			
	Part A: time to complete:	sec	trla1	
	Part A: total correct:		trla2	
	Part A: total errors:		trla3	
	Part B: time to complete:	sec	trlb1	
	Part B: total correct:		trlb2	
	Part B: total errors:		trlb3	
[verfit1]				1
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	
				J

20 Form "Premature End of Study (End)"



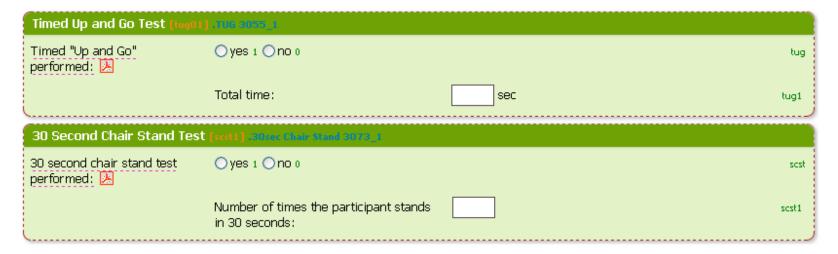
21 Form "Hospital Anxiety and Depression Scale/Snaith Irritability Scale (HADS-SIS)"



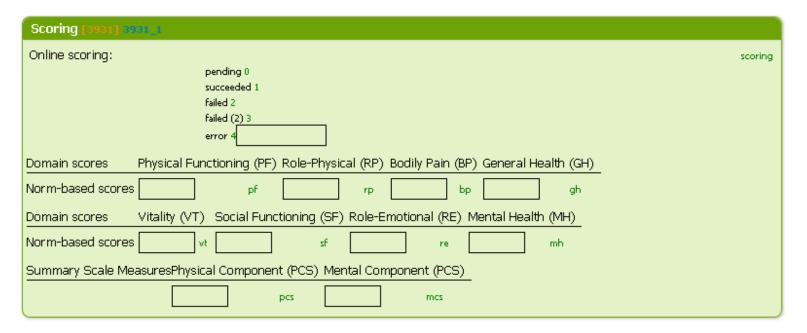
22 Form "Mini Mental State Examination (MMSE) (US)"



23 Form "Physiotherapy Outcomes Measures (Physio)"



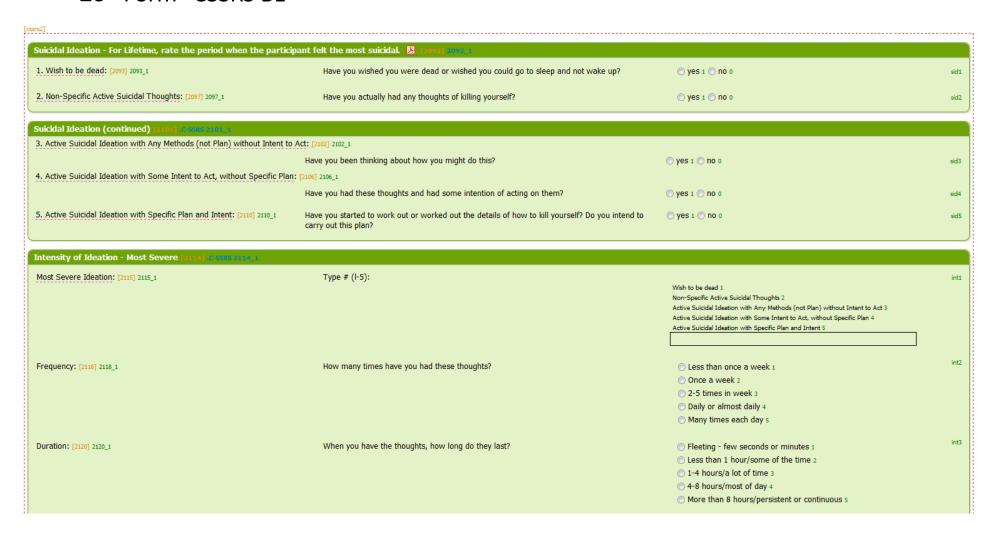
24 Form "Short Form Health Survey – 12v2 (SF-12)"



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



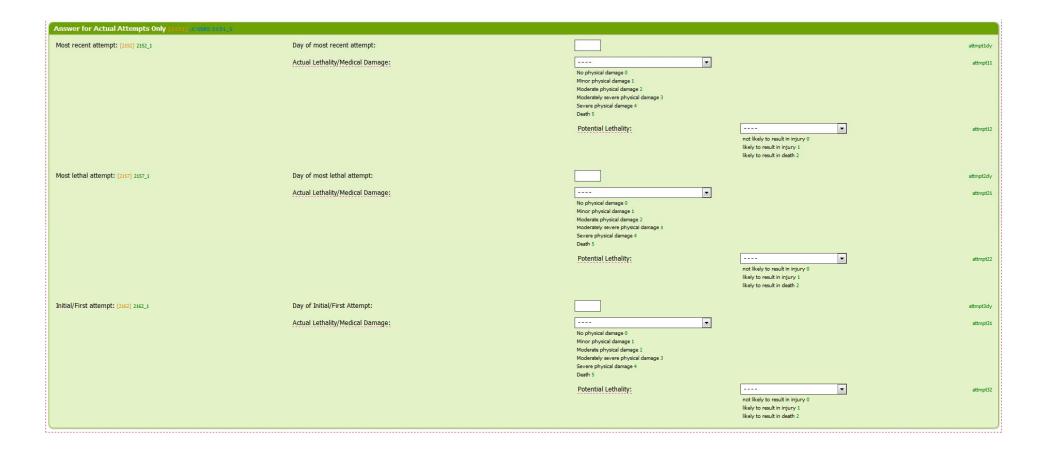
26 Form "CSSRS BL"



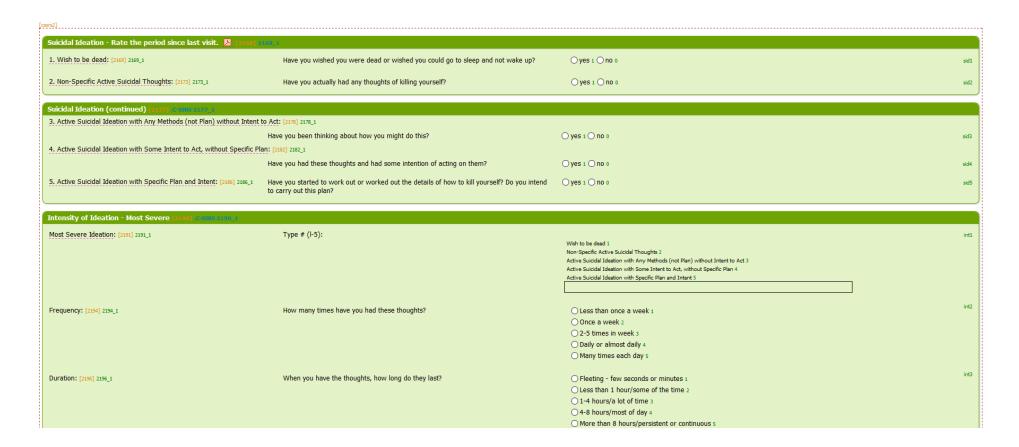
Annotated Case Report Form (CRF) for PDS | PDS4

Version 1

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 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: [2124] 2124_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 	intS
Reasons for Ideation: [2126] 2126_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 o 	int6
Suicidal Behavior [2128] 2128_1			
Suicidal Behavior (2128) 212814 Actual Attempt: (2129) 2129_1	Actual attempt:	⊙ yes 1 ⊙ no 0	sbh1
***************************************	Actual attempt:	○ yes 1 ○ no 0 Total # of attempts:	sbh1 sbh1n
***************************************	Actual attempt: Has subject engaged in Non-Suicidal Self-Injurious Behavior?		
***************************************		Total # of attempts:	sbh1n
Actual Attempt: [2129] 2129_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? Has there been a time when you started to do something to end your life but someone or	Total # of attempts: O yes 1 O no 0	sbhin sbhi
Actual Attempt: [2129] 2129_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? Has there been a time when you started to do something to end your life but someone or	Total # of attempts: O yes 1 O no 0 yes 1 O no 0	sbh1n sbh2 sbh3
Actual Attempt: [2129] 2129_1 Interrupted Attempt: [2135] 2135_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? 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? Has there been a time when you started to do something to try to end your life but you	Total # of attempts: O yes 1 O no 0 O yes 1 O no 0 Total # of interrupted:	sbh1n sbh2 sbh3 sbh3n
Actual Attempt: [2129] 2129_1 Interrupted Attempt: [2135] 2135_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? 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? Has there been a time when you started to do something to try to end your life but you	Total # of attempts:	sbh1n sbh2 sbh3 sbh3n sbh4



27 Form "CSSRS FUP"



Annotated Case Report Form (CRF) for PDS | PDS4

Version 1

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 s Does not attempt to control thoughts o 	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 	intS
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 o 	int6
Suicidal Behavior [2204] 2204_1			
Suicidal Behavior [2204] 280051. Actual Attempt: [2205] 2205_1	Actual attempt:	⊙ yes 1 ⊙ no 0	sbh1
	Actual attempt:	⊘ yes t ○ no o Total ≠ of attempts:	sbh1 sbh1n
	Actual attempt: Has subject engaged in Non-Suicidal Self-Injurious Behavior?		
		Total # of attempts:	sbh1n
Actual Attempt: [2205] 2205_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? Has there been a time when you started to do something to end your life but someone or	Total # of attempts: O yes 1 O no 0	sbh1n sbh2
Actual Attempt: [2205] 2205_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? Has there been a time when you started to do something to end your life but someone or	Total # of attempts:	sbh1n sbh2 sbh3
Actual Attempt: [2205] 2205_1 Interrupted Attempt: [2211] 2211_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? 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? Has there been a time when you started to do something to try to end your life but you	Total # of attempts: yes 1 no 0 yes 1 no 0 Total # of interrupted:	sbh1n sbh2 sbh3 sbh3n
Actual Attempt: [2205] 2205_1 Interrupted Attempt: [2211] 2211_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? 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? Has there been a time when you started to do something to try to end your life but you	Total # of attempts: yes 1 no 0 yes 1 no 0 Total # of interrupted: yes 1 no 0	sbh1n sbh2 sbh3 sbh3n sbh4
Actual Attempt: [2205] 2205_1 Interrupted Attempt: [2211] 2211_1 Aborted Attempt: [2216] 2216_1	Has subject engaged in Non-Suicidal Self-Injurious Behavior? 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? 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? Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such	Total # of attempts: ② yes 1 ② no 0 ③ yes 1 ③ no 0 Total # of interrupted: ③ yes 1 ② no 0 Total # of aborted:	sbh1n sbh2 sbh3 sbh3n sbh4



28 Form "Missed Visit"

Documentation of Missed	Follow-Up [mvfup] 4032_1		
Source of information:	 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	mvsrc
Reason for missed follow-up visit:		nd FUP, open to future FUPs 1 her FUP visits, open to further phone contacts 2 her FUP visits and to further phone contacts 3	mvrsn
	If participant is alive [4056] 4056_1 Level of care required:	 O = 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 	crlvl
		Days since full-time dependency:	dpdy

Revision History

Version	Summary of Changes
2018-10-R1	Initial version of annotated CRF for Enroll-HD Periodic Dataset.