

Annotated Case Report Form (CRF) for REGISTRY Periodic Dataset

Version 2016-10-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 REGISTRY's eCRF (electronic Case Report Form) within the Enroll-HD system. 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 plus 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. The following table defines how forms and data files are related.

Form / Data File	Profile	Partici- pation	Pharmaco Tx	NutSuppl	NonPhar- macoTx	Comorbid	R3	R2
Enrollment	✓	✓						
Demog	✓							
HD CC	✓							
PharmacoTx			✓					
NutSuppl				✓				
NonPharmacoTx					✓			
Comorbid						✓		
End		✓						
Mortality	✓							
Variable BL							✓	\checkmark
Variable FUP							✓	\checkmark
Motor							✓	✓
TFC							✓	\checkmark
Function							\checkmark	\checkmark

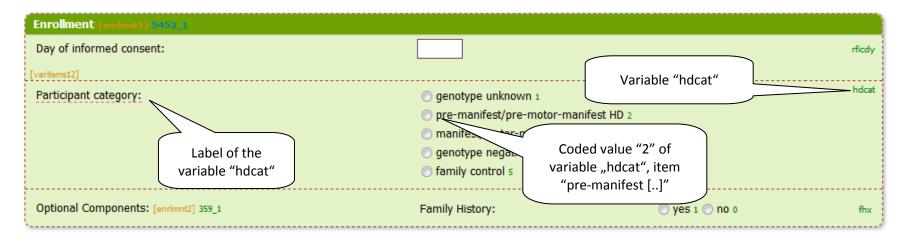


Form / Data File	Profile	Partici- pation	Pharmaco Tx	NutSuppl	NonPhar- macoTx	Comorbid	R3	R2
PBA-s							✓	
Cognitive							\checkmark	✓
HADS-SIS							✓	
SF36-v1								✓
SF36-v2							✓	
HADS-SIS							✓	
CSSRS BL							✓	
CSSRS FUP							✓	
Behaviour							✓	
BDI								✓
Hamilton								✓

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.



3 Form "Enrollment" (R3)





4 Form "Enrollment" (R2)

Enrollment [enrimnt1] 5459_1	
Day of informed consent:	rficdy



5 Form "Demographics (Demog)"

Demographics (invariable) [dm1] 116_1					
Age at enrollment:	age				
Gender: [dm2]	○ female r ○ male m sex				
Ethnicity:	Caucasian 1 American - Black 2 Hispano or Latino Origin 3 American Indian/Native American/Amerindian 8 Asian 16 mixed 15 other 6				
[dm4]					
Handedness: 🔼	Oright 1 handed Oleft 2 Omixed 3				



6 Form "HD Clinical Characteristics (HD CC)"

Family History [hdcc6] 594_1		
Mother affected:	© yes 1	momhd
	Age at onset of symptoms in mother:	momagesx
Father affected:	⊙ yes 1 ⊙ no 0	dadhd
	Age at onset of symptoms in father:	dadagesx
HD Clinical Characteristics and Age-of-O	nset 😕 [bdex2] 981 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	ссфер
	At what age did the depression begin? [539] 539_1	
	age (years)	
	ccdepage	
Has irritability ever been a part of the participant's medical history?	yes 1	ccirb
	At what age did the irritability begin? [545] 545_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? [551] 551_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? [557] 557_1	
	age (years)	
	ccaptage	



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? [563] 563_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? [569] 569_1	
	age (years)	
	ccpsyage	
	Does the participant have a family history of a psychotic	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? [576] 576_1	
	age (years)	
	age (years)	
	cccogage	
		ر
History of HD Motor Sypmtoms[hdoc7] 391	8_4	
Have motor symptoms ever been a part of the participant's medical history?	yes 1	ccmtr
	At what age did the participant's motor symptoms begin? [533] 533_1	
	age (years)	
	oge (reary)	
	ccmtrage	
		ر



HD History [hdhx] 2976_1									
Symptoms first noted by participant:								SXS	subj
Symptoms first noted by family:								SX	xfam
Date of clinical HD diagnosis:								hddi	iiagn
Can you, as a rater, estimate the time of symptom onset:	yes 1 no 0							s	sxest
	Rater's estimate of symptom onset:							sxra	ater
	Confidence with which this estimation is m	ade:		nigh (1 (low 2			sxesto	tcfd
What are these symptoms? [symptoms]		motor	cognitiv	e psychiatric	oculomoto	r other	mixed		
2988_1	Initial major symptom noted by participant	1	2		4	© 5	6 sxsubjm		
	Initial major symptom noted by family	0 1		⊙ 3	4	O 5	6 sxfamm		
	Rater's judgement of initial major symptom	n 🔘 1			∅ 4	5	6 sxraterm		
Suicial Behavior[hdcc7] 3918_1									
Previous suicidal ideation or attempts?	⊚ yes ı ⊚ no o							h	hxsid
Local genetic test [hdcc5] 601_1									
Has an HD genetic test been done?	⊚ yes ı ⊚ no o							hd	dtest



7 Form "Pharmacotherapy (PharmacoTx)"



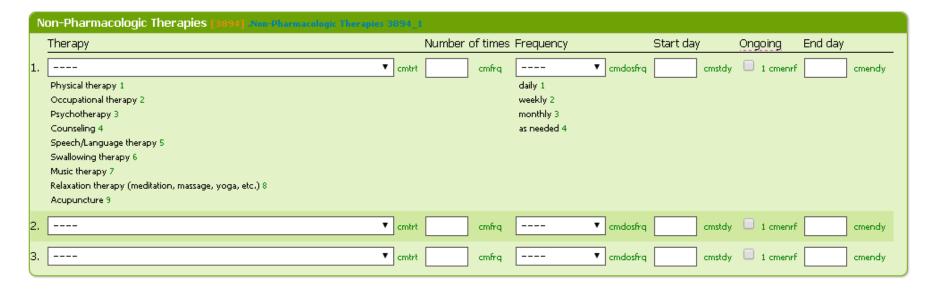


8 Form "Nutritional Supplements (NutSuppl)"



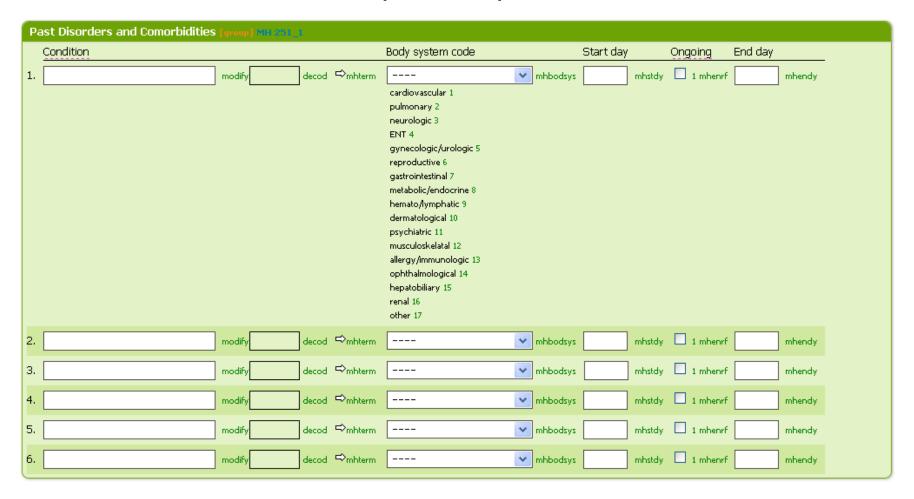


9 Form "Non-Pharmacologic Therapies (NonPharmaTx)"





10 Form "Comorbid Conditions (Comorbid)"



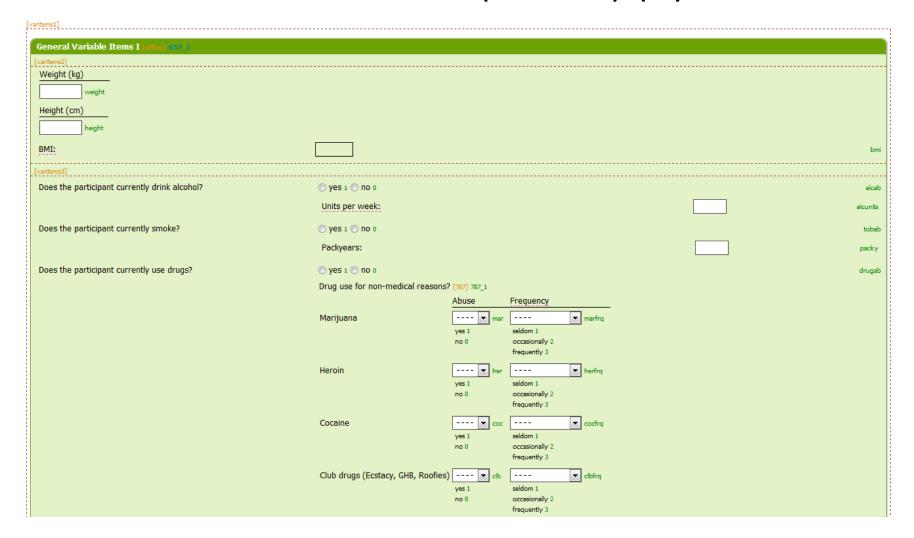


11 Form "Mortality"

Death Report Form [mor	rtrpt] 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



12 Form "Variable Items - Baseline Visit (Variable BL)" (R3)





	Amphetamines	v 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		inhfra
	Innaiants	inh	- Inning
		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	barfro
	Barbiturates/sedatives		barrid
		yes 1	seldom 1
		no 0	occasionally 2
			frequently 3
	Tranquilizers	v trq	trqfrq
		yes 1	seldom 1
		no 0	occasionally 2
			frequently 3
L			

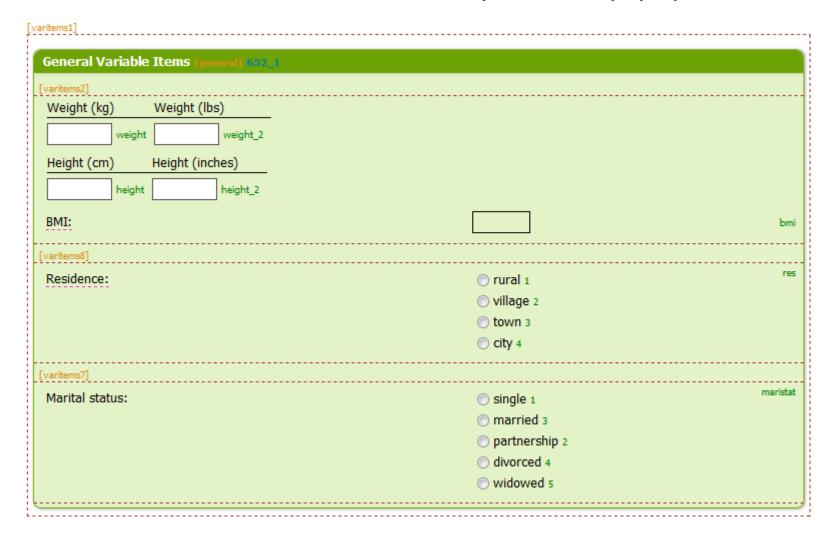
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General Variable Items II [rarely] 658.1		
[varitems7]		
Marital status:	🖱 single 1	maristat
	© married ₃	
	opartnership 2	
	O divorced 4	
	widowed 5	
	legally separated 6	
[varitems8]		
Residence:	🔘 rural 1	res
	⊚ village 2	
	⊚ town ₃	
	City 4	
[varitems10]		
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	

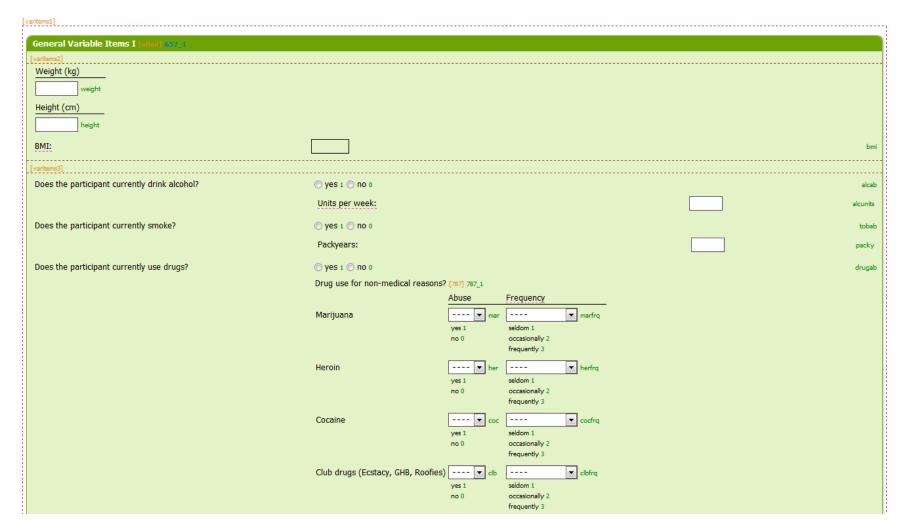


13 Form "Variable Items - Baseline Visit (Variable BL)" (R2)





14 Form "Variable Items - Follow-Up Visit (Variable FUP)" (R3)

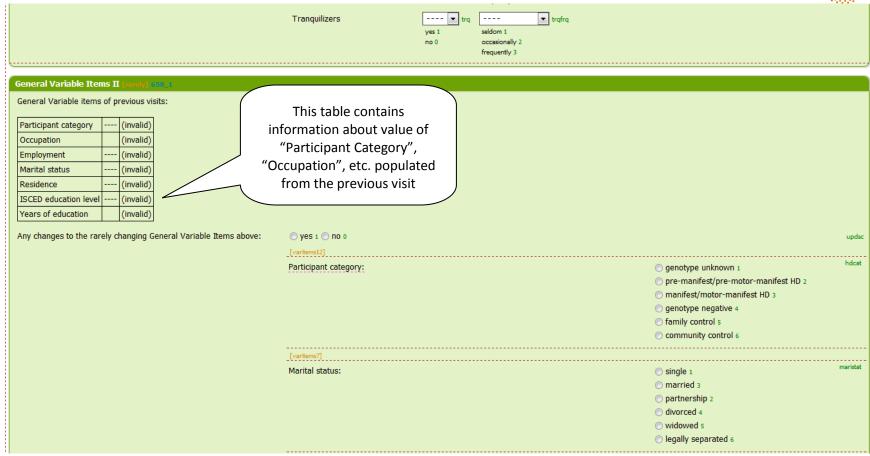




Amphetamines	▼ amp	■ ampfrq
Amphetamines		seldom 1
	yes 1 no 0	occasionally 2
	110 0	frequently 3
		nequently 3
Ritalin	rit	ritfrq
	yes 1	seldom 1
	no 0	occasionally 2
		frequently 3
Hallucinogens	🔻 hal	halfrq
	yes 1	seldom 1
	no 0	occasionally 2
		frequently 3
Inhalants	v inh	inhfrq
	yes 1	seldom 1
	no 0	occasionally 2
		frequently 3
Opium	opi	opifrq
	yes 1	seldom 1
	no 0	occasionally 2
		frequently 3
Painkillers	v 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

Annotated Case Report Form (CRF) for REGISTRY Periodic Dataset Version 2016-10-R1



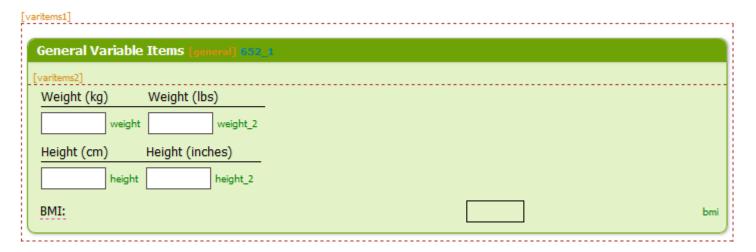




	[varitems8]		
	Residence:	🔘 rural 1	res
		🔘 village 2	
		⊚ town ₃	
		© city ₄	
	[varitems10]		
	ISCED education level: 📐	⊚ ISCED 0 o	isced
		⊚ ISCED 1 1	
		⊚ ISCED 2 2	
		⊚ ISCED 3 ₃	
		⊚ ISCED 4 4	
		⊚ ISCED 5 5	
		◯ ISCED 6 6	J
varitems11]			
Since the last visit have there been [chklist] 036_1			
Any changes to participant's medication?	yes 1		updmed
Any changes to participant's comorbid conditions?	yes 1		updmh
Any updates to the clinical characteristics and/or onset of HD?	yes 1 no 0		updhdh

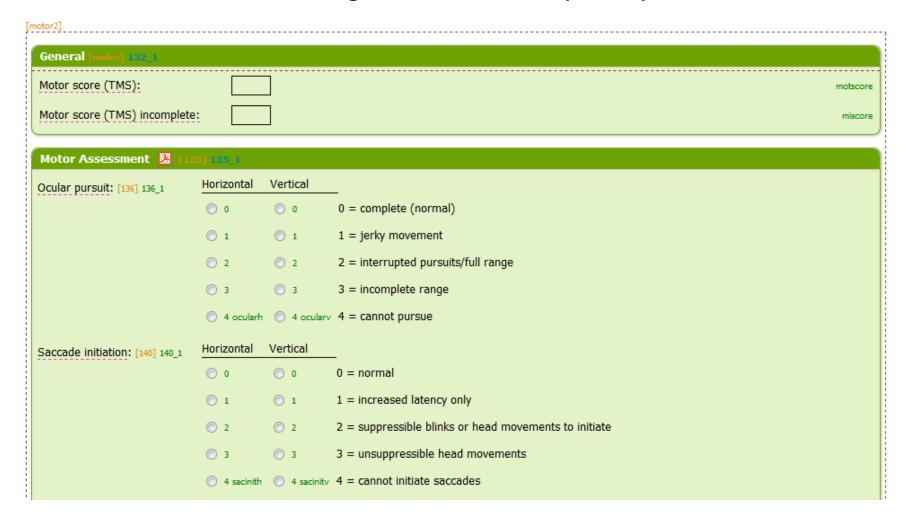


15 Form "Variable Items - Follow-Up Visit (Variable FUP)" (R2)





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





Horizontal	Vertical		
0	○ 0	0 = normal	
0 1	1	1 = mild slowing	
		2 = moderate slowing	
⊙ 3	⊙ 3	3 = severely slow, full range	
6 4 sacvelh	4 sacvely	4 = incomplete range	
⊚ 0 = norm	al o		dysarth
1 = uncle	ar, no need t	to repeat 1	
	-		
0 4 – allait	IIIIa 4		
	old tongue fo	ully protruded for 10 sec o	tongue
	_		
0 4 = Callin	or protrude to	origue beyond rips 4	
Right	Left	_	
○ 0	○ 0	0 = normal (≥15/5 sec.)	
O 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	4 fingtapl	4 = can barely perform task (0-2/5 sec.)	
	0 0 1 2 2 3 3 4 sacvelh 0 1 = uncle 2 = must 3 = mostl 4 = anart 0 1 = canno 2 = canno 4 = canno Right 0 0 1 2 2 3 3	0 0 0 1 1 2 2 3 3 3 4 sacvell 4 sacvelv 0 = normal 0 1 = unclear, no need of 1 = unclear, no need of 2 = must repeat to be 3 = mostly incompreh 4 = anarthria 4 0 = can hold tongue for 1 = cannot keep fully 2 = cannot keep fully 3 = cannot fully protructive 4 = cannot protrude to 1 = cannot protrude to 2 = cannot protrude to 3 = cannot protrude to 3 = cannot protrude to 2 = cannot protrude to 3 = cannot protrude to 3 = cannot protrude to 2 = cannot protrude to 3 = cannot protrud	0 0 0 0 = normal 1 = mild slowing 2 0 2 2 = moderate slowing 3 3 3 = severely slow, full range 4 sacvelv 4 = incomplete range 0 = normal 0 1 = unclear, no need to repeat 1 2 = must repeat to be understood 2 3 = mostly incomprehensible 3 4 = anarthria 4 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 Right Left 0 0 0 0 0 = normal (≥15/5 sec.) 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.)



Pronate/supinate-hands:	Right	Left	_	******
[154] 154_1	○ 0	○ 0	0 = normal	
	1	O 1	1 = mild slowing and/or irregular	
		2	2 = moderate slowing and irregular	
			3 = severe slowing and irregular	
	4 prosup	r 🔘 4 prosupl	4 = cannot perform	
Luria:	1 = <4 ii2 = ≥4 ii3 = <4 ii	n 10 sec, no c n 10 sec, no c n 10 sec with n 10 sec with not perform 4	ue 1 cues 2	luria
Rigidity-arms: [159] 159_1	Right	Left		
	○ 0	○ 0	0 = absent	
	0 1	O 1	1 = slight or present only with activation	
			2 = mild to moderate	
	⊙ 3		3 = severe, full range of motion	
	6 4 rigarmr	4 rigarml	4 = severe with limited range	
Bradykinesia-body:	2 = mild3 = mod	mally slow (?r ly but clearly s erately slow,		brady



Maximal dystonia: [164] 164_1	Trunk	RUE	LUE	RLE	LLE		
Production of the last of the	⊙ 0	⊙ 0	© 0	© 0	© 0	0 = absent	
		0 1	0 1	1	0 1	1 = slight/intermittent	
		2				2 = mild/common or mod	lerate/intermittent
	3			⊙ 3	⊙ 3	3 = moderate/common	
	4 dysttrnk	4 dystrue	4 dystlue	4 dystrle	0 4 dystlle	4 = marked/prolonged	
Maximal chorea: [171] 171_1	Face	BOL	Trunk	RUE	LUE	RLE LLE	_
	© 0	© 0	© 0	© 0	© 0	© ©	0 = absent
	(i) 1	© 1	© 1	1	① 1	© © 1	1 = slight/intermittent
	© 2	© 2	© 2	© 2	© 2	© © 2	2 = mild/common or moderate/intermittent
	© 3		© 3	⊙3	© 3	© © 3 3	3 = moderate/common
	chorface	chorbol	Chortrnk	Chorrue	chorlu	ue	4 = marked/prolonged
Gait:	0 = norma 1 = wide 2 = wide 3 = walks 4 = canno	base and/or so base and wall only with ass	slow 1 ks with difficu	lty 2			g



! I		1,44,44,44
Tandem walking:	○ 0 = normal for 10 steps o	tandem
	○ 1 = 1 to 3 deviations from straight line 1	
	© 2 = >3 deviations 2	
	⊘ 3 = cannot complete 3	
	∅ 4 = cannot attempt 4	
Retropulsion pull test:	⊙ 0 = normal o	retropls
	○ 1 = recovers spontaneously 1	
	© 2 = would fall if not caught 2	
	⊘ 3 = tends to fall spontaneously 3	
	∅ 4 = cannot stand 4	
Diagnostic Confidence I	melow21 DCI 195-4	

Diagnostic Confidence [motor3] .00	IL 185_1	
Diagnostic confidence level (DCL):	○ 0 = normal (no abnormalities) 0	gconf
	○ 1 = non-specific motor abnormalities (less than 50 % confidence) 1	
	○ 2 = motor abnormalities that may be signs of HD (50 - 89 % confidence) 2	
	4 = motor abnormalities that are unequivocal signs of HD (≥ 99 % confidence) 4	
	(2 99 % confidence) 4	



17 Form "UHDRS Total Funtional Capacity (TFC)"

General [tfc] 893_1		
Functional score:		tfcscore
Functional Canacity #	· New ·	
Functional Capacity [fu	notcapj 895_1	
Occupation:	○ 0 = unable o	occupatn
	1 = marginal work only 1	
	2 = reduced capacity for usual job 2	
	○ 3 = normal 3	
Financos	O obla -	finances
Finances:	0 = unable o	
	1 = major assistance 1	
	2 = slight assistance 2	
	○ 3 = normal 3	
Domestic chores:	\bigcirc 0 = unable 0 \bigcirc 1 = impaired 1 \bigcirc 2 = normal 2	chores
ADI		adl
ADL:	0 = total care o	
	1 = gross tasks only 1	
	2 = minimal impairment 2	
	○ 3 = normal 3	
Care level:	○ 0 = full time skilled nursing o	carelevl
	1 = home or chronic care 1	
	○ 2 = home 2	



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

General [function] 849_1		
Functional assessment score:		fascore
Functional score incomplete:		fiscore
Independence Scale [indep1] .Indepo	indence 693_1	
Subject's independence in %:	 100 = no special care needed 100 95 95 90 = no physical care needed if difficult tasks are avoided 90 85 95 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 	indepscl



19 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 I	ID 😕 [2630] .RBA-s 2630_1		
1. Depressed mood: [2631] 2631_1	a. Severity:	© 0 = absent o	pbas1sv
Trooprossed mood, [case] associ	3.55.4.4	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	pbas1fr
		○ 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 o	pbas1wo
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	



2. Suicidal ideation: [2635] 2635_1	a. Severity:		pbas2sv
		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	pbas2fr
		○ 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:		pbas2wo
		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
3. Anxiety: [2639] 2639_1	a. Severity:	○ 0 = absent o	poessav
		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 0	pbas3fr
		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	pbas3wo
		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. Irritability: [2643] 2643_1	a. Severity:	 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 	pbas4sv
	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 	pbas4fr
	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 	pbas4wo
5. Angry or aggressive behaviour: [2647]	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 	pbas5sv
	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 	pbas5fr
	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 	pbas5wo



			pbas6sv
6. Lack of initiative (apathy): [2651] 2651_1	a. Severity:	○ 0 = absent o	pbasosv
		○ 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 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	
7. Perseverative thinking or behaviour:	a. Severity:		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	
		7 - Severe (diffuse filtular able 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:		pbas7wo
		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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8. Obsessive-Compulsive Behaviours:	a. Severity:		pbas8sv
[2659] 2659_1	5135151321	1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
			pbas8fr
	b. Frequency:	0 = never/almost never o	pouson
		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 o	pbas8wo
		1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		○ 3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	
9. Delusions / paranoid thinking: [2663]	a. Severity:	○ 0 = absent o	pbas9sv
2663_1		○ 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	pbas9fr
	51 Trequency 1	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	
		O r daily, aimost daily for most (or ally or day r	-10
	c. Worst:	○ 0 = absent o	pbas9wo
		○ 1 = slight, questionable 1	
		2 = mild (present, not a problem) 2	
		3 = moderate (symptom causing problem) 3	
		4 = severe (almost intolerable for carer) 4	



10. Hallucinations: [2667] 2667_1	a. Severity:	 0 = absent 0 1 = slight, questionable 1 2 = mild (present, not a pro 3 = moderate (symptom car 4 = severe (almost intolerated) Please specify [modsv] 2669_1 	using problem) 3	pbas10sv
		Modality of hallucinations:	auditory 1 visual 2 tactile 3 olfactory 4 gustatory 5	pbas10sm
	b. Frequency:	 0 = never/almost never o 1 = seldom (less than once) 2 = sometimes (up to four t 3 = frequently (most days/5 4 = daily/almost daily for m 	imes a week) 2 i, 6 or 7 times a week) 3	pbas10fr
	c. Worst:	 0 = absent o 1 = slight, questionable 1 2 = mild (present, not a pro 3 = moderate (symptom cail 4 = severe (almost intolerated) Please specify [modwo] 2673_1	using problem) 3	pbas10wo
		Modality of hallucinations:	auditory 1 visual 2 tactile 3 olfactory 4 gustatory 5	pbas10wm



ò				
H	11. Disoriented Behaviour: [2675] 2675_1	a. Severity:	○ 0 = absent o	pbas11sv
į			○ 1 = slight, questionable 1	
l			2 = mild (present, not a problem) 2	
ij			© 3 = moderate (symptom causing problem) 3	
Ì			4 = severe (almost intolerable for carer) 4	
l				pbas11fr
l		b. Frequency:	○ 0 = never/almost never o	poastin
l			\bigcirc 1 = seldom (less than once/week) 1	
H			2 = sometimes (up to four times a week) 2	
l			⊙ 3 = frequently (most days/5, 6 or 7 times a week) 3	
l			4 = daily/almost daily for most (or all) of day 4	
į		c. Worst:	© 0 = absent 0	pbas11wo
H		C. WOISC	1 = slight, questionable 1	
i				
H			② 2 = mild (present, not a problem) 2	
			(a) 3 = moderate (symptom causing problem) 3	
H				
			4 = severe (almost intolerable for carer) 4	
			4 = severe (almost intolerable for carer) 4	
	Information [pbs1] .PBA 1006_1		4 = severe (almost intolerable for carer) 4	
		Snouse or partner 1	⊕ 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	Spouse or partner 1	⊕ 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	oparent 2	© 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	parent 2	4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	parent 2 sibling 3 child 4	• 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	parent 2 sibling 3 child 4 other relative 5	• 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	parent 2 sibling 3 child 4 other relative 5 friend or neighbor 6	• 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	parent 2 sibling 3 child 4 other relative 5 friend or neighbor 6 professional care worker 7	• 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	parent 2 sibling 3 child 4 other relative 5 friend or neighbor 6 professional care worker 7 other 8	© 4 = severe (almost intolerable for carer) 4	pbainfo
	i) Is informant a relative?	parent 2 sibling 3 child 4 other relative 5 friend or neighbor 6 professional care worker 7	• 4 = severe (almost intolerable for carer) 4	
	i) Is informant a relative?	parent 2 sibling 3 child 4 other relative 5 friend or neighbor 6 professional care worker 7 other 8	household member (i.e. relative or friend who lives with participan	
	i) Is informant a relative?	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		it) 1 ^{pbahshd}
	i) Is informant a relative?	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	 household member (i.e. relative or friend who lives with participan not a household member but has frequent contact with participant 	it) 1 ^{pbahshd}
	i) Is informant a relative?	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	 household member (i.e. relative or friend who lives with participan not a household member but has frequent contact with participant (most days) 2 not a household member and sees participant less than three or form 	it) 1 ^{pbahshd}

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20 Form "Core and Extended Cognitive Assessment (Cognitive)" (R3)

[cogs1]					
Specifics [cog	n3] .Cognitive Assessn	nent 2288_1			
assessment in language and	pant complete the their native with normal or ormal vision and	⊚ yes ı ⊚ no o			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	gen6
Core Cogniti	ve Assessment [co	gnitive] 2341_1			
[sdmt1]					
Symbol Digit N completed:		yes 1 no 0			sdmt
		Total correct:			sdmt1
		Total errors:			sdmt2



rfct1]			
erbal Fluency Test (Category) mpleted: 😕	⊚ yes 1 ⊚ no 0	verl	fct
	Category:	animals 1	d
		other 2	
	Total correct (1 min):	verfct	5
	Total intrusion errors:	verfct	6
	Total perseverative errors:	verfct	7
nti]			
roop Color Naming Test mpleted: 😕	yes 1 no 0	sc	nt
	Total correct:	scnt	1
	Total errors:	scnt	2
	Total self-corrected errors:	scnt	3
rt1]			
roop Word Reading Test mpleted: 😕	yes 1	sv	/rt
	Total correct:	swrt	1
	Total errors:	swrt	2
	Total self-corrected errors:	swrt	3
	ribal Fluency Test (Category) mpleted: roop Color Naming Test mpleted: roop Word Reading Test	rotal Fluency Test (Category) mpleted: ▶ Category: Total correct (1 min): Total intrusion errors: Total perseverative errors: Total perseverative errors: **Total correct: Total correct: Total correct: Total errors: Total self-corrected errors: **Total self-corrected errors: **Total correct: Total correct:	rope Fluency Test (Category) Open 1



Extended Cognitive Assessmen	Nt [cognitiveex] 2342_1		
[sit1]			
Stroop Interference Test completed: 📐	yes 1 no 0		sit
	Total correct:		sit1
	Total errors:		sit2
	Total self-corrected errors:		sit3
[tm1]			
Trailmaking Test completed: 😕	yes 1 no 0		trl
	Trailmaking Test [2780] 2780_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		verfit
	Total correct (3 min):		verfit05
	Total intrusion errors:		verfit06
	Total perseverative errors:		verfit07

Annotated Case Report Form (CRF) for REGISTRY Periodic Dataset Version 2016-10-R1



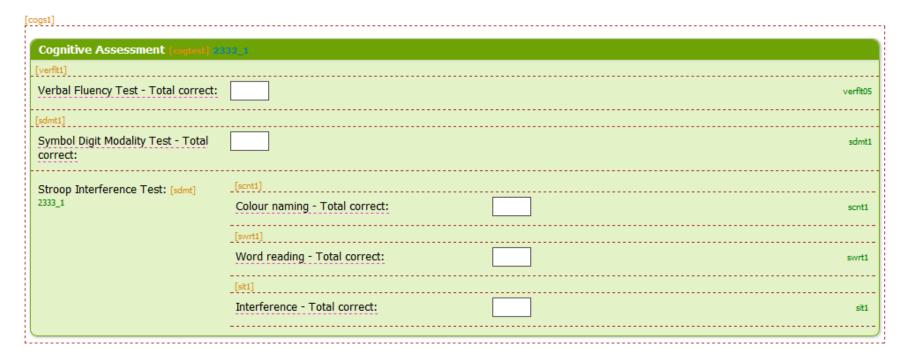
1				*****	- 1
	Extended Neuropsychological As [hvlt1]	ssessment [tests] 2777_1			١
	Hopkins Verbal Learning Test-R completed (optional):	© yes 1 ⊚ no 0		hvlt	
		Hopkins Verbal Learning Test-R [2741] 2741_1			l
i		Used form:	v	hvltd	l
			form 1 1 form 2 2		l
			form 3 3		l
		Trial 1: correct:		hvltt11	
		Trial 2: correct:		hvltt21	l
		Trial 3: correct:		hvltt31	l
-		Delayed recall correct:		hvlt1	l
		Total repetitions (trials 1-3 & delayed):		hvlt2	
		Total intrusions (trials 1-3 & delayed):		hvlt3	l
-		Recognition: true positives:		hvlt4	
		Recognition: false positives:		hvlt5	
H					1:



[c	drs1]		2000	
<u>(</u>	Dementia Rating Scale-2 completed (optional):	yes 1	mdi	5
		Dementia Rating Scale-2 [2789] 2789_1		
		Attention:	mdrst	
		Initiation / perseveration:	mdrs2	
		Construction:	mdrs	
		Conceptualization:	mdrs4	
		Memory:	mdrs5	



21 Form "Core and Extended Cognitive Assessment (Cognitive)" (R2)





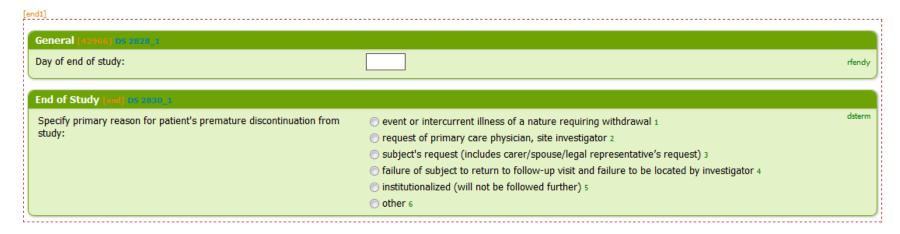
Extended Neuropsychological A	Assessment [tests] 2777_1		
[hvlt1]			
Hopkins Verbal Learning Test-R completed (optional):	⊚ yes 1 ⊚ no 0		hvlt
	Hopkins Verbal Learning Test-R [2753] 2753_1		
	Used form:		hvltd
		form 1 1	
		form 2 2	
		form 3 3	
	Trial 1: correct:		hvltt11
	Trial 2: correct:		hvltt21
	Trial 3: correct:		hvltt31
	Delayed recall correct:		hvlt1
	Total repetitions (trials 1-3 & delayed):		hvlt2
	Total intrusions (trials 1-3 & delayed):		hvlt3
	Recognition: true positives:		hvlt4
	Recognition: false positives:		hvlt5



[drs1]		
Dementia Rating Scale-2 completed (optional):	yes 1 no 0	mdrs
	Dementia Rating Scale-2 [2789] 2789_1	
	Attention:	mdrs1
	Initiation / perseveration:	mdrs2
	Construction:	mdrs3
	Conceptualization:	mdrs4
	Memory:	mdrs5



22 Form "Premature End of Study (End)"





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

General [hads] .HAD\$ 1972_1	
Anxiety subscore:	anxscore
Depression subscore:	hads_depscore
Irritability subscore:	irrscore
Outward irritability subscore:	outscore
Inward irritability subscore:	inwscore



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



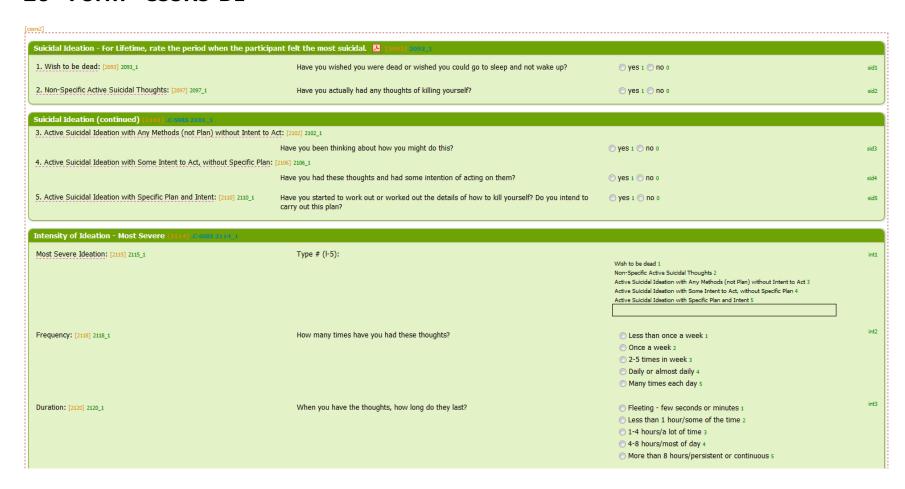


25 Form "Short Form Health Survey – 36v2 (SF-36)"





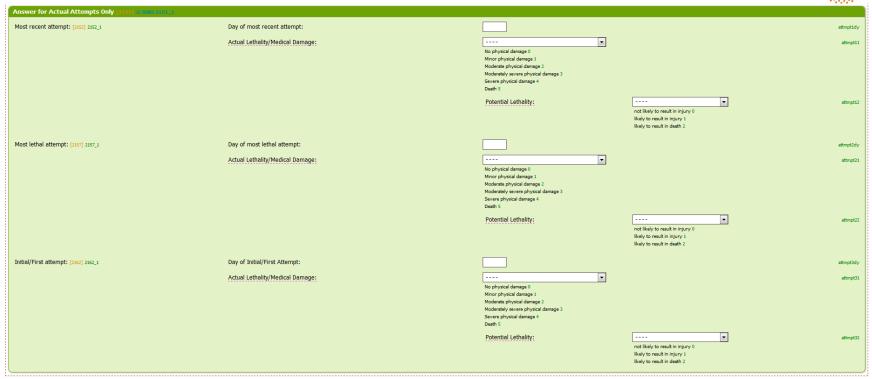
26 Form "CSSRS-BL"





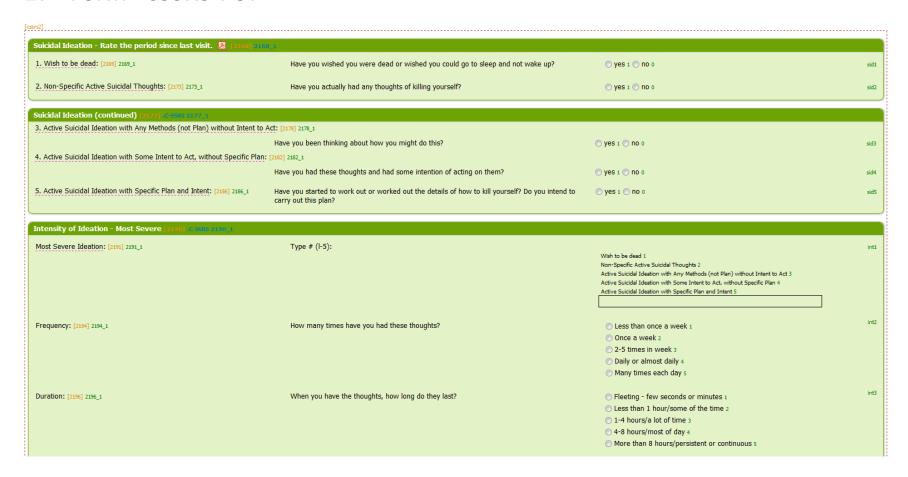
Controllability: [2122] 2122_1	Could/can you stop thinking about killing yourself or wanting to die if you want to?	© Easily able to control thoughts 1 © Can control thoughts with little difficulty 2 © Can control thoughts with a lot of difficulty 3 © Can control thoughts with a lot of difficulty 4 © Unable to control thoughts ≤ © Does not attempt to control thoughts ∘	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 © Incertain that deterrents stopped you 3 © Deterrents most likely did not stop you from attempting suicide 4 © Deterrents definitely did not stop you s © Does not apply; wish to die only o	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 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). s Does not apply o	int6
Suicidal Behavior [2128] 2128,1			
Suicidal Behavior (2128) 2189(1) Actual Attempt: (2129) 2129_1	Actual attempt:	© yes i ⊙ no o	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: ○ yes 1 ○ no 0	sbh1n sbh2
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: ○ yes 1 ○ no 0 ○ yes 1 ○ no 0	sbh1n sbh2 sbh3
Actual Attempt: [2128] 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: ② yes 1 ② no 0 ③ yes 1 ② no 0 Total ≠ of interrupted:	sbh1n sbh2 sbh3 sbh3n
Actual Attempt: [2128] 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: (a) yes 1 (a) no 0 (b) yes 1 (a) no 0 (c) yes 1 (a) no 0 (c) yes 1 (a) no 0	sbh1n sbh2 sbh3 sbh3n sbh4







27 Form "CSSRS-FUP"





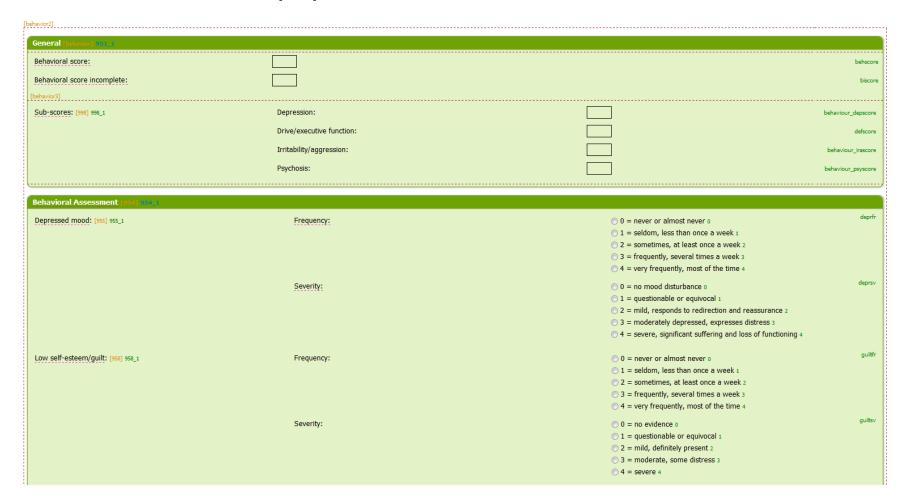
Controllability: [2198] 2198_1	Could/can you stop thinking about killing yourself or wanting to die if you want to?	 Easily able to control thoughts 1 Can control thoughts with little difficulty 2 Can control thoughts with some difficulty 3 Can control thoughts with a lot of difficulty 4 Unable to control thoughts 5 Does not attempt to control thoughts 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 s ○ 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			
Suicidal Behavior [2204] 2000; 1 Actual Attempt: [2205] 2205,1	Actual attempt:	○ yes 1 ○ no 0	sbh1
	Actual attempt:	○ yes i ○ 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: yes 1 on 0 yes 1 no 0	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 Total # of aborted:	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: yes 1 no 0 yes 1 no 0 Total # of interrupted: yes 1 no 0 Total # of aborted:	sbh1n sbh2 sbh3 sbh3n sbh4n







28 Form "Behaviour" (R3)





al Control of the Con		V 474 7
Anxiety: [961] 961_1	Frequency:	○ 0 = never or almost never o
		1 = seldom, less than once a week 1
		2 = sometimes, at least once a week 2
		○ 3 = frequently, several times a week 3
		O 4 = very frequently, most of the time 4
	Severity:	© 0 = no evidence o
		1 = questionable or equivocal 1
		© 2 = mild, responds to reassurance 2
		○ 3 = moderate, impacts on everyday life 3
		4 = severe, causing a profound restriction of activities 4
Suicidal thoughts: [964] 964_1	Frequency:	○ 0 = not thinking about suicide or self harm o
		\odot 1 = seldom thinking about suicide - less than once a month 1
		2 = sometimes thinking about suicide - at least once a month 2
		3 = frequently thinking about suicide - at least once a week 3
		\odot 4 = often thinks about suicide - sometimes for days and weeks on end 4
	Severity:	© 0 = no suicidal thoughts o
		1 = no thoughts at current time, but person talks about suicide as a potential option 1
		2 = fleeting thoughts about it 2
		3 = seriously considered suicide but has no plan 3
		4 = has a plan and is actively preparing 4
Disruptive or aggressive behavior: [967] 967_1	Frequency:	© 0 = never or almost never o aggrfr
		1 = seldom, less than once a month 1
		2 = sometimes, at least once a month 2
		⊙ 3 = frequently, at least once a week 3
		○ 4 = very frequently, everyday 4
	Severity:	0 = behavior well-controlled o
		1 = verbal threats or intimidating behavior 1
		2 = mild physically or verbally threatening behavior 2
		 3 = clear physical threat (moderately aggressive), bumping, shoving, verbal outburst 3
		4 = clear physical threat (severe aggression) striking/hitting, or definite intention to cause injury 4
		initir
Irritable behavior: [970] 970_1	Frequency:	0 = never or aimost never o
		1 = seldom, less than once a week 1
		2 = sometimes, at least once a week 2
		3 = frequently, several times a week 3
		⊕ 4 = very frequently, most of the time 4
	Severity:	○ 0 = behavior well-controlled 0
		○ 1 = questionable or equivocal 1
		○ 2 = definite but mild 2
		3 = moderate, others change their behavior to avoid irritating subject 3
		4 = severe irritability 4



Perseverative/obsessional thinking: [973] 973_1	Frequency:	0 = never or almost never o	obsessfr
To botto data y obsessional dimining [275] 275_1	Traductor!	1 = seldom, less than once a week 1	
		2 = sometimes, at least once a week 2	
		3 = frequently, several times a week 3	
		4 = very frequently, most of the time 4	
		7 = very frequency, most of the time 4	obsesssy
	Severity:	0 = thinking is always flexible o	ODSesssV
		1 = questionable or equivocal 1	
		2 = gets stuck on certain ideas but can be easily redirected 2	
		3 = moderate - gets stuck on certain ideas, difficult to redirect 3	
		4 = severe - gets stuck on certain ideas, and does not respond to redirection 4	
			compulfr
Compulsive behavior: [976] 976_1	Frequency:	0 = never or almost never o	
		1 = seldom, less than once a week 1	
		2 = sometimes, at least once a week 2	
		○ 3 = frequently, several times a week 3	
		O 4 = very frequently, most of the time 4	
	Severity:	○ 0 = behavior always well-controlled o	compulsv
		1 = equivocal - has a mild impulse not sufficient to act on 1	
		2 = mild - has impulse, acts on impulse, but can stop 2	
		○ 3 = moderate - has impulse, acts on it and sometimes cannot stop 3	
		4 = severe - has impulse, acts on it and cannot stop 4	
Delusions: [979] 979_1	Frequency:	⊙ 0 = no evidence o	delusfr
		1 = seldom, less than once a month 1	
		\bigcirc 2 = sometimes, at least once a month 2	
		○ 3 = frequently, at least once a week 3	
		4 = very frequently, sometimes for days on end 4	
	Severity:	0 = no evidence o	delussv
		1 = has delusional idea(s), not sure it is true 1	
		2 = convinced of idea(s) but allows that the idea is not true 2	
		3 = utterly convinced of the idea(s) 3	
		4 = utterly convinced of the idea(s), behavior is determined by the delusion(s) 4	
Hallucinations: [982] 982_1	Frequency:	○ 0 = no evidence of hallucinations o	hallucfr
		1 = seldom, less than once a month 1	
		2 = sometimes, at least once a month 2	
		○ 3 = frequently, at least once a week 3	
		4 = often, sometimes for days on end 4	
	Severity:	⊙ 0 = no evidence o	hallucsv
	Severity.	1 = has hallucinations, but doubts they are real 1	
		 1 = nas natiounations, but doubts they are real 1 2 = convinced of the reality of the hallucinations, but allows that it is possible that they are not real 2 	
		3 = utterly convinced of the hallucinations being real, but not acting on them 3	
		3 = uctory convinced of the hallucinations being real, but not acting on them 3 4 = severe - has hallucinations that are vivid, subject is utterly convinced they are real and the hallucinations severely disrupt	
		 4 = severe - nas nanucinations that are vivid, subject is utterly convinced they are real and the nanucinations severely distributed behavior 4 	



Apathy: (965) 965_1	Frequency: Severity:	0 = never 0 1 = seldom apathetic, less than once a week 1 2 = sometimes, at least once a week 2 3 = frequently, several times a week 3 4 = very frequently, most of the time 4 0 = no evidence 0 1 = equivocal 1 2 = mild apathy - subject not initiating conversation or activity but is responsive 2 3 = moderate apathy - sometimes responds to efforts to get involved in conversation/activities 3 4 = severe apathy - generally unresponsive to attempts to involve subject in activities or conversation 4	apathfr apathsv
Behavioral Milestones: [988] 988_1	Does the examiner believe the participant is confused?	0 1 = yes 1 0 0 = no 0	confus
	Does the examiner believe the participant is demented?	① 1 = yes 1 ② 0 = no 0	dement
	Does the examiner believe the participant is depressed?	○ 1 = yes 1 ○ 0 = no 0	deprexam
	Does the participant require pharmacotherapy for depression?	○ 1 = yes 1 ○ 0 = no 0	deprrfr
	Does the participant require pharmacotherapy for irritability?	○ 1 = yes 1 ○ 0 = no 0	irritrfr
Information sources: [994] 994_1	Was the behavioral assessment information obtained from:	\bigcirc 1 = participant only 1 \bigcirc 2 = participant and family/companion 2	isobt



29 Form "Behaviour" (R2)





		TANKA PARAMETER AND
Suicidal thoughts: (964) 964_1	Frequency:	0 = not thinking about suicide or self harm o 1 = seldom thinking about suicide - less than once a month 1 2 = sometimes thinking about suicide - at least once a month 2 3 = frequently thinking about suicide - at least once a week 3 4 = often thinks about suicide - sometimes for days and weeks on end 4
	Severity:	 0 = no suicidal thoughts o 1 = no thoughts at current time, but person talks about suicide as a potential option 1 2 = fleeting thoughts about it 2 3 = seriously considered suicide but has no plan 3 4 = has a plan and is actively preparing 4
Disruptive or aggressive behavior: (%7) %7_1	Frequency:	 0 = never or almost never o 1 = seldom, less than once a month 1 2 = sometimes, at least once a month 2 3 = frequently, at least once a week 3 4 = very frequently, everyday 4
	Severity:	 0 = behavior well-controlled o 1 = verbal threats or intimidating behavior 1 2 = mild physically or verbally threatening behavior 2 3 = clear physical threat (moderately aggressive), bumping, shoving, verbal outburst 3 4 = clear physical threat (severe aggression) striking/hitting, or definite intention to cause injury 4
Irritable behavior: [970] 970_1	Frequency:	 0 = never or almost never o 1 = seldom, less than once a week 1 2 = sometimes, at least once a week 2 3 = frequently, several times a week 3 4 = very frequently, most of the time 4
	Severity:	 0 = behavior well-controlled o 1 = questionable or equivocal 1 2 = definite but mild 2 3 = moderate, others change their behavior to avoid irritating subject 3 4 = severe irritability 4
Perseverative/obsessional thinking: [973] 973_1	Frequency:	○ 0 = never or almost never o ○ 1 = seldom, less than once a week 1 ○ 2 = sometimes, at least once a week 2 ○ 3 = frequently, several times a week 3 ○ 4 = very frequently, most of the time 4
	Severity:	© 0 = thinking is always flexible o © 1 = questionable or equivocal 1 © 2 = gets stuck on certain ideas but can be easily redirected 2 © 3 = moderate - gets stuck on certain ideas, difficult to redirect 3 © 4 = severe - gets stuck on certain ideas, and does not respond to redirection 4



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Compulsive behavior: [976] 976_1	Frequency:	○ 0 = never or almost never o	ulfr
		○ 1 = seldom, less than once a week 1	
		2 = sometimes, at least once a week 2	
		○ 3 = frequently, several times a week 3	
		 4 = very frequently, most of the time 4 	
	Severity:	0 = behavior always well-controlled o comp	ulsv
		○ 1 = equivocal - has a mild impulse not sufficient to act on 1	
		○ 2 = mild - has impulse, acts on impulse, but can stop 2	
		3 = moderate - has impulse, acts on it and sometimes cannot stop 3	
		4 = severe - has impulse, acts on it and cannot stop 4	
		del	of c
Delusions: [979] 979_1	Frequency:	U = no evidence o	usir
		1 = seldom, less than once a month 1	
		2 = sometimes, at least once a month 2	
		3 = frequently, at least once a week 3	
		4 = very frequently, sometimes for days on end 4	
	Severity:	○ 0 = no evidence o	ISSV
		1 = has delusional idea(s), not sure it is true 1	
		2 = convinced of idea(s) but allows that the idea is not true 2	
		⊙ 3 = utterly convinced of the idea(s) 3	
		 4 = utterly convinced of the idea(s), behavior is determined by the delusion(s) 4 	
		hali	ucfr
Hallucinations: [982] 982_1	Frequency:	0 = no evidence or natificinations o	
		1 = seldom, less than once a month 1	
		2 = sometimes, at least once a month 2	
		3 = frequently, at least once a week s	
		4 = often, sometimes for days on end 4	
	Severity:	○ 0 = no evidence o	csv
		\odot 1 = has hallucinations, but doubts they are real 1	
		\bigcirc 2 = convinced of the reality of the hallucinations, but allows that it is possible that they are not real 2	
		3 = utterly convinced of the hallucinations being real, but not acting on them 3	
		 4 = severe - has hallucinations that are vivid, subject is utterly convinced they are real and the hallucinations severely disrupt behavior 4 	
A	F	age a	thfr
Apathy: [985] 985_1	Frequency:	0 = never 0	
		1 = seldom apathetic, less than once a week 1	
		2 = sometimes, at least once a week 2	
		3 = frequently, several times a week 3	
		O 4 = very frequently, most of the time 4	.
	Severity:	○ 0 = no evidence o	nsv
		1 = equivocal 1	
		2 = mild apathy - subject not initiating conversation or activity but is responsive 2	
		3 = moderate apathy - sometimes responds to efforts to get involved in conversation/activities 3	
		4 = severe apathy - generally unresponsive to attempts to involve subject in activities or conversation 4	



dement
prexam
deprrfr
irritrfr
isobt
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30 Form "Hamilton"

[ham1]	
General [2344] 2344_1	
Hamilton Score:	hamscore



Revision History

Version	Summary of Changes
2016-10-R1	Initial version of annotated CRF for the first REGISTRY Periodic Dataset.