目 Data Dictionary Codebook

01/26/2024 11:05am

	#	Variable / Field Name	Field Label Field Note	Field Attributes (Field Type, Validation, Choices, Calculations, etc.)	
Inst	rum	ent: Demographic In	fo (demographic_info_toronto_only)		[collapsed]
nst	rum	ent: Mini MDD (mini	_mdd)		[collapsed]
nst	rum	ent: Mini MDD Note	(mini_mdd_note)		[collapsed]
nst	rum	ent: Medical History	Form (Revised 3/27/17) (medical_histor	y_form_revised_32717)	[collapsed]
Instrument: Medical History Form (Revised 3/30/17): USE THIS ONE! (medical_history_form_revised_33017_use_this_one)				[collapsed]	
Instrument: Psychiatric Medication Form V2 (psychiatric_medication_form_v2)					[collapsed]
nst	rum	ent: Drug Abuse Scre	eening Test (DAST) (drug_abuse_screening	g_test_dast)	[collapsed]
nst	rum	ent: Medication Forr	n V2 (medication_form_v2)		[collapsed]
nst	rum	ent: NIH Toolbox Bas	seline (nih_toolbox_baseline)		[collapsed]
nst	rum	ent: Randomization	Form Step 2 (randomization_form_step_2	please_do_not_actually_c)	[collapsed]
			e History Risk And Protective ory_risk_and_protective_facto)		[collapsed]
Inst	rum	ent: Blinded Central	MADRS (blinded_central_madrs)		[collapsed]
		ent: Cumulative Illno ative_illness_rating_scal	ess Rating Scale For Geriatrics (CIRS-G le_for_geriatrics_cir))	[collapsed]
Inst	rum	ent: Baseline Forms	(baseline_forms)		
	654	[baseline_forms_date]	Date	text (date_mdy)	
Section Header: The Patient Health Questionnaire (PHQ-9) Has the PHQ-9 been completed within the past week? Section Header: The Patient Health Questionnaire (PHQ-1) 1 Yes 0 No Custom alignment: RH Field Apportation: @DEFALLE		1 Yes 0 No	='0'		
	656	[base_phq9_1] Show the field ONLY if: [phq9_win_past_wk] = '0'	Section Header: 1. Little interest or pleasure in doing things	radio, Required 0 0- Not at all 1 1- Several days 2 2- More than half the day 3 3- Nearly every day	1/5
	657	[base_phq9_2] Show the field ONLY if: [phq9_win_past_wk] = '0'	2. Feeling down, depressed, or hopeless	radio, Required 0 0- Not at all 1 1- Several days	

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			2 2- More than half the days	
			3 3- Nearly every day	
658	[base_phq9_3]	3. Trouble falling or staying asleep, or	radio, Required	
	Show the field ONLY if:	sleeping too much	0 0- Not at all	
	[phq9_win_past_wk] =		1 1- Several days	
	'0'		2 2- More than half the days	
			3 3- Nearly every day	
659	[base_phq9_4]	4. Feeling tired or having little energy	radio, Required	
033	Show the field ONLY if:	The coming three of Having intil cities gy	0 0- Not at all	
	[phq9_win_past_wk] =		1 1- Several days	
	'0'		2 2- More than half the days	
			3 3- Nearly every day	
660	[hasa nha0 F]	5 Poor apposite or overeating		
660		5. Poor appetite or overeating	radio, Required 0 0- Not at all	
	Show the field ONLY if: [phq9_win_past_wk] =		1 1- Several days	
	'0'		2 2- More than half the days	
			3 3- Nearly every day	
664		C Facility is a large at a second constant of		
661	[base_phq9_6]	6. Feeling bad about yourself or that you are a failure or have let yourself or your	radio, Required 0 0- Not at all	
	Show the field ONLY if: [phq9_win_past_wk] = '0'	family down	1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
662	2 [base_phq9_7] Show the field ONLY if: [phq9_win_past_wk] = '0'	7. Trouble concentrating on things, such as reading the newspaper or watching television	radio, Required 0 0- Not at all	
		The state of the s		
			1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
663	[base_phq9_8]	8. Moving or speaking so slowly that other people could have noticed? Or the opposite	radio, Required	
	Show the field ONLY if: [phq9_win_past_wk] =	being so fidgety or restless that you have	0 0- Not at all	
	[buda_wiii_bast_wk] =	been moving around a lot more than usual	1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
664	[base_phq9_9]	9. Thoughts that you would be better off	radio, Required	
	Show the field ONLY if:	dead or of hurting yourself in some way	0 0- Not at all	
	[phq9_win_past_wk] = '0'		1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
665	[base_phq9_suicide]	Please conduct the Suicide Risk Management protocol	descriptive	

	Show the field ONLY if: [phq9_9] = '3' or [phq9_ 9] = '2' or [phq9_9] = '1'		
666	[base_phq9_total_score] Show the field ONLY if: [phq9_win_past_wk] = '0'	PHQ-9 Total Score:	calc Calculation: [base_phq9_1]+ [base_phq9_2]+[base_phq9_3]+ [base_phq9_4]+[base_phq9_5]+ [base_phq9_6]+[base_phq9_7]+ [base_phq9_8]+[base_phq9_9] Custom alignment: LV
667	[base_phq9_how_difficult] Show the field ONLY if: [phq9_win_past_wk] = '0'	If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	radio 1 1- Not difficult at all 2 2- Somewhat difficult 3 3- Very difficult 4 4- Extremely difficult
668	[base_se_1]	Section Header: <i>Side Effect</i> 1. Have you had any side effects from any of your medications?	yesno 1 Yes 0 No
669	[base_se1_name] Show the field ONLY if: [base_se_1] = '1'	Please list the Side Effect?	text BIOPORTAL:SNOMEDCT BIOPORTAL:SNOT
670	[base_se1_curr_sev] Show the field ONLY if: [base_se_1] = '1'	Current Severity (how bad is it now?) Would you say that it's mild, moderate, or severe?	radio 1 Mild 2 Moderate 3 Severe Custom alignment: LV
		If clarification is needed: Mild: Discomfort noticed, but no disruption of normal daily activityModerate: Discomfort sufficient to reduce or affect normal daily activitySevere: Incapacitating, with inability to work or to perform normal daily activity	
671	[base_se1_onset] Show the field ONLY if: [base_se_1] = '1'	Onset Date (When did it start?)	text (date_mdy)
672	[base_se1_ongoing] Show the field ONLY if: [base_se_1] = '1'	Is it still going on?	yesno 1 Yes 0 No
673	[base_se1_end] Show the field ONLY if: [base_se1_ongoing] = '0'	End Date (When did it stop?)	text (date_mdy)
674	[base_se2_name]	Section Header:	text

	Show the field ONLY if: [base_se_1] = '1'	Please list the next side effect?	BIOPORTAL:SNOMEDCT BIOPORTAL:SNOW
675	[base_se2_curr_sev] Show the field ONLY if: [base_se_1] = '1'	Current Severity (how bad is it now?) Would you say that it's mild, moderate, or severe?	radio 1 Mild 2 Moderate 3 Severe Custom alignment: LV
		If clarification is needed: Mild: Discomfort noticed, but no disruption of normal daily activityModerate: Discomfort sufficient to reduce or affect normal daily activitySevere: Incapacitating, with inability to work or to perform normal daily activity	
676	[base_se2_onset] Show the field ONLY if: [base_se_1] = '1'	Onset Date (When did it start?)	text (date_mdy)
677	[base_se2_ongoing] Show the field ONLY if: [base_se_1] = '1'	Is it still going on?	yesno 1 Yes 0 No
678	[base_se2_end] Show the field ONLY if: [base_se2_ongoing] = '0'	End Date (When did it stop?)	text (date_mdy)
679	[base_se3_name] Show the field ONLY if: [base_se_1] = '1'	Section Header: Please list the next side effect?	text BIOPORTAL:SNOMEDCT BIOPORTAL:SNOW
680	[base_se3_curr_sev] Show the field ONLY if: [base_se_1] = '1'	Current Severity (how bad is it now?) Would you say that it's mild, moderate, or severe?	radio 1 Mild 2 Moderate 3 Severe Custom alignment: LV
		If clarification is needed: Mild: Discomfort noticed, but no disruption of normal daily activityModerate: Discomfort sufficient to reduce or affect normal daily activitySevere: Incapacitating, with inability to work or to perform normal daily activity	
681	[base_se3_onset] Show the field ONLY if: [base_se_1] = '1'	Onset Date (When did it start?)	text (date_mdy)
682	[base_se3_ongoing]	Is it still going on?	yesno

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	Show the field ONLY if: [base_se_1] = '1'		1 Yes
			0 No
683	[base_se3_end]	End Date (When did it stop?)	text (date_mdy)
	Show the field ONLY if: [base_se3_ongoing] = '0'		
684	[base_se4_name]	Section Header:	text
	Show the field ONLY if: [base_se_1] = '1'	Please list the next side effect?	BIOPORTAL:SNOMEDCT BIOPORTAL:SNOM
685		Current Severity (how bad is it now?)	radio
	Show the field ONLY if:		1 Mild
	[base_se_1] = '1'		2 Moderate
		Would you say that it's mild, moderate, or	3 Severe
		severe?	S Severe
			Custom alignment: LV
		If clarification is needed:	
		Mild: Discomfort noticed, but no disruption of normal daily activityModerate: Discomfort sufficient to reduce or affect normal daily activitySevere: Incapacitating, with inability to work or to perform normal daily activity	
686	[base_se4_onset]	Onset Date (When did it start?)	text (date_mdy)
	Show the field ONLY if: [base_se_1] = '1'		
687	[base_se4_ongoing]	Is it still going on?	yesno
	Show the field ONLY if:		1 Yes
	[base_se_1] = '1'		0 No
688	[base_se4_end]	End Date (When did it stop?)	text (date_mdy)
	Show the field ONLY if: [base_se4_ongoing] = '0'		
689	[base_se5_name]	Section Header:	text
	Show the field ONLY if: [base_se_1] = '1'	Please list the next side effect?	BIOPORTAL:SNOMEDCT BIOPORTAL:SNOM
690	[base_se5_curr_sev]	Current Severity (how bad is it now?)	radio
	Show the field ONLY if:		1 Mild
	[base_se_1] = '1'		2 Moderate
		Would you say that it's mild, moderate, or severe?	3 Severe
			Custom alignment: LV
1			

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		Mild: Discomfort noticed, but no disruption of normal daily activityModerate: Discomfort sufficient to reduce or affect normal daily activitySevere: Incapacitating, with inability to work or to perform normal daily activity			
691	[base_se5_onset] Show the field ONLY if: [base_se_1] = '1'	Onset Date (When did it start?)	text (date_mdy)		
692	[base_se5_ongoing] Show the field ONLY if: [base_se_1] = '1'	Is it still going on?	yesno 1 Yes 0 No		
693	[base_se5_end] Show the field ONLY if: [base_se5_ongoing] = '0'	End Date (When did it stop?)	text (date_mdy)		
694	[base_adherence_1]	Section Header: Expectations for Adherence 1. Do you anticipate having any problems taking the antidepressant we prescribe daily?	yesno 1 Yes 0 No		
695	[base_adherence_2]	2. Can you think of anything that might make it difficult for you to take the medication every day without missing doses?	yesno 1 Yes 0 No		
696	[base_adherence_3] Show the field ONLY if: [base_adherence_2] = '1' or [base_adherence_ 1] = '1'	Describe & provide adherence counseling as needed *Note: procedures not yet developed	notes		
697	[base_fall_1]	Section Header: Falls 1. In the past six months, how many times have you had a fall, including a slip or trip in which you lost your balance and landed on the floor or ground or lower level?	radio 1 Zero (0) 2 One time (1) 3 Two times (2) 4 Three or more (>2)		
698	[base_fall_2] Show the field ONLY if: [base_fall_1] = '2' or [ba se_fall_1] = '3' or [base_ fall_1] = '4'	2. Did any of your falls result in the following? (check all that apply)	checkbox 1 base_fall_21 1. No injury 2 base_fall_22 2. Minor bruising or cuts 3 base_fall_23 3. Reduced mobility 4 base_fall_24 4. Severe and persistent pain 5 base_fall_25 5. Injury		
699	[base_fall_3] Show the field ONLY if: [base_fall_1] = '2' or [ba se_fall_1] = '3' or [base_ fall_1] = '4'	Description:	notes		

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70	[baseline_forms_compl ete]	Section Header: Form Status Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete
nstrui	ment: ATHF Form1 (at	hf_form1_treatments_110)	[collapsed]
	ment: Alcohol Use Disconding	orders Identification Test (AUDIT)	[collapsed]
		Needed - Treatments 11-20) (athf_form	<u> </u>
mstrui	ment. ATHF FOTHIZ (II I	veeded - Heatments 11-20) (atm_form	z_n_needed_treatments_1120) [collapsed
nstrui	ment: ATHF Form3 (If I	Needed - Treatments 21-30) (athf_form	3_if_needed_treatments_2130) [collapsed
nstrui	ment: ATHF Form4 (If I	Needed - Treatments 31-40) (athf_form	4_if_needed_treatments_3140) [collapsed
nstrui	ment: Contact Informa	ation Form (contact_information_form)	[collapsed
nstrui	ment: Participant Trac	king Form (participant_tracking_form)	[collapsed
nstrui	ment: Decision Suppor	rt Form (decision_support_form)	
35	550[decision_d]	Review the following information in the tracking arm: patient name, contact info, preferred contact	descriptive
		method, contact log medication list (specifically psychiatric medications) running side effect list running adverse event list physician name, contact info, preferred contact method, contact log	
35	[decision_date]	Date:	text (date_mdy), Required
35	552[decision_rater]	Rater	text, Required
35	55 3 [phq9 _1]	Section Header: The Patient Health Questionnaire (PHQ-9) Over the last 2 weeks how often have you been bothered by any of the following problems? (Click the circle to indicate your answer) 1. Little interest or pleasure in doing things	radio 0 0- Not at all 1 1- Several days 2 2- More than half the days 3 3- Nearly every day
35	554 [phq9_2]	2. Feeling down, depressed, or hopeless	radio 0 0- Not at all 1 1- Several days 2 2- More than half the days 3 3- Nearly every day
35	555 [phq9_3]	3. Trouble falling or staying asleep, or sleeping too much	radio 0 0- Not at all 1 1- Several days

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			2 2- More than half the days	
			3 3- Nearly every day	
355	56 [phq9_4]	4. Feeling tired or having little energy	radio	
		3 3	0 0- Not at all	
			1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
355	7 [phq9_5]	5. Poor appetite or overeating	radio	
	Levide Ze 3	and the same of th	0 0- Not at all	
			1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
355	5 8 [phq9_6]	6. Feeling bad about yourself or that you	radio	
		are a failure or have let yourself or your	0 0- Not at all	
		family down	1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
355	59 [phq9_7]	7. Trouble concentrating on things, such as reading the newspaper or watching television	radio	
			0 0- Not at all	
			1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
356	0 [phq9_8]	8. Moving or speaking so slowly that other people could have noticed? Or the opposite being so fidgety or restless that you have been moving around a lot more than usual	radio	
			0 0- Not at all	
			1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
356	51 [phq9_9]	9. Thoughts that you would be better off	radio	
		dead or of hurting yourself in some way	0 0- Not at all	
			1 1- Several days	
			2 2- More than half the days	
			3 3- Nearly every day	
356	52 [phq9_suicide] Show the field ONLY if: [phq9_9] = '3' or [phq9_ 9] = '2' or [phq9_9] = '1'	For any score > 0 on #9, conduct Suicide Risk Management protocol	descriptive	
356	3[phq9_total_score]	PHQ-9 Total Score:	calc Calculation: [phq9_1]+[phq9_2]+[phq9_3]+ [phq9_4]+[phq9_5]+[phq9_6]+[phq9_7]+ [phq9_8]+[phq9_9]	

3564	1[phq9_how_difficult]	If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	radio 1 1- Not difficult at all 2 2- Somewhat difficult 3 3- Very difficult 4 4- Extremely difficult		
3565	[decision_se_1]	Section Header: <i>Side Effect</i> 1. Have you had any side effects in the past	yesno 1 Yes		
		week from your antidepressant?	0 No		
3566	[decision_se_y]	If Yes, access and add to running list in	descriptive		
	Show the field ONLY if: [decision_se_1] = '1'	tracking arm.			
3567	[decision_se_2]	2. Given the side effect (s) you told me about, would you be comfortable with continuing at	radio		
	Show the field ONLY if: [decision_se_1] = '1'	this dose?	1 Yes		
	[uccision_sc_1] = 1		0 No 2 Unsure		
25.00	25.1	2 (16 side offs the said a days in succession			
3500	I decision_se_3 I Show the field ONLY if:	3.(If side effects and a dose increase is otherwise warranted) Given the side effect (s)	radio 1 Yes		
	[decision_se_1] = '1'	you told me about, would you be comfortable with increasing this dose?	0 No		
			2 Unsure		
3569	[decision_change_1]	Section Header: Health and Medical Changes	yesno		
		1. Have you had any new problems with your health since we last spoke with you?	1 Yes		
			0 No		
3570	[decision_change_1y]	If Yes, access and add to running AE list in tracking arm.	descriptive		
	Show the field ONLY if: [decision_change_1] = '1'	tracking arm.			
357	[decision_change_2]	2. Have you seen a medical professional since	yesno		
		we last talked with you?"	1 Yes		
			0 No		
3572	2[decision_change_2y]	Reason for visit: "What for"?	text		
	Show the field ONLY if: [decision_change_2] = '1'				
3573	B[desicision_change_3]	3. Have you had any medication changes since we last talked with you?	yesno		
		Since we last tained with you:	1 Yes 0 No		
257	15 dicicion abores 2013	If Voc. undate medication list in tracking arm			
<i>3</i> 3/4	[dicision_change_3y] Show the field ONLY if:	If Yes, update medication list in tracking arm.	descriptive		
	[desicision_change_3] =				

			· // ·	
3575	[desicion_change_4]	4. Have you had any medical procedures since we last talked with you?	yesno 1 Yes 0 No	
3576	Show the field ONLY if: [desicion_change_4] = '1'	If Yes, access and add to running AE list in tracking arm.	descriptive	
3577	<code>7[decision_change_5]</code>	5. Note specific details from the patient and follow up with physician and or medical records if unclear:	notes	
3578	<pre>B[decision_alc_cons_te xt]</pre>	Section Header: Alcohol Consumption 1. How many drinks containing alcohol did you have in the last week (7 days)? Record a numeric response of the patient's best estimation. Probe for specifics if needed on frequency, # of drinks, and volume estimations. Document any additional pertinent information in the comments field and report to study psychiatrist any amount greater than 7 drinks in a week.	descriptive	
3579	[decision_num_drinks]	Number of drinks	text (number)	
3580)[decision_alc_cons_comm]	Comments:	notes Custom alignment: LV	
3581	[decision_fall_1]	Section Header: <i>Falls</i> 1. Have you had any falls since your last assessment? A fall is defined as a slip or trip in which you lost your balance and landed on the floor or ground or lower level.	radio 1 Zero (0) 2 One time (1) 3 Two times (2) 4 Three or more (>2)	
3582	Show the field ONLY if: [decision_fall_1] = '2' or [decision_fall_1] = '3' or [decision_fall_1] = '4'	2. Did any of your falls result in the following?	checkbox 1 decision_fall_21 1. No injury 2 decision_fall_22 2. Minor bruising or cuts 3 decision_fall_23 3. Reduced mobility 4 decision_fall_24 4. Severe and persistent pain 5 decision_fall_25 5. Injury	
3583	Show the field ONLY if: [decision_fall_2(3)] = '1' or [decision_fall_2(4)] = '1' or [decision_fall_2 (5)] = '1'	Please add the Fall to the AE form!	descriptive	
3584	1[decision_fall_5] Show the field ONLY if:	NO NEED to add the Fall to the AE form!	descriptive	

	[decision_fall_2(1)] = '1' or [decision_fall_2(2)] = '1'		
3585	Show the field ONLY if: [decision_fall_1] = '2' or [decision_fall_1] = '3' or [decision_fall_1] = '4'	Description:	notes
3586	[adherence_1]	Section Header: Adherence 1. Review the decisional support provided at the last assessment with the participant: SAY "At your last assessment, we recommended that your doctor continue/ reduce/ increase your dose of to mg per day (if applicable - while continuing to take mg of)."	descriptive
3587	[adherence_2]	2. Did you receive the recommended medication and dose?	yesno 1 Yes 0 No
3588	S [adherence_2_d] Show the field ONLY if: [adherence_2] = '0'	Describe and problem solve any barriers to obtaining medication:	notes
3589	adherence_3]	3. Since your last assessment, how often did you miss your recommended dose of each medication?	descriptive
3590	[adherence_3_med1]	Section Header: Recommended medication 1 Drug name	text BIOPORTAL:RXNORM BIOPORTAL:RXNORM
359°	[type_in_rec_med1]	Please type in the drug name.	text
3592	[adherence_3_dose1]	Recommended dose	text
3593	[adherence_3_unit1]	Unit	dropdown 1 g 2 kg 3 mcg 4 mg 5 mL 6 tab 7 tabs 8 tbsp 9 tsp 10 L 11 umol 12 mmol 13 ng

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					14	puff
					15	drop
					16	IU
					17	, %
					18	mEq
-	3	594	[adherence_3_freq1]	Frequency	dro	pdown
			[uuner enee_5_11 eq1]	, requestey		Not taking it at all (missed all doses)
					-	Missed dose more often than not
					3	Missed dose more often than 2 times a week
					1	Missed dose more often than 1 time
						a week
					5	Missed dose 1 time a week
					6	Missed dose less than 1 time a week
					7	Never missed a dose
	3	595	[adherence_3_med2]	Section Header: Recommended medication 2	tex	t
				Drug name	ВІ	OPORTAL:RXNORM BIOPORTAL:RXNOR
	3	596	[type_in_rec_med2]	Please type in the drug name.	tex	t
	3	597	[adherence_3_dose2]	Recommended dose	tex	t
	3	598	[adherence_3_unit2]	Unit	dro	pdown
					1	g
					2	kg
					3	mcg
					4	mg
					5	mL
					6	tab
					7	tabs
					8	tbsp
					9	tsp
					10	L
					11	umol
					12	mmol
					13	g
					14	puff
					15	drop
					16	IU
					17	%
					18	mEq
	3	599	[adherence_3_freq2]	Frequency	dro	ppdown
		- 1		•	•	,

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			1 Not taking it at all (missed all doses)
			2 Missed dose more often than not
			3 Missed dose more often than 2 times a week
			4 Missed dose more often than 1 time a week
			5 Missed dose 1 time a week
			6 Missed dose less than 1 time a week
			7 Never missed a dose
36	OO [adherence_4]	4.Have you been taking a different antidepressant medication instead of or in addition to the ones we recommended?	yesno 1 Yes 0 No
36	O1[adherence_4_name]	Name of medication	text
	Show the field ONLY if: [adherence_4] = '1'	Name of medication	BIOPORTAL:RXNORM BIOPORTAL:RXNOR
360	02[adherence_5]	5. Have you been taking a different dose of the medication than what we recommended?	yesno 1 Yes 0 No
36	03[adherence_5_dose]	Dose	text
	Show the field ONLY if: [adherence_5] = '1'	mg	
36	04[adherence_comments]	Comments	notes
36	05[tip]	Treatment Initiation and Participation (TIP) as needed	descriptive
36	O6[phq9_total_score_cop y]	Section Header: Decision Support Recommendation PHQ-9 Total Score:	calc Calculation: [phq9_1]+[phq9_2]+[phq9_3]+ [phq9_4]+[phq9_5]+[phq9_6]+[phq9_7]+ [phq9_8]+[phq9_9]
36	07[dose_chg_table]	Please use this table to determine what dose change, if any, is needed.	descriptive
36	08[decision_rec_dose1_n	Section Header: Documentation of Recommendation	text
	ame]	Recommended Medication 1:	BIOPORTAL:RXNORM BIOPORTAL:RXNOR
36	09[rec_med1]	Please type in Recommended Medication 1	text
36	10[decision_rec_dose1]	Recommended Medication 1:	radio 1 Increase dose 2 Continue taking 3 Reduce dose 4 Stop taking 5 Start taking
36	11 [decision_rec_dose1_ 1]	Increase dose of Med. 1 to mg	text (number)
	Show the field ONLY if:		

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	[decision_rec_dose1] = '1'		
3612	2 [decision_rec_dose1_ 2] Show the field ONLY if: [decision_rec_dose1] = '2'	Continue taking Med. 1 atmg	text (number)
3613	[decision_rec_dose1_3] Show the field ONLY if: [decision_rec_dose1] = '3'	Reduce dose of Med. 1 tomg	text (number)
3614	[decision_rec_dose2_n ame]	Recommended Medication 2:	text BIOPORTAL:RXNORM BIOPORTAL:RXNO
3615	[rec_med2]	Please type in Recommended Medication 2	text
3616	[decision_rec_dose2]	Recommended Medication 2:	radio 1 Increase dose 2 Continue taking 3 Reduce dose 4 Stop taking 5 Start taking
3617	[decision_rec_dose2_ 1] Show the field ONLY if: [decision_rec_dose2] = '1'	Increase dose of Med. 2 to mg	text (number)
3618	Show the field ONLY if: [decision_rec_dose2] = '2'	Continue taking Med. 2 atmg	text (number)
3619	[decision_rec_dose2_ 3] Show the field ONLY if: [decision_rec_dose2] =	Reduce dose of Med. 2 tomg	text (number)
3620	[decision_check]	Section Header: Decision Support Checklist Decision Support Checklist	checkbox 1 decision_check1 Communicated with study Dr. regarding patient status and dose recommendation 2 decision_check2 Communicated dose recommendation to patient

				3	decision_check3	Patient verbalized understanding and agreement with dose recommendation
				4	decision_check4	Communicated dose recommendation and patient status to provider
				5	decision_check5	Provider or representative acknowledged receipt of recommendation
	362	[decision_check_com]	Method of Communication	che	eckbox	
		Show the field ONLY if:		1	decision_check_cor	m1 via EHR
		[decision_check(4)] = '1'		2	decision_check_cor	n2 via fax
				3	decision_check_cor	m3 via e-mail
				4	decision_check_cor	m4 via phone
	3622	<code>?[decision_note]</code>	Decision Support Note:	no	tes	<u> </u>
	3623	B[date_next_call]	Section Header:	tex	t (date_mdy)	
			Date of next Decision Support Call			
	3624	[decision_support_for	Section Header: Form Status	dro	ppdown	
		<pre>m_complete]</pre>	Complete?	0	Incomplete	
				1	Unverified	
				2	Complete	
Inst	rum	ent: Suicide Risk Ma	nagement Protocol (SRMP) (suicide_ris	k_m	anagement_protoc	ol_srmp) [collapsed]
Inst	rum	ent: Blinded SRMP (suicide_risk_management_protocol_srmp_2)			[collapsed]
Inst	rum	ent: NIH Toolbox Fol	lowup (nih_toolbox_followup)			[collapsed]
Inst	rum	ent: Spontaneous Re	eport of Side Effects V2 (spontaneous_re	por	t_of_side_effects_v2	2) [collapsed]
Inst	rum	ent: Adverse Event \	/2 (adverse_event_v2)			
	3865	[adverse_d_v2]	See OPTIMUM Study Protocol for Adverse Event definitions and reporting procedures. The Redcap database will be the primary method for documenting Adverse Events. The presence of Adverse Events will be assessed at each timepoint by asking whether the patient has had any new problems with their health, but new AE's should be documented promptly if they occur between timepoints. If clarification is needed: Mild: Discomfort noticed, but no disruption of normal daily activityModerate: Discomfort	des	scriptive	

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		sufficient to reduce or affect normal daily activitySevere: Incapacitating, with inability to work or to perform normal daily activity Note that determining expectedness should take into account the product information AND the population under study (depressed older adults).		
	3866[date_ae_entered]	Section Header:	text (date_mdy)
		Date Entered		
	3867 [ae_rater]	Documented by:	text	
	3868[reference_guide]	Reference Guide		riptive
	3869[ae_title]	Section Header: Brief title for AE NOTE: PLEASE DO NOT ENTER INTO THIS FIELD ANYMORE. THIS FIELD WILL SOON BE DEACTIVATED.	text Field	Annotation: @HIDDEN
	3870[uku_sym_cat]	Symptom Category (UKU)		down, Required
			20	Accommodation Disturbances
			16	Akathesia
			38	Amenorrhea
				Asthenia/Lassitude/Increased Fatiguability
			40	Breast Enlargement
			52	Cold/Flu Symptoms
			1	Concentration Difficulties
			25	Constipation
			60	COVID-19
				Decreased Appetite Without Weight Loss
			24	Diarrhea
			42	Diminished Sexual Desire
			55	Dizziness
			46	Dry Vagina
			11	Dystonia
			44	Ejaculatory Dysfunction
			10	Emotional Indifference
			17	Epileptic Seizures
			43	Erectile Dysfunction
			4	Failing Memory
			56	Fall
			39	Galactorrhea
			19	Headache
			49	Hospitalization (non-psychiatric)
			48	Hospitalization (psychiatric)

26/24,	11:07 A	M	OPTIMUM Main Database (Fina	I) RE	DCap
				50	Hospitalization (With Surgery)
				14	Hyperkinesia
				13	Hypokinesia/Akinesia
				57	Increased Appetite Without Weight Gain
				9	Increased Dream Activity
				7	Increased Duration of Sleep
				34	Increased Pigmentation
				21	Increased Salivation
				41	Increased Sexual Desire
				30	Increased Tendency to Sweating
				58	Irritability or Emotional Lability
				37	Menorrhagia
				26	Micturition Disturbances
				23	Nausea/Vomiting
				45	Orgasmic Dysfunction
				59	Outpatient Surgery
				29	Palpitations/Tachycardia
				18	Paraesthesias
				33	Photosensitivity
				27	Polyuria/Polydipsia
				32	Pruritus
				31	Rash
				8	Reduced Duration of Sleep
				22	Reduced Salivation (Dryness of Mouth)
				12	Rigidity
				3	Sleepiness/Sedation
				6	Tension/Inner Unrest
				15	Tremor
				35	Weight Gain
				36	Weight Loss (Baseline=0)
				47	Other Side Effect That Does Not Fit Any Above
	387	[sae_text]	PLEASE RECORD THIS AS AN SAE.	desc	riptive
		Show the field ONLY if: [uku_sym_cat] = '48' or [uku_sym_cat] = '49' or [uku_sym_cat] = '50'			
	3872	[psychic_side_effect 1]	Difficulties in ability to concentrate, to collect one's thoughts, or sustain one's attention.	radio	0
,			1	l	

		Of Thirow Main Database (Fina	, ,	- I
	Show the field ONLY if: [uku_sym_cat] = '1'		1	1: The patient must try harder than usual to collect his/her thoughts, but not to the degree that it hampers the patient in his everyday life.
			2	2: The difficulties in concentrating are pronounced enough to hamper the patient in his everyday life.
			3	3: The patient's difficulties in concentrating are obvious to the interviewer during the interview.
			Cu	stom alignment: LV
387	[psychic_side_effect	The patient's experience of lassitude and lack	rac	lio
	Show the field ONLY if: [uku_sym_cat] = '2'	of endurance. The assessment is based upon the patient's reported statements.	1	1: The patient tires more easily than usual; however, this does not mean that the patient needs to rest more than usual during the day.
			2	2: Must rest now and then during the day because of lassitude.
			3	3: Must rest most of the day because of lassitude.
			Cu	stom alignment: LV
3874	74[psychic_side_effect	Diminished ability to stay awake during the	rac	lio
	3] Show the field ONLY if:	day. When possible, the assessment is based on clinical signs during the interview.	1	1: Slightly sleep/drowsy as regards facial expression and speech.
	[uku_sym_cat] = '3'		2	2: More markedly sleepy/drowsy. The patient yawns and tends to fall asleep when there is a pause in the conversation.
			3	3: Difficult to keep the patient awake and to wake the patient, respectively.
			Cu	stom alignment: LV
387	[psychic_side_effect	Impaired memory. Assessment should be	rac	lio
	4] Show the field ONLY if: [uku_sym_cat] = '4'	independent of any concentration difficulties.	1	1: Slight, subjective feeling of reduced memory compared with the patient's usual condition; however, not interfering with functioning.
			2	2: The failing memory hampers the patient and or slight signs of this are observed during the interview.
			3	3: The patient shows clear signs of failing memory during the interview.
			Cu	stom alignment: LV

3876	[psychic_side_effect 6] Show the field ONLY if: [uku_sym_cat] = '6'	Inability to relax, nervous restlessness. This item is to be assed on the basis of the patient's experience and must be distinguished from motor akathesia.	radio 1 1: The patient states that he is slightense and restless; however, this does not interfere with his
	[functioning. 2 2: Considerable tension and inner unrest; however, without this being so intense or constant that the patient's daily life is influenced to a marked degree.
			3 3: The patient feels tension or restlessness that is so marked that his daily life is clearly affected.
			Custom alignment: LV
3877	[psychic_side_effect	This should be assessed on the basis of the	radio
	7] Show the field ONLY if:	average of sleep over three preceding nights. The assessment is to be made in relation the patient's usual pre-illness state.	1 1: Sleep up to 2 hours longer than usual.
	[uku_sym_cat] = '7'	patient's usual pre-limess state.	2 2: Sleeps 2 or 3 hours longer than usual.
			3: Sleeps more than 3 hours longe than usual.
			Custom alignment: LV
3878	[psychic_side_effect	Should be assessed on the basis of the average of sleep over the preceding nights. The assessment is to be made in relation to the patient's usual pre-illness state.	radio
	Show the field ONLY if: [uku_sym_cat] = '8'		1 1: Sleep up to 2 hours shorter thar usual.
			2 2: Sleeps 2 or 3 hours shorter than usual.
			3: Sleeps more than 3 hours shorted than usual.
			Custom alignment: LV
3879	[psychic_side_effect	Should be assessed independently of dream	radio
	Show the field ONLY if:	content and based on the average of sleep over the preceding nights in relation to the usual pre-illness dream activity.	1 1: Slightly increase dream activity, which does not disturb the nights sleep, however.
	[uku_sym_cat] = '9'		2 2: More pronounced increase of dream activity.
			3 3: Very pronounced increase of dream activity.
			Custom alignment: LV
3880	[psychic_side_effect1	A diminution of the patient's empathy,	radio
	O] Show the field ONLY if:	leading to apathy.	1 1: Slight subduing of the patient's empathy.
	[uku_sym_cat] = '10'		2 2: Obvious emotional indifference.
			3 3: Pronounced indifference so that the patient behaves apathetically in

		,		relation to his surroundings.
			Cu	stom alignment: LV
3881	[neuro_side_effect11]	Acute forms of dystonia in the forms of tonic	rac	lio
	Show the field ONLY if: [uku_sym_cat] = '11'	muscular contractions localized to one or several muscle groups, particularly in the mouth, tongue, and/or neck. The assessment is to be made on the basis of the last seven	1	1: Very slight or short spasms, for instance in the musculature of the jaws or neck.
		days preceding the examination.	2	2: More pronounced contractions of a longer duration and/or a wider localization.
			3	3: Marked forms of, for instance, oculogyric crisis or opisthotonos.
			Cu	stom alignment: LV
3882	<pre>2[neuro_side_effect12]</pre>	Increased muscle tone of a uniform and	rac	lio
	Show the field ONLY if: [uku_sym_cat] = '12'	general nature, observed on the basis of a uniform, steady resistance to passive movements of the limbs. Special importance is attached to the muscles around the elbow joints and shoulders.	1	1: Slight rigidity in neck, shoulder, and extremities. It must be possible to observe the rigidity on the basis or resistance to passive movements of the elbow joints.
			2	2: Medium rigidity assessed on the basis of resistance to passive movements of for instance the elbow joints.
			3	3: Very marked rigidity.
				stom alignment: LV
3883	[neuro_side_effect13]	Slow movements (bradykinesia), reduced	rac	lio
	Show the field ONLY if: [uku_sym_cat] = '13'	facial expression, reduced arm swinging, reduced length of stride, perhaps leading to cessation of movement (Akinesia).	1	1: Slights reduced movement, for instance slightly reduced swinging of an arm when walking or slightly reduced facial expression.
			2	2: More clear reduction of mobility, for instance slow walking.
			3	3: Very marked reduction of mobility, bordering on and including akinesia, e.g. Parkinsonian mask and/or very short length of stride.
			Cu	stom alignment: LV
3884	[neuro_side_effect14]	Involuntary movements, most frequently	rac	lio
	Show the field ONLY if: [uku_sym_cat] = '14'	affecting the oro-facial region in the form of the so-called bucco-lingual-masticatory	1	1: Slight hyperkinesias. Only present intermittently.
		syndrome. However, it is often also seen in the extremities, especially the finger, more rarely in the musculature of the body and respiratory system. Both initial and tardive hyperkinesias are included.	2	2: Moderate hyperkinesias present most of the time.
			3	3: Severe hyperkinesias, present most of the time with marked tongue protrusion, opening of the mouth, facial hyperkinesia, with or without involvement of the extremities.

			Custom alignment: LV
3885	[neuro_side_effect15]	This item comprises all forms of tremor.	radio
	Show the field ONLY if: [uku_sym_cat] = '15'		1 1: Very slight tremor that does not hamper the patient.
			2 2: Clear tremor hampering the patient. The amplitude of finger tremor being less than 3 cm.
			3 3: Clear tremor with an amplitude of more than 3 cm and which cannot be controlled by the patient.
			Custom alignment: LV
3886	[neuro_side_effect16]	A subjective felling and objective signs of	radio
	Show the field ONLY if: [uku_sym_cat] = '16'	muscle unrest, particularly in the lower extremities, so that it may be difficult for the patient to remain seated. Assessment of this	1 1: Slight akathesia; however, the patient can keep still without effort.
		item is based on clinical signs observed during the interview, as well as on the patient's report.	2 2: Moderate akathesia; however, the patient can, with an effort, remain sitting during the interview.
			3: When the patient has to rise to his feet several times during the interview because of akathesia.
			Custom alignment: LV
3887	[neuro_side_effect17] Show the field ONLY if:	Only generalized tonic-clonic seizures are to be recorded here.	radio 1 1: One seizure within the last six
	[uku_sym_cat] = '17'		months. 2 2: 2 or 3 seizures within the last six
			months. 3 3: More than 3 seizures within the
			last six months. Custom alignment: LV
2000)	Drieling cropping or burning constitions in	radio
3000	Ineuro_side_effect18] Show the field ONLY if: [uku_sym_cat] = '18'	Pricking, creeping, or burning sensations in the skin.	1 1: Mild paraethesias, scrarely bothering the patient.
	[uku_sylli_cat] = 10		2 2: Moderate paraesthesias, clearly bothering the patient.
			3 3: Sever paraesthesia, markedly bothering the patient.
			Custom alignment: LV
3889	[neuro_side_effect19]		radio
	Show the field ONLY if:		1 1: Slight headache.
	[uku_sym_cat] = '19'		2 2: Moderate hampering headache which does not interfere with the patient's daily life.

				3 3: Pronounced headache interfering with the patient's daily life.
				Custom alignment: LV
	389([autonomic_side_effec t20] Show the field ONLY if: [uku_sym_cat] = '20'	Difficulty in seeing clearly or distinctly at close quarters (with or without glasses), whereas the patient sees clearly in a long distance. If the patients uses bifocal glasses, the condition must be asses on the basis of the use of the distance glasses.	 radio 1 1: Newspaper text can be read, but the patient's eyes tire rapidly and/or he must hold the paper further away. 2 2: The patient cannon read an ordinary newspaper text, but still manages to read texts printed in
				larger types. 3 3: The patient can read large type, such a as headlines, only with aid, such as a magnifying glass.
				Custom alignment: LV
:	389 ¹	[autonomic_side_effec	Increased, non-stimulated salivation.	radio
		t21] Show the field ONLY if:		1 1: Salivation clearly increased, but not bothersome.
		[uku_sym_cat] = '21'		2 2: Disturbing increase of salivation; need for spitting or frequent swallowing of saliva; only exceptional dribbling, perhaps concomitant speech disturbances.
				3 3: Frequent or constant dribbling, perhaps concomitant speech disturbances
				Custom alignment: LV
	3892	2[autonomic_side_effec	Dryness of mouth because of diminished salivation. May result in increased	radio
		t22] Show the field ONLY if:	consumption of liquids, buy must be distinguished from thirst.	1 1: Slight dryness of mouth not disturbing to the patient.
		[uku_sym_cat] = '22'		2 2: Moderate and slightly disturbing dryness of mouth.
				3 3: Dryness of mouth which clearly disturbs the patient's daily life.
				Custom alignment: LV
	3893	B[autonomic_side_effec	To be recorded on the basis of the last seven	radio
		t23]	days.	1 1: Slight nausea.
		Show the field ONLY if: [uku_sym_cat] = '23'		2 2: Disturbing nausea, but without vomiting.
				3 3: Nausea and vomiting.
				Custom alignment: LV
:	3894	1[autonomic_side_effec	Increased frequency and/or thinner	radio
		t24] Show the field ONLY if:	consistency of feces.	1 1: Clearly present, but does not disturb work, or other performance.

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		[uku_sym_cat] = '24'		2	2: Disturbing, with need for several daily, inconvenient stools.
				3	3: Marked, imperative need for defecation, threatening or actual incontinence, results in frequent interruptions of work.
				Cu	stom alignment: LV
	389	[autonomic_side_effec	Reduced frequency of defecation and/or	rac	lio
		t25] Show the field ONLY if:	thicker consistence of feces. (rate on pts response & if on laxative add 1 point)	1	1: Slight constipation, but bearable. (if take fiber = 1)
		[uku_sym_cat] = '25'		2	2: More marked constipation which hampers the patient. (slight constipation on laxative =2)
				3	3: Very pronounced constipation.
				Cu	stom alignment: LV
	3896	[autonomic_side_effec	Feeling of difficulty in starting and of	rac	lio
		t26]	resistance to micturition, weaker stream and/or increased time of nicturition. Should	1	1: Clearly present, but bearable.
		Show the field ONLY if: [uku_sym_cat] = '26'	be assessed on the basis of the last 7 days.	2	2: Poor stream, considerable increased time of micturition, feeling of incomplete emptying of bladder.
				3	3: Retention of urine with high volume residual urine and/or threatened or actual or acute retention.
				Cu	stom alignment: LV
	3897	[autonomic_side_effec	Increased urine production resulting in	rac	lio
		t27] Show the field ONLY if: [uku_sym_cat] = '27'	inreaced frequency of miturition and discharge of an abundant quantity of urine at each micturiton; secondarily increased	1	1: Clearly present, but not hampering. Nocturia: At most once per night (in young people.
			consumption of fluid.	2	2: Moderately hampering because of frequent thirst, nocturia two or three times a night, or micturition more frequent than every two hours.
				3	3: Very hampering, almost constant thirst, nocturia at least four times a night, or micturition at least every hour.
				Cu	stom alignment: LV
	3898	B[autonomic_side_effec	Palpitations, feeling of rapid, strong and/or	rac	_
	3030	t29] Show the field ONLY if: [uku_sym_cat] = '29'	irregular heartbeats.	1	1: Clearly present, but not hampering, only short occasional attacks or more constant, but not marked palpitations.
				2	2: Hampering frequent or constant palpitations that worries the patient

			or disturbs his night's sleep; however, without concomitant symptoms.
			3 3: Suspicion of real tachycardia, for instance because of concomitant feeling of weakness and need to lie down, dypsnea, tendency to fainting, or precordial pain.
			Custom alignment: LV
3899	[autonomic_side_effec	Localized to the whole body, not only palms	radio
	t30] Show the field ONLY if: [uku_sym_cat] = '30'	and soles of the foot.	1 1: Clearly present, but mild, for example a profuse outburst of sweat only after considerable effort.
			2 2: Hampering, requires frequent change of clothes, profuse sweating after moderate activity, for instance walking upstairs.
			3: Profuse outbursts of sweat after slight activity or when resting, the patient is constantly wet, must change clothes several times a day and must also change night clothes or bedclothes.
			Custom alignment: LV
3900	[other_side_effect31]		radio
	Show the field ONLY if: [uku_sym_cat] = '31'		1 1: Localized to less than 5 percent of the skin surface, for instance to the palms.
			2 2: Scattered all over the skin, but covers less than 1/3 of the skin surface.
			3 3: Universal, i.e. covers more than 1/3 of the skin surface.
			Custom alignment: LV
3901	[other_side_effect32]		radio
	Show the field ONLY if:		1 1: Slight pruritus.
	[uku_sym_cat] = '32'		2 2: Pronounced pruritus, so that the patient is being hampered. There may be scratch marks.
			3 3: Severe pruritus that markedly hampers the patient. There are distinct skin changes because of scratching.
			Custom alignment: LV
3902	[other_side_effect33]	Increased sensitivity to sunlight	radio
	Show the field ONLY if: [uku_sym_cat] = '33'		1 1: Slight, but not hampering.
	[

			3	to the patient.
			Cu	stom alignment: LV
3903[other_sid	le_effect34]	Increased skin pigmentation of brown or	rac	lio
	ield ONLY if:	other color, often localized to parts of the	1	1: Slightly increased pigmentation.
[uku_sym_o	cat] = '34'	skin exposed to light.	2	2: Such marked pigmentation, generally or localized, that it worries the patient but is not conspicuous to others.
			3	3: So pronounced that the pigmentation can easily be observed by other people.
			Cu	stom alignment: LV
3904[other_sid	le_effect35]	The rating is to be made on the basis of the	rac	lio
Show the fi	ield ONLY if: cat] = '35'	preceding month. May or may not be associated with increased appetite.	1	1: Weight gain amounting to 1-2 kg during the preceding month.
			2	2: Weight gain amounting to 3-4 kg during the preceding month.
			3	3: Weight gain amounting to more than 4 kg during the preceding month.
			Cu	stom alignment: LV
3905[other_sid	le_effect36]	The rating is to be made on the basis of the	rac	
Show the fi [uku_sym_o	ield ONLY if: cat] = '36'	preceding month. May or may not be associated with reduced appetite.	1	1: Weight loss amounting to 1-2 kg during the preceding month.
			2	2: Weight loss amounting to 3-4 kg during the preceding month.
			3	3: Weight loss amounting to more than 4 kg during the preceding month.
			Cu	stom alignment: LV
3906[other_sid	le_effect37]	Hypermenorrhoea, polymenorrhoea, or	rac	
Show the fi [uku_sym_o	ield ONLY if: cat] = '37'	metrorrhagia during the last 3 months.	1	1: Hypermenorrhoea, i.e. the menstrual flow is more intense than usla, the intervals being normal.
			2	2: Polymenorrhoea, i.e. the menstrual flow occurs more frequently and is more intense than normal.
			3	3: Metrorrhagia, i.e. irregular intervals and intensity, the blood loss being more frequent and intense compared with the usual pattern.

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3907 [other_side Show the fie [uku_sym_c	eld ONLY if:	oomenorrhea, oligomenorrhea, or enorrhea during the last 3 months.	1	1: Hypomenorrhea, i.e. uterine bleeding of less than the normal amount, but occurring at normal intervals.
			2	2: Oligomenorrhea, i.e. prolonged intervals compared with the usual condition; the intensity may also be lower than usual.
			3	3: Amenorrhea, i.e. menstruation has been absent for more than 3 months
			Cu	stom alignment: LV
3908[other_side	_	reased secretion of milk outside periods of	rac	lio
Show the fie [uku_sym_c	eld ONLY If:	ast feeding.	1	1: Galactorrhea present, but to a ver slight degree.
			2	2: Galactorrhea is present to a moderate degree and is felt to be somewhat disturbing.
			3	3: Galactorrhea is very pronounced and clearly disturbing.
			Cu	stom alignment: LV
3909[other_side		essive development of the mammary	rac	dio
Show the fie [uku_sym_c	field ONLY if: _cat] = '40'	1	1: Gynecomastia present to a very slight degree compared with the usual state.	
			2	2: Gynecomastia clearly present; however, only hampering when patient is undressed.
			3	3: Gynecomastia present to such a severe degree that it affects the patient cosmetically as it can be observed even if he is dressed.
			Cu	stom alignment: LV
3910[other_side	e_effect41] Incr	reased desire for sexual activity.	rac	lio
Show the fig [uku_sym_c			1	1: Slight increase, which is, however still felt as natural by the partner.
			2	2: Clear increase that has given rise to comments and discussions with the partner.
			3	3: When the usual desire has increased to such a severe extent that the patient's life with his partners is considerably disturbed.
			Cu	stom alignment: LV

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3911	[other_side_effect42] Show the field ONLY if:	Reduced desire for sexual activity.	1 1: The desire for sexual activity is		
	[uku_sym_cat] = '42'		slightly diminished, but without hampering the patient.		
			2 2: A distinct reduction of the patient's desire for and interest in sexual activity so that it becomes a problem for the patient.		
			3: Desire and interest have diminished to such an extent that sexual intercourse occurs extremely seldom or has stopped.		
			Custom alignment: LV		
3912	<pre>2[other_side_effect43]</pre>	Difficulty in attaining or maintaining an	radio		
	Show the field ONLY if: [uku_sym_cat] = '43'	erection.	1 1: Slightly diminished ability to attain or maintain an erection.		
			2 2: A distinct change in the patient's ability to attain or maintain an erection.		
			3: The patient only rarely (or never) can attain or maintain an erection.		
			Custom alignment: LV		
3913	[other_side_effect44]	Dysfunction of the patient's ability to control	radio		
	Show the field ONLY if: [uku_sym_cat] = '44'	ejaculation. Includes a) premature or b) delayed ejaculation.	1 1: It is somewhat more difficult than usual for the patient to control ejaculation, but it does not trouble him.		
			2 2: A distinct change in the patient's ability to control ejaculation, so that is becomes a problem for him.		
			3: The patient's ability to control ejaculation is influenced to such an extent that it has become a dominating problem in his sexual intercourse and thus to a great extent influences his experience of orgasm.		
			Custom alignment: LV		
3914	[other_side_effect45]	Difficulty in obtaining and experiencing	radio		
	Show the field ONLY if: [uku_sym_cat] = '45'	satisfactory orgasm.	1: It is more difficult for the patient than usual to obtain orgasm and/or the experience of orgasm is slightly influenced.		
			2 2: The patient states that there is a clear change in the ability to obtain orgasm and or in the experience of orgasm. This change has reached such a degree that it troubles the patient.		

			3 3: When the patient rarely or never can obtain orgasm and/or the experience of orgasm is markedly reduced.
			Custom alignment: LV
391	[other_side_effect46]	Dryness of vagina with sexual stimulation.	radio
	Show the field ONLY if: [uku_sym_cat] = '46'		1 1: Slight dryness of vagina with sexual stimulation.
			2 2: Moderately disturbing dryness of vagina with sexual stimulation.
			3 3: Severely disturbing, marked dryness of vagina making coitus difficult (or necessitating the use of lubricants)
			Custom alignment: LV
391	[other_side_effect_de sc]	Please list the side effect in 1 or 2 words.	text
	Show the field ONLY if: [uku_sym_cat] = '47'		
391	[side_effect_52]	Cold/Flu Symptoms Severity.	radio
	Show the field ONLY if: [uku_sym_cat] = '52'		1 1: Mild: Discomfort noticed, but no disruption of normal daily activity
			2 2: Moderate: Discomfort sufficient to reduce or affect normal daily activity
			3 3: Severe: Incapacitating, with inability to work or to perform normal daily activity
			Custom alignment: LV
391	[side_effect_54]	Decreased Appetite Without Weight Loss	radio
	Show the field ONLY if: [uku_sym_cat] = '54'	Severity.	1 1: Mild: Discomfort noticed, but no disruption of normal daily activity
			2 2: Moderate: Discomfort sufficient to reduce or affect normal daily activity
			3: Severe: Incapacitating, with inability to work or to perform normal daily activity
			Custom alignment: LV
391	[side_effect_55]	Feeling of dizziness, weakness, everything	radio
	Show the field ONLY if: [uku_sym_cat] = '55'	going black, buzzing in the ears, or increased tendency to faint. May be associated with	1 1: Clearly present, but requires no special countermeasures
		changing from supine or sitting position to upright position.	2 2: Hampering, but can be neutralized (for example, by slow and/or stagewise change to upright position).

			3 3: Threatening fainting or real episodes of fainting despite careful change of position, with a tendency to this type of dizziness as long as the patient is in an upright position. Custom alignment: LV
3920	 [side_effect_56]	Note that falls are also assessed on the	radio
	Show the field ONLY if: [uku_sym_cat] = '56'	Decision Support Form and all falls should be captured there. Only falls resulting in reduced	1 1: Mild: Discomfort noticed, but no disruption of normal daily activity.
		mobility, severe and persistent pain, or injury should be documented as Adverse Events. A fall resulting in injury and/or hospitalization	2 2: Moderate: Discomfort sufficient to reduce or affect normal daily activity.
		should only be documented as one Adverse Event.	3 3: Severe: Incapacitating, with inability to work or to perform normal daily activity.
			Custom alignment: LV
3921	[side_effect_49] Show the field ONLY if: [uku_sym_cat] = '49'	Hospitalization (Non-Psychiatric) Severity	radio 3 3: Severe
	-		Custom alignment: LV
3922	2[side_effect_48]	Hospitalization (Psychiatric) Severity	radio 3 3: Severe
	Show the field ONLY if: [uku_sym_cat] = '48'		Custom alignment: LV
3923	B[side_effect_50]	Hospitalization (With Surgery) Severity	radio
	Show the field ONLY if: [uku_sym_cat] = '50'		3 3: Severe Custom alignment: LV
3924	l[side_effect_57]	Increased Appetite Without Weight Gain	radio
	Show the field ONLY if: [uku_sym_cat] = '57'	Severity.	1 1: Mild: Noticeable, but no disruption of normal daily activity.
			2 2: Moderate: Discomfort sufficient to reduce or affect normal daily activity.
			3 3: Severe: Incapacitating, with inability to work or to perform normal daily activity.
			Custom alignment: LV
3925	[side_effect_58]	Irritability or Emotional Lability Severity.	radio
	Show the field ONLY if: [uku_sym_cat] = '58'		1 1: Mild: Discomfort noticed, but no disruption of normal daily activity.
			2 2: Moderate: Discomfort sufficient to reduce or affect normal daily activity.
			3 3: Severe: Incapacitating, with inability to work or to perform normal daily activity.

			Custom alignment: LV
3926	[side_effect_59]	Outpatient Surgery Severity.	radio
	Show the field ONLY if: [uku_sym_cat] = '59'		2 2: Moderate (minimally invasive procedure with minimal recovery time)
			3 3: Severe (more extensive recovery needed)
			Custom alignment: LV
3927	[side_effect_60]	COVID-19	radio
	Show the field ONLY if:		1 1: Mild: Treated at home
	[uku_sym_cat] = '60'		2 2: Moderate: Required inpatient hospitalization
			3 3: Severe: Required ICU
3928	[covid_status]	COVID-19 Test status	radio
	Show the field ONLY if:		1 1. Confirmed positive
	[uku_sym_cat] = '60'		2 2. Suspected but not tested
3929	ae_sev]	Severity	radio
	Show the field ONLY if:		1 1: Mild
	[uku_sym_cat] = '47'		2 2: Moderate
			3 3: Severe
3930	[ae_severity]	Severity	radio
	Show the field ONLY if:	NOTE: PLEASE DO NOT ENTER INTO THIS FIELD ANYMORE. THIS FIELD WILL SOON BE DEACTIVATED.	1 Mild
	[uku_sym_cat] = '47'		2 Moderate
			3 Severe
			Field Annotation: @HIDDEN
3931	[ae_onset_date]	Section Header:	text (date_mdy), Required
		Onset Date:	
3932	2[ae_onset_during]	Onset occurred during:	dropdown, Required
			1 Step 1 Acute
			2 Step 2 Acute
			3 Step 1 Continuation
			4 Step 2 Continuation
			5 Neuro Follow-up
393	B[ae_narrative]	Section Header:	notes
		Narrative Description of AE (if needed).	Custom alignment: LV
3934	[ae_outcome]	Section Header:	radio, Required
		Outcome	1 Resolved
			2 Ongoing
			3 Death

3935	[ae_death_notify] Show the field ONLY if:	Please notify site PI and Dr. Lenze (lenzee@wustl.edu)!	descriptive
3936	[ae_outcome] = '3' [ae_end_date] Show the field ONLY if: [ae_outcome] = '1'	Section Header: End Date:	text (date_mdy)
3937	7[ae_relevant_info]	Section Header: List any relevant tests, laboratory data, history, including preexisting medical conditions	notes Custom alignment: LV
3938	[ae_relationship]	Section Header: Relationship	radio 1 Probably related 2 Possibly related 3 Not likely related
3939	[ae_reported_as_se]	Section Header: Was this AE described by the patient as a side effect of a study medication?	yesno 1 Yes 0 No
3940	[ae_expected]	Section Header: Expected?	radio 1 Yes 2 No, it is an Unexpected AE
3941	[ae_action]	Section Header: Action Taken NOTE: PLEASE DO NOT ENTER INTO THIS FIELD ANYMORE. THIS FIELD WILL SOON BE DEACTIVATED.	radio 1 Study Medication Stopped 2 Study Medication Dose Reduced 3 Study Medication Dose Increased 4 Study Medication Dose Delayed 5 Other Field Annotation: @HIDDEN
3942	2[ae_action_taken]	Action Taken	radio, Required 5 No Change to Study Med 1 Study Medication Stopped 2 Study Medication Dose Reduced 3 Study Medication Dose Increased 4 Study Medication Dose Delayed 6 Other
3943	[ae_action_other] Show the field ONLY if: [ae_action_taken] = '6'	Other:	text Field Annotation: @HIDDEN
3944	[ae_study_term]	Section Header: AE resulted in study termination (withdrawn from study)?	yesno, Required 1 Yes 0 No

 		<u> </u>	·
3945	[ae_study_term_text] Show the field ONLY if: [ae_study_term] = '1'	Please complete the Termination Form!	descriptive
3946	[ae_serious]	Section Header: Serious AE?	yesno, Required 1 Yes 0 No
3947	[ae_death_notify2] Show the field ONLY if: [ae_serious] = '1'	Please notify site Pl and Dr. Lenze (lenzee@wustl.edu)!	descriptive
3948	[ae_category] Show the field ONLY if: [ae_serious] = '1'	Category of SAE:	1 Death 2 Life-threatening 3 Hospitalization - initial or 4 Disability / incapacityConganomaly / birth defect 5 Required intervention to p 6 Permanent impairment 7 Other
3949	[ae_category_other] Show the field ONLY if: [ae_category] = '7'	Other	rext
3950	[ae_other_category]	Other AE Category this variable was added after data collection	dropdown None apply Accommodation probler vision Akathesia Anxiety / Tension Asthenia/Lassitude/Incre Fatiguability Bronchitis Chest Pain Cold/ flu symptoms Concentration Difficultie Decreased Appetite With Loss Diarrhea Disturbed Sleep dizziness/impaired balar elevated blood sugar Extremity Swelling Failing memory

26/24, 11:07 <i>F</i>	1141	OPTIMUM Main Database (Fina	1) INL	БСар
			16	Fall
			17	Gl distress
			35	Hospitalization - non-psychiatric
			34	Hospitalization - with surgery
			18	Hypertension
			19	Increased Appetite Without Weight Gain
			20	Increased Dream Activity
			38	Increased Salivation
			21	Irritability or Emotional lability
			39	Micturition Disturbances
			22	Muskuloskeletal Pain
			36	Outpatient surgery
			23	Pneumonia
			24	Polyuria/Polydipsia
			25	Pruritus
			40	Rash
			26	Reduced Salivation (Dryness of Mouth)
			27	shakiness
			28	Shortness of breath
			29	slurred speech
			30	Tinnitus
			41	Tremor
			31	Urinary Incontinence
			32	Urinary tract infection
			33	Vertigo
			Field	Annotation: @HIDDEN
395	[ae_imp_to_pt_safety] Show the field ONLY if: [ae_serious] = '0' and ((([psychic_side_effect1] = '1' or [psychic_side_ef fect1] = '2') or ([psychic_side_effect2] = '1' or [p sychic_side_effect2] = '2') or ([psychic_side_effect3] = '1' or [psychic_si de_effect3] = '2') or ([ps ychic_side_effect4] = '1' or [psychic_side_effect 4] = '2') or ([psychic_sid e_effect6] = '1' or [psyc hic_side_effect6] = '2') o	Section Header: AE deemed important to participant safety?	l	Yes No

r ([psychic side effect 7] = '1' or [psychic_side _effect7] = '2') or ([psyc hic_side_effect8] = '1' o r [psychic_side_effect8] = '2') or ([psychic_side_ effect9] = '1' or [psychic _side_effect9] = '2') or ([psychic_side_effect10] = '1' or [psychic_side_ef fect10] = '2') or ([neuro _side_effect11] = '1' or [neuro_side_effect11] = '2') or ([neuro_side_effe ct12] = '1' or [neuro_sid e_effect12] = '2') or ([ne uro side effect13] = '1' or [neuro_side_effect1 3] = '2') or ([neuro_side _effect14] = '1' or [neur $o_side_effect14] = '2') o$ r ([neuro_side_effect15] = '1' or [neuro_side_eff ect15] = '2') or ([neuro_ side_effect16] = '1' or [neuro_side_effect16] = '2') or ([neuro_side_effe ct17] = '1' or [neuro_sid e_effect17] = '2') or ([ne uro_side_effect18] = '1' or [neuro_side_effect1 8] = '2') or ([neuro_side _effect19] = '1' or [neur $o_side_effect19] = '2') o$ r ([autonomic_side_effe ct20] = '1' or [autonomi $c_side_effect20] = '2') o$ r ([autonomic_side_effe ct21] = '1' or [autonomi $c_side_effect21] = '2') o$ r ([autonomic_side_effe ct22] = '1' or [autonomi c_side_effect22] = '2') o r ([autonomic_side_effe ct23] = '1' or [autonomi c_side_effect23] = '2') o r ([autonomic_side_effe ct24] = '1' or [autonomi $c_side_effect24] = '2') o$ r ([autonomic_side_effe ct25] = '1' or [autonomi $c_side_effect25] = '2') o$ r ([autonomic_side_effe ct26] = '1' or [autonomi c_side_effect26] = '2') o r ([autonomic_side_effe ct27] = '1' or [autonomi $c_side_effect27] = '2') o$

r ([autonomic side effe ct29] = '1' or [autonomi $c_side_effect29] = '2') o$ r ([autonomic_side_effe ct30] = '1' or [autonomi $c_side_effect30] = '2') o$ r ([other_side_effect31] = '1' or [other_side_effe ct31] = '2') or ([other_si de_effect32] = '1' or [ot her_side_effect32] = '2') or ([other_side_effect3 3] = '1' or [other side e ffect33] = '2') or ([other _side_effect34] = '1' or [other_side_effect34] = '2') or ([other_side_effe ct35] = '1' or [other_sid e_effect35] = '2') or ([ot her_side_effect36] = '1' or [other_side_effect3 6] = '2') or ([other_side_ effect37] = '1' or [other _side_effect37] = '2') or ([other_side_effect38] = '1' or [other_side_effect 38] = '2') or ([other_side _effect39] = '1' or [othe $r_side_effect39] = '2') or$ ([other_side_effect40] = '1' or [other_side_effect 40] = '2') or ([other_side _effect41] = '1' or [othe $r_side_effect41] = '2') or$ ([other_side_effect42] = '1' or [other_side_effect 42] = '2') or ([other_side _effect43] = '1' or [othe $r_side_effect43] = '2') or$ ([other_side_effect44] = '1' or [other_side_effect 44] = '2') or ([other_side _effect45] = '1' or [othe $r_side_effect45] = '2') or$ ([other_side_effect46] = '1' or [other_side_effect 46] = '2') or ([side_effect _52] = '1' or [side_effect _52] = '2') or ([side_effe ct_54] = '1' or [side_effe ct_54] = '2') or ([side_eff ect_55] = '1' or [side_eff ect_55] = '2') or ([side_e ffect_56] = '1' or [side_e ffect_56] = '2') or ([side_ effect_57] = '1' or [side_ effect_57] = '2') or ([side _effect_58] = '1' or [side

	_effect_58] = '2') or ([sid e_effect_59] = '2')) or (([ae_sev]='1' or [ae_se v]='2')))					
39	52 [ae_dod] Show the field ONLY if: [ae_category] = '1'	Section Header: Date of death	text (date_mdy)			
39	53[adverse_event_v2_com plete]	Section Header: Form Status Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete			
Instrur	ment: Relapse (IF MAD	PRS>=15) (relapse_if_madrs15)		[collapsed]		
Instrur	ment: Termination For	m (termination_form)		[collapsed]		
Instrur	ment: Medication Forr	n (Please use V2) (medication_for	m_please_use_v2)	[collapsed]		
Instrur	ment: Psychiatric Med	lication Form (Please use V2) (p	sychiatric_medication_form_please	e_use_v2) [collapsed]		
	ment: Spontaneous Re taneous_report_of_side_e	eport Of Side Effects (Please use effects_please_use_v2)	· V2)	[collapsed]		
Instrur	ment: Adverse Event (Please use V2) (adverse_event_plea	ase_use_v2)	[collapsed]		
Instrument: Partial Remission (Toronto only) (partial_remission_toronto_only)						
Instrument: Short Blessed Test (Toronto only) (short_blessed_test_toronto_only)						
Instrument: Medical Conditions (Toronto only) (medical_conditions_toronto_only)						
Instrument: Athf Form (under testing, DO NOT USE) (athf_form_under_testing_do_not_use)						
Instrument: Running Clinical Notes (Please transition to v2) (running_clinical_notes)						
Instrur	ment: Running Clinica	Notes (v2) (running_clinical_notes	5_v2)	[collapsed]		
Instrur	ment: Height and Weig	ght (height_and_weight)		[collapsed]		
Instrur	ment: Local Repeat M	ADRS (local_repeat_madrs)		[collapsed]		
Instrur	ment: Local Repeat PH	IQ-9 (repeat_phq9)		[collapsed]		
Instrur	ment: Labs (labs)			[collapsed]		
Instrument: Labs (Follow-up) (labs_fup)						
Instrument: ECG (Follow-up) (ecg_followup)						
Instrument: Survey Reminder (survey_reminder)						
Instrur	ment: ATHF Form1 V2	(athf_form1_v2)		[collapsed]		
Instrur	Instrument: ATHF Form2 (If Needed - Treatments 11-20) V2 (athf_form2_if_needed_treatments_1120_v2) [collapse					
Instrur	ment: ATHF Form3 (If I	Needed - Treatments 21-30) V2	(athf_form3_if_needed_treatments	_2130_v2) [collapsed]		

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Instrument: ATHF Form4 (If Needed - Treatments 31-40) V2 (athf_form4_if_needed_treatments_	3140_v2) [collapsed]
Instrument: Neuro MRI Form (optimum_neuro_mri)	[collapsed]
Instrument: Analyzed MRI Data - Brain Volumes (analyzed_mri_data)	[collapsed]
Instrument: Demographics (demographics)	[collapsed]
Instrument: Consent Termination Reconsent (consent_termination_reconsent)	[collapsed]
Instrument: Clinical Assessments Dates (clinical_assessments_dates)	[collapsed]
Instrument: Neurocog Assessments Dates (neurocog_assessments_dates)	[collapsed]
Instrument: Biomarkers MRI (biomarkers_mri)	[collapsed]
Instrument: Payment (payment)	[collapsed]
Instrument: Storage (storage)	[collapsed]
Instrument: GUID (guid)	[collapsed]
Instrument: Self Reporting Hearing and Noise Exposure (HNE) (self_reporting_hearing_and_noise_exposure_hne)	[collapsed]
Instrument: Documentation of Missing and Verified Data (missing_data_documentation)	[collapsed]
Instrument: Participant Email (participant_email)	[collapsed]
Instrument: WU COVID 19 Verbal Consent (wu_covid_19_verbal_consent)	[collapsed]
Instrument: Columbia's COVID E-Consent (columbias_covid_econsent)	[collapsed]
Instrument: Columbia's Compensation Form (columbia_compensation_form)	[collapsed]
Instrument: Duke Social Support (DSSI) (duke_social_support_dssi)	[collapsed]
Instrument: Perceived Stress Scale (perceived_stress_scale)	[collapsed]
Instrument: UCLA Revised Loneliness Scale (ucla_revised_loneliness_scale)	[collapsed]
Instrument: Connor-Davidson Resilience Scale (CD-RISC) (connordavidson_resilience_scale_cdri	sc) [collapsed]
Instrument: CAAM COVID Survey (caam_covid_survey)	[collapsed]
Instrument: CAAM COVID Survey Antidepressant Section (complete the CAAM COVID Survey (covid_survey_antidepressant_section)	vey First) [collapsed]
Instrument: PHQ-9 (COVID) (phq9_covid)	[collapsed]
Instrument: Physical Activity (physical_activity_optn_at_month_24)	[collapsed]
Instrument: COVID-19 (covid19)	[collapsed]