

ONTARIO INSTITUT BRAIN ONTARIEN INSTITUTE DU CERVEAU

Data Quality Framework

REDCap Tools & Procedures

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Written and reviewed by the Brain-CODE Team



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Introduction

Given the importance of high-quality data to research and translation to clinical care, OBI's Data Quality Framework (DQF) intends to set standards across its sponsored research studies and uphold the best data quality practices. REDCap is a tool on the Brain-CODE platform used to build and manage databases for clinical data. REDCap provides many features that help ensure the usability and quality of the data that is collected. This manual describes the REDCap Data Quality Tools and elements of project design and data collection that will help Data Producers meet the requirements of the Data Quality Framework. Usage of these tools will help ensure the study data are trustworthy and shareable, and any changes made are well-documented.

Study Design

As described in the "OBI DQF Study Quality Checklist" (see DQF Stage 1 document #5), it is important to design REDCap electronic case reports forms (eCRFs) with survey administration, data entry, and future usability of the data in mind. Forms *must* be designed with consideration of participant burden and should be easy to use and understand. Forms *must* also have consistent variable naming, well-designed form display and branching logic, appropriate data types, and proper field validation. Missing data codes (see below) are *strongly recommended* to be hardcoded within REDCap projects to replace and explain any missing data.

The table below describes various categories of missingness as part of the DQF standards (see Stage 2 document #3, "OBI DQF Data Quality Reporting Guide") that are meant to be used for blank or partially completed forms within REDCap. With these elements in place, Data Producers are *strongly recommended* to use the data quality tools in REDCap to regularly check for any discrepancies within the data (described in the Study Monitoring <u>section</u>).

Furthermore, the Brain-CODE team has developed two study-specific forms that can be generated in an automated pipeline once the rest of your REDCap project development is complete: the Missing Data Flagging and Participant Status forms. The Missing Data Flagging form (MDFF) is *strongly recommended* to be used to explain form-level missing data and to quickly flag many unanswered fields within partially completed forms with a single missing data code (form-level missing data flagging is not a current REDCap feature). Please note that this form does not apply missing data codes to any fields and does not affect the Data Quality Rules feature in REDCap; the data in this form will be used in OBI's external Data Quality Reporting pipeline to determine what data is missing. The MDFF is intended to work with forms that were not completed as surveys – the flagging process for survey data is under development. Additionally, it is *strongly recommended* that Data Producers use the Participant Status form (PSF) to track participant status and their study progression.



MISSING DATA CODING GUIDE

Code	Label	Definition
unable_to_perform	Unable to perform	The participant could not participate in the assessment/task due to a physical or cognitive condition.
task_declined Task declined		The participant chose not to participate in the assessment/task or declined to provide a response.
out_of_time	Ran out of time	The participant was unable to complete the assessment/task within the scheduled timeslot.
admin_error	Administrative error	The administrator of the assessment/ task made a mistake that caused the entry to be invalid or otherwise unobtainable. E.g., miscalibration of equipment by administrators; incorrect administration; scheduling conflicts.
technical_error	Technical error	The equipment or tools (hardware or software) used for data acquisition, collection, or processing failed. E.g., computer crashed; power failure; response button box or keyboard was not properly hooked up or defective.
missing_other	Other	Data is missing for a reason that is not explained by any of the available missing data codes. <i>Please</i> <i>provide a description if possible.</i> *
answer_unknown	Unknown value	The participant could not provide a response to the question because they did not know how to answer it. <i>This code is only to be used if the field</i> <i>does not include a "do not know" option.</i> **
not_applicable	Not applicable	The assessment/task was not performed, or a value could not be derived because it did not apply to the participant. E.g., a questionnaire asks if a participant can organize his/her own medications, but the participant does not take any medications, so the question does not apply. <i>This code is only to be used if the field does not include a "not applicable" option.</i> ***

*If this code is used, please include a description as a comment within a data query or data verification textbox within the <u>Data Resolution Workflow</u> if possible. For missing forms, please use the text box once this option is selected within the Missing Data Flagging form.

**Please note these scenarios are not considered missing data, as "do not know" is an answer and any items that are "not applicable" are not expected to contain data. It is strongly recommended that these Missing Data Codes



are all hardcoded in REDCap so the missingness data can be captured from the single missing code dropdown menu.

Study Launch & Data Entry

ACCOUNT REQUEST FORM

Once the study is launched, ensure that all team members have appropriate user rights according to their role (e.g., opening and closing data queries, locking records, editing completed surveys, etc.). This can be done by the Program Manager or Neuroinformatics Lead submitting requests through the Account Request form on the <u>Brain-CODE website</u> under *Forms*.

Please view the following articles in the Knowledge Base for more information on <u>user roles</u> and <u>access requests</u>.

FORM STATUS

REDCap automatically adds a Form Status dropdown field at the end of each form. This field is used to flag the form as 'Complete', 'Unverified', or 'Incomplete' and this data is represented using different coloured circles on the Record Status Dashboard.

Forms that have no blank fields should be marked as 'Complete'; this includes forms that use missing data codes. Forms that contain blank fields should be marked as 'Incomplete'. The Missing Data Flagging <u>form</u> relies in part on Form Status data, so it is critical to ensure that the Form Status field is used consistently and accurately.

Data Collection Instrument	baseline	followup1	followup2	admin
Record Description				۲
Demographics Adult	۲			
Medical History (survey)				
PHQ-9 (survey)	۲	۲		
WHOQOL-BREF	۲			
PSQI				
Participant Status Form				۲
Missing Data Flagging Form				۲



REDCAP MISSING DATA CODE FEATURE

After participants have completed their forms, whether it be done directly or with a coordinator or caregiver, there may be fields that were left unanswered. Please follow the steps below to fill blank fields with missing data codes. *Note:* the missing data codes feature is only meant to be used to replace blank fields within partially completed forms, NOT incomplete forms where all fields are blank.

- 1. Within the participant record, select a form.
 - If the form was completed as a survey directly by the participant, the box shown below will appear at the top of the form. Click the **Edit response** button.



- 2. Click the **M** button beside the blank response field. *Should the M button not be visible, please contact the Neuroinformatics Lead as this feature may not have been enabled.*
- 3. Select the applicable missing data code from the dropdown.

Record ID	OBI00_TST_0001
Postal Code	
Taura Chaban	Mark field as:
Form Status	[Clear value]
Complete?	Unable to perform (unable_to_perform)
	Task declined (task_declined)
Lock this instrument?	Ran out of time (out_of_time)
If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.	Administrative error (admin_error)
	Technical error (technical_error)
	Other (provide description) (missing_other)
	Unknown value (value_unknown)
	Not applicable (not_applicable)

For more information on this feature and its set up, please view this <u>article</u> in the Knowledge Base.



MISSING DATA FLAGGING FORM

The Missing Data Flagging form is a study-specific form to flag missing data within a REDCap project. This form works in conjunction with the Participant Status <u>form</u> and each form's Form Status field through branching logic to only show forms that are expected to be complete based on the participant's progress through the study protocol. Please note that this form only supports the first instance of a given instrument (i.e., all forms with repeat instances disabled or the first instance for those with repeat instances enabled).

For a form to be shown in the Missing Data Flagging form, the following conditions need to be met:

- 1. A form's Form Status is marked as 'Incomplete', 'Unverified', or is blank (i.e., the form has not been opened).
- 2. The scheduled timepoint for the form is marked as complete in the Participant Status <u>form</u>.
- 3. The form was not specified in the MDFF creation process as a form to ignore (ignored forms are listed in an orange banner at the top of the MDFF).

Excluded forms: record_description			
If forms from a timepoint you expect are not showing up below, please mark those timepoints as complete in the Participant Status Form			
BASELINE_ARM_1			
Medical History:	H P		
PHQ-9:	H V		
WHOQOL-BREF:			

The MDFF is used in two ways. Firstly, the form can be used to flag missing forms with a missing data code (flagging forms with missing data codes is not currently a REDCap feature). Secondly, for forms that are not missing but that contain blank fields (i.e., partially completed forms), a missing data code can be selected which will be externally applied in the Data Quality Reporting pipeline to all blank fields in that form. *Please note that this form does not apply the specified missing data codes to the identified forms in REDCap; the Missing Data Flagging form data will be reviewed as part of the Data Quality Reporting pipeline external to REDCap.*

To use this form, please follow the steps below:

1. For each shown form, select the relevant missing data code. If the form contains no data, this missing data code will be used to flag the entire form as missing in the Data



Quality Reporting pipeline. If the form is partially complete (i.e., contains some data but has blank fields), the missing data code that is selected from the dropdown menu will be applied to each blank field in the form in the Data Quality Reporting pipeline. This is implemented to reduce the time required to apply a single missing data code to all blank fields in lengthier forms when the reason for missingness is the same. If a form has items that are missing for multiple reasons, please insert the appropriate missing data code by using the M button beside each blank field in that form. The MDFF can still be used to apply a single missing data code to any remaining blank fields.

BASELINE_ARM_1			
Medical History:	Ð		~
PHQ-9:	H	Not a missing form Unable to perform	
WHOQOL-BREF:	H P	Task declined Out of time Admin error	\bigtriangledown
Form Status		Technical error	
Complete?	H	Missing other Not applicable	
Lock this instrument? If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.		Participant no longer in study	

2. To indicate that a form is not missing, select 'Not a missing form' from the dropdown menu. A warning will appear to remind you that the Form Status of the specified form should be marked as 'Complete'. Please fill in any missing items with missing data codes as described in the <u>previous section</u> before changing the **Form Status** to 'Complete'.

BASELINE_ARM_1			
Medical History:	⊖ Not a missing form 🗢		
Return to this form an	d change the form status to "Complete"		
PHQ-9:			
WHOQOL-BREF:			
Form Status			
Complete?	🕒 Incomplete 👻		

3. *Additional features*: Branching logic is built into the dropdown menus. When a participant is marked as 'Active' or 'Complete' in the PSF, the 'Participant is no longer in



the study' option is hidden but it appears when the participant is marked as 'Withdrew consent', 'Withdrawn by PI', 'Lost to follow-up', or 'Screen fail'.

BASELINE_ARM	<i>I</i> _1	
PHQ-9:		
Form Status	Not a missing form Unable to perform	
Complete?	Task declined Out of time	
Lock this instrument? If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.	Admin error Technical error	
	Missing other Not applicable Participant no longer in study	

If the participant withdraws before completing the final timepoint, there is no need to flag forms with missing data codes at timepoints after the timepoint at which the withdrawal occurred; these forms will not be displayed in the MDFF but will be accounted for in the Data Quality Reporting pipeline.

Please note that this form may not behave as designed due to how REDCap treats the Form Status field of forms that are completed as surveys. If the only missing data in a survey exists in fields not marked as "required", the Form Status will be set to 'Complete' and cannot be changed. This leads to the exclusion of the survey form from the MDFF. For forms that only contain fields marked as "required", if the participant attempts to submit the survey when it contains any missing data, the survey is saved, not submitted, and its Form Status is set to 'Partially Complete'. This use of the Form Status field matches how the MDFF was designed so it will behave as intended. Similarly, if a survey contains no missing data or all its fields are marked as "required", the MDFF will behave as intended. The OBI Data Quality team is developing a method to flag surveys that contain missing forms where all fields are not marked as "required".

PARTICIPANT STATUS FORM

The Participant Status form allows Data Producer team members to mark whether participants are active, complete, withdrawn, or lost to follow-up, and if the study has multiple visits, which visits have been completed. When using this form, "completing" a timepoint means that no further data collection is expected; it does not matter whether the participant provided data for every scheduled form or if the forms contain missing data codes or blank fields. The PSF will be customized according to the visit schedule for the given study. This form is intended to be updated when a participant's status change (e.g., withdrawal), and if there are multiple



timepoints, after a participant has completed a subsequent visit. Please follow the steps according to the participant lifecycle below:

 Enrollment: once a participant has enrolled in the study and their consent has been collected, they are part of active data collection. The 'Active' option is to be selected under participant status and a banner appears labelled as ACTIVE. At this stage, leave all fields blank and the Form Status as 'Incomplete' to indicate that this form will be returned to (enter additional comments as necessary).

	Participant Status: <u>ACTIVE</u>	
The partic	ipant is still actively enrolled in the study.	
What is the status of the participant?		θ
* must provide value		ightarrow M
 Active Complete Withdrew consent Withdrawn by Pl Lost to follow-up Screen fail 		
Active (undergoing study protocol), Complete (completed all tir	nepoints), Withdrawn (no longer part of study), Lost to fol	ow-up (unreachable)
Which timepoints has the participant complet	ed (no further data collection is expected a	at this timepoint)?
 baseline_arm_1 followup1_arm_1 followup2_arm_1 		
Additional notes:	e P M	
		Expand
Form Status		
Complete?	🕒 🕞 Incomplete 🗸	

2. Active data collection in longitudinal studies: once a participant has completed the required form(s) for a particular timepoint or no further data collection is expected at that timepoint (e.g., the participant withdraws or is lost to follow-up, or the participant provides data for some forms but declines to answer other forms), return to the form and mark the respective checkbox. Keep the **Form Status** marked as **'Incomplete'**.



	Participant Status: <u>ACTIVE</u>	
The particip	pant is still actively enrolled in the study.	
What is the status of the participant?		Н
* must provide value		$\sim M$
Active Complete Withdrew consent Withdrawn by Pl Lost to follow-up		
○ Screen fail		
Active (undergoing study protocol), Complete (completed all time	points), Withdrawn (no longer part of study), Lost to follow-up (unreachable)	reset
Which timepoints has the participant completed	d (no further data collection is expected at this timepoint)?	H Q M
 baseline_arm_1 followup1_arm_1 followup2_arm_1 		
Additional notes:	H P M	Expand
Form Status		схрана
ronn status		
Complete?	⊖ Incomplete ✓	

3. *Study protocol complete*: once a participant has gone through the entirety of the study protocol and no further data collection will occur, check off all timepoints' checkboxes and change the participant status to 'Complete'. The banner will then change to be labelled as **COMPLETE**. Mark the **Form Status** as **'Complete'**. Please ensure all missing data is addressed using the missing data codes feature and/or the Missing Data Flagging form.



	Participant Status: <u>COMP</u>	LETE	
The participa	ant has completed the entir	re study protocol.	
What is the status of the participant?			Η
* must provide value			ightarrow M
 Active Complete Withdrew consent Withdrawn by Pl Lost to follow-up 			
\odot Screen fail			reset
Active (undergoing study protocol), Complete (completed all tir	mepoints), Withdrawn (no longer pa	art of study), Lost to follow-up (unreachable)	Teser
Date of study completion:			(H P M
Which timepoints has the participant complet Subseline_arm_1 Subseline_arm_1 Subseline_arm_1 Subseline_arm_1 Subseline_arm_1	ed (no further data collec	tion is expected at this timepoint)?	e M
Additional notes:	e M		Expand
Form Status			
Complete?	Ş	Complete 🗸	

- 4. Withdrawal: should a participant withdraw from the study (whether of their own accord or deemed necessary by the principal investigator) or be lost to follow-up, set the participant status to the relevant option. The banner will be labelled as WITHDRAWN or LOST TO FOLLOW-UP. Provide the date of withdrawal or loss to follow-up and select a reason for withdrawal from the dropdown. If any visits had been completed prior to withdrawal or being lost to follow-up, check off the relevant timepoints. Mark the Form Status as 'Complete'.
 - a. If the participant has withdrawn and has requested for their data to be removed from Brain-CODE, please contact the <u>Brain-CODE Help Desk</u>.
 - b. If a participant does not provide their data and does not respond to follow-up communications (according to site/study procedures) from the study team, the participant is considered as 'Lost to Follow-up'. Should a participant become responsive again, please update the form and status accordingly.



Participant Statu	IS: <u>WITHDRAWN</u>	
The participant has with	drawn from the study.	
What is the status of the participant?		H
* must provide value		() M
○ Active		
○ Complete		
Withdrew consent		
○ Withdrawn by PI		
○ Lost to follow-up		
○ Screen fail		
Active (undergoing study protocol), Complete (completed all timepoints), Withdrawn	(no longer part of study). Lost to follow-up (upreachable)	rese
Date of withdrawal:	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	H P M
2024-08-27 🛅 Today Y-M-D		20
Reason for withdrawal of consent (select primary reason):	$\stackrel{\mathbb{H}}{\mathrel{\bigcirc}\mathbb{M}}$ Medical reasons unrelated to reported co	ondi 🗸
Which timepoints has the participant completed (no further d	ata collection is expected at this timepoint)?	H P M
☑ baseline_arm_1		
✓ followup1_arm_1		
□ followup2_arm_1		
	Θ	
Additional notes:	$\sim M$	
		Expand
Form Status		
Complete?	Complete V	
	~ · · · ·	

5. Additional features: using the Participant Status form will also allow for customized Form Display Logic within the REDCap project that will disable forms at timepoints not marked as 'Complete' for participants that were marked as 'Withdrawn consent', 'Withdrawn by PI', or 'Lost to follow-up'. Therefore, coordinators will be able to easily identify participants for whom no further data collection is expected using the Record Status Dashboard. Note: for forms to remain enabled, the participant must be marked as 'Active' or 'Complete'. If the participant is marked as 'Withdrew consent', 'Withdrawn by PI', or 'Lost to follow-up', the form's scheduled timepoint must be checked off as complete.



Participant Statu	us: <u>WITHD</u>	RAWN	
The participant has with	idrawn fro	m the study.	
What is the status of the participant?			Э
* must provide value			$\supset M$
○ Active			
○ Complete			
Withdrew consent			
igodoldoldoldoldoldoldoldoldoldoldoldoldol			
○ Lost to follow-up			
○ Screen fail			
Active (undergoing study protocol), Complete (completed all timepoints), Withdrawn	(no longer p	art of study), Lost to follow-up (unreachable)	reset
Date of withdrawal:			$\sim M$
2024-08-27 📴 Today Y-M-D			
Reason for withdrawal of consent (select primary reason):			
Reason for withdrawal of consent (select primary reason):	$\sim M$	Prefer not to answer	~
Which timepoints has the participant completed (no further d	lata colle	ction is expected at this timepoint)?	H P M
✓ baseline_arm_1			
□ followup1_arm_1			
□ followup2_arm_1			
	Ð		
Additional notes:			
	20		
			Expand
			Expanu
Form Status			
Complete?		Complete 🗸	
	φ	complete V	

Data Collection Instrument	baseline	followup1	followup2	admin
Record Description				۲
Demographics Adult	۲			
Medical History (survey)				
PHQ-9 (survey)				
WHOQOL-BREF				
PSQI				
Participant Status Form				۲
Missing Data Flagging Form				



Study Monitoring

DATA REVIEW FREQUENCY

While data is being collected and entered, it is important that Neuroinformatics Leads (or Data Monitors) are reviewing the study data regularly. The Neuroinformatics Lead *must* conduct a final quality check before notifying the OBI Data Quality team that the data is ready for review.

DATA QUALITY RULES

To accurately identify any missing data or errors, it is *recommended* to use the Data Quality Rules tool. *Please note that these tools do not include or account for any data entered in the Missing Data Flagging form*. Please follow the steps below to check for the predefined discrepancies and any custom rules that were created:

1. The Data Quality page will display a Data Quality Rules dashboard with a predefined set of discrepancies that are searched for and the ability to add any new rules that are necessary to the project at the bottom.

			Upload or do	wnload Data Quality Ru	les ▽
a Qualit	y Rules	Execut	e rules: All	All except A&B Clear	
Rule #	Rule Name	Rule Logic (Show discrepancy only if)	Real-time execution ?	Total Discrepancies	Delet rule
А	Missing values*			Execute	
В	Missing values* (required fields only)			Execute	
С	Field validation errors (incorrect data type)			Execute	
D	Field validation errors (out of range)			Execute	
E	Outliers for numerical fields (numbers, integers, sliders, calc fields)**	-		Execute	
F	Hidden fields that contain values***	-		Execute	
G	Multiple choice fields with invalid values			Execute	
н	Incorrect values for calculated fields			Execute	
1	Fields containing "missing data codes"			Execute	
Add	Enter descriptive name for new rule (e.g., Participants below age 18)	Enter logic for new rule (e.g., [age] < 18) How do Luce special functions?	Execute in real time on data entry forms ?		

2. To find any discrepancies for each individual rule, click the **Execute** button for that rule or click **All** in the top-right corner to execute all rules. REDCap will analyze each rule and provide you with a total number of discrepancies found.



			Upload or do	wnload Data Quality Rules 🗢 🛛
Data Qualit	y Rules	Processing Complete! Execut	_	All except A&B Clear
Rule #	Rule Name	Rule Logic (Show discrepancy only if)	Real-time execution ?	Total Discrepancies Delete rule?
А	Missing values*	-		2 <u>export</u> <u>view</u>
В	Missing values* (required fields only)	-		0
С	Field validation errors (incorrect data type)	-		0
D	Field validation errors (out of range)	-		0
E	Outliers for numerical fields (numbers, integers, sliders, calc fields)**	-		0
F	Hidden fields that contain values***	-		0
G	Multiple choice fields with invalid values	-		0
н	Incorrect values for calculated fields			1 export view
1	Fields containing "missing data codes"			0
Add			C Execute in	
	Enter descriptive name for new rule (e.g., Participants below age 18)	Enter logic for new rule (e.g., [age] < 18) How do Luse special functions?	real time on data entry forms ?	

3. To view the list of results, click the **View** button in the **Total Discrepancies** column for a given rule. These data can be exported as a .csv for further analysis.

Rule: Missing values* Discrepancies found: 1 Image: CSV (2 exclusions not displayed - view)					
Record	Discrepant fields with their values	Status	Resolve issue 😡		
test_001 Baseline	" <i>Nome</i> :" test_name = [<u>no data]</u>	Missing value	💭 0 comments		

- 4. The **Resolve Issue** column brings up the Data Resolution Workflow pop-up (described in the next section), which allows project users to open, respond to, or close a data query which is used for documenting details of the data issue, including the origin of the issue, who resolved the issue, and how it was resolved.
- 5. Please resolve these issues with the necessary actions, such as following up with the participant, using missing data codes, etc.

For more information on this tool, please view this <u>article</u> in the Knowledge Base.



DATA RESOLUTION WORKFLOW

The Data Resolution Workflow (DRW) module works with the Data Quality Rules tool and enables users to open a workflow for tracking and documenting the process of resolving issues with data in the project. It is *recommended* to use this tool to identify and resolve any errors or missing values within your team. Please follow the steps below:

1. As mentioned earlier, during your quality checks, you may have found an error or blank field that hadn't been accounted for. Once identified, click the grey balloon next to the field.

Record ID	OBI00_TST_0001
Postal Code	
Form Status	
Complete?	B Complete V

2. This prompts the DRW pop-up to appear that allows you to open a query. You can assign another user to the query to notify them of the issue to resolve and leave a comment.

🗣 Data Resolution \	🗣 Data Resolution Workflow			
Users with appropriate with the data. Opened	user privileges may ope data queries may thus b e issue has been resolved	UDEO: Data Resolution Workflow low for the specified record for a given field and/or Data Quality rule. n data queries to begin a documented process of resolving an issue e responded to by users with appropriate privileges, and then they d. All data queries can also be viewed on the Resolve Issues page in		
Event: Baseline (Arm 1 Field: test5_pstl_cde ("I Status: P Not Opened	: Arm 1) Postal Code")			
Date/Time	User	Comments and Details		
07/19/2024 9:35am	jzych2	 Verified data value OR Open query Assign query to a user (optional): select user Notify this user of their assignment using: Email REDCap Messenger Comment: Please use a missing data code.		
		Open query Cancel		

3. Once a query is opened, the grey balloon beside the field changes to yellow with a red exclamation mark.



Record ID	OBI00_TST_0001
Postal Code)
Form Status	
Complete?	B Complete V

4. To respond or close the query, click on the yellow balloon. This will prompt the DRW pop-up to appear again. You can respond to the query using the **Choose Response** dropdown, or if the issue was resolved, leave a comment regarding the action taken and close the query.

Date/Time Comments and Details 07/19/2024 9:36am jzych2 07/19/2024 9:36am jzych2	🗣 Data Resolution V	Norkflow	×
Event: Baseline (Arm 1: Arm 1) Field: test5_pstl_cde ("Postal Code") Status:	Users with appropriate with the data. Opened of may be closed once the	user privileges may ope data queries may thus b	low for the specified record for a given field and/or Data Quality rule. n data queries to begin a documented process of resolving an issue e responded to by users with appropriate privileges, and then they
O7/19/2024 9:36am jzych2 Action: Opened query Comment: "Please use a missing data code." O7/19/2024 9:36am jzych2 • Reply with response: choose response Upload file (optional): • Upload document - OR • Close the query O7/19/2024 9:36am jzych2 • Close the query O7/19/2024 9:36am jzych2 • Close the query	Event: Baseline (Arm 1 Field: test5_pstl_cde ("F Status: 🙀 Open / Unre	: Arm 1) Postal Code") solved (unresponded)	
07/19/2024 9:36am jzych2 comment: "Please use a missing data code." Comment: "Please use a missing data code." Comment: "Please use a missing data code." 07/19/2024 9:36am jzych2 Comment: "Close the query 07/19/2024 9:36am jzych2 Comment: "Followed up with participant. Entered 'task declined' missing	Date/Time	User	
07/19/2024 9:36am jzych2 Upload file (optional): <u>Upload document</u> • OR – • Close the query Comment: Followed up with participant. Entered 'task declined' missing	07/19/2024 9:36am	jzych2	Comment: "Please use a missing data code."
	07/19/2024 9:36am	jzych2	Upload file (optional): O Upload document OR — OR — OR — Comment: Followed up with participant. Entered 'task_declined' missing

5. Once a query has been resolved and closed, the yellow balloon beside the field now has a green check mark.

Close the query Cancel

Record ID	OBI00_TST_0001
Postal Code	task_declined
	Task declined (task_declined)
Form Status	
Complete?	Complete 🗸



6. To view the query history or to reopen the query if need be, click the yellow balloon.

🗣 Data Resolution Workflow

x

E VIDEO: Data Resolution Workflow

This pop-up displays the Data Resolution Workflow for the specified record for a given field and/or Data Quality rule. Users with appropriate user privileges may open data queries to begin a documented process of resolving an issue with the data. Opened data queries may thus be responded to by users with appropriate privileges, and then they may be closed once the issue has been resolved. All data queries can also be viewed on the Resolve Issues page in this project.

Record ID: <u>OBIO0_TST_0001</u> Event: Baseline (Arm 1: Arm 1) Field: test5_pstl_cde ("Postal Code") Status: 🥪 Closed / Resolved

Date/Time	User	Comments and Details
07/19/2024 9:36am	jzych2	Action: Opened query Comment: "Please use a missing data code." <i>≢</i> Assign query to a user
07/19/2024 9:39am	jzych2	Action: Closed query Comment: "Followed up with participant. Entered 'task_declined' missing data code."
07/19/2024 9:41am	jzych2	Data Changes Made: test5_pstl_cde = 'task_declined'
07/19/2024 9:41am	jzych2	Comment:
		Reopen query Cancel

 Alternatively, data queries can be accessed from the Resolve Issues page on the lefthand menu. Here, the Data Resolution Dashboard shows all queries (whether open or closed). You can view a data query by selecting the comments button with the yellow balloon in the first column.

Data Resolution	n Dashboard	Filters:	Open / unresolved issues (2) ▼ All fields and rules ▼ All events ▼ User assigned (all users) or not assigned ▼				
Click button to view data query	Record	Data Quality and/or Field	rule	User Assigned	Days Open	First Update	Last Update
Ga 3 comments	OBIO0 TST 000 Baseline	Field: pstl_cd (Postal Code)		-	0	jzych2 (02/09/2024 4:31pm): "Please use a missing data code"	jzych2 (02/09/2024 4:45pm): "test"

For more information on this tool, please view this <u>article</u> in the Knowledge Base.



OBI Data Quality Reports

Upon receival of data from Data Producers, the OBI Data Quality team will conduct a secondary REDCap data quality check. As part of this process, they will review the results of the Data Quality Rules tool, the Data Resolution Dashboard, Participant Status form, and the Missing Data Flagging form for all records, before generating the Data Quality Report that will be shared with the Data Producer. If the secondary check identifies any data quality issues, the OBI Data Quality team will notify the Data Producer, allowing for the Data Producer team members to resolve the issues.

Help & Resources

For account reactivation, please contact your Neuroinformatics Lead or Program Manager.

For password reset and technical assistance, please contact the Brain-CODE help desk at <u>help@braincode.ca</u>.

General Assistance and Questions:

Please refer to Brain-CODE for Knowledge Base articles, training videos, and help desk ticket submission:

https://www.braincode.ca/content/help-resource

Test Project:

The Brain-CODE team has created a REDCap project that includes several OBI Common Data Elements and the Participant Status and Missing Data Flagging forms with locked sample records so that Data Producers can test the procedures described in this document outside of their own REDCap project. Please see DQF Stage 2 supporting document "OBI REDCap Data Quality Test Project" for a detailed description of the project.

Please contact the OBI Data Quality team for access to this project.