

INSTRUCTION FOR SENDING THE RESPOND QUERY FORM WI R11.0							
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1. PURPOSE AND SCOPE

The WI describes the process of querying mismatches, clarifications of uncertainties and missing reporting related to RESPOND events forms (including CoDe forms), including downloading and uploading of the query file in the 'Query form' project in REDCap.

2. RESPONSIBILITY

a) The RESPOND secretariat is responsible for:

- i. Granting cohort investigators access to the Query form project
- ii. Uploading the query file in an Excel format (see Figure 1)
- iii. Annually revising and maintaining the query file in real time

b) The cohort is responsible for:

- i. Providing names and email addresses of the investigators who require access to the form.
- ii. Downloading the query file and strive to resolve and complete all the queries before the given deadline (see 4. Timeline)
- iii. Uploading the revised query file (see Figure 2)

3. PROCEDURES

a) Query form

The Query form project is added to the cohort's list of projects in REDCap. It is designed to maintain all the communication in one form and avoid sending extensive emails alternating between RESPOND cohorts and the secretariat.



b) Query file

The uploaded query file within the Query form contains the following query issues as indicated in the "Query issue" column (See Figure 1). See also Table 1 for an overview of the query classifications and descriptions in the query file.

Figure 1. Query file in Excel format

PID •	REST_Even t_ID	REST_Spec	REST_Date	REDCap_FU _Event ID	REDCap_FU _Spec	REDCap_FU_ event_date_	REDCap_Eve nt_ID	REDCap_even t_Spec	REDCap_even t_date	Query issue	Query_free text_CHIP	Comment_cohort_	Resolved
###	FRA	LOAR	01-01-2012				FRA	LOAR	02-02-2012	Mismatch_event_date	Between REST and RESPOND event form		1
###	FRA	LOAR	03-05-2018				FRA	LOLG	03-05-2018	Mismatch_spec	Between REST and RESPOND event form		
###				Death		05-05-2018	CoDe		25-05-2019	Mismatch_code_date	Between FU form and CoDe form		
	Death		02-08-2019							Missing_code_form			
###	NADM	LUNG	01-01-2017							Missing_event_form	h taland		
###					Ischaemic infarction	21-05-2022	STR	Ischaemic infarction	21-05-2022	Event_form_clarification	It was noted that the patient had not any symptoms. Why imaging was performed?		
###	Death		02-01-2022				CoDe		02-01-2022	CoDe_form_clarification	Is there any additional information or medical documentation available?		9



Table 1. Overview of the query issues, classification, and description

Query issue	Query classification	Description
	Mismatch_event_date	Mismatch in event dates between REST/follow-up and RESPOND event form
Mismatch/discrepancies between the submitted dataset and the RESPOND event/CoDe forms	Mismatch_spec	Mismatch in event specifications between REST/follow-up and RESPOND event form
	Mismatch_code_date	Mismatch in death dates between REST/follow-up and CoDe form
	Missing_code_form	Missing CoDe form
Missing forms	Missing_event_form	Missing RESPOND event form
Data/information that needs	Event_form_clarification	Nonclarified data/information in RESPOND event
clarification	Code_form_clarification	form Nonclarified data/information in CoDe form

c) Form structure

The Query form consists of two sections:

- A section for the secretariat staff "Query file (from CHIP)"
- A section for the cohort investigators "Query reply (for site/cohort investigators)"

Once the file is uploaded in the Query form, save the page by clicking the 'save' button at the bottom of the form.

d) Uploading a query file

- 1. The secretariat informs the cohort by email when a query file is uploaded to the field "Query file (from CHIP)" (see Figure 2, 1). By this time, all the investigators from the cohort have access to the Query form.
- The cohort investigator downloads the query file and resolves all the queries. A free text column (comment_cohort) is provided in the file for the cohort to enter any additional comments (see Figure 1).
- 3. The cohort uploads the revised query file in the field "Query reply *For site/cohort investigators*" (see Figure 2, 3). Upon uploading the query file, the secretariat will be automatically notified.
- 4. The secretariat reviews the revisions made by the cohort. If necessary, the file is re-uploaded in the field "Query file (from CHIP) with further questions. Here, the secretariat will inform the cohort about the re-upload by email.
- 5. Once the queries are resolved and the cohort has submitted the missing RESPOND event and CoDe forms and clarified/corrected the discrepancies, the secretariat sets the form status to "Complete" and locks the form in REDCap. Consequently, the cohort can no longer alter the file and comments in the form once the form is locked.

Figure 2. Screenshot of Fields in Query form





4. TIMELINES

The first query file* is uploaded to REDCap by the secretariat during data submission (October – November) based on the submitted data by the cohort. The second query file is uploaded in January after the dataset submission and the third query file is uploaded in March before the reimbursement deadline. See Table 2 for an overview of the deadlines for file uploads by the secretariat and cohort.

Table 2. Overview of the deadlines for uploading query file

Query file	Deadline for query file upload by the RESPOND Secretariat	Deadline for query completion by cohort
First file*	October – November	1 st of December
Second file	January	1 st March
Third file	15 th March	1 st May

Note! The reimbursement deadline for submitted RESPOND event- and CoDe forms is the **1**st **of April**, forms submitted after this date will be reimbursed in the coming year. The final deadline to submit clinical events- and CoDe forms to be included in the dataset is the **1**st **of May**.

5. REFERENCES

6. HISTORY LOG

WORK INSTRUCTION



