

## 10. Data Cleaning – Query Management

Whenever **data are missing, implausible or inconsistent**, Data Management or the responsible CRAs will generate **Queries** to clean them.

- A Query will be allocated to the data field in question.
- Queried data are expected to be provided or corrected based on the source data.
- If the queried data cannot be improved, the Query answer should reflect this by **confirming the data** within the Query answer together with an **explanatory comment**.
- Details regarding Query Management can be found in the GUM section 9.

## 10. Data Cleaning – Query Management

- **To avoid Queries** regarding data that ultimately cannot be provided as requested, a **comment can be written directly at the end of the form**, confirming the data and providing an explanatory comment why the data are insufficient or missing.
- Obviously this option is only possible on forms offering a ‘Comments’ field at the bottom of the page.
- In trials with a high number of patients, Queries might be sent nonetheless. However, comments are required anyway to explain the situation and can be used as reference to answer Queries.

# 10a. Data Cleaning – Video: How to find Queries

The screenshot displays the SAKK clinical trial system interface for patient 3819\_023. The header shows the patient's date (09.08.2021 - 12:02 CEST), centre (SAKK 38/19/Training), and country (Switzerland). The navigation bar includes tabs for 'Visit plan', 'Adverse Events (1)', 'Drug Accountability/Exposure Acalabrutinib', 'Additional Treatments', and 'PRF'. The main content area shows a visit plan table with columns for Pre-Registration, Registration, Baseline, C1 day1, C1 day8, C2 day1, and Next visit. The table lists various data points such as Planned visits, Pre-registration, Eligibility, Medical History, Physical Examinations, Lab Assessments, Trial Drug Exposure RCHOP and CNS prophylaxis, Tumor Assessments, and Cohort Allocation. Each data point is associated with a date and a status icon (e.g., green document, red triangle, yellow document).

	Pre-Registration	Registration	Baseline	C1 day1	C1 day8	C2 day1	Next visit
Planned visits	13.11.20	14.11.20	14.11.20	15.11.20	22.11.20	06.12.20	
Pre-registration	📄						
Eligibility		📄					
Medical History			📄				
Physical Examinations		📄	📄	📄	📄	📄	
Lab Assessments		📄	📄	📄	📄	📄	
Trial Drug Exposure RCHOP and CNS prophylaxis				📄		📄	
Tumor Assessments		📄					
Cohort Allocation		📄					

# 10b. Data Cleaning – Video: How to answer Queries

secuTrial<sup>SM</sup> SETUP | SAKK | CRC Investigator | CRC internal Project | SAKK 38/19 (05.08.2021 - 13:43:08 (CEST)) | Close | Reload | Excel | Print

**2.0 Query report (58 Queries)**

Show:  Status  Patient  Centre  Query from  Created  resolved  Doc-No.  Form  Item  Event  Current entry

Type	No.	Status	Patient	Centre	Query from	Created	resolved	Doc-No.	Form	Item	Event	Violating value	Current entry
<input type="checkbox"/>	All	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >	
<input type="checkbox"/>	▶	M#301	✓	3819_024	SAKK 38/19Training	CRA internal	21.06.2021	21.06.2021	1843	Radiotherapy	1 : Start date	Additional Treatments	Done.
<input type="checkbox"/>	▶	M#322	?	3819_006	SAKK 38/19Training	CRA internal	19.07.2021		1674	Patient registration	Eligibility criteria met	Registration	correct
<input type="checkbox"/>	▶	M#341	!	3819_020	SAKK 38/19Training	CRA internal	20.07.2021		1201	Physical examination	Heart rate (bpm)	C1 day8	Query automatically answered because of value change with reason: "gfdgdfg"
<input type="checkbox"/>	▶	M#361	!	3819_020	SAKK 38/19Training	Bolek	21.07.2021		1200	Trial drug exposure - RCHOP and CNS prophylaxis	Intrathecal methotrexate administered within this cycle?	C1 day1	Query automatically answered because of value change with reason: "data updated"
<input type="checkbox"/>	▶	M#362	!	3819_020	SAKK 38/19Training	CRA internal	21.07.2021		1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Date dispensed	Drug Accountability/Exposure Acalabrutinib	Query automatically answered because of value change.
<input type="checkbox"/>	▶	M#363	*	3819_020	SAKK 38/19Training	CRA internal	21.07.2021	22.07.2021	1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Tablets dispensed	Drug Accountability/Exposure Acalabrutinib	b
<input type="checkbox"/>	▶	M#364	?	3819_020	SAKK 38/19Training	CRA internal	21.07.2021		1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Tablets dispensed Not done	Drug Accountability/Exposure Acalabrutinib	Input required
<input type="checkbox"/>	▶	M#365	?	3819_020	SAKK 38/19Training	CRA internal	21.07.2021		1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Date returned	Drug Accountability/Exposure Acalabrutinib	Input required
<input type="checkbox"/>	▶	M#366	?	3819_020	SAKK 38/19Training	CRA internal	21.07.2021		1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Tablets returned	Drug Accountability/Exposure Acalabrutinib	Input required
<input type="checkbox"/>	▶	M#367	!	3819_020	SAKK 38/19Training	CRA internal	21.07.2021		1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Tablets returned Not done	Drug Accountability/Exposure Acalabrutinib	Query automatically answered because of value change.
<input type="checkbox"/>	▶	M#368	!	3819_020	SAKK 38/19Training	CRA internal	21.07.2021		1727	CNS prophylaxis after trial treatment phase	1 : End date	Additional Treatments	Query automatically answered because of value change.
<input type="checkbox"/>	▶	M#369	?	3819_020	SAKK 38/19Training	CRA internal	21.07.2021		1865	Radiotherapy	2 : End date	Additional Treatments	Input required
<input type="checkbox"/>	▶	M#381	!	3819_020	SAKK 38/19Training	CRA training 38/19	22.07.2021		1201	Physical examination	ECOG performance status	C1 day8	Query automatically answered because of value change with reason: "gfdgdfg"
<input type="checkbox"/>	▶	M#382	?	3819_020	SAKK 38/19Training	CRA training 38/19	22.07.2021		1201	Physical examination	Body temperature Clinically significant	C1 day8	Please check if 37.0 is actually CS
<input type="checkbox"/>	▶	M#383	!	3819_020	SAKK 38/19Training	CRA training 38/19	22.07.2021		1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Tablets dispensed	Drug Accountability/Exposure Acalabrutinib	Query automatically answered because of value change.
<input type="checkbox"/>	▶	M#384	?	3819_020	SAKK 38/19Training	CRA training 38/19	22.07.2021		1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Intake omitted	Drug Accountability/Exposure Acalabrutinib	Input required
<input type="checkbox"/>	▶	M#385	*	3819_020	SAKK 38/19Training	CRA training 38/19	22.07.2021	03.08.2021	1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Reason	Drug Accountability/Exposure Acalabrutinib	not necessary
<input type="checkbox"/>	▶	M#386	*	3819_020	SAKK 38/19Training	CRA training 38/19	22.07.2021	03.08.2021	1204	Drug accountability /exposure Acalabrutinib	Line 2: Acalabrutinib - Please specify	Drug Accountability/Exposure Acalabrutinib	not necessary
<input type="checkbox"/>	▶	M#401	?	3819_020	SAKK 38/19Training	CRA training 38/19	02.08.2021		2044	AE Adverse Event	AE - Development 1: Start date	6. "Gastrointestinal disorders - Other, specify"	Input required
<input type="checkbox"/>	▶	M#402	*	3819_022	SAKK 38/19Training	CRA training 38/19	02.08.2021	04.08.2021	2065	Physical examination	Exam date	C1 day8	Incorrect query
<input type="checkbox"/>	▶	M#403	*	3819_022	SAKK 38/19Training	CRA training 38/19	02.08.2021	04.08.2021	2065	Physical examination	Assessment date	C1 day8	incorrect q
<input type="checkbox"/>	▶	M#404	?	3819_022	SAKK 38/19Training	CRA training 38/19	02.08.2021		2066	Lab Assessments	Collection date	C1 day8	Date not 8 days after previous visit (-2 days). Please correct or confirm data.
<input type="checkbox"/>	▶	M#421	?	3819_022	SAKK 38/19Training	Bolek	04.08.2021		2065	Physical examination	Assessment date	C1 day8	Date not 8 days after previous visit (-1.4 days). Please correct or confirm

## 10. Data Cleaning – How to answer Queries

- To answer queries by **adding/ correcting data**, updates have to be performed **directly within the eCRF**. The **saving of the data** happens at the bottom of the form (**Reason for modification + Save button**).
- Queries are automatically answered after a data update, when they are allocated to data fields that have been modified.
- In case a **Query is allocated to a data field different from the one that actually was updated**, it has to be **answered manually within the Query pop up window**, confirming the respective data and providing an explanatory comment.
- Whenever there are still **Warnings on the form** after updates have been done, a **second click on the save button** is necessary to save the modifications performed.



## 10. Data Cleaning – How to answer Queries

- Only when a pop up window confirms data saving, new and modified data have been actually saved!
- **Casenodes in older trials** should not be set on status DEC as long as additional data or data updates are expected, to avoid any blocking of the forms by SDV or allocation of Queries.
- **Casenodes in newer trials** (activated from 2021 on), used for ongoing data recording, will not offer the status DEC anymore. SDV and Query allocation can be performed in parallel to data updates.

## 10. Data Cleaning – How to answer Queries

- When a **Query is allocated to a header section** and lead to an **opening of a previously hidden subsection**, the subsection can usually **not be populated right after** as the query blocks all sections on the form with exception of the one it is allocated to. New unresolved queries are needed.
- Sometimes subsections are not easy to recognize, as there is no visible line in-between. Only separate tags and buttons identify them.
- **Avoid answering queries with temporary answers** like: ‘Will be provided later’. Those Queries have to be reopened immediately and only causing unnecessary work for all involved.

## 10. Data Cleaning – Protocol Deviation tags

- Beside Query tags  (triangles), there are in more recent trials also Protocol Deviation tags  to find (D shaped tags).
- Instead of manually populated data listings, protocol deviations are now recorded integrated within the eCRF.
- They are displayed to you but you do not need to follow up on them. They are managed exclusively by SAKK CC.





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# Thank you for watching!

The Swiss Oncology Research Network