

## 9. Data Entry – Registration forms (current version)

- Data Entry starts with the registration forms. Highly secured forms as they are used to document eligibility and inclusion of a patient.
- Prior completing the eCRF registration forms an Eligibility Worksheet available on [portal.sakk.ch](https://portal.sakk.ch) has to be completed and signed by the treating investigator. (See *trial protocol section 7 for details*)
- Registration forms have to be completed entirely and correctly as well as in the correct order!

Current registration files (from 2020 on) consists of 2 forms:

EV Eligibility evaluations  
ER Patient registration (and randomization)

- Depending on the protocol, a pre-registration might also be necessary.
- A form has to be saved and closed (DEC) before the next one can be filled in.
- After all forms are completed, saved and closed, an email will be sent to your attention, confirming the patient's registration

# 9a. Data Entry – Video: registration forms (current version)

The screenshot displays a web browser window with the following details:

- Browser Tabs:** SAKK secuTrial, ST - DataCapture - 6.1.0.7 (SAKK) Tr, auffordern - LEO: Übersetzung
- Address Bar:** Not secure | sakkst02.siak.ch/apps/WebObjects/ST21-productive-DataCapture.woa/1/wo/9b81xEFEkFGooCLpyWARw\_0SAKPP/152.0.1.1.31.NavigationMenuBar.2.11#
- Page Header:**
  - SAKK Logo:** WE BRING PROGRESS TO CANCER CARE
  - Date:** 24.02.2021 - 19:31 (CET)
  - Centre:** CH-0999 Bern/TrainingCenter 23/18
  - CRCC/Investigator Project:** CRC Training SAKK 23/18 (1\_0\_001)
  - Country:** Switzerland
  - Patient:** UPN 2318\_014
  - Time left:** 39:46
  - Navigation:** Centre | Help | Logout
- Breadcrumbs:** Welcome -> CH-0999 Bern/TrainingCenter 23/18 -> Patient 2318\_014
- Navigation Bar:** My Reports | Patient | New patient | Select (Patient, Centre)
- Main Content Area:**
  - Visit plan / Adverse Events:** Two tabs are visible.
  - Planned visits:** A table with columns for visit type and date. One entry is shown: Screening Eligibility on 24.02.21, with a 'Next visit' label.
  - Medical History:** A section with a minus sign icon.
  - Tumor Assessment:** A section with a minus sign icon.
  - Clipping Procedure:** A section with a minus sign icon.
  - Clinical Examinations:** A section with a minus sign icon.
  - Intervention:** A section with a minus sign icon.
  - Pathology:** A section with a minus sign icon.
  - Follow Up:** A section with a minus sign icon.
  - Patient / Visit:** Two icons at the bottom of the main area.

The Windows taskbar at the bottom shows the search bar, various application icons, and the system tray with the date 24.02.2021 and time 19:31.

## 9. Data Entry - What to take away from the video

- Trying to save an eCRF form always initiates an internal data validation.
- Missing or incorrect data will trigger 'Warnings'.
  - 'Warnings' can be setup as 'Hard'- (HC) or 'Soft'- (SC) Checks
- The existence of **HC Warnings** (red) on a form prevents any saving of data!
- The existence of **SC Warnings** (orange) on a form requires repeated saving, if new or modified data need to be saved!
- If there are no data to be saved, a form can be left using the '**Cancel**' button.
- If data should be saved, there are two options:
  - Using the '**Save**' button → only saves the data
  - Using the '**Save + close entry**' button → saves the data and gives the form a new status:  
**Data Entry Complete (DEC)** – green colored icons

## 9. Data Entry Complete (DEC) - a fundamental concept in sT

- In order to save the data of a form you can click on the ‘**Save**’ button or on ‘**Save + close entry**’.
- If you enter data but you cannot complete the whole form, you can use the ‘**Save**’ button, to revisit and finalize it later. (Only if there is no HC Warning on the form!)



- Do this only if you are sure to have the data soon. Otherwise, rather follow up as described below and reopen the form later, respectively wait for queries asking to record the missing data.



- If you have completed the form and there is no information to be added later on, you must close the data entry with the “Save + close entry” button.



## 9. Data Entry Complete (DEC) - a fundamental concept in sT

- Forms closed with **'Save + close entry'** cannot be edited anymore unless you use the **'Reopen data entry'** button. 
- Closed forms are a trigger for source data verification (SDV) by the CRA or data validation by Data Management → Queries.
- As soon as one of these processes have been started, the **'Reopen data entry'** button will no longer be available.
- To modify a DEC form, ask the responsible CRA or DM to put a new Query in the section of the form you like to update. This will open only this section.

## 9b. Data Entry - Video: Saving data; Data Entry Complete (DEC)

**SAKK** WE BRING PROGRESS TO CANCER CARE

Date: 20.04.2021 - 10:52 (CEST) Centre: CH-0999 Bern/TrainingCenter 23/16  
CRC/Investigator: CRC Training Country: Switzerland  
Project: SAKK 23/16 (2.8\_011) Patient: UPN 2316\_0624 Rand-Gr: Arm A: ALND

Time left: 39:50  
Welcome | Help | Logout

> Welcome > Patient 2316\_0624 | My Reports | Patient | New patient | Select (Patient, Centre)

**Visit plan** | Adverse Events | Surgical procedures | Radiotherapy | Systemic treatment | Pathology | PRF

**Registration**

Planned visits	Pre-registration	Eligibility	Randomization	Baseline	SG - Week 1	Next visit
	06.04.21	07.04.21	07.04.21	08.04.21	09.04.21	
Eligibility - Pre-registration						
Eligibility - Registration						
Randomization						
Medical History						
Physical Examinations						
Quality of Life						

⊖ Patient   ⊖ Visit   ⊖ Visit   ⊖ Visit   ⊖ Visit   ⊖ Visit

## 9. Data Entry - Addendum: Older Registration forms

- In older trials, we have more 3 or 4 registration forms. Plus pre-registration and randomization forms if applicable.

ER Information on patient registration

IE Inclusion / exclusion criteria (separate forms in very old trials)

EV Eligibility evaluations

- The principles of completing them are similar to what we have seen previously for the latest version of the registration forms.
- The differences are:
  - the order of the forms is different. However, as long as you complete them from the left to the right you do not need to care.
  - and more important, the treating investigator has to provide his signature on the previously completed and printed **eCRF ER** form. (See *protocol section 7 for details*)

## 9c. Data Entry – Video: Older registration forms

 **SAKK**  
WE BRING PROGRESS TO CANCER CARE

Date: 26.02.2021 - 10:39 (CET) Centre: CH-0999 Bern/TrainingCenter 23/16  
CRC/Investigator: CRC Training Country: Switzerland  
Project: SAKK 23/16 (2.8\_011) Patient: UFN 2316\_0622 Rand-Gr

Time left: 39:53  
Welcome | Help | Logout

> Welcome > Patient 2316\_0622 My Reports | Patient | New patient | Select (Patient, Centre)

**Visit plan** | Adverse Events | Surgical procedures | Radiotherapy | Systemic treatment | Pathology | PRF

**Registration**

	Pre-registration	Eligibility	Randomization	Next visit
Planned visits	18.02.21	19.02.21	19.02.21	
Eligibility - Pre-registration				
Eligibility - Registration				
Randomization				
⊖ Patient	⊖ Visit	⊖ Visit	⊖ Visit	

## 9. Data Entry - Important data entry rules

- The latest version of Data Entry rules can be found in the current version of the **General User Manual - section 7**.
- Relevant for a specific study are the instructions given in the respective **Trial Specific Manual**.

# 9d. Data Entry – Video: Data Entry Principles I (eCRF sections, dates, radio-button, subordinate data fields, free text fields, 'Comments' section)

> Welcome > Patient 3819\_024 > Baseline > Physical examination My Reports

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**PE PHYSICAL EXAMINATION**

**PHYSICAL EXAMINATION**

Was the physical examination performed?  Yes  No

Examination date -- dd.mm.yyyy

Result  Normal  Abnormal

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**VITAL SIGNS**

Were vital signs collected?  Yes  No

Assessment date -- dd.mm.yyyy

	Result	Clinically significant	Assessment date (Enter dates below only if different from assessment date on top)	Not done
Heart rate	<input type="text"/> bpm	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy	<input type="radio"/> <input type="checkbox"/>
Systolic blood pressure	<input type="text"/> mmHg	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy	<input type="radio"/> <input type="checkbox"/>
Diastolic blood pressure	<input type="text"/> mmHg	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy	<input type="radio"/> <input type="checkbox"/>
Body temperature	<input type="text"/> °C	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy	<input type="radio"/> <input type="checkbox"/>
Body weight	<input type="text"/> kg	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy	<input type="radio"/> <input type="checkbox"/>
Height	<input type="text"/> cm	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy	<input type="radio"/> <input type="checkbox"/>

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**COMMENTS**

To add a comment, press the MORE button.  
Please use English language only.

No.

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Last signed by at Project version: --      Validity Signature meaning: Not signed      Language: --

Date: 17.06.2021 - 12:14 (CEST)    CRC/Investigator: CRC internal    Project: SAKK 38/19 (07.06.2021 - 10:18:52 (CEST))    Centre: SAKK 38/19Training    Country: Switzerland  
UPN: 3819\_024    Baseline: 14.11.2020 (CET)    Form family: Physical Examinations    Form: Physical examination

## 9. Data Entry – Data Entry Principles II – Repetition Groups

- To complete a flexible number of records with identical items, so called ‘Repetition Groups’ are used.
- A ‘Repetition Group’ can be identified on the eCRF by the ‘More’ button, that comes with it.
- Typical eCRFs with a ‘Repetition Group’ are Casenodes like Adverse Event or Concomitant Medication.
- Regular visit forms can come with it too, as shown in the ‘Data entry principles I’ video by presenting how to add and delete records within the ‘Comments’ section.

## 9. Data Entry – Data Entry Principles II – Casenodes

- Previously we learned that all forms have to be set on status Data Entry Complete (DEC) to allow CRA and DM to follow up on them.
- There is now an exception to it. The **latest generation of Casenodes**, used to document data in an ongoing manner, does **not require the DEC status** anymore and hence can be completed continuously even after SDV or Query allocation.

## 9e. Data Entry – Video: Data Entry Principles II – Casenodes / Repetition Groups

> Welcome > SAKK 38/19Training > Patient 3819\_020

Visit plan

Adverse Events (2)

Drug Accountability/Exposure Acalabrutinib

Additional Treatments

PRF

Concomitant medication



CNS prophylaxis after trial treatment phase



Radiotherapy



## 9. Data Entry – Data Entry Principles III – Catalogs

- In SAKK trials the following catalogs are used:
  - CTCAE for Adverse Events and Baseline Symptoms
  - ATC for medication

For medication, alternatively free text fields without a catalog can be provided or dropdown menus with predefined options.

# 9f. Data Entry – Video: Data Entry Principles III – CTCAE



Date: 26.07.2021 - 16.26 (CEST)

CRC/Investigator: CRC training 38/19

Project: SAKK 38/19 (22.07.2021 - 12.30.27 (CEST))

Centre: SAKK 38/19 Training, Switzerland

Patient: UPN 3819\_022

2. AE Adverse Event: 26.07.2021 (CEST)

Form family: Adverse Events

Form: AE Adverse Event

Time left: 36:48

[Back](#) | [Reload](#) | [Help](#) | [Logout](#)

[My Reports](#)

> Welcome > Patient 3819\_022 > AE Adverse Event

**2. ADVERSE EVENT**

**Adverse Event Term CTCAE v5.0**

*Document AEs for Cohort A & B patients only!*

*Leave the form using the CANCEL button, to not set up the AE.*

**Catalog**

System organ class (SOC)

Term

Specify 'other' here:

*AEs of special interest (AESIs) are Ventricular arrhythmias e.g.: ventricular tachycardia, ventricular fibrillation, etc.*

Is this event an adverse event of special interest (AESI)?  No  Yes

Is this event a serious adverse event (SAE)?  No  Yes

**DEVELOPMENT**

**AE - Development 1**

Start date:  dd.mm.yyyy

Grade:

Relation to Acalabrutinib:

End date:  dd.mm.yyyy

Ongoing:

Validity:  Not signed

Signature meaning:

Language:

[Cancel](#) [Save](#)

Date: 26.07.2021 - 16.26 (CEST) CRC/Investigator: CRC training 38/19 Project: SAKK 38/19 (22.07.2021 - 12.30.27 (CEST)) Centre: SAKK 38/19 Training Country: Switzerland

UPN: 3819\_022 2. AE Adverse Event: 26.07.2021 (CEST) Form family: Adverse Events Form: AE Adverse Event

## 9g. Data Entry — Video: Data Entry Principles IV — document medication & ATC

Soon to come

## 9. Data Entry – AE and SAE

- **AEs** have to be recorded according to trial protocol chapter 10
- **SAEs** according to trial protocol chapter 11.
- For trials with a **paper based SAE reporting process**, each **SAE reported requires an AE form to be completed in addition** with equivalent data.
- For trials with **eSAE process**, **no such separate AE needs to be reported anymore**, as it is integrated in the eSAE form.
- AEs, which happen prior to the start of trial treatment, are considered as **Baseline Symptoms**.
- Baseline Symptoms are documented separately under the form family: Medical History.
- Baseline Symptoms, which are worsening after trial treatment start, have to be documented as AEs from the time point of worsening. (Check the protocol for possible restrictions regarding this rule).
- Always check the trial protocol and TSM for special requirements not covered above.

# 9h. Data Entry – Video: old AE and eSAE forms



Date 07.12.2021 - 10.27 (CET) Centre CH-0002 Basel/Universitätsspital Basel 19/17  
 CRC/Investigator CRC training 19/17 Country Switzerland  
 Project SAKK 19/17 (2.1\_000) Patient UPN 1917\_037

Time left: 39:10

Welcome | Help | Logout

> Welcome > Patient 1917\_037

My Reports | Patient | New patient | Select (Patient)

**Visit plan** | Adverse Events | Further systemic anti-cancer treatment | Central PD-L1 testing | PRF

	Pre-Treatment Phase	Cycle 1		Cycle 2		Cycle 3		Cycle 4	Next visit
	Pre-Treatment Phase	C1 - Day 1	C1 - Day 15	C2 - Day 1	C2 - Day 15	C3 - Day 1	C3 - Day 15	C4 - Day 1	
Planned visits	06.05.21	07.05.21	20.05.21	02.06.21	16.06.21	30.06.21	14.07.21	06.08.21	
Eligibility									
Medical History									
Physical Examinations									
Lab Assessments									
Questionnaires									
Tumor Assessments									
Trial Drug Exposure									
End of Treatment									
Follow up									



## 9i. Data Entry – Video: Latest AE and eSAE forms

Soon to come