



## Overview

- Access to secuTrial® >> 3
- Patient registration >> 10
- Form Overview >> 18
- Visit plan >> 23
- Data Entry >> 33
- AE reporting >> 51
- Query Management >> 63
- Reports and Statistics >> 71
- Guidelines, Training & Support >> 77

# Access to secuTrial®

3 Clinical Data Management



## Access to secuTrial®

- One login for all secuTrial® trials
- Rights to access the data of a particular trial have to be allocated by the clinical data manager at the SAKK CC
- Site staff can only access data of the own site
- How to get access to secuTrial®?
  - Send authorization list to the SAKK CC
  - Trial coordinator forwards request the clinical data management
  - Login details (User-ID and password) will be sent to site staff within 2 working days

4 Clinical Data Management



# Access to secuTrial®

>> [www.sakk.ch/edc](http://www.sakk.ch/edc)



Welcome to the SAKK EDC trials. Please select the trial from the list below that you would like to enter data for. You will then be forwarded to the appropriate EDC system login page.

Trial Number	Project Group	EDC System
SAKK 01/10	Urogenital Cancers	secuTrial ®
SAKK 08/11	Urogenital Cancers	secuTrial ®
SAKK 09/10	Urogenital Cancers	sinatras (only registration)
SAKK 16/08	Lung Cancers	sinatras
SAKK 17/04	Lung Cancers	sinatras (only registration)
SAKK 19/09	Lung Cancers	sinatras
SAKK 24/09	Breast Cancers	sinatras
SAKK 35/10	Lymphomas	sinatras (only registration)
SAKK 39/10	Lymphomas	secuTrial ® (paper trial)
SAKK 40/04	Gastrointestinal Cancers	sinatras (only registration)
SAKK 41/06	Gastrointestinal Cancers	sinatras (only registration)
SAKK 41/08	Gastrointestinal Cancers	sinatras (only registration)
SAKK 41/10	Gastrointestinal Cancers	secuTrial ®
SAKK 56/07	Gastrointestinal Cancers	sinatras (only registration)
SAKK 75/08	Gastrointestinal Cancers	sinatras (only registration)
SAKK 77/08	Gastrointestinal Cancers	sinatras

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[www.sakk.ch](http://www.sakk.ch)



# Access to secuTrial®



Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung  
Groupe Suisse de Recherche Clinique sur le Cancer  
Swiss Group for Clinical Cancer Research  
Gruppo Svizzero di Ricerca Clinica sul Cancro  
The Swiss Oncology Research Network

## SAKK EDC Trials: Registering new patients, filling in CRFs

(SAKK)  
This area is non-public and accessible for registered participants only. If you are a registered user, please enter your user-ID and password in the respective fields. When you enter for the first time you will be required to change your password when manually using the "Change password" button.  
Please be aware that by logging in, you are taking responsibility for the actions undertaken login and/or password to any other person, as their actions will be attributed to you.

For news check: [www.sakk.ch](http://www.sakk.ch)

User-ID

test

Password

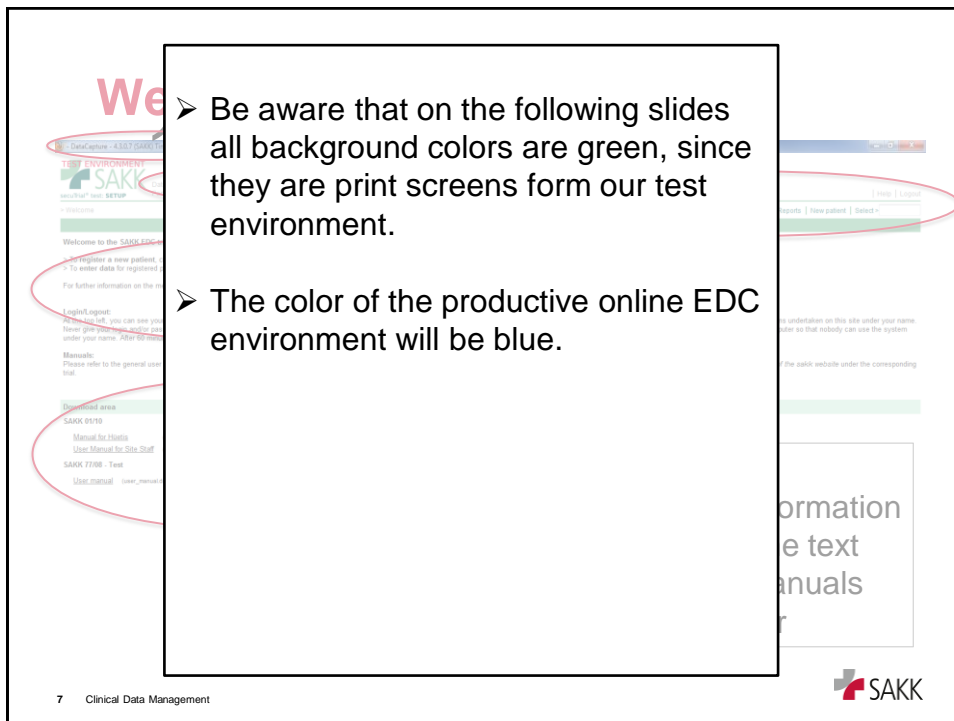
\*\*\*\*\*

Login

Change password

- Pop-up blockers have to be switched off
- Password has to be changed at the first login



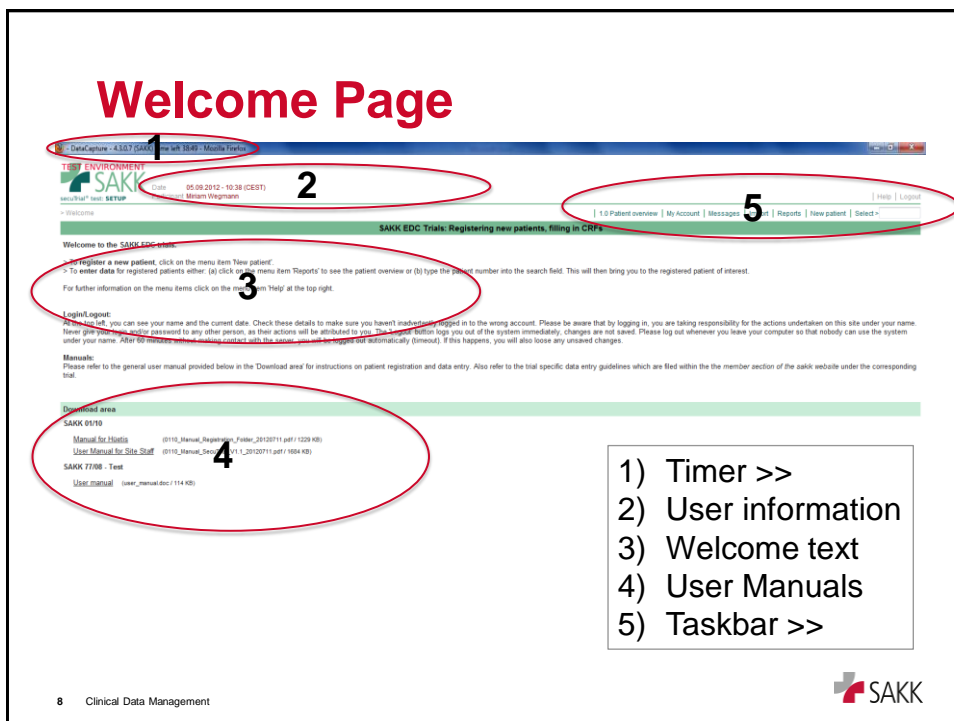


**We**

- Be aware that on the following slides all background colors are green, since they are print screens from our test environment.
- The color of the productive online EDC environment will be blue.

7 Clinical Data Management

SAKK



## Welcome Page

- 1
- 2
- 3
- 4
- 5

SAKK EDC Trials: Registering new patients, filling in CRFs

Welcome to the SAKK EDC trials:

- To register a new patient, click on the menu item 'New patient'.
- To enter data for registered patients either: (a) click on the menu item 'Reports' to see the patient overview or (b) type the patient number into the search field. This will then bring you to the registered patient of interest.

For further information on the menu items click on the menu item 'Help' at the top right.

**Login/logout:**  
Please be aware that you can see your name and the current date. Check these details to make sure you haven't inadvertently logged in to the wrong account. Please be aware that by logging in, you are taking responsibility for the actions undertaken on this site under your name. Never give your password to any other person, as their actions will be attributed to you. The system will log you out of the system immediately, changes are not saved. Please log out whenever you leave your computer so that nobody can use the system under your name. After 60 minutes without activity contact with the system, you will be logged out automatically (timeout). If this happens, you will also lose any unsaved changes.

**Manuals:**  
Please refer to the general user manual provided below in the 'Download area' for instructions on patient registration and data entry. Also refer to the trial specific data entry guidelines which are filed within the member section of the sakk website under the corresponding trial.

**Download area**

SAKK 0510

Manual for Patients (0510\_Manual\_Registering\_Patient\_20120711.pdf / 1228 KB)

User Manual for Site Staff (0510\_Manual\_Site\_Staff\_20120711.pdf / 1004 KB)

SAKK 7700 - Test

User manual (user\_manual.doc / 114 KB)

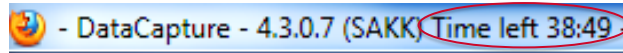
1) Timer >>  
2) User information  
3) Welcome text  
4) User Manuals  
5) Taskbar >>

8 Clinical Data Management

SAKK

## Welcome Page

➤ Timer:



After 40 minutes without any active use, the system will automatically log you out

➤ Taskbar:



- 1) Go to reports and statistics
- 2) Register a new patient
- 3) Enter patient number to select a patient
- 4) Log out to prevent unauthorized access

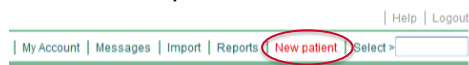
# Patient registration

## Patient registration

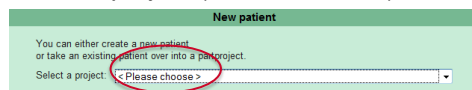
- Patients have to be registered online by the site staff (only in case of system breakdown, it is allowed to register the patient by faxing the E form)
- Hard errors are implemented on the E forms → Only correct data can be saved
- The forms have to be entered in the right order: E1 → E2 → E3...
- In case you have created a new patient by mistake or you have realized only at the time point of registration that the patient is ineligible, please contact the SAKK CC

## Patient registration

1. Click on 'new patient'.



2. Select a project (choose the trial).



3. Select a centre (your site), if not already preselected.

## Patient registration

4. For the 'entry date' enter the date of the planned treatment start.

**New patient**

You can either create a new patient or take an existing patient over into a participant.

Select a project: SAKK 0811 (05.09.2012 - 07.24.08 (CEST)) [\[Project\]](#)

Select a centre: Spitalay - 0811

**Create Visit plan**

Please enter date of entry after end of the last visit for the visit plan.

Entry date: 05 / 09 / 2012 [\[Entry date\]](#)

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

5. Save.

- The system will generate a unique patient number
- The entry date will be used as base for the visit plan
- Form E1 will be opened automatically

## Patient registration

6. Note the unique number in the screening, enrollment and identification list

**TEST ENVIRONMENT**

**SAKK**

Date: 05.09.2012 - 11.12 (CEST) Patient ID: g0494 Patient Registration Number: 0811\_027

Download: Malign Melanoma Project: SAKK 0811 (05.09.2012 - 07.24.08 (CEST)) Form family: E\_Eligibility Form: E1 Information on Patient Registration

[\[Back\]](#) [\[Help\]](#) [\[Logout\]](#)

[\[1/10 Patient overview\]](#)

**E1 INFORMATION ON PATIENT REGISTRATION**

**PROTOCOL TITLE**

SAKK 0811 - Oral and maintenance therapy in patients with metastatic castration resistant prostate cancer and non-progressive disease after first-line docetaxel therapy. A multicenter randomized double-blind placebo-controlled phase III trial.

[\[Comment\]](#)

- The screening, enrollment and identification list is the only link between the patient's identity and the patient number
- Retrospective assignment of patients to a patient number is not possible

## Patient registration

7. Enter form E1 and click **'Save + close entry + print'**



- A 'print window' will pop-up automatically (pop-up blocker has to be switched off; if no pop-up window shows, press 'ctrl+p' to print)
- Do not use the 'Save + print' button

## Patient registration

8. Print form E1, fill in date and signature.

- **only the treating investigator is allowed to sign the form**

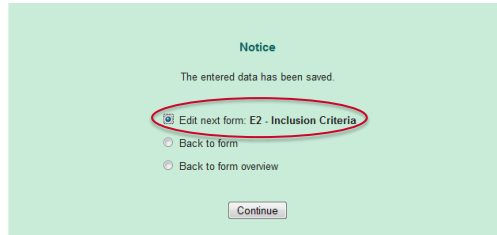
SIGNATURE OF TREATING INVESTIGATOR	
<small>INSTRUCTIONS: This form has to be printed and signed by the treating investigator. Please send the signed form by mail or fax within a month after registration to: SAKK Coordinating Center, Effingerstrasse 40, CH-3008 Bern, Fax +41 31 389 92 00.</small>	
<small>I herewith confirm that the above information and all eligibility criteria are correct.  Treatment will be conducted in accordance with the trial protocol.  I will comply with all applicable laws and regulations.  I ensure that the CRF will be entered online in a timely manner at the specified time points.</small>	
Date	Signature (Treating Investigator)

9. Send form E1 to SAKK CC by fax (+41 31 389 92 00) or mail within one month after registration



## Patient registration

10. Open the next form by clicking 'continue'.



- If the next form is not presented on the screen, make sure you clicked 'save+close' on the previous form
11. Complete all E forms with **'save + close entry'**
  12. You will receive an email confirming patient registration

## Form Overview

## Form Overview

1. User > Role and name

2. Centre > Site

3. Patient > Patient number, Rando No (if applicable)

4. Welcome > back to welcome page

5. Visitplan / Adverse Events / Other forms etc. >>

19 Clinical Data Management


## Form Overview – Visit plan

Forms part of the visit plan

20 Clinical Data Management

# Form Overview – Adverse Events

TEST ENVIRONMENT



Date05.09.2012 - 14:16 (CEST)

DeveloperMiriam Wegmann

ProjectSAKK 0611 (05.09.2012 - 07.24.08 (CEST))

CentreSplachy - 0811

Country-

Patient IDgls494

RandomisationHINDI

Welcome | Help | Logout

Welcome > Patient gls494

Edit visit plan | Patient file | New patient | Select >

Visit plan


Adverse Events

Other forms

New Adverse Event


➤ Reporting of AEs

21Clinical Data Management



# Form Overview – Other forms, etc

TEST ENVIRONMENT



Date05.09.2012 - 14:16 (CEST)

DeveloperMiriam Wegmann

ProjectSAKK 0611 (05.09.2012 - 07.24.08 (CEST))

CentreSplachy - 0811

Country-

Patient IDgls494

RandomisationHINDI

Welcome | Help | Logout

Welcome > Patient gls494

Edit visit plan | Patient file | New patient | Select >

Visit plan

Adverse Events

Other forms

PRF

P1


P1 Pathology

P2 Pathology

CB Code Breaking Form

➤ Forms not part of the visit plan

22Clinical Data Management



# Visit plan

23 Clinical Data Management



## Visit plan

- Stick to the excel scheduler
- Date of planned visits are calculated on base of the entry date when creating a new patient

24 Clinical Data Management



## Visit plan

**TEST ENVIRONMENT**  
**SAKK**  
 Date: 05.09.2012 - 14:16 (CEST) Centre: Splakty - 0811  
 Project: SAKK 0811 (05.09.2012 - 07.24.08 (CEST)) Patient: PatID: gsa494  
 Random: MNCH

Welcome | Help | Logout

**6** Edit Visit plan Patient file New patient Select >

**1** Planned visits

**2** Add scheduled or unscheduled visits

**3** Form families

**4** Available forms at different visits

**5** Forms of family 'E\_Eligibility'

**6** Edit visit plan >>

25 Clinical Data Management

**SAKK**

## Changing dates of planned visits

1. Click 'Edit visit plan'.

Welcome | Help | Logout

**Edit Visit plan** Patient file New patient Select >

2. Change date and click 'Preview'. The dates of subsequent visits will be shifted.

**Edit Visit plan**

After date change all subsequent visits will be shifted accordingly as long as the dates has not been changed for themselves.  
 The last scheduled or the last unscheduled visit of the same type without data entry can be deleted.

Entry date	05.09.2012 (CEST)	05.09.2012	1st.mm.yyyy (CET/CEST)
Registration	05.09.2012 (CEST)	05.09.2012	1st.mm.yyyy (CET/CEST)
Pretreatment Visit	05.09.2012 (CEST)	05.09.2012	1st.mm.yyyy (CET/CEST)
Visit 1	05.09.2012 (CEST)	05.09.2012	1st.mm.yyyy (CET/CEST)
15d after v1	19.09.2012 (CEST)	19.09.2012	1st.mm.yyyy (CET/CEST)
Visit 2	03.10.2012 (CET)	03.10.2012	1st.mm.yyyy (CET/CEST)
15d after v2	17.10.2012 (CET)	17.10.2012	1st.mm.yyyy (CET/CEST)
Visit 3	31.10.2012 (CET)	31.10.2012	1st.mm.yyyy (CET/CEST)
Visit 4	28.11.2012 (CET)	28.11.2012	1st.mm.yyyy (CET/CEST) Delete

Cancel Reset **Preview**

# Changing dates of planned visits

- 3. Enter a reason for modification and confirm by clicking 'Save'.

Edit Visit plan

After date change all subsequent visits will be shifted accordingly as long as the dates has not been changed for themselves.  
The last scheduled or the last unscheduled visit of the same type without data entry can be deleted.

Current visit plan		New visit	
Entry date	05.09.2012 (CEST)	Entry date	05.09.2012 (CEST)
Registration	05.09.2012 (CEST)	Registration	05.09.2012 (CEST)
Pretreatment Visit	05.09.2012 (CEST)	Pretreatment Visit	05.09.2012 (CEST)
Visit 1	05.09.2012 (CEST)	Visit 1	05.09.2012 (CEST)
15d after v1	19.09.2012 (CEST)	15d after v1	17.09.2012 (CEST)
Visit 2	03.10.2012 (CEST)	Visit 2	01.10.2012 (CEST)
15d after v2	17.10.2012 (CEST)	15d after v2	15.10.2012 (CEST)
Visit 3	31.10.2012 (CET)	Visit 3	29.10.2012 (CET)
Visit 4	28.11.2012 (CET)	Visit 4	26.11.2012 (CET)

Reason for modification:  
shifted due to holidays

CancelBackSave

# Deleting pre-defined visits

- 1. Click 'Edit visit plan'.
- 2. In case the patient did go off study before completing all pre-defined visits, you can delete empty visits.

Welcome | Help | Logout

Edit Visit plan

Patient file | New patient | Select >

Edit Visit plan

After date change all subsequent visits will be shifted accordingly as long as the dates has not been changed for themselves.  
The last scheduled or the last unscheduled visit of the same type without data entry can be deleted.

Entry date	05.09.2012 (CEST)	05.09.2012	dd.mm.yyyy (CET/CEST)
Registration	05.09.2012 (CEST)	05.09.2012	dd.mm.yyyy (CET/CEST)
Pretreatment Visit	05.09.2012 (CEST)	05.09.2012	dd.mm.yyyy (CET/CEST)
Visit 1	05.09.2012 (CEST)	05.09.2012	dd.mm.yyyy (CET/CEST)
15d after v1	19.09.2012 (CEST)	19.09.2012	dd.mm.yyyy (CET/CEST)
Visit 2	03.10.2012 (CEST)	03.10.2012	dd.mm.yyyy (CET/CEST)
15d after v2	17.10.2012 (CEST)	17.10.2012	dd.mm.yyyy (CET/CEST)
Visit 3	31.10.2012 (CET)	31.10.2012	dd.mm.yyyy (CET/CEST)
Visit 4	28.11.2012 (CET)	28.11.2012	dd.mm.yyyy (CET/CEST)

CancelResetPreviewDelete

# Deleting pre-defined visits

- 3. Enter a reason for deletion and confirm by clicking 'Save'.

After data change all subsequent visits will be shifted accordingly as long as the dates has not been changed for themselves.  
The last scheduled or the last unscheduled visit of the same type without data entry can be deleted.

Current visit plan		New visit	
Entry date	05.09.2012 (CEST)	Entry date	05.09.2012 (CEST)
Registration	05.09.2012 (CEST)	Registration	05.09.2012 (CEST)
Pre-treatment Visit	05.09.2012 (CEST)	Pre-treatment Visit	05.09.2012 (CEST)
Visit 1	05.09.2012 (CEST)	Visit 1	05.09.2012 (CEST)
15d after v1	19.09.2012 (CEST)	15d after v1	19.09.2012 (CEST)
Visit 2	03.10.2012 (CEST)	Visit 2	03.10.2012 (CEST)
15d after v2	17.10.2012 (CEST)	15d after v2	17.10.2012 (CEST)
Visit 3	31.10.2012 (CET)	Visit 3	31.10.2012 (CET)
Visit 4	29.11.2012 (CET)		

Reason for modification:

off study

Cancel

Back

Save

- Do not delete visits if they should have taken place.
- Only delete visits if they are already pre-defined, but the patient got off study earlier or visits were added by mistake.
- You can only delete empty visits.

# Adding scheduled visits

- 1. Click 'next visit'

Visit plan

Adverse Events

Other forms

Planned visits	Registration	Pre-treatment Visit	Visit 1	15d after v1	Visit 2	15d after v2	Visit 3	Visit 4
	05.09.12	05.09.12	05.09.12	19.09.12	03.10.12	17.10.12	31.10.12	29.11.12
E_Eligibility								
A_Baseline								
B_Visit								
L_Lab								
T_TumorAssessment								
QI_QualityOfLife								
C_EndofTreatment								
F_FollowUp								
TR_Translational Research								

## Adding scheduled visits

2. Choose scheduled visit: 'Visit No'. The planned date is already filled in, change if necessary. Click 'Save'.

**Next visit**

Please specify if the next visit is a regular or unscheduled visit in compliance with the study protocol.  
 Unscheduled visits are ignored during the generation of the regular visit plan.

☒ Scheduled visit: "Visit 5"

☐ Unscheduled visit: End of treatment

Date: 26 / 12 / 2012 dd.mm.yyyy (CET/CEST)

3. The next form will open automatically.

## Adding unscheduled visits

1. Click 'next visit'
2. Choose unscheduled visit: e.g. 'End of treatment'. The planned date is already filled in, change if necessary. Click 'Save'.

**Next visit**

Please specify if the next visit is a regular or unscheduled visit in compliance with the study protocol.  
 Unscheduled visits are ignored during the generation of the regular visit plan.

☐ Repeat previous group of planned visits: "Visit 8"

☒ Unscheduled visit: End of treatment

Date: 22 / 03 / 2013 dd.mm.yyyy (CET/CEST)

3. The next form will open automatically.



# Data Entry

33 Clinical Data Management



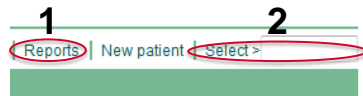
## Data entry

- All forms are entered online by the site staff, except forms SAE and PRF
- In case of system breakdown, an 'emergency E form' (→ SAKK website) can be sent by fax
- The forms SAE and PRF are sent by fax and entered by SAKK CC staff
- Never close a form, switch from one form to another, change the browser page, use the 'backwards' function of the browser or leave the computer without saving the data, otherwise the entered data will be lost

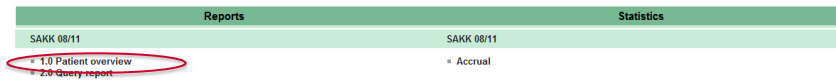
34 Clinical Data Management



## Accessing patients





- 1) Click on 'Reports', choose 'Patient overview', choose patient number (see Reports&Statistics)
- This function is only accessible from the welcome page



- 2) Enter the patient number into the 'Select' field, press enter.

## Access to forms

- Click on the form family icon in the visit plan 
- The form opens immediately if the form family consists of only one form.
- If the form family consists of two or more forms, an overview appears at the bottom of the visit plan. Click the form icon to open the form. 

## Saving data



- 1) Click '**save**' for started, but not completed data entry or for buffering data
  - 2) Click '**save + close entry**' for completed forms
- E forms have to be completed with "Save + close entry" (see patient registration)
  - Forms closed with "Save + close entry" by mistake can be edited again by clicking "Reopen data entry".
  - Closing data entry is a trigger for monitors to perform SDV. After SDV data can not be edited anymore, unless a query is asked.

## Unknown data

- Fill in data for each field on each CRF.
- If this should not be possible, there are three reasons why data cannot be filled in:
  - not done
  - not applicable
  - unknown
- Some forms/question already have a choice to check one of the three reasons (leave the field(s) empty and tick the reason)

Total bilirubin	ULN	Date	Not done	Comment
<input type="text"/> $\mu\text{mol/L}$	<input type="text"/> $\mu\text{mol/L}$	<input type="text"/> dd.mm.yyyy	<input type="radio"/>	

- Wherever none of the three above reasons is provided, follow the following guideline for unknown data >>

## Unknown data (numeric values)

1. Leave the field empty and click on 'comment'.

The screenshot shows a data entry form with fields for 'Start date', 'End date', 'Dose per day', 'Is there a dose deviation?', and '\*Specify toxicity/other here:'. The 'Dose per day' field is circled in red, and the 'Comment' button is also circled in red.

2. Choose the appropriate field and write one of the three reasons as comment (e.g. 'unknown'), click save.

The screenshot shows a 'Comment' dialog box with a text area containing the word 'unknown'. The 'Save' button is highlighted.

## Unknown data (numeric values)

3. Go back to form.

The screenshot shows a 'Notice' box with the text 'The comment has been added to the data.' and two buttons: 'Back to form' (highlighted) and 'Back to comments'.

- Commented fields are marked with a little red 'c' at the left of the question-row.

The screenshot shows the data entry form with the 'Start date' field marked with a red 'c' in a circle, indicating it is commented.

- Commented forms are marked with a 'c'



## Unknown data (dates)

- Unknown day (dd):  
If only month and year is known, fill in 15. as an estimated day and add the comment: "estimated day" into the comment field (as described for numeric values).
- Unknown day and month (dd.mm):  
If only year is known, fill in 30.06. as estimated day and month and add the comment: "estimated day and month" into the comment field (as described for numeric values).

## Unknown data (not values, dates)

- For text fields enter one of the three reasons into the field.


- For dropdown lists with none of the three reasons as an option add a comment into the comment field (as described for numeric values).

## Warnings

In case of inconsistent or missing data, a warning message is displayed by the item when clicking 'save/save+close'. The data are not saved yet .

TR TRANSLATIONAL RESEARCH - URINARY STEROID METABOLITES	
<b>Please check marked entries before saving.</b>	
<b>INSTRUCTIONS:</b> - During pretreatment evaluations (between day -14 and day 0; before any drug administration) - 12 weeks after treatment start (day 1 of cycle 4)	
<b>URINE</b>	
Sampling date	05 / 09 / 2012 dd.mm.yyyy
<b>DRUGS</b>	
Input required:	
None	<input type="radio"/>
Input required:	
ACEI/ARB	<input type="radio"/>
Ca-antagonist	<input type="radio"/>

## Warnings

- Read all warning messages and check your data.
- Confirm the data by clicking 'save/save+close' again, your data will be saved (except for form family E, see patient registration).
- Saved forms containing missing or incorrect data are marked with a grey exclamation mark. 
- In case of incorrect warnings, contact the SAKK CC.

## Form Symbols

Welcome **Help** Logout  
 Edit Visit plan Patient file New patient Select >

You can find an overview of the form symbols by clicking 'help' on the visit plan screen.

Help - Form overview		
Icon	Status	Description
	without db-table	These forms will not be stored in the database.
	not stored	No data has been entered yet.
	empty	The form has been saved empty. In the form family at least one form has been stored empty.
	partially filled	At least some data has been entered but not all mandatory fields have been filled.
	completely filled	All mandatory fields have been filled.
	data entry complete	The data entry is finished. This status does not display the underlying completion status.
Color	Status	Description
	standard form	Used for the capture of normal data.
	Adverse Event form	For capturing data during the workflow of Adverse Events.
	Serious Adverse Event form	For capturing data during the handling of Serious Adverse Events.
Symbol	Status	Description
	validation	The rule validation of this form finished with problems (warning, error).
	comment	At least one comment has been posted.

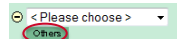
45 Clinical Data Management



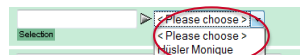
## Extendable dropdown lists

Dropdown lists with a button 'Others' underneath are extendable:

1. The needed entry is not listed in the dropdown list, click 'Others'.



2. Check if the entry was already added before.



(If you clicked 'Others' by mistake, you can always go back to the original dropdown list via 'Selection'.)

3. If the entry was not already listed, fill in the new entry into the text field and click on the grey arrow.



4. The new entry will be added to the list. Report wrongly added entries to the SAKK CC.

46 Clinical Data Management



# Repetition groups

- Elements with an indented header and buttons delete/more can be repeated several times by clicking 'more'.

A 2 BASELINE HISTORY

MEDICAL HISTORY

Are there any clinically significant diseases other than prostate cancer? ☐ No ☐ Yes, specify below Help Comment

Medical History 1

Disease ☐ < Please choose > ☐ not active ☐ active \*Specify 'other': Comment

Delete More

Medical History 2

Disease ☐ < Please choose > ☐ not active ☐ active \*Specify 'other': Comment

Delete

Medical History 3

Disease ☐ < Please choose > ☐ not active ☐ active \*Specify 'other': Comment

Delete More

# Catalogues

- In the AE form a catalogue with the CTCAE v4.0 is implemented (see AE reporting).

1. ADVERSE EVENT

Adverse Event Term CTCAE v4.0

Catalogue System organ class (SOC) ☐ Comment

Term ☐ (If other, specify below)

\*Specify 'other' here: ☐ Comment

AE - Development 1

Start date  dd.mm.yyyy Grade ☐ < Please choose > Relation to treatment ☐ < Please choose > End date  dd.mm.yyyy Help Comment

Delete More

Still ongoing at 30 days after treatment or prior to next treatment Comment

☐ (End date not applicable)

Cancel Save Save = close entry ☒ Check data



# Scores

- Scores are automatically calculated data. Scores are calculated when clicking on 'Score' or when 'saving/saving + closing' the form.

Estimated creatinine clearance

Score

156 mL/min

> 40 mL/min

- Scores are often needed for checks/warnings. Those sections are marked with the title 'Calculated Values', they are for internal use only.

CALCULATED VALUES

INSTRUCTIONS: This section only contains calculation steps. No information can be filled in.

Age [years]	<div><div></div><div>Score</div></div> 53 years	Comment
Age [days]	<div><div></div><div>Score</div></div> 15240 days days	
Bilirubin ULN x 1.5	<div><div></div><div>Score</div></div> 15	Comment
Bilirubin ULN x 3	<div><div></div><div>Score</div></div> 30	

# Unit Calculator

- For some lab values there is the possibility to convert lab values, should you have other units at your site. Use 'score' to calculate the asked conversion and add the calculated value in the appropriate field above.

UNIT CALCULATOR

INSTRUCTIONS: This calculator can be used to convert lab values in case other units are used as standard at the site. Note that converted lab values have to be entered manually in the upper part of the CRF.

Comment

Total bilirubin (mg/dL to µmol/L)	Converted value	Comment
<div><div></div><div>Score</div></div> mg/dL	<div><div></div><div>Score</div></div> µmol/L	
Serum creatinine (mg/dL to µmol/L)	Converted value	Comment
<div><div></div><div>Score</div></div> mg/dL	<div><div></div><div>Score</div></div> µmol/L	

# AE reporting

51 Clinical Data Management



## AE reporting

- The investigator has to report all AEs according to the protocol
- The start and end date as well as any change in grading have to be reported
- Baseline symptoms have to be recorded and followed during treatment

52 Clinical Data Management



# AE reporting

- 1. Click on 'Adverse Events' tab
- 2. Click 'New Adverse Event'
- 3. Choose 'Adverse Event' and click 'Continue'

Visit plan   **Adverse Events**   Other Forms

**New Adverse Event**

☒ Adverse Event

Cancel   Continue



# AE reporting

- 4. To choose the CTCAE term, click on 'Catalog'

**1. ADVERSE EVENT**

**Adverse Event Term CTCAE v4.0**

**Catalog**   System organ class (SOC)   Comment

Term   Comment

\*Specify 'other' here:   Comment

**AE - Development 1**

Start date   Grade   Relation to treatment   End date   Help

dd.mm.yyyy   < Please choose >   < Please choose >   dd.mm.yyyy   Comment

Still ongoing at 30 days after treatment or prior to next treatment   Comment

☐ (End date not applicable)

Cancel   Save   Save + close entry   ☒ Check data

Date: 06.09.2012 (CEST)   Developer: Miriam Wegmann   Project: SAKK 08/11 (05.09.2012 - 07.24.08 (CEST))   Centre: Spitzky - 0811   Country: PIR-ID: gis494   UPR: 0811\_027   1. AE Adverse Event: 06.09.2012 (CEST)   Form family: Adverse Events   Form: AE Adverse Event



# AE reporting

5. Enter the term or a symptom into the 'Search for' text field and click 'Search'

CTCAE\_4.03\_2010-06-14\_valid

Search for:

Search in: ☒ Dictionary ☒ Version ☒ Editor ☒ SOC

☒ Term ☒ Term Definition ☒ MedDRA Code

☒ Grade ☒ Grade Definition

Display

Dictionary	Version	Editor	SOC
CTCAE	V4.03	National Cancer Institute	Blood and lymphatic system disorders
CTCAE	V4.03	National Cancer Institute	Cardiac disorders

- Alternatively, the right term can be manually chosen by clicking on the arrows left to the SOC terms

Dictionary	Version	Editor	SOC
CTCAE	V4.03	National Cancer Institute	Blood and lymphatic system disorders
CTCAE	V4.03	National Cancer Institute	Cardiac disorders
CTCAE	V4.03	National Cancer Institute	Congenital, familial and genetic disorders
CTCAE	V4.03	National Cancer Institute	Ear and labyrinth disorders
CTCAE	V4.03	National Cancer Institute	Endocrine disorders
CTCAE	V4.03	National Cancer Institute	Eye disorders
CTCAE	V4.03	National Cancer Institute	Gastrointestinal disorders
CTCAE	V4.03	National Cancer Institute	General disorders and administration site conditions
CTCAE	V4.03	National Cancer Institute	Hepatobiliary disorders



# AE reporting

6. Click on the term.

CTCAE\_4.03\_2010-06-14\_valid

Search for:

Search in: ☒ Dictionary ☒ Version ☒ Editor ☒ SOC

☒ Term ☒ Term Definition ☒ MedDRA Code

☒ Grade ☒ Grade Definition

Display

Dictionary	Version	Editor	SOC	Term	Term Definition	MedDRA Code	Grade	Grade Definition
CTCAE	V4.03	National Cancer Institute	Blood and lymphatic system disorders	Thrombocytopenic purpura	A disorder characterized by the presence of microangiopathic hemolytic anemia, thrombocytopenic purpura, fever, renal abnormalities and neurological abnormalities such as seizures, hemiplegia, and visual disturbances. It is an acute or subacute condition.	1004348		
CTCAE	V4.03	National Cancer Institute	Gastrointestinal disorders	Enterocolitis	A disorder characterized by inflammation of the small and large intestines.	1001483	3	Severe or persistent abdominal pain, <b>fever</b> , <b>leuc</b> , peritoneal signs
CTCAE	V4.03	National Cancer Institute	Gastrointestinal disorders	Typhlitis	A disorder characterized by inflammation of the cecum.	1004521	3	Symptomatic (e.g., abdominal pain, <b>fever</b> , change in bowel habits with <b>fever</b> ), peritoneal signs
CTCAE	V4.03	National Cancer Institute	General disorders and administration site conditions	Chills	A disorder characterized by a sensation of cold that often marks a physiologic response to existing fever.	1000831		
CTCAE	V4.03	National Cancer Institute	General disorders and administration site conditions	<b>Fever</b>	A disorder characterized by elevation of the body's temperature above the upper limit of normal.	1001658		
CTCAE	V4.03	National Cancer Institute	General disorders and administration site conditions	Flu like symptoms	A disorder characterized by a group of symptoms similar to those observed in patients with the flu. It includes <b>fever</b> , chills, body aches, malaise, loss of appetite and dry cough.	1001671		
CTCAE	V4.03	National Cancer Institute	Immune system disorders	Allergic reaction	A disorder characterized by an adverse local or general response from exposure to an allergen.	1000178		



# AE reporting

- 7. The SOC and the term will be entered automatically into the AE form
  - In case of 'other' do not forget to specify

1. ADVERSE EVENT

Adverse Event Term CTCAE v4.0

Category

System organ class (SOC)

General disorders and administration site conditions

Comment

Term

Fever

(If other, specify below)

Specify 'other' here:

Comment

AE - Development 1

Start date

dd.mm.yyyy

Grade

< Please choose >

Relation to treatment

< Please choose >

End date

dd.mm.yyyy

Help

Comment

Discontinue

More

Still ongoing at 30 days after treatment or prior to next treatment

Comment

☐ (End date not applicable)

Cancel

Save

Save + close entry

☒ Check data

Date: 06.09.2012 (CEST) Developer: Miriam Wegmann Project: SAKK 0811 (05.09.2012 - 07.24.08 (CEST)) Centre: Spitzky - 0811 Country: Pat-ID: gsa494 UPN: 0811\_027 1. AE Adverse Event: 06.09.2012 (CEST) Form family: Adverse Events Form: AE Adverse Event

57 Clinical Data Management

SAKK

# AE reporting

- 8. Report start date, grade and relation to treatment

AE - Development 1

Start date

01

09

2012

dd.mm.yyyy

Grade

2 - Moderate

Relation to treatment

1 - Unrelated

End date

02

09

2012

dd.mm.yyyy

Help

Comment

Discontinue

More

Still ongoing at 30 days after treatment or prior to next treatment

Comment

☐ (End date not applicable)

➤ In case of changing grade, enter an end date, click 'more' and enter the new start date, grade and relation to treatment.

AE - Development 1

Start date

01

09

2012

dd.mm.yyyy

Grade

2 - Moderate

Relation to treatment

1 - Unrelated

End date

02

09

2012

dd.mm.yyyy

Help

Comment

Discontinue

More

AE - Development 2

Start date

03

09

2012

dd.mm.yyyy

Grade

1 - Mild

Relation to treatment

1 - Unrelated

End date

05

09

2012

dd.mm.yyyy

Help

Comment

Discontinue

More

Still ongoing at 30 days after treatment or prior to next treatment

Comment

☐ (End date not applicable)

58 Clinical Data Management

SAKK

29

## AE reporting - ongoing

### 9. a) AE is ongoing:

Leave the end date empty, 'save' and confirm the missing end date by clicking 'save' again.

- A grey exclamation mark indicates that AE reporting is not completed.
- As soon as one AE is filled in the tab color 'Adverse Events' changes to red.

## AE reporting - resolved

### 9. b) AE is resolved:

Enter end date, click 'Save+close entry' and go back to the form overview.

- The green color indicates the AE is complete.

## AE reporting - end of treatment

### 9. c) AE still ongoing 30 days after treatment

Leave the end date empty and tick the checkbox for 'still ongoing',  
'Save+close entry' and go back to form overview.

The screenshot shows the 'AE - Development 1' form. The 'Start date' is 01.09.2012, 'Grade' is 2 - Moderate, and 'Relation to treatment' is 1 - Unrelated. The 'End date' field is empty. Below the form, the checkbox 'Still ongoing at 30 days after treatment or prior to next treatment' is checked, and the text '(End date not applicable)' is displayed.

- The form status indicates that AE reporting is completed.

The screenshot shows the 'Adverse Events' tab in the system. It displays a list of events, with the first one being '1. "Fever"'. Below the list, there is a 'New Adverse Event' button.

## AE reporting - unknown dates

If the exact dates for start and/or end date are not known,  
enter the following dates:

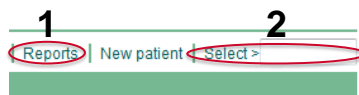
- Start date: fill in the date one day after the last visit, where the AE did not yet appear/where grade did not yet change
- End date: fill in the date one day before the next visit, where the AE did no longer appear/where the grade did change

# Query Management

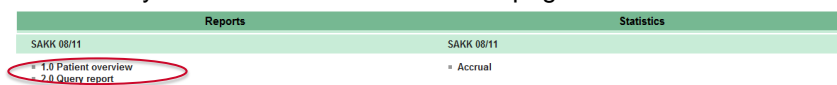
63 Clinical Data Management



## Finding queries



- 1) Click on 'Reports', choose 'Query report' or 'Patient overview', check for queries  
> Only accessible from the welcome page



- 2) Enter patient number into the 'Select' field, press enter, check for queries.

64 Clinical Data Management





# Finding queries - Reports

Query report:

- All queries are listed.
- Filter them according to the status
  - ! – Query answered
  - ? – Query asked
  - ✓ - Query resolved

2.0 Query report (13 Queries)									
Status	Patient	Centre	Author	Released	resolved	Form	Item		
< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >		
! M#248	fse702	Spitalxy - 0811	Wegmann	08.02.12		E5 Laboratory Values - Absolute neutrophil count (ANC)			
? M#249	fse702	Spitalxy - 0811	Wegmann	08.02.12		E4 Physical Examination - WHO performance status			
✓ M#287	wsb520	Spitalxy - 0811	Wegmann	28.06.12	28.06.12	E1 Information on Patient Registration - Did the patient agree that urine samples and tissue samples are being used in scientific studies for further research?			
? M#288	wsb520	Spitalxy - 0811	Wegmann	28.06.12		E1 Information on Patient Registration - Did the patient agree that samples/data may be used in as of yet undetermined biomedical research projects without being informed in specific instances and providing consent?			
✓ M#289	wsb520	Spitalxy - 0811	Wegmann	28.06.12	28.06.12	E2 Inclusion Criteria -			



# Finding queries - Reports

Patient Overview:

- Find queries via symbols



1.0 Patient overview																			
Display the following status: <input checked="" type="checkbox"/> Completion status <input checked="" type="checkbox"/> Review / frozen <input checked="" type="checkbox"/> Queries <input checked="" type="checkbox"/> Comments <input checked="" type="checkbox"/> Source Data verification <input checked="" type="checkbox"/> Patient status																			
▼ Spitalxy - 0811 (4)																			
Patient ID	SDV/Registration	Pre-treatment Visit	Visit 1	15d after v1	Visit 2	15d after v2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	End of treatment	End of treatment	FU in absence of event	FU in absence of event	FU after event	Additional Form T	Additional Form T	Other forms
M#234 (TLA)																			



## Finding queries – visit plan

### Visit plan:

- Find queries via symbols



> Welcome > Patient mju234

Visit plan	Adverse Events	Other forms
Planned visits	Registration 08.08.12	Pretreatment Visit 08.08.12
		15d after v1 23.08.12
		Visit 3 05.09.12
E_Eligibility		
A_Baseline		
B_Visit		
L_Lab		
T_TumorAssessment		
QL_QualityOfLife		
C_EndofTreatment		
F_FollowUp		
TR Translational Research		

67 Clinical Data Management



## Answer queries

1. Check query report (or patient overview), click on patient number or go directly to the patient.
2. Check form status, open forms with the symbol for asked queries



3. Check for questions marked with a red '?' on the left side

?	Serum creatinine	ULN	Date	Comment
25	µmol/L	10 <sup>9</sup> /L	dd.mm.yyyy	Query

68 Clinical Data Management



## Answer queries

4. a) click 'query', choose the field and answer the query, save or

- b) fill in the answer directly into the field.

- Answered queries are marked with a little red '!' at the left of the question-row.

## Answer queries

5. Provide a reason for the modification at the bottom of the form and 'save modification'.

- Forms with answered queries are marked with a '!'

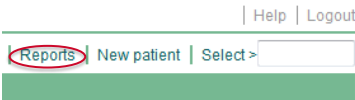


# Reports and Statistics



## Reports & Statistics

- All reports are accessible from the welcome page by clicking 'Reports'



- You find all reports listed under the appropriate trial

Reports		Statistics	
SAKK 08/11		SAKK 08/11	
• 1.0 Patient overview		• Accrual	
• 2.0 Query report			



## Reports & Statistics

- One most used report can be chosen under 'my account'.

My Account | Messages | Import | Reports | New patient | Select >

**My Account**

Last name: \* Wegmann  
 First name: Miriam  
 Title:  
 Gender: ☒ Female ☐ Male  
 Phone:  
 Mobile phone:  
 Fax:  
 Email: miriam.wegmann@sakk.ch  
 Private location - Street:  
 Zipcode /City:  
 Country: < Please choose >  
 Preferred report: SAKK 08/11 (U0811) - 1.0 Patient overview ☒ only as menu item  
 Preferred language: < default >

- The link to this report will appear in the task bar on every screen

1.0 Patient overview | My Account | Messages | Import | Reports | New patient | Select >

**My Account**

73 Clinical Data Management



## 1.0 Patient overview

Pat.ID	ISOV	Registration	Pretreatment Visit	Visit 1	15d after v1	Visit 2	15d after v2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	End of treatment	End of treatment	FU in absence of event	FU in absence of event	FU after event	Additional Form T	Additional Form T	Other forms	Adverse Events
mp234																					
u085 (TLK)																					

- Summary of the form status
- The level of detail can be chosen in the header
- Explanation on the symbols can be found via the 'help' of the visit plan (see data entry)
- Click on a patient number, the form overview of the patient will be opened

74 Clinical Data Management

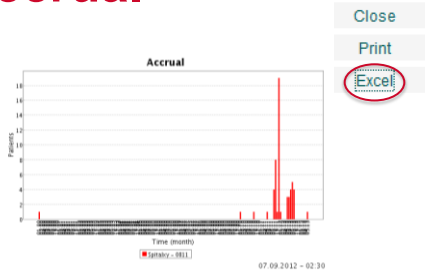


## 2.0 Query report

2.0 Query report (13 Queries)							
Status	Patient	Centre	Author	Released	resolved	Form	Item
< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >
MM248	fse702	Spitalxy - 0811	Wegmann	08.02.12		E5 Laboratory Values - Absolute neutrophil count (ANC)	
MM249	fse702	Spitalxy - 0811	Wegmann	08.02.12		E4 Physical Examination - WHO performance status	
MM287	wsb520	Spitalxy - 0811	Wegmann	28.06.12	28.06.12	E1 Information on Patient Registration - Did the patient agree that urine samples and tissue samples are being used in scientific studies for further research?	
MM288	wsb520	Spitalxy - 0811	Wegmann	28.06.12		E1 Information on Patient Registration - Did the patient agree that samples/data may be used in as of yet undetermined biomedical research projects without being informed in specific instances and providing consent?	
MM289	wsb520	Spitalxy - 0811	Wegmann	28.06.12	28.06.12	E2 Inclusion Criteria -	

- Summary of open, answered and resolved queries
  - ? = open query
  - ! = answered query
  - ✓ = solved query
  - x = recalled queries
- The report can be sorted by clicking on the column name
- The report can be filtered with the dropdown items

## Accrual



- The accrual data can be exported into excel

	A	B	C	D	E
1	Project	SAKK 08/11			
2	Date	07.09.2012 - 02:30 (CEST)			
3	Accrual				
4					
5		01.00	02.00	03.00	04.00
6	Spitalxy - 0811	1	0	0	0

# Guidelines, Training & Support

77 Clinical Data Management



## Guidelines

- This trial specific manual can be downloaded from download area of the welcome page (see access to secuTrial®).
- A General user manual can be found in the members section on the sakk website under 'guidelines & documents'.
- Where applicable, use the 'Help' buttons on the right side of the questions for data entry guidelines.

**ASSESSMENT OF ANALGESICS**

*INSTRUCTIONS: Evaluate the consumption of analgesics during the last 24 hours before the visit on day 1 of cycle 2-7. Enlist the analgesics according to the WHO analgesics ladder and report the highest code (for further specifications click the button 'help').*

WHO analgesics pain ladder code ☐ < Please choose >

Not applicable (trial treatment duration is  $\geq 6$  months) ☐

**Help**

**HELP: WHO analgesics ladder**

Code	Type	Examples
0	no analgesics	

78 Clinical Data Management



## Training

- 1) Open the following link:

<https://secutrialdev.sakk.ch/apps/WebObjects/ST21-setup-DataCapture.woa/wa/choose?customer=SAKKD>



- Make sure you are in the 'Test Environment' (green logo with red writing 'test environment', green background and forms)

## Training

2. You can log into a training platform with test data with User-ID: 'trainSite' and password 'training12'

- You are logged into a test database.
- The trial set up for training is fictional and consists of the most commonly used forms.
- Be aware that changes or interruptions are possible and test data can be overwritten or deleted.



## Support

Contact the trial coordinator at the SAKK CC in case of:

- wrong warnings
- needed support
- needed additional training
- login failure
- wrongly entered patient

Your request will be processed by the trial coordinator or forwarded to the clinical data management team.