SAKK

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

secuTrial®

Manual for Sites

The Swiss Oncology Research Network

Overview

Access to secuTrial®

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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

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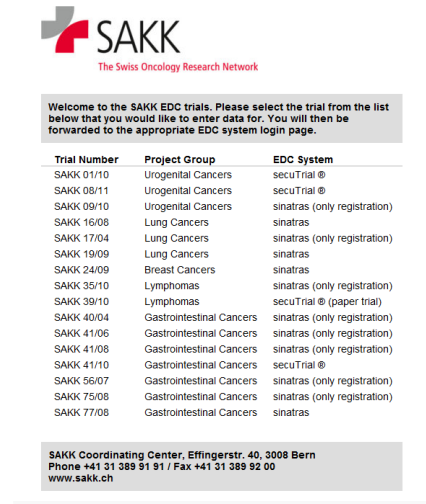
Access to secuTrial®

>> www.sakk.ch/edc



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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

SAKK Coordinating Center, Effingerstr. 40, 3008 Bern
Phone +41 31 389 91 91 / Fax +41 31 389 92 00
www.sakk.ch

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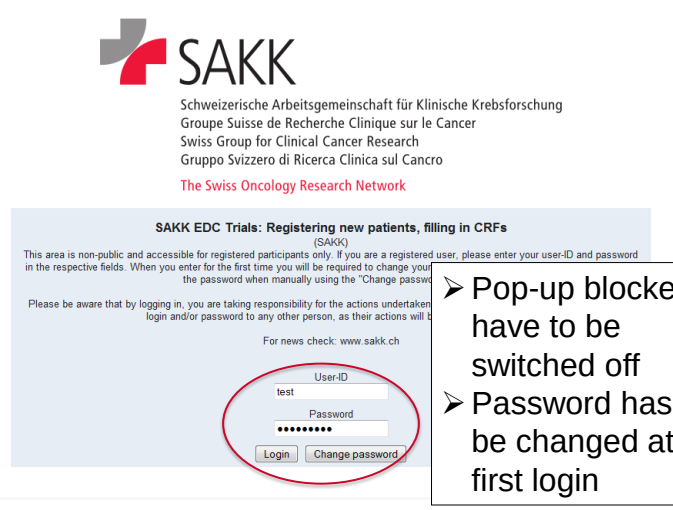
Access to secuTrial®



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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
the password when manually using the "Change passwo

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 b

For news check: 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

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

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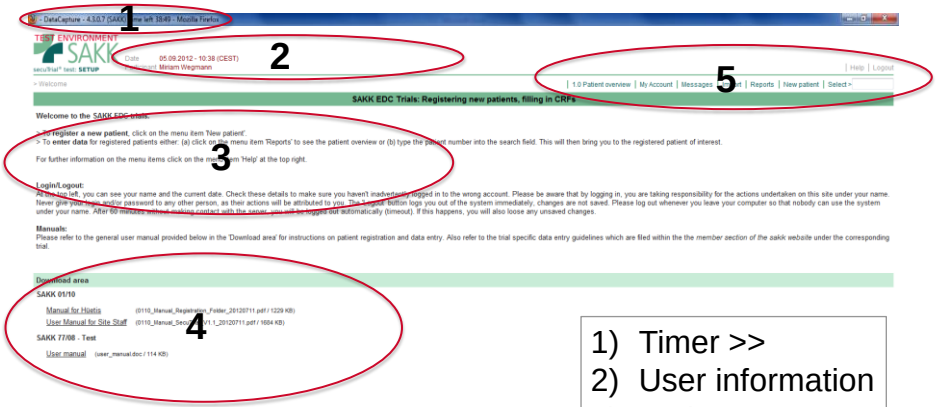
Welcome Page



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

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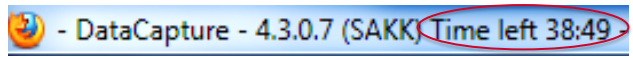
Welcome Page

- 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

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Patient registration

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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

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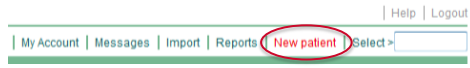
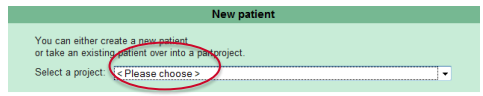
Patient registration

1. Click on ‘new patient’.



2. Select a project (choose the trial).



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

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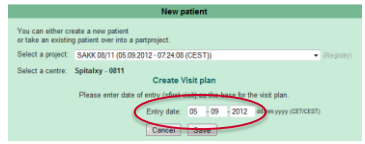
Patient registration

4. For the ‘entry date’ enter the date of the planned treatment start.



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

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Patient registration

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

- 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

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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

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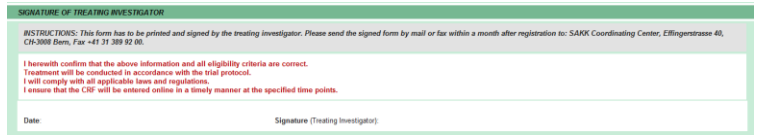
Patient registration

8. Print form E1, fill in date and signature.
   - **only the treating investigator is allowed to sign the form**


SIGNATURE OF TREATING INVESTIGATOR

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.

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.

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

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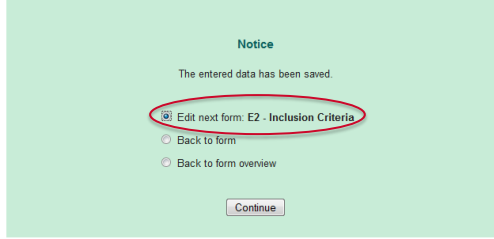
Patient registration

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

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Form Overview

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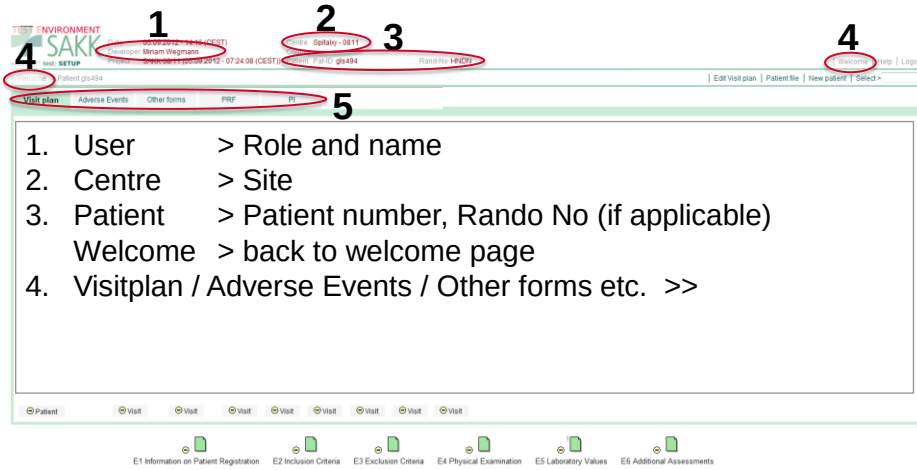
Form Overview



1. User > Role and name
2. Centre > Site
3. Patient > Patient number, Rando No (if applicable)
   Welcome > back to welcome page
4. Visitplan / Adverse Events / Other forms etc. >>

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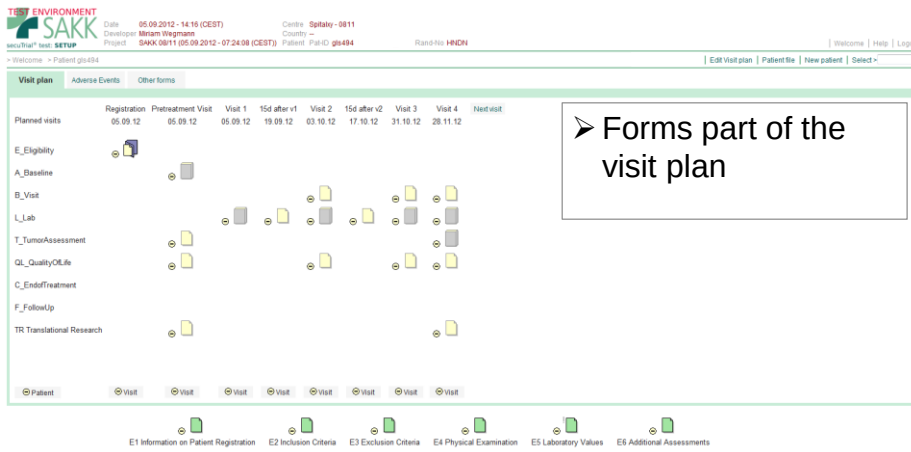
Form Overview – Visit plan



- Forms part of the visit plan

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Form Overview – Adverse Events

- Reporting of AEs

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Form Overview – Other forms, etc

- Forms not part of the visit plan

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Visit plan

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Visit plan

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

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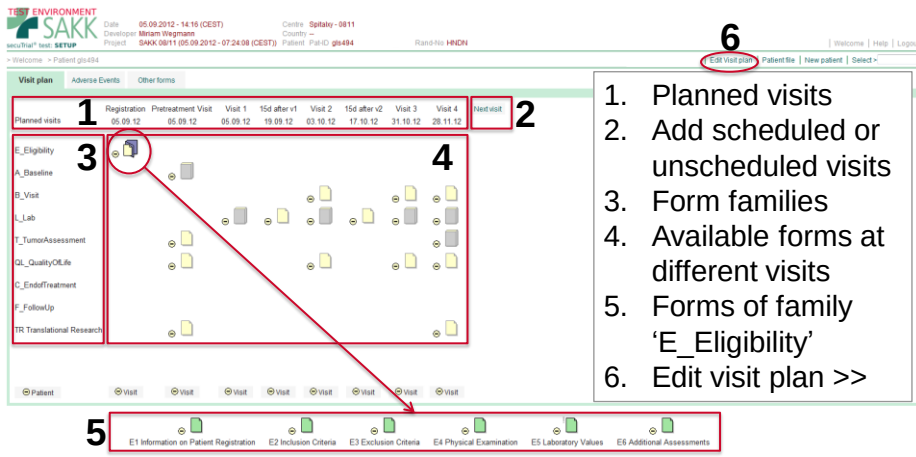
Visit plan



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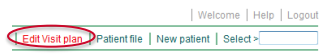
Changing dates of planned visits

1. Click 'Edit visit plan'.



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

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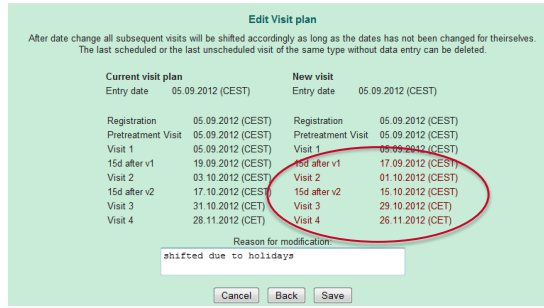
Changing dates of planned visits

3. Enter a reason for modification and confirm by clicking ‘Save’.



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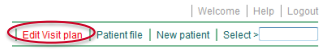
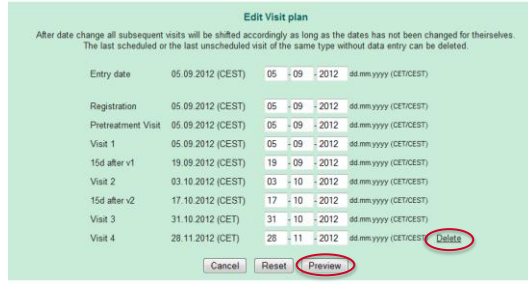
Deleting pre-defined visits

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.



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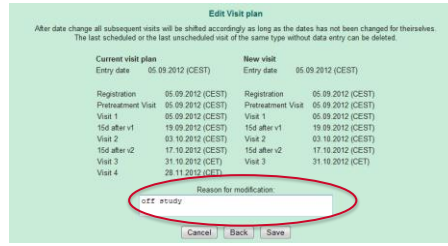
Deleting pre-defined visits

3. Enter a reason for deletion and confirm by clicking ‘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.

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Adding scheduled visits

1. Click ‘next visit’

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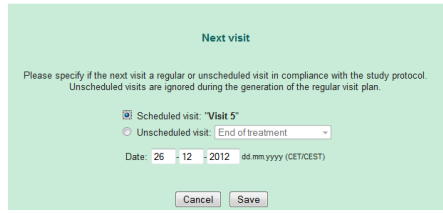
Adding scheduled visits

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



3. The next form will open automatically.

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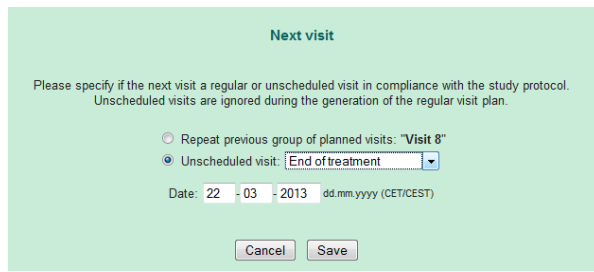
Adding unscheduled visits

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’.



3. The next form will open automatically.

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Data Entry

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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

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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.

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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 consits of two or more forms, an overview appears at the bottom of the visit plan. Click the form icon to open the form. 

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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.

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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)

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

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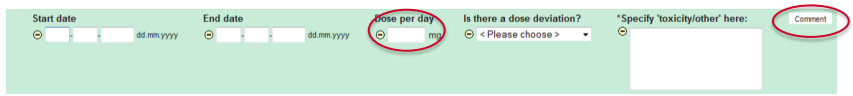
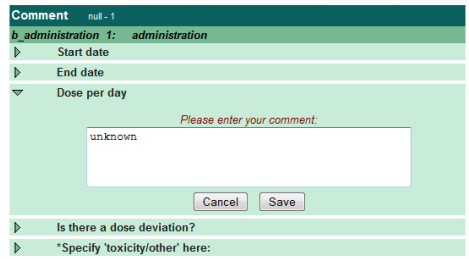
Unknown data (numeric values)

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



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



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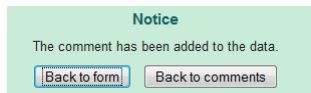
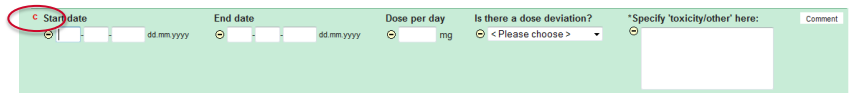
Unknown data (numeric values)

3. Go back to form.



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



- Commented forms are marked with a ‘c’

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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).

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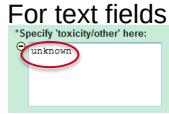
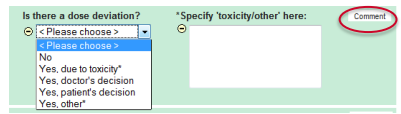
Unknown data (not values, dates)

- 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).



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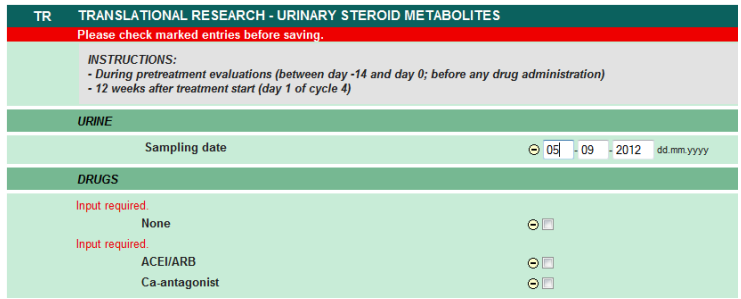
Warnings

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 .



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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.

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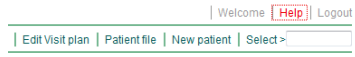
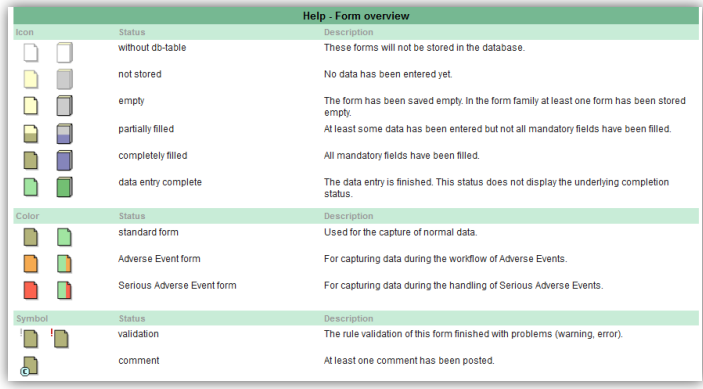
Form Symbols



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.

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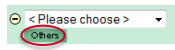
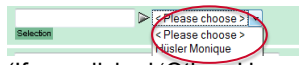
Extendable dropdown lists

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.

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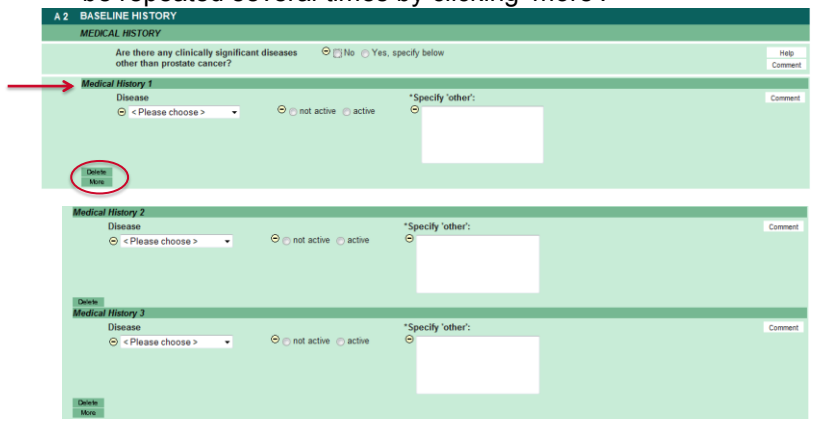
Repetition groups

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



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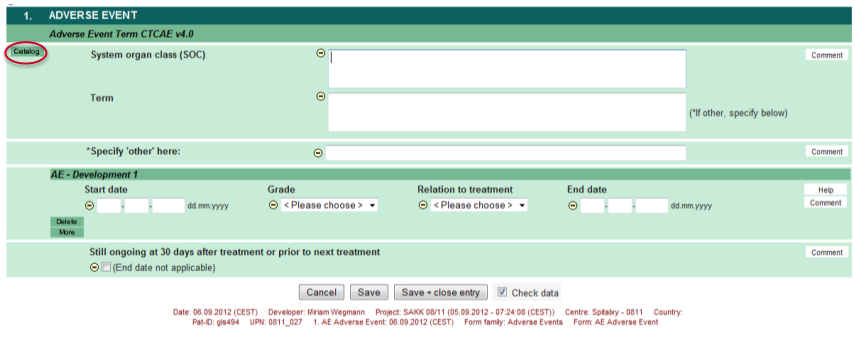
Catalogues

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



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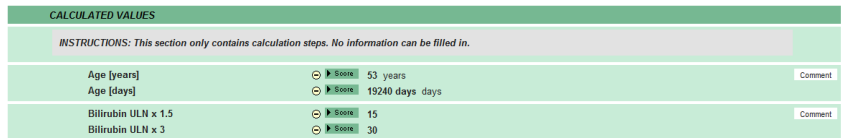
Scores

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

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



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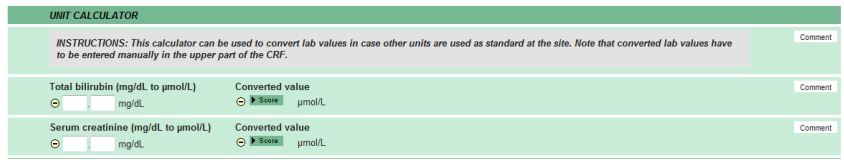
Unit Calculator

- 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.



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AE reporting

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AE reporting

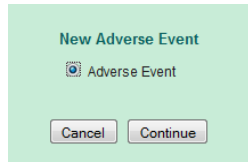
- The investigator has to report all AEs according to the protocol
- The start and end date as well as any change in grading have to be reported
- Baseline symptoms have to be recorded and followed during treatment

SAKK

AE reporting

1. Click on ‘Adverse Events’ tab
2. Click ‘New Adverse Event’

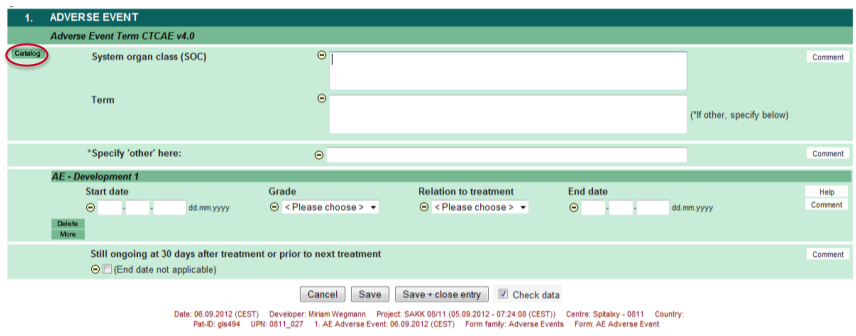
3. Choose ‘Adverse Event’ and click ‘Continue’



SAKK

AE reporting

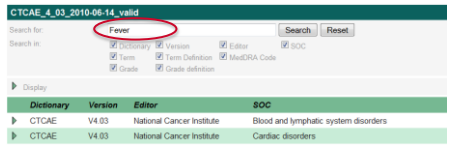
4. To choose the CTCAE term, click on ‘Catalog’



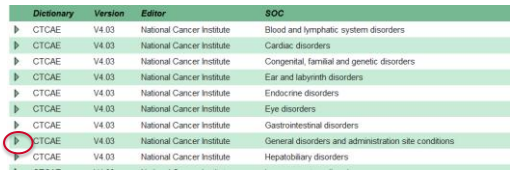
SAKK

AE reporting

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



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



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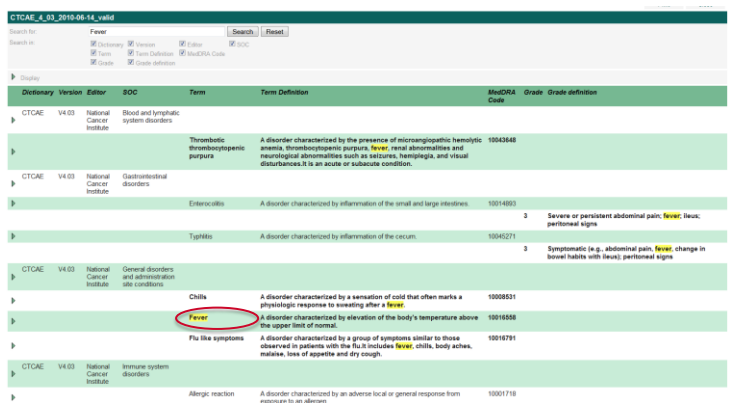
AE reporting

6. Click on the term.



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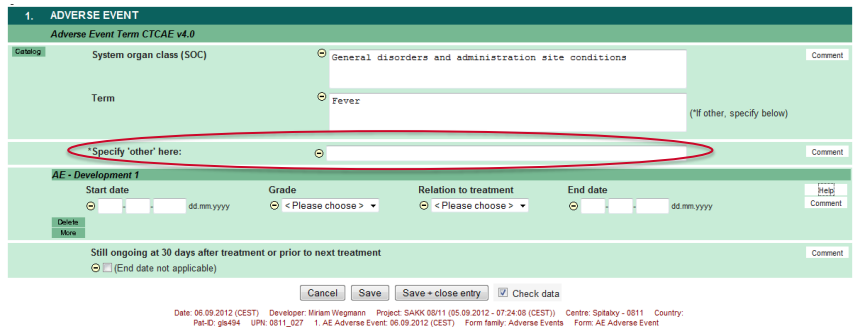
AE reporting

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



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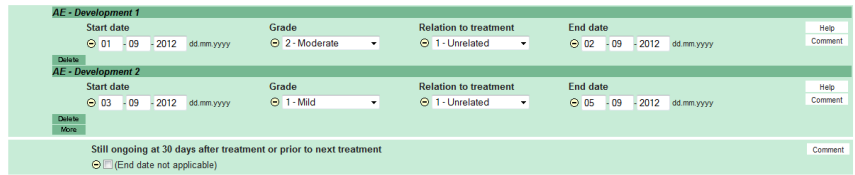
AE reporting

8. Report start date, grade and relation to treatment

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



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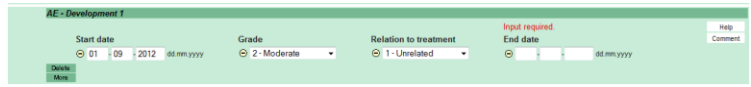
AE reporting - ongoing

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.

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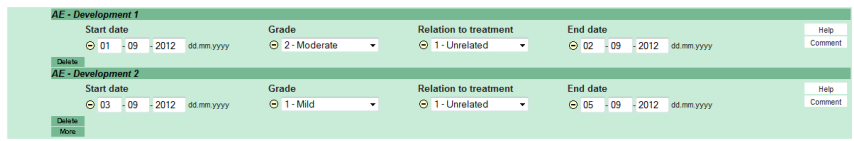
AE reporting - resolved

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.

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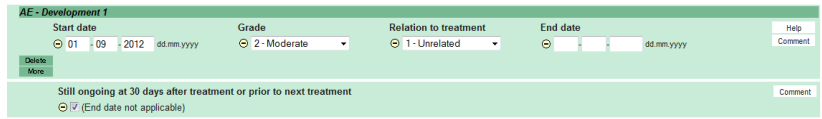
AE reporting - end of treatment

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 form status indicates that AE reporting is completed.

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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

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Query Management

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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.

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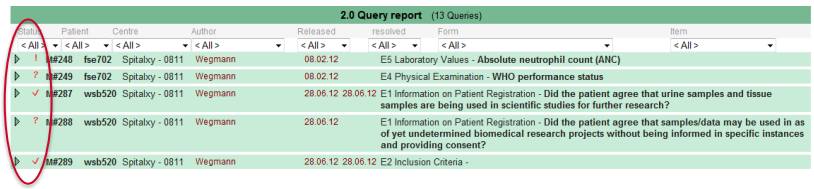
Finding queries - Reports

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 -	

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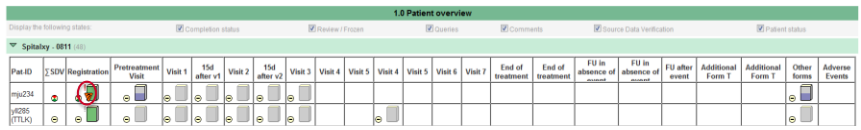
Finding queries - Reports

Patient Overview:

- Find queries via symbols 



1.0 Patient overview

Display the following states: Completion status | Review / Frozen | Queries | Comments | Source Data Verification | Patient status

Spitalxy - 0811 (48)

Pat.ID	∑ SDV	Registration	Pretreatment Visit	Visit 1	15d after v1	Visit 2	15d after v2	Visit 3	Visit 4	Visit 5	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
mju234																							
yil285 (TTLK)																							

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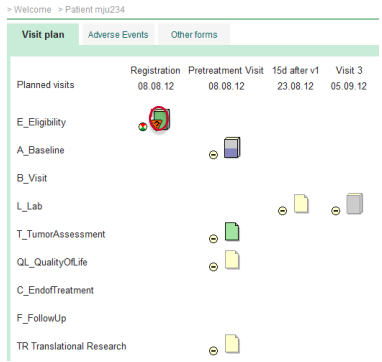
Finding queries – visit plan

Visit plan:

- Find queries via symbols 



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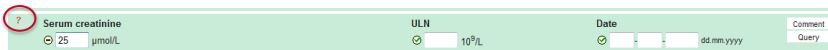
Answer queries

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



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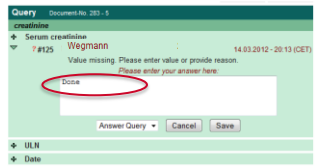
Answer queries

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.

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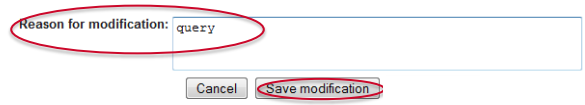
Answer queries

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



- Forms with answered queries are marked with a ‘!’

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Reports and Statistics

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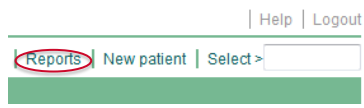
Reports & Statistics

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



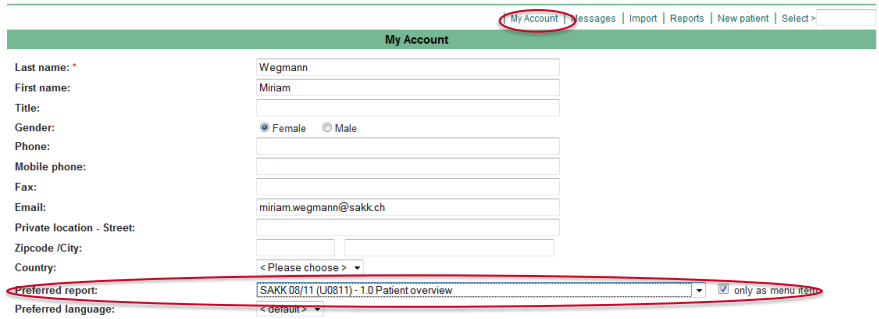
- You find all reports listed under the appropriate trial

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

SAKK

Reports & Statistics

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



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

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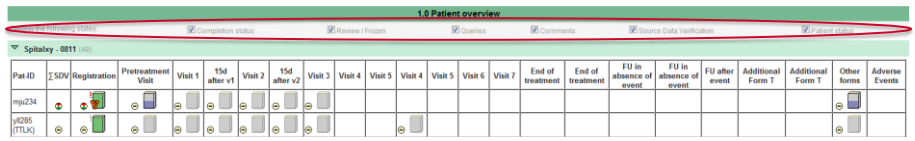
1.0 Patient overview



- 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

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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 >
!	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 -

- 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

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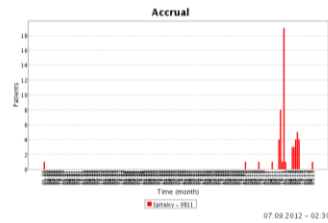
Accrual

Close
Print
Excel



- 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

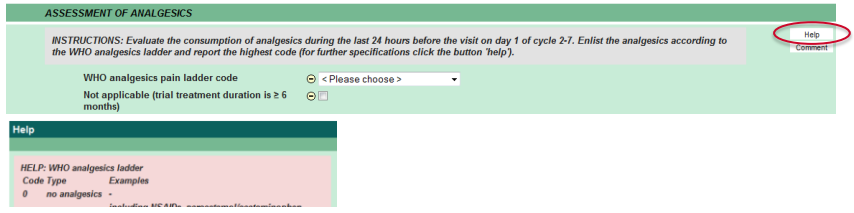
SAKK

Guidelines, Training & Support

SAKK

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.



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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 an forms)

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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.

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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.

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