VTIQ

Evaluation of Virtual Touch Tissue Imaging Quantification (VTIQ – 2D-SWE) in the assessment of BI-RADS 3 and 4 lesions: Can patient selection for biopsy be improved? – A multi-center-study

Study-specific data entry instructions

Contents

Clincase Investigator User Guide

Detailed information about handling the remote data entry system called Clincase Application is provided in 'Clincase Investigator User Guide (Web Client), adapted version' which is also available for download on the web pages of the Institute of Medical Biometry and Informatics. It is helpful to read this user guide prior to performing data entry of real participant data and to use it as reference book later on.

Getting started

Once your user account is established you can access to the online database for the VTIQ trial by entering URL https://clincase.med.uni-heidelberg.de/vtiq/app into the address bar of your internet browser. After confirming this with the Enter Key, you will get the Clincase Application's login screen. If you log in for the first time, click 'Forgotten Password' below the 'Sign In' button. After providing your user name or your Email-Address, a password will be sent to you via Email. After login you will see the homepage for the VTIQ trial. Do not forget to change this preliminary password within one hour.

Data entry for productive data will be performed by clicking 'Open Study Books'. All data will be transferred to the study database.

If you want to do some training on the system first, use button, 'Open Training Books'. Data entered here will not be transferred to the study database.

It is important to be clear on your intention (data entry of real (productive) data or training) before opening either book because the wrong selection might cause a lot of unnecessary work.

Creating an electronic Case Report Form (eCRF) for a new patient

Please note that both screening failures and study participants are to be documented in the VTIQ eCRF. To create a new study book (eCRF for a screened/enrolled patient), click on the 'Create new patient' link in the Actions panel. You will be asked to confirm that you want to create a new patient. Click on the OK button to continue. After a few seconds the cover page of a new study book opens (see figure 1).

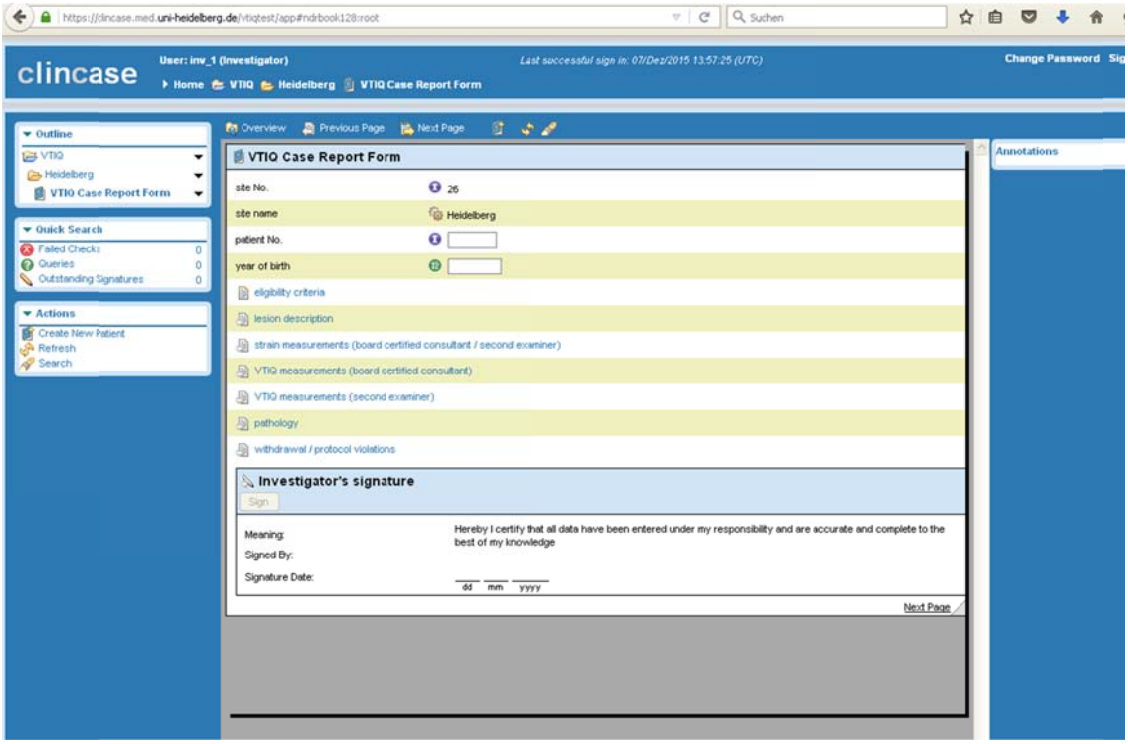

Figure 1: eCRF cover page

It is important, that patient No. (that is equivalent to the screening number of the participant) and year of birth are completed first and that these data are entered correctly. Please enter the patient No. without leading zeros, because this data field is defined as numeric. The site No. and site name will be filled in automatically because your site allocation is known via your user name. In the header panel you can find the composite study-ID (center-ID plus patient No.) of the patient you are currently editing. This composite study-ID will be the unequivocal identification of the patient and will appear in the booklist. Completion of the above named fields is the precondition for further data entry.

Below the field 'year of birth' you find links which lead you to the data entry masks of the different sections of the eCRF. It is divided into the following pages: eligibility criteria, strain measurements (board certified consultant/second examiner), VTIQ measurements (board certified consultant), VTIQ measurements (second examiner), pathology and withdrawal/protocol violation, so you can jump within the eCRF to the relevant pages. First of all please click on the link 'eligibility criteria' and answer whether they are fulfilled or not. For all screening failures data entry is completed by answering the question 'Patient enrolled?', no further data will be collected in this case. Only if the above question is answered with 'yes', data entry of further items will be enabled. Once you have answered the question 'Patient enrolled?', please refresh the page (either by clicking 'refresh' in the navigation panel or by clicking the defined link), so the Next Page button on the bottom will be displayed (for all enrolled patients) or not be displayed (for all screening failures). There are different ways to move to the next page of the study book, for example you can use the Previous and Next Page buttons in the toolbar or click on the links displayed in the Outline panel. (For further options see 'Clincase Investigator User Guide').

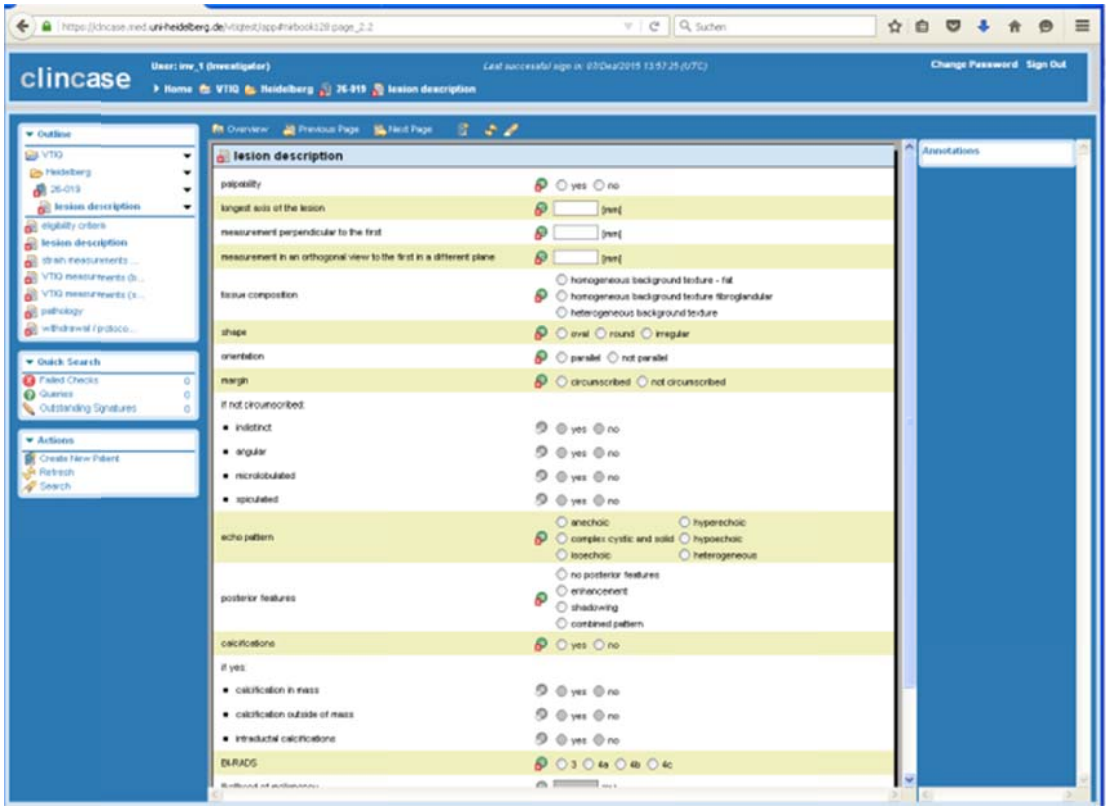

Figure 2: structure of a data entry mask (example)

Missing Values

The icon of a data field with status ‘required’ will be flagged missing as long as no value is entered or status is explicitly changed to ‘not applicable’, ‘not known’ or ‘not done’. To do so, open the context menu with a left or right mouse click on the question’s icon (on the left hand side) and choose the respective variable value. A change of the question’s icon to indicates that this action was successful. The ‘not Available’ option is also available for whole pages or sections. But it is disabled for mandatory items, i.e. patient No. and year of birth on the cover page.

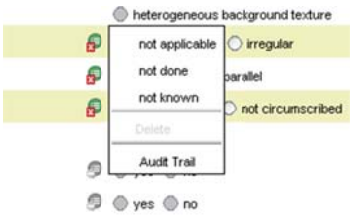

Figure 3: completion of missing values in the eCRF

The most common form elements within this eCRF are option buttons which allow single selection as well as numeric fields and some free text fields. Decimal numbers have to be entered seperated by a

point (not a comma). If you would like to delete the selection of an option button please do click the button again and the field status will be set to missing again.

Constraints

Response to subordinate questions is controlled by so called constraints. A condition referring to a superior question (e.g. if yes, please specify) induces, dependent on the respective answer, that the field of the subordinate question is accessible for data entry or not. So data fields in the eCRF that do not have to be completed in the individual study course will be locked automatically and need not to be skipped actively during the process of data entry.

Edit checks

Fields validated for plausibility or consistency will show up a so called edit check once the underlying validation rule is not fulfilled. There are two different types of edit checks.

Soft edit checks allow to be accepted providing a reason if the entered value is correct. For example a plausibility check for the longest axis of the lesion will check whether the entered value is more than 40 mm (see Figure 4).

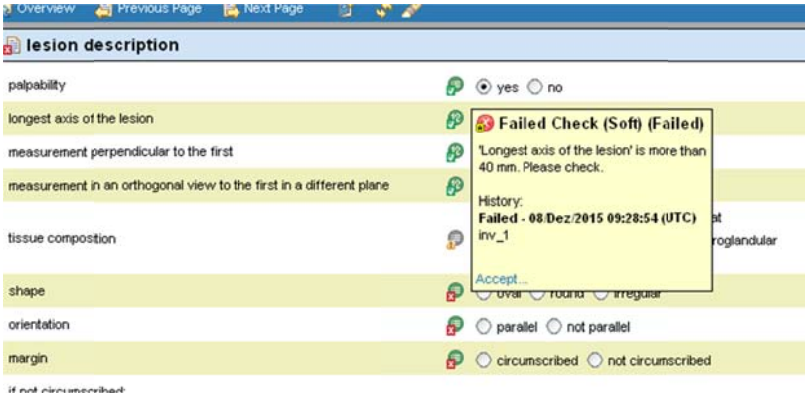

Figure 4: Soft edit check

A soft edit check will be signalized by the icon  on the right of the data field asking for verification. The intention of such a plausibility check is to separate outliers form mistypes. If the value is correct a left mouse click on the edit check's icon will show a window containing details of the edit check. To accept it, click 'Accept…' and provide a reply such as 'value is correct, although longest axis should be < 40 mm in fact' (see Figure 5).

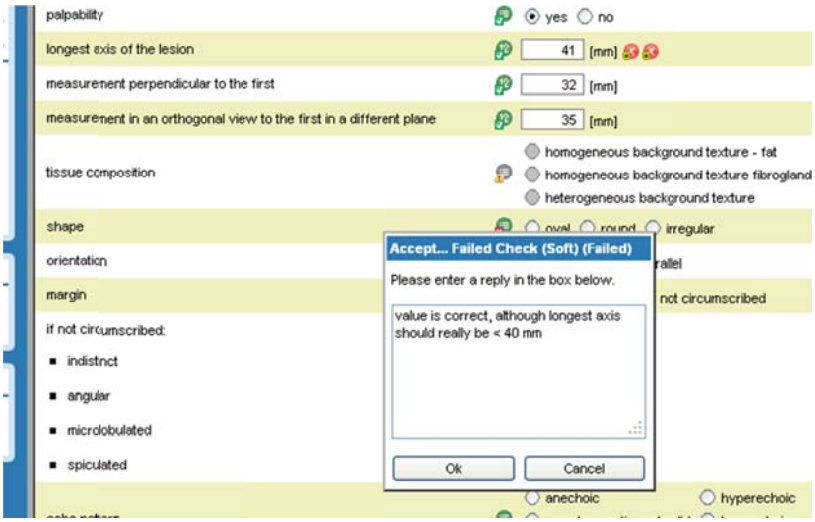

Figure 5: Accepting a soft edit check

When acceptance was successful, the icon will change to  .

Taking the example from above (edit check caused by entry of longest axis of the lesion 41 mm), the other possibility would be that the value of 41 mm was entered by mistake (for example 41 instead of 31 mm). So the value has to be corrected and the edit check will disappear afterwards, because the entered value is then within the defined range. If you have left the page in the meantime, you may have to provide a reason for change during the correction (Figure 6).

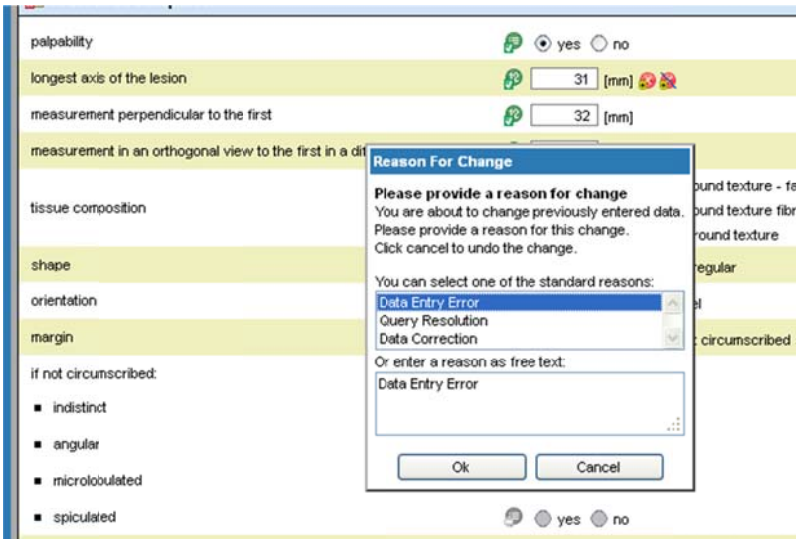

Figure 6: Correction of data entry error

Hard edit checks (Figure 7) will not allow to be accepted but force correction of the entered value in order to achieve consistence of data. Please note that the option ‘Accept…’ is not available.

Figure 7: Hard edit check

Queries

If there are any queries regarding the entered data, both monitor and data manager can raise questions by creating a query to get information or clarification from the Investigator. A query is marked by the icon . To resolve the query, do a left mouse click on this icon, then a window will appear, where you can click ‘Answer…’ to respond the question. The status will change to ‘Answered’ and the icon will be displayed. In the following step the query can be closed by the monitor/data manager, if it is resolved, or it can be re-queried.

Signature Field

After completion of all forms the eCRF of a study participant has to be signed. If a patient is not enrolled in the trial (screening failure), there is no signature required. You find the signature field on the cover page below the links to the several pages. In the header of the signature field you can find the actual status (e.g. ‘The eCRF still has missing data’ or ‘Please click the ‘Sign’ button to sign the entered data’). To sign the Signature the ‘Sign’ button must be clicked. The ‘meaning’ of the signature is displayed and the user has to confirm by entering the password. The status in the header will change to ‘Signed’. If there were any data corrections after the eCRF was signed, the header will display ‘The eCRF has been changed after the signature has been applied and needs to be signed again’.

Data Management Contact Information

For further questions concerning data entry please contact Data Management (Regine John, Email: john@imbi.uni-heidelberg.de, Phone: +49 (0)6221 56 4127).