# TrialDriver E-CRF Cheat Sheet

## Log In to the E-CRF

Start the E-CRF client application using the icon on your desktop.

1. Enter your login name
   (As sson as the name is recognized, a list of your assigned studies appears.
2. Select the study you wish to work with
3. Enter your password and press RETURN

## Register and Enroll Subjects

To Register a new Subject:

1. Select a “NOT REGISTERED” subject from your subject list.
2. Click the “Register This Subject” link
3. Enter the subject initials – must be three characters. Use ‘-’ for the middle initials if necessary.

When you click OK, a new subject E-CRF will be created, which at first contains only the Screening section of the CRF book.

To Enroll a successfully screened subject:

1. Select the SCREENING subject from you subjects list.
2. Click the “Enroll This Subject” link.
3. Confirm the subject is eligible. *(Note: if the E-CRF contains questions about the subject eligibilty, these must be answered YES to enroll successfully)*

Thereafter the subject E-CRF will contain all pages of the CRF.

## Open a Subject CRF

Double-Click an entry in your subjects list to open the E-CRF for that subject.

In the CRF Table of Contents (left side of screen):

- Click a page item to view the page and enter data
- Click a Visit item to view the visit summary.

## Color-Coding of E-CRF Data Fields

- **RED** fields indicate invalid data (an error message will appear beneath the page image)
- **GREEN** fields indicate valid data
- The **YELLOW** field indicates the active field
- **GREY** fields are locked (by submission to Data Management, investigator sign-off, Source Verification and/or Read-Only field)

## Entering Data into E-CRF Fields

- Click in a field to activate it
- TAB and SHIFT-TAB jump to the next/previous field
- Clicking a Checkbox field checks/unchecks it

## If Data is Missing or Unknown

- For a Text Field
  Click in a field to activate it, then type one of the Missing Data codes into the field
- For a Checkbox Field
  Activate the field, then use one of the Missing Data buttons (checkboxes will be struck-thru)

Missing Data codes and buttons are located at the top of the Data Assistance panel at right

- NI – No Information
- NA – Not Applicable
- UNK – Unknown
- ND – Not Done

## Errors and Warnings

- **RED** colored fields are invalid and in error. While a page contains such fields, it cannot be submitted to Data Management.
- There may also be warnings generated from your page data. A yellow bar appears beneath the page showing the warnings. Such pages may be submitted to Data Management

## Submitting Pages to Data Management

When valid page data has been entered into an E-CRF page:

- Check the “Page is Ready for Transmission” box in the CRF header
- Click the “SUBMIT” button at bottom left of the screen. *Note: you can submit multiple pages at once – all pages which are READY (yellow icon in the Table of Contents) will be submitted at this time)*
- After submission, pages are locked

## Revising already submitted data

If you need to revise data from pages which have already been submitted:

- Enter a Reason for Change in the input box at the bottom of the Data Assistance panel on the right side of the screen.
- If you are changing data due to a **query** from Data Management, enter the Query ID (with leading zeros) in the box provided.
- Click the “Revise Data” button

The E-CRF page will be unlocked and you can change data. The page will need to be resubmitted to Data Management as noted above.

## Resolving Queries

If Data Management issues a query against data which you have submitted, you will receive a PDF file which lists one or more items.

If you intend to revise data on the basis of the query:

- Unlock the E-CRF page as noted above
- Make the data change and resubmit

If you do **NOT** intend to make any changes to data

- Print the query PDF
- Note the reason why you will not change data
- Fax the Data Clarification Form back to Data Management.