

TrialDriver

Visual Data Management for Global Clinical Trials



Electronic Investigator Forms

E-CRFs for on-site data entry and global data transmission

User Guide

Version 3.5

www.trialdriver.com

The Basics

TrialDriver E-CRF were conceived to leverage the experience that clinical investigators and monitors already have with paper CRFs. The on-screen metaphor of a paper-based CRF book is maintained throughout. Data is entered into interactive CRF fields and is validated at every keystroke - color coding displays the validation status. Data is entered and saved continuously online. When ready, it is submitted to the study database in a batch mode. PDF printouts of CRF pages, patient CRF books and blank CRFs are all available on demand. Source Document Verification can be performed remotely online or on-site against printed copies of the electronic forms in the same way as in any other, paper-based study. Full 21CFR11 compliant audit trails are maintained locally and on the central study server.

CRF Table of contents

CRF Page Controls

The screenshot displays the TrialDriver E-CRF 2.9.0.2 interface. On the left, a 'CRF Table of contents' lists various pages and sections such as SCREEN, TREATMENT, and UNSCHEDULED. Below this is a 'CRF Page Controls' section with buttons for REPEAT PAGE, REPEAT SECTION, and OPTIONAL SECTION, along with a legend for data status (Invalid, Validated, Submitted) and verification status (Unverified, Verified). The main area is the 'Interactive Data Entry Fields' for 'Patient Information', including fields for Investigator Number (06), Patient Number (007), Patient Initials (DDD), Date of Birth (101358), Sex (Male), Ethnicity (Hispanic), and Vital Signs (Body Temperature: 93.8, Blood Pressure: 120/84, Pulse rate: 88, Respiratory rate: 15, Weight: 150). The right side features a 'Data Entry Assistance Panel' with instructions for missing data (NE, NA, UNK, ND), field instructions (e.g., VSWT), and a 'REVISE DATA' button. A 'Source Doc. Verification' section is also visible at the bottom right.

Data Entry Assistance Panel

Interactive Data Entry Fields

Getting Started

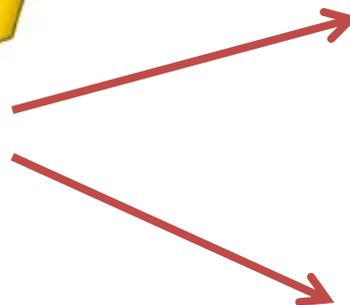
TrialDriver E-CRFs are stored on a central study server, which are accessed using the TrialDriver E-CRF client application. Before starting work with a TrialDriver E-CRF, you need the following

- The TrialDriver E-CRF client application must be installed on a PC running Windows XP, Vista or 7
- The PC should have a broadband internet connection. *(Note: If behind a Firewall, port 3306 should be open)*
- The PC can optionally be attached to a printer if E-CRF pages will be printed and stored in the patient files



Standard PC with:

- Microsoft Windows XP, Vista, 7
- TrialDriver E-CRF Client Application



Broadband Internet Connection



Printer

Logging in to the E-CRF

TrialDriver E-CRFs are password protected. When you launch the E-CRF application via the desktop icon, the first screen will ask you to provide your username and password, which will have been provided to you by the data management team. Based on the user name you provide, you will be presented with a list of studies to which you have access.

IMPORTANT: The TrialDriver E-CRF client requires internet access at all times.

LOGIN TO E-CRF

1. Enter your assigned user name, then
2. Select the study with which you want to work, then
3. Enter your password and click the LOGIN button

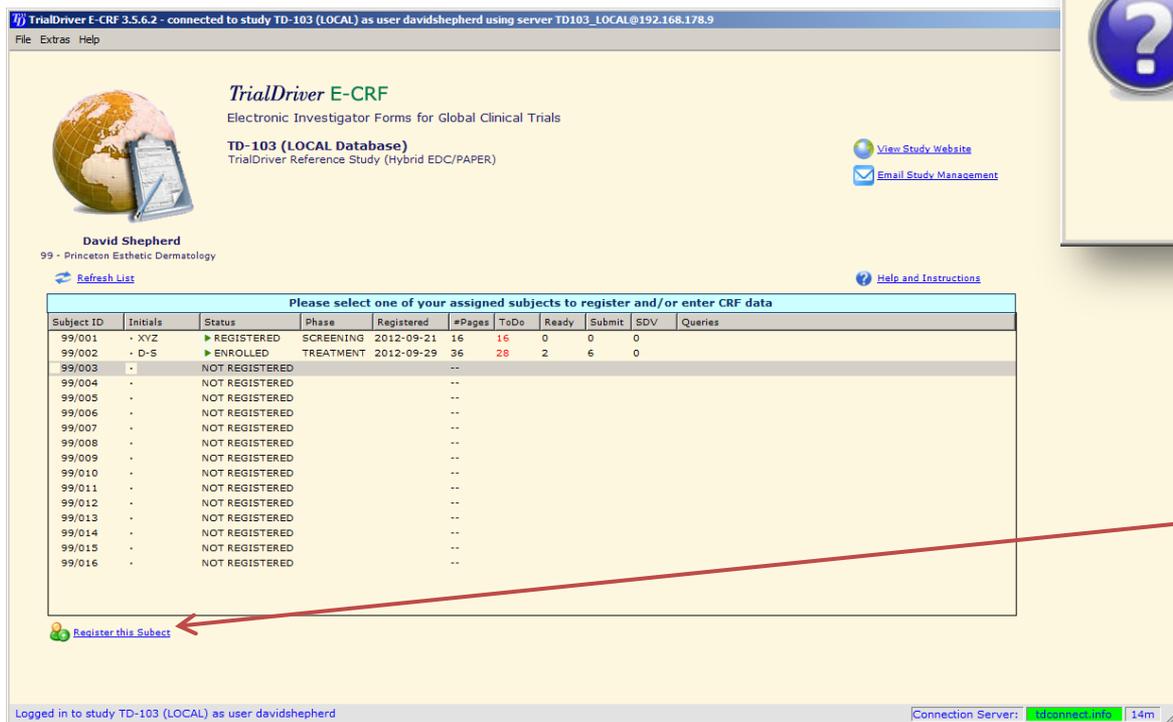
Online help is available in all screens where you see this message

If this box is green then your internet connection is good

Registering and Enrolling Study Subjects

TrialDriver E-CRFs can include CRF books for multiple subjects. The subjects are pre-configured by data management and are presented in a list. At first all subjects are marked as “NOT REGISTERED”. Select a subject in the list and click the “[Register this Subject](#)” link. This will display a dialog in which you will enter the initials of the subject you are registering.

If the study design calls for a screening procedure to be undertaken, the subject status after registration will appear in the list as “SCREENING”, otherwise the subject status will be “ENROLLED”. To complete enrollment for a “Screening” subject, click the “[Enroll this Subject](#)” link.



The screenshot shows the TrialDriver E-CRF interface. The main window displays a list of subjects with columns for Subject ID, Initials, Status, Phase, Registered, #Pages, ToDo, Ready, Submit, SDV, and Queries. A red arrow points from the 'Register this Subject' link at the bottom left of the subject list to a dialog box titled 'Register Subject'.

The dialog box, titled 'Register Subject', contains a question mark icon and the text: 'Register subject 06/008. Enter 3 characters for subject initials. Use a dash (-) if initial is unknown.' Below this text is a text input field labeled 'Subject Initials' and two buttons: 'OK' and 'Cancel'.

Subject ID	Initials	Status	Phase	Registered	#Pages	ToDo	Ready	Submit	SDV	Queries
99/001	-XYZ	REGISTERED	SCREENING	2012-09-21	16	16	0	0	0	
99/002	-D-S	ENROLLED	TREATMENT	2012-09-29	36	28	2	6	0	
99/003	-	NOT REGISTERED			--					
99/004	-	NOT REGISTERED			--					
99/005	-	NOT REGISTERED			--					
99/006	-	NOT REGISTERED			--					
99/007	-	NOT REGISTERED			--					
99/008	-	NOT REGISTERED			--					
99/009	-	NOT REGISTERED			--					
99/010	-	NOT REGISTERED			--					
99/011	-	NOT REGISTERED			--					
99/012	-	NOT REGISTERED			--					
99/013	-	NOT REGISTERED			--					
99/014	-	NOT REGISTERED			--					
99/015	-	NOT REGISTERED			--					
99/016	-	NOT REGISTERED			--					

Click this link to register a subject
(or double-click an unregistered subject)

The Study Main Page

After successfully logging in to the study, you are presented with a list of your subjects. Four additional links provide access to study resources: “*View Study Website*” opens a web page dedicated to study management. “*Email Study Management*” opens your email program. “*CRF Source Documents*” provides access to the source documents for this study, which you can print and fill in prior to entering the data in the E-CRF. “*Supplementary Documents*” provides a list of miscellaneous documents which you can print.

TrialDriver E-CRF
Electronic Investigator Forms for Global Clinical Trials

EB1010-301 (TESTING Database)
A Double-Blind, Paroxetine- and Placebo-Controlled Study of 50 mg/day and 100 mg/day of EB-1010 among Outpatients with Major Depressive Disorder Who have Responded Inadequately to Prior Selective Serotonin Reuptake Inhibitors

Dr. David Shepherd
999 - Testing Site (David)

[Refresh List](#) [Help and Instructions](#)

Please select one of your assigned subjects to register and/or enter CRF data

Subject ID	Initials	Status	Registration Date	#Pages	ToDo	Ready	Submit	SDV
999/001	ABC	ENROLLED	2010-12-19T14:22:43	172	152	0	20	4
999/002	XXX	ENROLLED	2010-12-20T12:42:40	172	172	0	0	0
999/003		NOT REGISTERED	--	--	--	--	--	--
999/004		NOT REGISTERED	--	--	--	--	--	--
999/005		NOT REGISTERED	--	--	--	--	--	--
999/006		NOT REGISTERED	--	--	--	--	--	--
999/007		NOT REGISTERED	--	--	--	--	--	--
999/008		NOT REGISTERED	--	--	--	--	--	--
999/009		NOT REGISTERED	--	--	--	--	--	--
999/010		NOT REGISTERED	--	--	--	--	--	--
999/011		NOT REGISTERED	--	--	--	--	--	--
999/012		NOT REGISTERED	--	--	--	--	--	--

[Enter CRF Data](#)

[View Study Website](#)

[Email Study Management](#)

[CRF Source Documents](#)

[Supplementary Documents](#)

CRF data updated

Connection Server: [reconnect.info](#)

Open Study Website

Email Study Management

CRF Source Documents

Supplementary Documents

Selecting a Subject for Data-Entry

Select one of your registered or enrolled subjects from the subject list and double-click it, or click the [“Enter CRF Data”](#) link.

Don't forget:

- A “SCREENING” subject will only have the CRF screening visit.
- An “ENROLLED” subject will have the entire CRF book.

The screenshot shows the TrialDriver E-CRF interface for study TD-103 (LOCAL). The interface includes a header with the logo, study name, and user information. Below the header is a table of subjects with columns for Subject ID, Initials, Status, Phase, Registered, #Pages, ToDo, Ready, Submit, SDV, and Queries. The table lists 16 subjects, with the first two being REGISTERED and ENROLLED, and the rest being NOT REGISTERED. At the bottom right of the table area, there is a link labeled "Enter CRF Data" with a red arrow pointing to it from the right side of the image.

Subject ID	Initials	Status	Phase	Registered	#Pages	ToDo	Ready	Submit	SDV	Queries
99/001	. XYZ	▶ REGISTERED	SCREENING	2012-09-21	16	16	0	0	0	
99/002	. D-S	▶ ENROLLED	TREATMENT	2012-09-29	36	28	2	6	0	
99/003	.	NOT REGISTERED			--					
99/004	.	NOT REGISTERED			--					
99/005	.	NOT REGISTERED			--					
99/006	.	NOT REGISTERED			--					
99/007	.	NOT REGISTERED			--					
99/008	.	NOT REGISTERED			--					
99/009	.	NOT REGISTERED			--					
99/010	.	NOT REGISTERED			--					
99/011	.	NOT REGISTERED			--					
99/012	.	NOT REGISTERED			--					
99/013	.	NOT REGISTERED			--					
99/014	.	NOT REGISTERED			--					
99/015	.	NOT REGISTERED			--					
99/016	.	NOT REGISTERED			--					

Click this link to perform data entry for a subject subject (or double-click the subject list entry)

Navigating the E-CRF (Main Screen)

The E-CRF screen is divided into 3 main areas:

- At left is the CRF Table of Contents (TOC). Click an entry in this list to display the corresponding CRF page. Beneath the TOC are controls which allow to create repeating pages and sections, create PDFs and submit CRF data
- In the middle is the image of the CRF page, overlaid with interactive data input fields. Page Zoom controls are at top.
- At right is Data Entry Assistance panel and the "Reason for Change" box, which enables data re-entry for pages which have already been submitted.

The screenshot displays the TrialDriver E-CRF 3.5.6.2 interface. On the left, the 'CRF Table of Contents' lists various pages and sections like 'SCREENING', 'CYCLE 1', 'CYCLE 2', and 'CYCLE 3'. Below this are 'Icon Legends' for data status (Valid, Validated, Submitted) and 'CRF Controls' for repeating pages and sections. At the bottom left are 'App Controls' for Close, PDF, and Submit. The main area shows a 'Pregnancy Test' form with fields for Subject ID (99-002), Date of Screening (20SEP2012), Date of Informed Consent (29SEP2012), and Demographics (Race: BRITISH, Ethnicity: Not Hispanic or Latino). On the right, the 'Data Entry Assistance' panel provides help and instructions, a 'Reason For Change' box, and a 'REVISE DATA' button. A 'Connection Server' status bar is at the bottom right.

CRF Table of Contents

Data Entry Assistance

Icon Legends

Data Entry Instructions/Warnings

CRF Controls

Reason For Change

App Controls

Show/Hide Detail Windows

Navigating the E-CRF (Visit Summaries)

Clicking on a Visit item in the E-CRF Table of Contents displays a Visit Summary

- The list display the page name, page status, submission and SDV details and the page description.
- Some visits (but not all) are allowed to be marked “Not Done” – in this case extra controls will appear on the visit summary sheet. (if a subject terminates early, this can be useful to mark all visit pages ‘Not Done’ in one operation)

Click a Visit item in the Table of Contents to display the summary sheet

Subject: **999/001 (ABC) VISIT0 (SCREENING)**

VISIT0
SCREENING (25 pages)

Page	#	Status	Submission	Ver.	SDV	Description
PAGE001	1	SUBMITTED	2011-01-11 11:36	1	V	Informed consent, De...
PAGE002	1	READY				Eligibility (Inclusion)
PAGE003	1	NOT READY				Eligibility (Exclusion 1)
PAGE004	1	NOT READY				Eligibility (Exclusion 2)
PAGE005	1	NOT READY				Eligibility (Exclusion 3)
PAGE006	1	NOT READY				Eligibility (Exclusion 4)
PAGE007	1	NOT READY				Medical History
PAGE008	1	NOT READY				Concomitant Medications
PAGE009	1	SUBMITTED	2011-01-11 11:31	1		Vital Signs, Phys. Ex.
PAGE010	1	NOT READY				Labs, Pregnancy Test, ...

Double-Click a page item to navigate to that page

If the visit is allowed to be ‘Not Done’, extra controls appear on the summary sheet

Subject: **999/001 (ABC) VISIT03 (PHASE1-WEEK1)**

VISIT03
PHASE1-WEEK1 (9 pages)

If this visit was not done check the box and click the "Update Visit" button. All pages will be marked "intentionally blank" and the page set ready for transmission.

Visit Not Done

Page	#	Status	Submission	Ver.	SDV	Description
PAGE040	1	NOT READY				Vital Signs, Med. Dispensation
PAGE041	1	NOT READY				MADRS
PAGE042	1	NOT READY				CGI, QIDS-SR

If a visit has been marked ‘Not Done’, a red cross appears next to the visit name

VISIT14 ✖ PHASE2-WEEK6 (ET)

- PAGE153 · Vital Signs, Med. Di...
- PAGE154 · Lab samples, Pregna...
- PAGE155 · ECG
- PAGE156 · Physical Exam

Entering Data into the E-CRF (basics)

- Click in an interactive data field to activate it. The active field is colored YELLOW.
- GREEN colored fields contain valid data, RED colored fields are invalid
- GREY colored fields are Read-Only
- Use the TAB and BACK-TAB key to jump from one data field to the next or previous one.
- Data are entered into TEXT fields and CHECKBOX fields.

NOTE: Page data are saved to the study server whenever you change page or exit the E-CRF. If you want to save data more frequently, click the [“Save Page”](#) link

TrialDriver E-CRF 2.9.0.2 - connected to study TD-101 as user david using server TD101ET@gclink3.net

File Extras Help

Visit / Page | Description

- SCREEN | Screening Visit
 - PAGE01 | Patient Information
 - PAGE02 | [1] Medical History...
 - PAGE03 | [1] Prior and Concu...
 - PAGE04 | Birth Control Infor...
 - PAGE05 | Lesion Count
 - PAGE06 | Erythema Assessm...
 - PAGE07 | Inclusion Criteria
 - PAGE08 | Exclusion Criteria
 - PAGE09 | Exclusion Criteria (...)
 - PAGE10 | Labs and Pregnanc...
 - PAGE11 | [1] Comments
 - PAGE11 | [2] Comments
- TREATMENT | Treatment visit
 - PAGE12 | Patient information
 - PAGE13 | New or Changed Ad...
 - PAGE14 | New or changed Co...
 - PAGE15 | Lesion Count
 - PAGE16 | Erythema Assessm...
 - PAGE17 | Chromameter Meas...
 - PAGE18 | Chromameter Meas...
 - PAGE19 | Chromameter Meas...
 - PAGE20 | [1] Comments
- ENDSTUDY | End of Study
 - PAGE21 | End of Study
- UNSCHEDULED | [1] Unscheduled visit
 - PAGE91 | Information
 - PAGE92 | New or Changed Ad...
 - PAGE93 | New or changed Co...

Legend:

- Invalid data (red)
- Validated (Ready) (yellow)
- Submitted (green)
- Unverified (grey)
- Verified (blue)

REPEAT PAGE | Repeat the selected CRF page

REPEAT SECTION | Repeat the selected study section

OPTIONAL SECTION | Add an optional section to the CRF

10101

Subject: **06/007 PAGE01**

Save Page Close this CRF

TD-101 TrialDriver Reference Study Page 1

Investigator Number: 06

Patient Number: 007

Patient Initials: DDD

Time (min): 1000

Date: 031010

Patient Information

Demographics

Date of Birth: 101358

Sex: Male Female

Race: Caucasian Asian Black Hispanic or Pacific Islander Native American Other (specify)

Ethnicity: Hispanic Non-Hispanic

Informed Consent

Informed Consent Signed? Yes No

Was the patient given a copy of the completed Informed Consent form? Yes No

Date of informed consent: 072611

Vital Signs

Body Temperature: 93.8 degrees F

Blood Pressure (sitting): 120/84 mm Hg

Pulse rate: 88 beats/min

Respiratory rate: 15 breaths/min

Weight: 150 lb

Data Entry Assistance

Help and Instructions

If required data is missing enter:

- NI - No information
- NA - Not applicable
- UNK - Unknown
- ND - Not done

DATE - Enter current date (F7)

Partial Dates: Enter two dashes for unknown parts ("--")

Field Instruction: RACE

Mark one box to indicate the race of the subject. If "other" enter text in the appropriate box

Codelist: RACE

- 1 = Caucasian
- 2 = Asian
- 3 = Black
- 4 = Hawaiian
- 5 = Native American
- 6 = Native Alaskan
- 9 = Other race

To resubmit revised data: To resubmit revised data, first specify the reason for change, then click the "Revise Data" button below.

If data is being resubmitted in response to a query, enter the

SDV Source Doc. Verification

Connection Server: gclink3.net

Loaded E-CRF for subject 06/007

Entering Data into the E-CRF (Checkboxes and “Checksets”)

- There are two types of data entry field: Text Entry and Checkbox Entry.
- There are two flavors of checkbox: Single checkboxes and sets of checkboxes (checksets)
- To check or uncheck a box with the mouse, just click in it
- To check a box using the keyboard:
 - For a single checkbox, the SPACE key will toggle the box on or off
 - For a set of checkboxes (“checkset”), hitting the number key displayed next to the box will activate that box

A single checkbox can be toggled by clicking in it, or by pressing the SPACE key

V1.5

Reference Study		Page 1
ng Visit		
ormation	Time (24hrs)	1000
	Date	031010
tionally left blank		
Race	1 <input checked="" type="checkbox"/> Caucasian	2 <input type="checkbox"/> Asian
	3 <input type="checkbox"/> Black	4 <input type="checkbox"/> Hawaiian or Pacific Islander
	5 <input type="checkbox"/> Native American	6 <input type="checkbox"/> Native Alaskan
	9 <input type="checkbox"/> Other (specify)	
Ethnicity	1 <input checked="" type="checkbox"/> Hispanic	2 <input type="checkbox"/> Non-hispanic

A box in a checkset can be activated by clicking in it, or by pressing the key corresponding to the number printed next to the box

V1.5

Reference Study		Page 1
ng Visit		
ormation	Time (24hrs)	1000
	Date	031010
tionally left blank		
Race	1 <input checked="" type="checkbox"/> Caucasian	2 <input style="color: red;" type="checkbox"/> Asian
	3 <input checked="" type="checkbox"/> Black	4 <input style="color: red;" type="checkbox"/> Hawaiian or Pacific Islander
	5 <input style="color: red;" type="checkbox"/> Native American	6 <input style="color: red;" type="checkbox"/> Native Alaskan
	9 <input style="color: red;" type="checkbox"/> Other (specify)	
Ethnicity	1 <input checked="" type="checkbox"/> Hispanic	2 <input style="color: red;" type="checkbox"/> Non-hispanic

Only a single box in a checkset may be active. If multiple boxes have been clicked, the checkset is displayed in **RED** color, indicating invalid data

Entering Data into the E-CRF (Missing Data)

If a field is empty and displayed in **RED**, this means that the field may not be empty. If however you have no data for this field, then you must indicate this by choosing one of the codes which indicate missing data. There are four such codes which are listed in the Data Entry Assistance area at the right of the screen. Enter the code into a text entry box or, if the field in question is a checkbox, click the appropriate button in the assistance area.

The screenshot shows a form with the following questions and options:

- Informed Consent Signed?** Yes (checkbox with 'X'), No (checkbox)
- Was the patient given a copy of the completed Informed Consent form?** Yes (checkbox with 'X'), No (checkbox)
- Date of informed consent** (MM DD YY) - This field is highlighted in red.

The **Data Entry Assistance** panel on the right lists the following codes:

- NI** - No information
- NA** - Not applicable
- UNK** - Unknown
- ND** - Not done
- DATE** - Enter current date (F7)
- Partial Dates**: Enter two dashes for unknown parts ("--")

The “missing data” codes are listed in the data assistance area. They are:

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

Enter the code text into a text box, or click the button for the appropriate code

This field is displayed in **RED** because it may not be left empty. So long as any field on a page is red, that page cannot be submitted to the study server.

If no data is available for the field, enter one of the “missing data” codes into the box, which will turn the field green

The screenshot shows the same form as above, but the **Date of informed consent** field is now green and contains the code **UNK**. The **Data Entry Assistance** panel on the right is still visible, showing the same list of codes.

Entering Data into the E-CRF (Partial Dates)

Sometimes you will not be able to provide complete dates.

- If you know the year, but the day and/or month are missing: Enter two dashes for the missing parts
- If the date is completely unknown: Leave the field blank or enter UNK

ITEM #	Code No.	Diagnosis and/or Procedure	Onset Date (MM DD YY)	Resolved (X)	Ongoing (X)
1	01	ROSACEA	----03	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2	02	DEPRESSION	UNK	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3	04	SORE THROAT	030409	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4				<input type="checkbox"/>	<input type="checkbox"/>

Entering Data into the E-CRF (Repeating Pages and Sections)

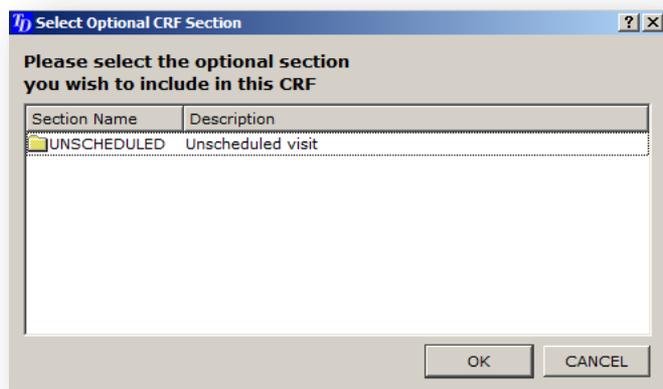
Some pages in a CRF are designated as “repeating pages”. Such pages are typically “logging” pages such as Medical History, Concomitant Medications and so on. If you need more entries than will fit on a single page:

1. Select the page you are interested in from the Table of Contents
2. Click the “REPEAT PAGE” button

Similarly, some studies may have complete sections (visits) which repeat an indeterminate number of times. To create a new repeating section:

1. Select any page in the section you are interested in
2. Click the “REPEAT SECTION” button

Some studies may contain optional (or unscheduled) sections which do not automatically appear in the subject CRF. To include such a section, click the “OPTIONAL SECTION” button. This will open a selection list containing all such sections which are defined for the current study.



Optional Sections Dialog

Repeat Controls →

- REPEAT PAGE** - Repeat the selected CRF page
- REPEAT SECTION** - Repeat the selected study section
- OPTIONAL SECTION** - Add an optional section to the CRF

Submitting Data to the Study Server (How to submit data)

When all the fields on a page are displayed in **GREEN**, this means that the page is ready to be submitted to the study server. Click the "SUBMIT" button at bottom right to initiate the data submission process. There is no necessity to submit pages one at a time – all pages which are ready for submission will be submitted at once. A dialog is displayed which tracks the progress of the data submission - at the end a message is displayed "Data successfully submitted". If an error message is displayed, please communicate this to the data management team.

Pages which are ready to be submitted to the Study Server have a **YELLOW** icon in the Table of Contents

The screenshot displays the TrialDriver E-CRF 2.9.0.2 interface. On the left, a 'Table of Contents' lists various pages under categories like SCREEN, TREATMENT, and UNSCHEDULED. A red arrow points to PAGE04, which has a yellow icon, indicating it is ready for submission. The main area shows the 'Birth Control Information' form for subject 06/007. The form includes fields for Investigator Number (06), Patient Number (007), Patient Initials (DDD), and Date (072610). Below these are checkboxes for birth control methods: Not applicable, IUD (checked), Diaphragm with spermicide, Depo-Provera, Norplant, Oral contraceptive with condoms, Condom with spermicide gel or foam, Implantable, transdermal or injectable contraceptive, Surgically sterile, and Monogamous relationship with sterile partner. A 'Date of signed waiver' field contains 072610. At the bottom right, a large 'SUBMIT' button is highlighted with a callout box. The interface also features a 'Data Entry Assistance' panel on the right with a legend and a 'REVISE DATA' button.

Use the **SUBMIT** button to start data transmission

Submitting Data to the Study Server (After data are submitted)

During data transmission a dialog is displayed indicating the progress. When the transmission is complete a message is displayed which allows you to choose to create a PDF of the submitted pages. This PDF can then be printed and the hard copies stored in the subject dossier. For reference, the CRF page is imprinted with the date and time of transmission.

Choose OK if you do **not** require a PDF at this point (you can create the PDF later if you wish)

The screenshot displays a software interface with a yellow dialog box in the foreground. The dialog box contains the following text:

All Items submitted.
Click PRINT to print paper hardcopies
 File the paper copies in the subject dossier

At the bottom of the dialog box are two buttons: **OK** and **Print**. A red arrow points from the **OK** button to a text box that reads: "Click OK in the dialog to create a PDF of the pages which were submitted".

The background shows a CRF form with the following sections:

- TD-001** (TrialDriver Reference Sheet)
- Screening Visit** (Date: 072610)
- Prior and Concurrent Medications** (Patient initials: DDD)
- Birth Control Information** (Date of onset: 072610)

At the bottom of the interface, there is a footer that says: "To print, use the Acrobat Toolbar Button above".

Submitting Data to the Study Server (How to re-submit updated page data)

After a page has been submitted, it is locked and no further data entry is allowed on it. All the fields are GREY, indicating their Read-Only status. The only exception to this rule concerns “logging” pages, which are expected to be updated periodically.

If you must revise data on a locked page, do the following:

- Select the page in the Table of Contents
- Enter a Reason for Change in the Data Assistance panel.
- Click the **REVISE DATA** button

The Page will be reactivated and you can change data. The page must now be re-submitted.

Birth control information
(Check ALL that apply)

If female of child-bearing potential,

Not applicable (male or post-menopausal)

IUD

Diaphragm with spermicide

Depo-Provera

Norplant

Oral contraceptive with condoms

Condom with spermicide gel or foam

Implantable, transdermal or injectable

Surgically sterile

Monogamous relationship with steady partner

Abstinence:

Other, please specify below

Data Assistance Panel:

[Help and Instructions](#)

If required data is missing enter:

NI - No information

NA - Not applicable

UNK - Unknown

ND - Not done

DATE - Enter current date (F7)

Partial Dates: Enter two dashes for unknown parts ("--")

Field Instruction:

To resubmit revised data:
To resubmit revised data, first specify the reason for change, then click the "Revise Data" button below.

The Birth Control Information was incorrect

If data is being resubmitted in response to a query, enter the Query-ID (from the DCF).

QueryID

REVISE DATA

SDV Source Doc. Verification

Connection Server: gcplink1.net

Optionally you can enter a “Query ID” if the data is being changed because of a data query.

Enter the **Reason For Change** here, then

Click the **REVISE DATA** button to re-enable the page

Dealing with Data Queries

Data Management may issue queries against data you have submitted. The TrialDriver E-CRF client allows you to view the Data Clarification Forms (DCF) online and to respond appropriately to them.

The sequence of operations is:

- The presence of a query is indicated by a flag in your subjects list.
- Open the CRF and click the “View Queries” button to see the queries list.
- Review each query in turn. Decide if you will make changes to the data.
- If YES, make the data changes. If NO, enter a brief comment. Finally click the “Return This Query” button

TrialDriver E-CRF
Electronic Investigator Forms for Global Clinical Trials
TD-103 (LOCAL Database)
TrialDriver Reference Study (Hybrid EDC/PAPER)

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99 - Princeton Esthetic Dermatology

Subject ID	Initials	Status	Phase	Registered	#Pages	ToDo	Ready	Submit	SDV	Queries
99/001	-XYZ	REGISTERED	SCREENING	2012-09-21	16	16	0	0	0	
99/002	-D-S	ENROLLED	TREATMENT	2012-09-29	36	28	2	6	0	QUERIED 2 Awaiting Response
99/003	-	NOT REGISTERED								
99/004	-	NOT REGISTERED								
99/005	-	NOT REGISTERED								
99/006	-	NOT REGISTERED								
99/007	-	NOT REGISTERED								
99/008	-	NOT REGISTERED								
99/009	-	NOT REGISTERED								
99/010	-	NOT REGISTERED								

99/002 SCREENING:PAGE001

TrialDriver Reference Study TD-102
Screening Page 1

Informed Consent Demographics Pregnancy Test

Subject ID: 99-002 Initials: D-S Date of Screening: 20SEP2012

Informed Consent signed prior to any study related procedure? NO YES

Date & Time of Informed Consent: 29SEP2012 Time (PST): 1214

Demographics: Date of Birth: 20JAN1977 Race: Other (specify): BRITISH

View CRA Queries View Source Documents Scan/Upload Documents CRF Sign-Off

Query Page/Visit	Field	Status	Text
PAGE001:1 (SCREENING:1)	BRTHDTC	Issued to site	Please verif...
PAGE004:1 (SCREENING:1)	MHDJAG:1	Issued to site	Please indic...

QUERY TEXT FROM CRA (DAVIDSHEPHERD)
Please verify date of birth - 1977 in source documents

QUERY RESPONSE FROM SITE (DAVIDSHEPHERD)

Return this Query

Active queries are flagged in the subjects list. Open the subject CRF to view the queries

Open the “View Queries “ window by clicking the button beneath the CRF image

Queries are listed in the left hand panel. Select a query to view the query text. Double-Click a query to navigate the CRF to the queried item

Enter your response to the query in the right-hand panel. Or just click the checkbox to indicate that you have made data changes

Finally click the “Return this Query” button

Investigator Sign-Off

- When a subject CRF is completed, the investigator is requested to sign-off on that CRF
- Not all users are allowed to sign off – this is a permission set in the user profile
- Some users are allowed to sign and un-sign, some may only un-sign but not sign
- When part or all of the E-CRF are signed off, the pages are locked to prevent further changes. The signature must be revoked (‘unsigned’) in order to make further changes

Click the CRF Sign-Off button beneath the CRF image to open the Sign-Off window

An overview of the Sign-Off status of the CRF is displayed

Specifically the Investigator is asked to confirm that any empty pages and visits are intentionally blank. Place a checkmark next to items requiring confirmation – or click the “Confirm All” button

Finally click the Sign-Off button. Any remaining pages and visits will be marked blank and submitted to Data Management. The CRF will be locked from further changes.

The screenshot shows the 'CRF Sign-Off' window with the following details:

- Header:** READY FOR SUBMISSION, Save Page
- Study Info:** TrialDriver Reference Study TD-102, Screening, Page 1
- Subject Info:** Subject ID 99-002, Initials D-S, Date of Screening 20SEP2012
- Informed Consent:** Informed Consent signed prior to any study related procedure? NO YES. Date & Time of Informed Consent: 29SEP2012 1214.
- Demographics:** Date of Birth 20JAN1977. Race: Other (Specify) BRITISH.
- Navigation:** New CRA Queries, View Source Documents, Scan/Upload Documents, CRF Sign-Off
- CRF Sign-Off Window:**
 - Buttons: REFRESH, CONFIRM ALL
 - Text: **Please review the CRF status**. For any items which are not done, your confirmation is required. Place a checkmark on the relevant item, or click "Confirm All". Click "Refresh" if you update CRF data.
 - Table:

Visit/Page	Item Status
<input type="checkbox"/> SCREENING	Empty pages require confirmation before sign-off
<input type="checkbox"/> CYCLE [1]	Empty pages require confirmation before sign-off
<input type="checkbox"/> CYCLE [2]	Empty pages require confirmation before sign-off
<input checked="" type="checkbox"/> CYCLE [3]	All pages ready for sign-off - CRF section will be m...
<input type="checkbox"/> FINAL	Empty pages require confirmation before sign-off
<input type="checkbox"/> ENDSTUDY	Empty pages require confirmation before sign-off
<input type="checkbox"/> LOCK	Pages must be signed-off before this time
 - Legend: OK for Sign-Off Confirmation required Cannot Sign-Off
 - Button: **Sign-Off and Lock CRF**

Creating PDFs

You can create PDFs of the CRF pages at any time. These can then be saved to your local disk, printed or emailed. PDFs are created which display the data you have entered.

Click the PDF button in the Page Controls area. This will bring up a dialog which allows you to determine which pages should be printed

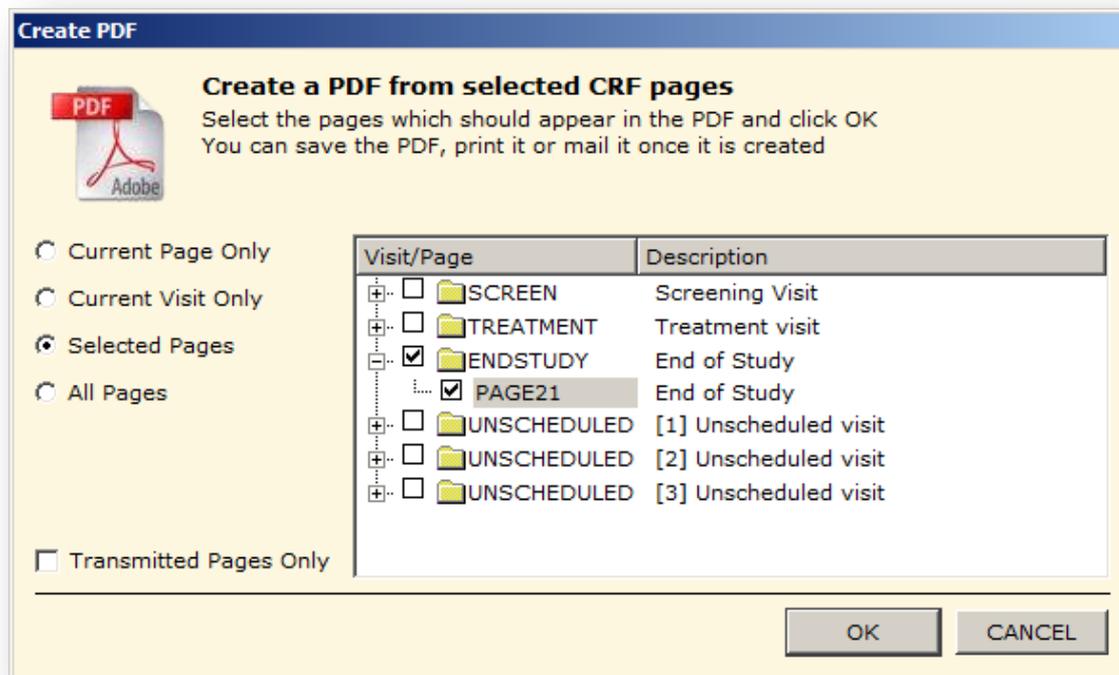


Your options are to create a PDF containing:

- Only the current page
- All pages in the current section
- Selected Pages – mark the pages you require in the list at right
- All pages

Additionally you can elect to include only those pages which have been submitted to the Study Server. Leaving this option unchecked will also include empty pages

The PDF will be displayed in an embedded PDF Reader window. Click the [“Close this Window”](#) link to return to the interactive CRF



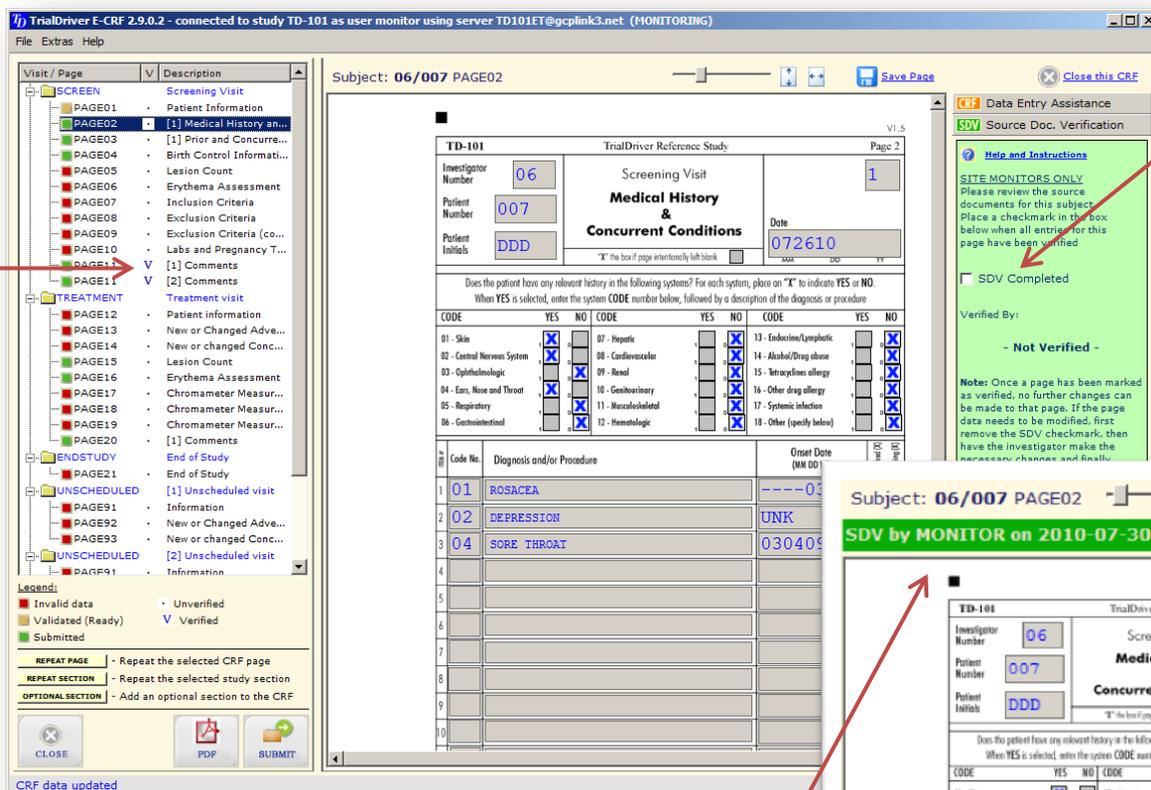
Source Document Verification (For study monitors and CRAs)

Study monitors can perform Source Document Verification (SDV) on TrialDriver E-CRFs. Monitors are provided with special login credentials which prevents them from entering data into the E-CRF but enables an SDV mode, so that they may provide an indication that they have compared the data in the E-CRF with those in the source documents and have found them to match.

Once the monitor has verified an E-CRF page, that page is completely locked and its' data cannot be modified – not even if a reason for change is given. If a page must be modified, the monitor must revoke the verification, which then enables the page again. After the change has been made, the verification process must be repeated.

A "V" icon next to a page indicates that SDV has been completed for that page.

No further changes can be made



Place a check mark here to indicate that a page is verified

A green bar above the page indicates SDV completed

Miscellaneous Options

Some miscellaneous options are available under the menu option “Extras”. These are:

View Audit Trail

Select this option to display a list of all logged operations for the current subject.

Choose “**Copy to Clipboard**” to copy the list in a comma delimited format (suitable for loading into Excel).

Double-click any list entry to hyperlink to the associated data field (if applicable)

LOGTIME	USERNAME	OPERATION	SUBJECT	PAGE	DETAILS
2010-03-10T15:05:54	DAVID	CHANGE	06/007	PAGE11#1	FIELD COVAL:1 - "" CHANGED TO "SDFSDFSA"
2010-03-10T15:05:54	DAVID	CHANGE	06/007	PAGE11#1	FIELD COINIT:1 - "0" CHANGED TO "1"
2010-03-10T15:05:54	DAVID	CHANGE	06/007	PAGE11#1	FIELD CODTC:1 - "" CHANGED TO "031010"
2010-03-10T15:07:00	DAVID	SUBMIT	06/007	PAGE11#1	PAGE VERSION = 3
2010-03-10T15:07:00	DAVID	RPC	06/007	PAGE11#1	RPC=ddd
2010-03-10T15:07:00	DAVID	CHANGE	06/007	PAGE11#1	FIELD COREP:2 - "" CHANGED TO "3"
2010-03-10T15:07:00	DAVID	CHANGE	06/007	PAGE11#1	FIELD COINIT:2 - "0" CHANGED TO "1"
2010-03-10T15:07:00	DAVID	CHANGE	06/007	PAGE11#1	FIELD CODTC:2 - "" CHANGED TO "031010"
2010-03-11T10:51:28	MONITOR	VERIFY	06/007	PAGE11#1	MONITOR@2010-03-11 08:10
2010-03-11T10:52:01	MONITOR	VERIFY	06/007	PAGE11#2	MONITOR@2010-03-11 08:12
2010-03-11T11:14:48	DAVID	SUBMIT	06/007	PAGE11#2	PAGE VERSION = 1
2010-03-11T11:14:49	DAVID	SUBMIT	06/007	PAGE20#1	PAGE VERSION = 2
2010-03-11T11:14:49	DAVID	RPC	06/007	PAGE20#1	RPC=sdffs
2010-03-11T11:14:49	DAVID	CHANGE	06/007	PAGE20#1	FIELD COINIT:1 - "0" CHANGED TO "1"
2010-04-09T20:49:18	DAVID	SUBMIT	06/007	PAGE16#1	PAGE VERSION = 1
2010-04-09T20:53:40	DAVID	SUBMIT	06/007	PAGE16#1	PAGE VERSION = 1
2010-04-09T20:54:59	DAVID	SUBMIT	06/007	PAGE16#1	PAGE VERSION = 2
2010-04-09T20:54:59	DAVID	RPC	06/007	PAGE16#1	RPC=sss
2010-04-09T20:54:59	DAVID	CHANGE	06/007	PAGE16#1	FIELD TTSCORE:0 - "8" CHANGED TO "9"
2010-04-09T20:56:23	DAVID	SUBMIT	06/007	PAGE16#1	PAGE VERSION = 3

Print Blank CRF

Choose this option to display a PDF of the entire CRF. The PDF will not contain any subject data

Supplemental Documentation

Choose this option to display a list of “supplemental documentation” associated with this study. These are PDFs which pertain to the study, but are not part of the CRF proper.

Select a document and click the **OPEN** button to display it in the PDF viewer, from where it may be saved or printed.

Document	Title
MEDWATCH3500	FDA Medwatch SAE Report Form
TD-101 PROTOCOL	Study Protocol for study TD-101