

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

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www.trialdriver.com

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Introduction

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 application window. The title bar indicates it is connected to study TD-101 as user david using server TD101ET@gcplink3.net. The interface is divided into three main sections:

- Left Sidebar (CRF Table of Contents):** A tree view showing the structure of the CRF. It includes sections like SCREEN (Patient Information, Medical History, etc.), TREATMENT (Patient Information, Lesion Count, etc.), and ENDSTUDY (End of Study). A legend at the bottom indicates data status: Invalid data (red), Validated (Ready) (yellow), Submitted (green), Unverified (white), and Verified (blue).
- Main Data Entry Area:** A form for Subject 06/007 PAGE01. It contains fields for Patient Information (Investigator Number: 06, Patient Number: 007, Patient Initials: DDD), Demographics (Date of Birth: 101358, Sex: Male, Ethnicity: Hispanic), Informed Consent (Signed: Yes, Date: 072610), and Vital Signs (Body Temperature: 93.8, Blood Pressure: 120/84, Pulse rate: 88, Respiratory rate: 15, Weight: 150). A barcode is visible at the bottom of the form.
- Right Sidebar (Data Entry Assistance Panel):** A panel providing help and instructions. It includes a 'Help and Instructions' link, a section for 'If required data is missing enter:' with options like 'NI - No information', 'NA - Not applicable', 'UNK - Unknown', and 'ND - Not done'. It also has a 'Field Instruction: VSWT' section and a 'To resubmit revised data:' section.

At the bottom of the window, the status bar shows 'CRF data updated' and 'Connection Server: gplink3.net'.

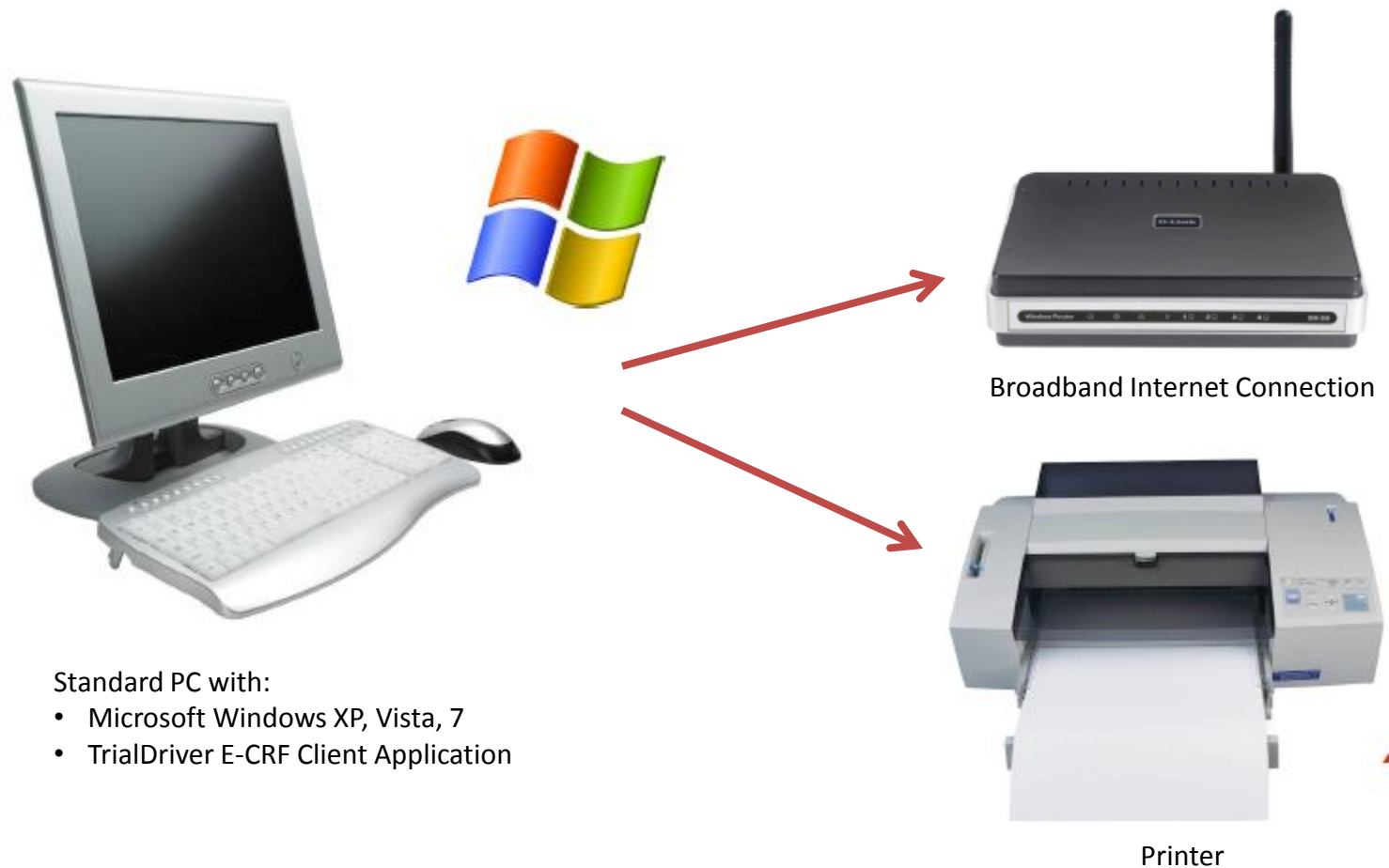
Data Entry
Assistance Panel

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



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.

TrialDriver E-CRF 3.5.6.2

File Extras Help

TrialDriver E-CRF
Electronic Investigator Forms for Global Clinical Trials

First enter your username, then select a study and enter your password

User Name

Available Studies

(List will be shown when the user name has been entered)

TD-103 [LOCAL - TD-103 Reference Study]

Test Study Connection Password

Help and Instructions

Logged out of study

Connection Server: Internet

LOGIN TO E-CRF

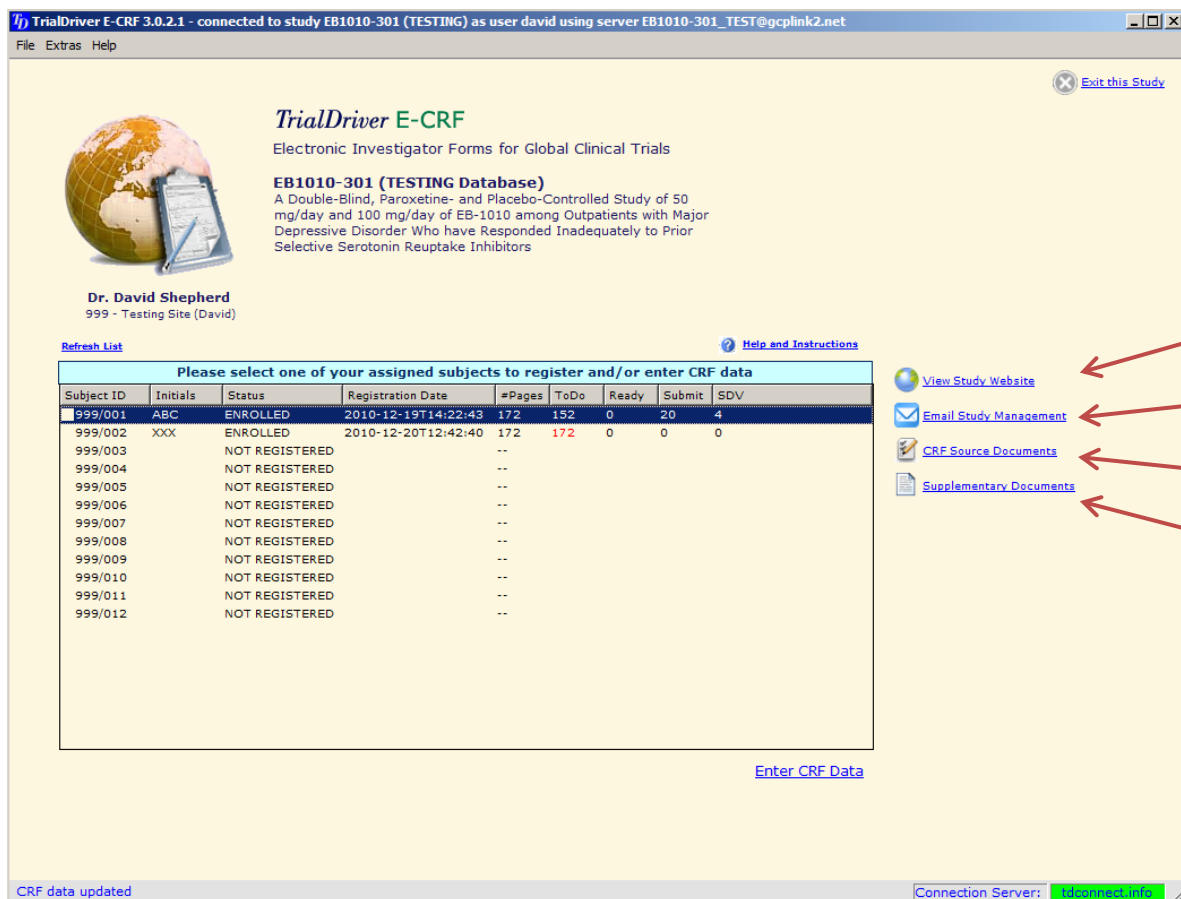
1. Enter your assigned user name, then
2. Select the study with which you want to work, then
3. Enter your password and click the LOGIN button

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

If this box is green then your internet connection is good

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: [tdconnect.info](#)

Open Study Website

Email Study Management

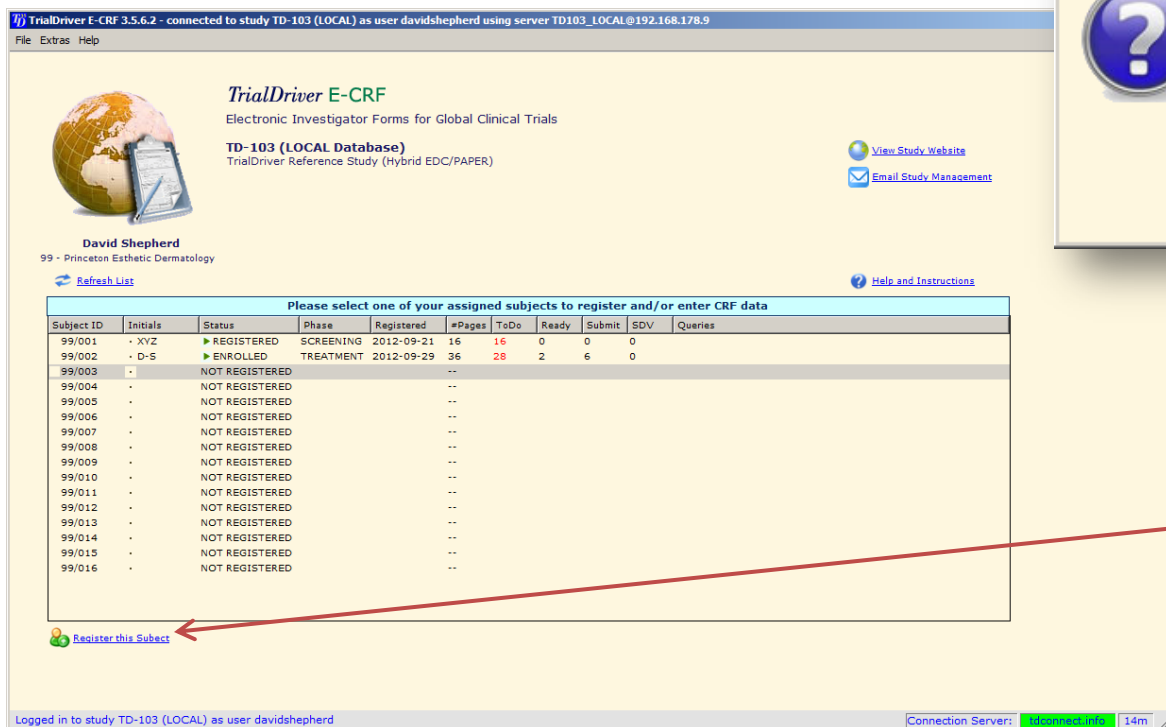
CRF Source Documents

Supplementary Documents

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 for study TD-103 (LOCAL). 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 the 'Register Subject' dialog box on the right.

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

David Shepherd
99 - Princeton Esthetic Dermatology

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

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			--					

Register this Subject

Logged in to study TD-103 (LOCAL) as user davidsshepherd

Connection Server: [tdconnect info](#) 14m

Register Subject

Register subject 06/008

Enter 3 characters for subject initials.
Use a dash (-) if initial is unknown

Subject Initials

OK Cancel

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

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 3.5.6.2 application window. The title bar indicates it is connected to study TD-103 (LOCAL) as user davidsshepherd. The main interface includes a logo, study name (TD-103 (LOCAL Database)), and a list of subjects. A red arrow points from the text 'Click this link to perform data entry for a subject subject (or double-click the subject list entry)' to the 'Enter CRF Data' link at the bottom right of the subject list table.

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. The main window is titled "TrialDriver E-CRF 3.5.6.2 - connected to study TD-103 (LOCAL) as user davidsshepherd using server TD103_LOCAL@192.168.178.9".

CRF Table of Contents: On the left, a tree view lists various CRF pages and sections, including SCREENING, CYCLE 1, CYCLE 2, and CYCLE 3. Below this list are controls for repeating pages and sections, and a legend for data status (Valid, Validated, Submitted).

CRF Controls: Below the Table of Contents, there are buttons for "REPEAT CRF PAGE", "REPEAT CRF SECTION", and "OPTIONAL SECTION".

App Controls: At the bottom left, there are buttons for "CLOSE", "PDF", and "SUBMIT".

CRF Page: The central area displays the "TrialDriver Reference Study TD-102" form. It includes sections for "Informed Consent", "Demographics", and "Pregnancy Test". The form contains various input fields for dates, times, and demographic information.

Data Entry Assistance: On the right, a panel titled "Data Entry Assistance" provides help and instructions. It includes a "Reason for Change" box for submitting revised data.

Icon Legends: A legend at the bottom left explains the status of data entries: Valid (green), Validated (yellow), Submitted (blue), Unverified (red), and Verified (green).

CRF Controls: Below the legend, there are buttons for "REPEAT CRF PAGE", "REPEAT CRF SECTION", and "OPTIONAL SECTION".

App Controls: At the bottom left, there are buttons for "CLOSE", "PDF", and "SUBMIT".

Connection Server: At the bottom right, a status bar shows the connection server information: "Connection Server: 192.168.178.9 14m".

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 **UPDATE VISIT**

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@gcplink3.net

File Extras Help

Visit / Page V 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 square)
- Validated (Ready) (Green square)
- Submitted (Blue square)
- Unverified (Yellow square)
- Verified (Green square)

REPEAT PAGE - Repeat the selected CRF page

REPEAT SECTION - Repeat the selected study section

OPTIONAL SECTION - Add an optional section to the CRF

Close PDF Submit

Subject: 06/007 PAGE01

Save Page Close this CRF

TD-101 TrialDriver Reference Study Page 1

Patient Information

Investigator Number: 06

Patient Number: 007

Patient Initials: DDD

Time (days): 1000

Date: 03/10/10

☒ Yes the last page intentionally left blank

Demographics

Date of Birth: 10/13/58

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: 07/26/11

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 reason for change.

SDV Source Doc. Verification

Loaded E-CRF for subject 06/007

Connection Server: gcplink3.net

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 HH MM	
	Date 03OCT2015 MM DD YY	
tionally left blank	☐	
Race 1 ☒ Caucasian 3 ☐ Black 5 ☐ Native American 9 ☐ Other (specify) 2 ☐ Asian 4 ☐ Hawaiian or Pacific Islander 6 ☐ Native Alaskan		
Ethnicity 1 ☒ Hispanic 2 ☐ 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 HH MM	
	Date 03OCT2015 MM DD YY	
tionally left blank	☐	
Race 1 ☒ Caucasian 3 ☒ Black 5 ☐ Native American 9 ☐ Other (specify) 2 ☐ Asian 4 ☐ Hawaiian or Pacific Islander 6 ☐ Native Alaskan		
Ethnicity 1 ☒ Hispanic 2 ☐ 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.

Informed Consent Signed? 1 ☒ Yes 0 ☐ No

Was the patient given a copy of the completed Informed Consent form? 1 ☒ Yes 0 ☐ No

Date of informed consent MM DD YY

CRF 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: YSTEMP

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

Informed Consent Signed? 1 ☒ Yes 0 ☐ No

Was the patient given a copy of the completed Informed Consent form? 1 ☒ Yes 0 ☐ No

Date of informed consent UNK MM DD YY

CRF 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: ICECTVEN

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	----2015	☐	☒
2	02	DEPRESSION	UNK	☐	☒
3	04	SORE THROAT	03OCT2015	☒	☐
4				☐	☐

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

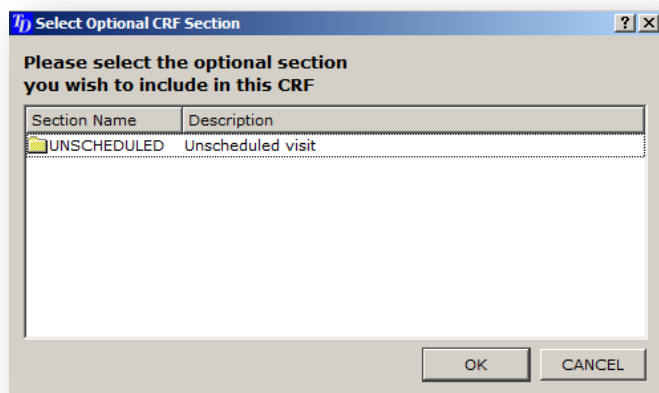
Some pages in a CRF are designated as “repeating pages”. Such pages are typically “logging” pages such as Medical History, Concomitant Medications and so on. If you need more entries than will fit on a single page:

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

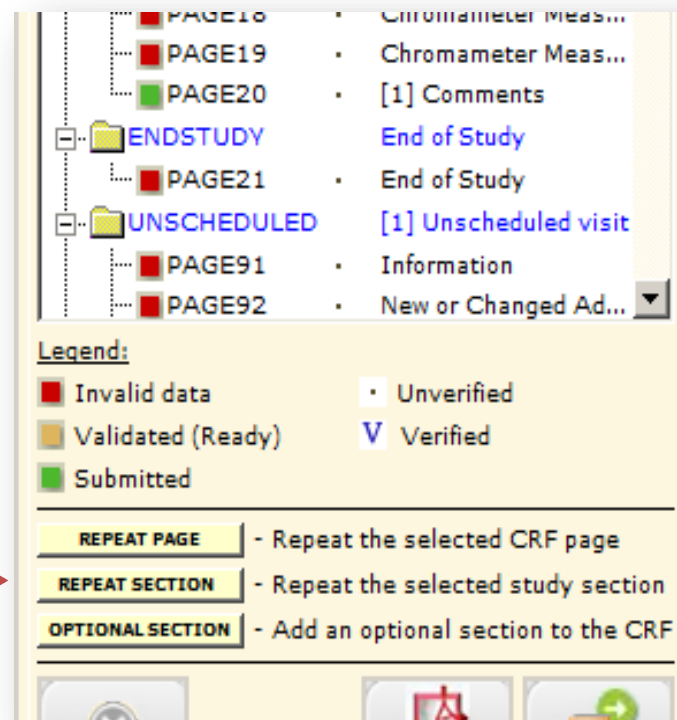
Similarly, some studies may have complete sections (visits) which repeat an indeterminate number of times. To create a new repeating section:

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

Pages and Visit Not Done

Many eCRF pages (but not all) can be marked as being “intentionally blank”. When you mark a page as “intentionally blank” you are saying that there are no data at all to be recorded on the page – effectively the page is “not done”.

The CRF page headers contain a check box which, when checked, will override all edit checks and make the page ready for submission

If all pages of a given visit may be marked as “intentionally blank”, then the entire visit may be marked as “not done”, as follows:

1. Select the visit entry from the eCRF Table of Contents.

PAGE011	Toxin Spread Assessments
PAGE012	HDSS, GSP
WEEK02	Week 2 Visit
PAGE013	Subject Questions, Vital S...
PAGE014	Toxin Spread Assessments
PAGE015	HDSS, GSP
WEEK04	Week 4 Visit
PAGE016	Subject Questions, Vital S...
PAGE017	HDSS, GSP
WEEK08	Week 8 Visit
PAGE018	Subject Questions, Vital S...

Select the visit entry

2. Check the “Visit Not Done” box and click “Update Visit”

All pages of the visit will be marked as “intentionally blank” and the pages made ready for submission

Page	#	Status	Submission	Ver.	SDV	Description
PAGE016	1	NOT READY	-	-	*	Subject Questions, Vi
PAGE017	1	NOT READY	-	-	*	HDSS, GSP

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

TrialDriver E-CRF 2.9.0.2 - connected to study TD-101 as user david using server TD101ET@gcplink3.net

File Extras Help

Visit / Page V Description

- SCREEN
 - 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 V [1] Comments
 - PAGE11 V [2] Comments
- TREATMENT
 - 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
 - PAGE21 • End of Study
- UNSCHEDULED
 - [1] Unscheduled visit
 - PAGE91 • Information
 - PAGE92 • New or Changed Ad...

Legend:

- Invalid data
- Validated (Ready)
- Submitted
- Unverified
- Verified

REPEAT PAGE - Repeat the selected CRF page

REPEAT SECTION - Repeat the selected study section

OPTIONAL SECTION - Add an optional section to the study

CLOSE PDF SUBMIT

Loading reference image PAGE04

Subject: **06/007 PAGE04**

Save Page Close this CRF

TD-101 TrialDriver Reference Study Page 4

Investigator Number **06**

Patient Number **007**

Patient Initials **DDD**

Date **072610**

Birth Control Information

(Check ALL that apply)

If female of child-bearing potential, what methods of birth control are **currently** being used?

- ☐ Not applicable (male or post-menopausal for at least 2 years)
- ☒ IUD
- ☐ Diaphragm with spermicide
- ☐ Depo-Provera
- ☐ Mirena
- ☐ Oral contraceptive with condoms
- ☐ Condom with spermicide gel or foam
- ☐ Implantable, transdermal or injectable contraceptive
- ☐ Surgically sterile
- ☐ Monogamous relationship with sterile partner
- ☐ Abstinence
- ☐ Other, please specify below

Date of signed waiver (required) **072610**

Specify other:

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:

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 Query-ID (from the DCF).

QueryID

REVISE DATA

SDV Source Doc. Verification

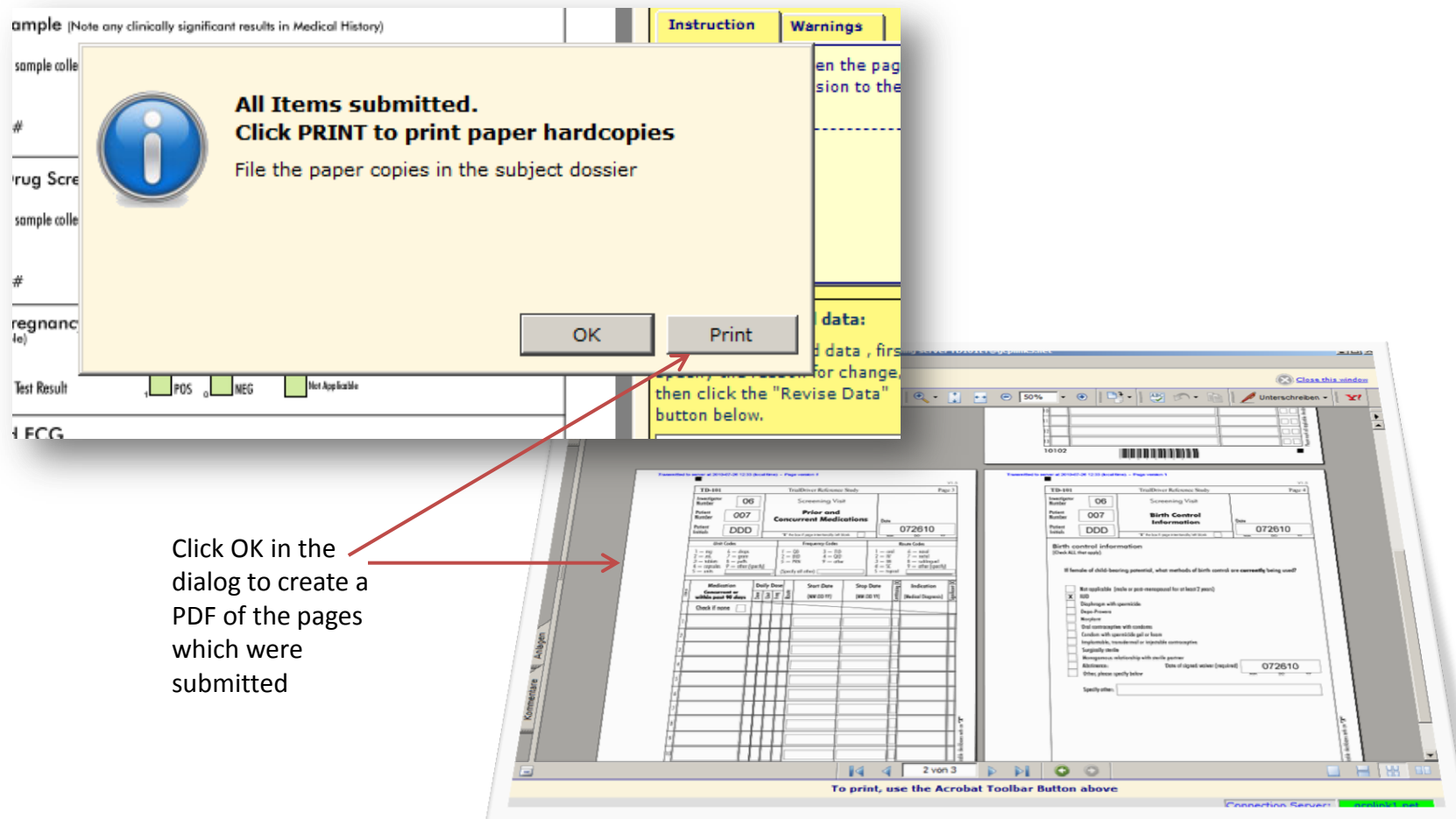
Connection Server: **gcplink3.net**

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)



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-men)

☒ 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

[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)

David Shepherd
99 - Princeton Esthetic Dermatology

View Study Website
Email Study Management

Refresh List

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

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	QUERIES 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								

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

99/002 SCREENING:PAGE001

TrialDriver Reference Study TD-102
Screening

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 1214

Demographics

Date of Birth: 20JAN1977

Race (Check one only): ☒ White ☐ African American ☐ Asian ☐ Native Hawaiian or Pacific Islander ☐ American Indian ☐ Alaskan Native ☒ Other (specify): BRITISH

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

DOUBLE-CLICK A LIST ENTRY TO NAVIGATE TO THE CRF ITEM

Query Page/Visit	Field	Status	Text
PAGE001:1 (SCREENING:1)	BRTHDTC	Issued to site	Please verify...
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

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

Creating Data Queries (For study monitors and CRAs)

When a CRA is monitoring the eCRF, either on-site or remotely, he/she can create online data queries. This is a two-step process: You first “create” the query and then you “issue” it to the site.

To **create** the query, the sequence of operations is:

- Open the Queries window by clicking the “View Queries” button beneath the CRF image.
- Navigate to the page where the query is to appear and click in the relevant data field (it turns yellow)
- Click the “Create Data Query” button – an editing window opens...

Enter the text of your query in the edit box and click OK.

You will have opportunity to change this text before you “issue” the query. Click “OK” to save the query

To **issue** the query, the sequence of operations is:

- Select the query from the list of “pending” queries.
- Click the “Issue Query to Site” button

You can edit the query text before issuing it. Click the red “Update Text” to save your edits

Click the “Issue Query to Site” button so that the site can see your query

You can also cancel the query before issuing it

Resolving Data Queries (For study monitors and CRAs)

After a site has responded to a CRA query, it is flagged with “Site Responded” in the queries list. The CRA will now review the site response and either (1) Mark the query as resolved or (2) re-issue the query with an updated query text.

To **resolve** the query, the sequence of operations is:

- Open the Queries window by clicking the “View Queries” button beneath the CRF image.
- Locate any returned queries in the queries list. The list can be filtered to show only returned queries.
- Double click the query to navigate to the relevant CRF page. Click the “Mark Query Resolved” button.

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

CREATE DATA QUERY The currently selected CRF item is: **PAGE017:1 (VISIT4:1) => LSRIRS01:1**

DOUBLE-CLICK A LIST ENTRY TO NAVIGATE TO THE CRF ITEM

Query Page/Visit	Field	Status	Text
PAGE017:1 (VISIT4:1)	LSRIRS01:1	Site Responded	asdf

QUERY TEXT FROM CRA (ACLMON) **UPDATE TEXT**

asdf

QUERY RESPONSE FROM SITE (ACLUSER)

N/A

DISPLAY ITEMS: ☒ **PENDING (0)** ☒ **ISSUED (0)** ☒ **RETURNED (1)** ☐ **RESOLVED (0)** **ALL**

REISSUE THIS QUERY **MARK QUERY RESOLVED**

☐ CHECK THIS BOX IF CRF DATA WAS UPDATED

To **re-issue** a query, click this button.

You can change the text of the query before it is re-issued.

Click this button to **resolve** the query and remove from the queries list.

You can filter the queries list to display resolved queries also. By default they are hidden

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

TrialDriver E-CRF 2.9.0.2 - connected to study TD-101 as user monitor using server TD101ET@gcplink3.net (MONITORING)

File Extras Help

Visit / Page V Description

- SCREEN
 - PAGE01 Patient Information
 - PAGE02 [1] Medical History an...
 - PAGE03 [1] Prior and Concurr...
 - PAGE04 Birth Control Informati...
 - PAGE05 Erythema Assessment
 - PAGE06 Lesion Count
 - PAGE07 Exclusion Criteria
 - PAGE08 Exclusion Criteria (co...
 - PAGE09 Exclusion Criteria (co...
 - PAGE10 Labs and Pregnancy T...
 - PAGE11 [1] Comments
 - PAGE12 [2] Comments
- TREATMENT
 - PAGE12 Patient information
 - PAGE13 New or Changed Adve...
 - PAGE14 New or changed Conc...
 - PAGE15 Lesion Count
 - PAGE16 Erythema Assessment
 - PAGE17 Chromameter Measur...
 - PAGE18 Chromameter Measur...
 - PAGE19 Chromameter Measur...
 - PAGE20 [1] Comments
 - PAGE21 End of Study
 - PAGE22 End of Study
- UNSCHEDULED
 - PAGE21 [1] Unscheduled visit
 - PAGE22 Information
 - PAGE23 New or Changed Adve...
 - PAGE24 New or changed Conc...
 - PAGE25 Information

Legend:

- Invalid data
- Validated (Ready)
- Submitted
- Unverified
- Verified

REPEAT PAGE - Repeat the selected CRF page

REPEAT SECTION - Repeat the selected study section

OPTIONAL SECTION - Add an optional section to the CRF

CLOSE PDF SUBMIT

CRF data updated

Subject: 06/007 PAGE02

Save Page Close this CRF

Investigator Number 06

Patient Number 007

Patient Initials DDD

Screening Visit

Medical History & Concurrent Conditions

Date 072610

Does the patient have any relevant history in the following systems? For each system, place an "X" to indicate YES or NO. When YES is selected, enter the system CODE number below, followed by a description of the diagnosis or procedure.

CODE	YES	NO	CODE	YES	NO	CODE	YES	NO
01 - Skin	X		07 - Hepatic	X		13 - Endocrine/Lymphatic	X	
02 - Central Nervous System	X		08 - Cardiovascular	X		14 - Alcohol/Drug abuse	X	
03 - Ophthalmologic	X		09 - Renal	X		15 - Tetrazolines allergy	X	
04 - Eyes, Nose and Throat	X		10 - Genitourinary	X		16 - Other drug allergy	X	
05 - Respiratory	X		11 - Musculoskeletal	X		17 - Systemic infection	X	
06 - Gastrointestinal	X		12 - Hematologic	X		18 - Other (specify below)	X	

Code No. Diagnosis and/or Procedure Onset Date (MM DD YY)

01	ROSACEA	---
02	DEPRESSION	UNK
04	SORE THROAT	030409

SDV by MONITOR on 2010-07-30 08:58

Investigator Number 06

Patient Number 007

Patient Initials DDD

Screening Visit

Medical History & Concurrent Conditions

Date 072610

Does the patient have any relevant history in the following systems? For each system, place an "X" to indicate YES or NO. When YES is selected, enter the system CODE number below, followed by a description of the diagnosis or procedure.

CODE	YES	NO	CODE	YES	NO	CODE	YES	NO
01 - Skin	X		07 - Hepatic	X		13 - Endocrine/Lymphatic	X	
02 - Central Nervous System	X		08 - Cardiovascular	X		14 - Alcohol/Drug abuse	X	
03 - Ophthalmologic	X		09 - Renal	X		15 - Tetrazolines allergy	X	
04 - Eyes, Nose and Throat	X		10 - Genitourinary	X		16 - Other drug allergy	X	
05 - Respiratory	X		11 - Musculoskeletal	X		17 - Systemic infection	X	

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

A green bar above the page indicates SDV completed

Partial Source Document Verification (For study monitors and CRAs)

Normally SDV is performed page-by-page. Once a monitor has placed an SDV mark on a page, all data fields are locked.

Occasionally individual fields need to be updated on a page which has previously been SDV'd. The monitor must update the SDV status of the page to allow this. If the SDV mark is completely revoked, then all fields of a page can potentially be updated.

Alternatively, individual fields on a page can be “opened” for editing while leaving all other fields locked, so that the monitor only need re-SDV the intended fields and not be concerned that other data may have changed.

SDV by ACLMON on 2015-12-22 12:49 (PARTIAL - 4 fields open for editing)

Eligibility

Is the subject eligible for randomization to study medication? ☐ NO ☒ YES (If NO, explain on Comments page)

Subject Kit number: EDC: This value will be automatically entered

✓ NOTE: Discharge ineligible subjects per protocol instructions.

Study Medication Treatment

Did all Target Lesions receive a treatment? ☒ NO ☐ YES (If NO, discontinue subject per protocol)

Treatment Completion Time HH MM

Was the subject monitored for at least 20 minutes after the Treatment Completion Time? ☒ NO ☐ YES (If NO, explain on Comments page)

✓ NOTE: Record any Adverse Events on logging page 901

SDV Source Doc. Verification

SITE MONITORS ONLY
Please review the source documents for this subject. Place a checkmark in the box below when all entries for this page have been verified

☒ SDV Completed

Verified By:

ACLMON
2015-12-22 12:49
4 fields open for editing

Note: Once a page has been marked as verified, no further changes can be made to that page. If the page data needs to be modified, first remove the SDV checkmark, then have the investigator make the necessary changes and finally re-verify the page

Partial SDV
Ctrl-Click in a field to unlock it for editing. To lock all fields, click the button below.

Monitor Page Notes

Footer: CREATE DATA QUERY | **There is 1 query which requires attention** | VIEW QUERIES | VIEW SRC DOCS | SCAN DOCUMENTS | CRF SIGN-OFF | Connection Server: **acclaris.trialdriver.in** | Use HTTP | 14m

To unlock a field for editing, CTRL-click in the field with the mouse.

An Icon is displayed next to the field.



CTRL-click again to lock the field and remove the icon

A message indicates how many data fields are open for editing

To re-lock all fields, click the “Lock all Fields” 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 – only Pis and Sub-Investigators
- PIs can sign and unsign an eCRF – Study Coordinators can also unsign, but not sign.
- When the eCRF is 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 which require confirmation – or just 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.

TrialDriver Reference Study

Screening

Page 1

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

EDC: Page is ready for submission

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 (Check one only): ☐ White ☐ African American ☐ Asian ☐ Native Hawaiian or Pacific Islander ☐ American Indian ☐ Alaska Native ☒ Other (Specify): BRITISH

CRF Sign-Off

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

Sign-Off and Lock CRF

Visit/Page	Item Status
SCREENING	Empty pages require confirmation before sign-off
CYCLE [1]	Empty pages require confirmation before sign-off
CYCLE [2]	Empty pages require confirmation before sign-off
CYCLE [3]	All pages ready for sign-off - CRF section will be m...
FINAL	Empty pages require confirmation before sign-off
ENDSTUDY	Empty pages require confirmation before sign-off

Legend: ☒ OK for Sign-Off ☐ Confirmation required ☐ Cannot Sign-Off

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 (bottom-left of screen). This will bring up a dialog which allows you to determine which pages should be printed

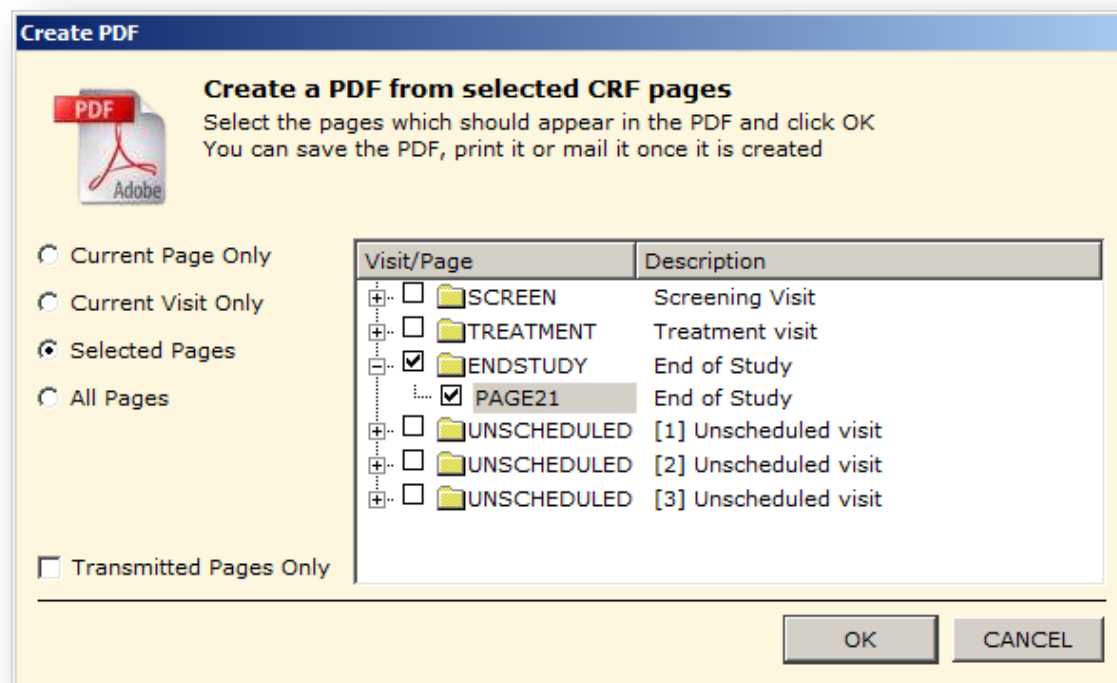


Your options are to create a PDF containing:

- 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



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	RFC	06/007	PAGE11#1	RFC=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 09:10
2010-03-11T10:52:01	MONITOR	VERIFY	06/007	PAGE11#2	MONITOR@2010-03-11 09:12
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	RFC	06/007	PAGE20#1	RFC=sdfas
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	PAGE15#1	PAGE VERSION = 1
2010-04-09T20:54:59	DAVID	SUBMIT	06/007	PAGE16#1	PAGE VERSION = 2
2010-04-09T20:54:59	DAVID	RFC	06/007	PAGE16#1	RFC=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

Technical Information

EDC Client

The TrialDriver EDC client is a native Windows application which is installed on the user's laptop or PC. (It does not run in a web browser). It can be installed on multiple machines. (On a Mac it can run under a Windows emulator such as Parallels)

The EDC client is available in an installer program which can be downloaded from one of our websites. (Link will be communicated separately).

By launching this installer program locally, the actual EDC client will be installed and configured. This installation will require administrative rights on the local computer. To launch the EDC client a desktop icon will also be installed.

Server Configuration

The TrialDriver EDC client connects to an Oracle/MySQL database server. The DBMS infrastructure runs in the Amazon Cloud (US east coast region). The server has an explicit TCP endpoint-url in the Amazon Cloud which replaces a fixed IP address (which the server does not have). Additionally a DNS alias is available which points to this endpoint via a CNAME record. These URLs are sponsor-specific and are communicated to you separately.

Firewall Configuration

Any Firewall at your site will need to allow outgoing connections to the TCP endpoint-url on port **3306** (MySQL standard port)

Encryption

Data are encrypted (AES-256) both on the wire (in-motion) and in the study database (at-rest). They are only ever decrypted in the EDC client program and other back-end data management tools.