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DIM-95005-001

PROMETCO

TrialMax Slate® and TrialManager® Site User Guide

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IMPORTANT POINTS

- Keep devices charged at all times. If a device gets shut down because of a drained battery, it might have an incorrect date and time once turned back on again.
- Setup site personnel by using the Personnel Manager PIN
- Set up subject when they are on site
- Activate a visit on the visit date when the subject is present and is going to complete the questionnaires
- Confirm to the subject that no site user can view any subject entered answers
- Once a subject has completed their questionnaires check if there is a tick for the visit and Send data
- View reports in TrialManager to monitor the study progress and subject compliance
- Create DCFs to change subject information
- If you cannot find help in this guide, then please call the Helpdesk

Device	Role	PIN Code
TrialMax Slate	Subject Training	1233
	Site Training	1245
	Site personnel	8899
	Personnel Management	2356
	Default subject	1234

TrialManager Website URL

https://trialmax.crfhealth.net/manager-6.0.0/A-1525-0006/login.faces

TrialManager login details will be sent to you via email

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Helpdesk

You may call the Helpdesk for any issue related to the TrialMax Slate and TrialManager website.

Please have the following information ready when you call:

- Protocol number (DIM-95005-001/PROMETCO)
- CRF project code (A-1525-0006)
- Your site number
- The subject number (if applicable)
- The specific problem

Helpdesk Operating Hours

The helpdesk is available 24 hours a day, 365 days a year.

If you are unable to reach an agent when you call, you can also leave a voicemail or send an email giving your contact information. The Helpdesk will contact you as soon as possible, at the latest by the next business day.

Helpdesk Telephone Numbers

Country	Number	Comment
Argentina	0800 444 1079	
Austria	0800 100 440	
Belgium	0800 58 022	
Croatia	0800 223 027	
Czech Republic	800 142 238	
	800 312 424	**Interpreter Queue**
Denmark	80 404 998	
France	0800 509 207	

Country	Number	Comment
Germany	0800 400 0230	
Hungary	06 800 153 84	
Ireland	1800 818 007	
Italy	800 90 5646	
Netherlands	0800 099 4403	
Portugal	800 2066 42	
Slovenia	0800 80 839	
Spain	900 210 163	
Sweden	020 120 9951	
	020 120 3209	**Interpreter Queue**
Switzerland	0800 142 580	
UK	0800 015 9215	

<u>Note</u>: All the Helpdesk numbers listed above are Toll Free numbers and are free from a landline; however local operator charges might be applied if calling from a mobile phone.

Helpdesk Email Address

For non-urgent issues, you can contact the Helpdesk by email

PROMETCO@support.signanthealth.comNote: do not share this email address with a subject. Subject's identity might be unintentionally revealed during communication via email.

Equipment

Site based TrialMax Slate Devices

- TrialMax Slate (tablet) with an incorporated SD memory card (this backs up the data for recovery if needed)
- A power cord

Additional Site Supplies

- This Manual
- Multi charger/Power strip

For this TrialSlate study, all subjects will be set up on the same device.

TrialMax Slate Basics

How to turn on the TrialMax Slate

Turn the TrialMax Slate on by pressing and holding the power button on the upper left side of the device until you see a white power button light.

Note: The inactivity period for the Trialslate is 10 minutes. If a subject is completing a questionnaire and then stops, with no activity for 10mins, the questionnaires will be incomplete, and the subject will need to login again to complete the questionnaires.
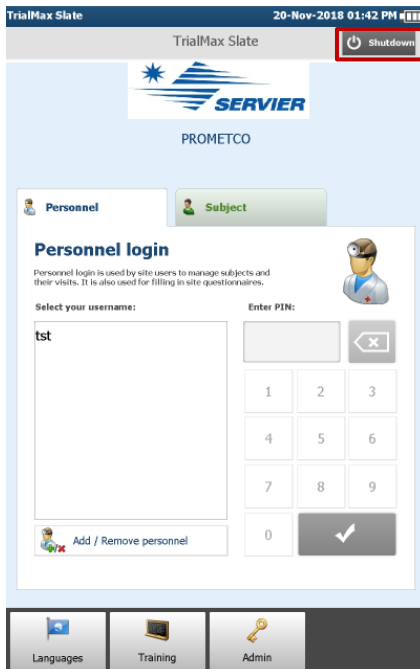
To turn off the TrialMax Slate, tap on the 'Shutdown' button on the upper right-hand corner of the screen. If you do not manually turn off the device, it will hibernate after 10mins of inactivity.

To activate the screen, tap on the screen or hold on to the button until screen switches on.

How to charge the TrialMax Slate

The TrialMax Slate should be charged for 4 hours before it is used. The port for the charging cable is located on the side of the device. The picture below indicates the location of where the charging cable should be connected to the device.

To determine when the device charge is low or full please turn on the device and check by looking at the battery indicator.

Important:

If the battery runs out on the TrialMax Slate, all answers that have <u>not been saved</u> (e.g. part way through completion) will be lost. If answers have been saved but not sent, they will remain on the TrialMax Slate.

Please charge the TrialMax Slate regularly to ensure that the battery remains charged.

Slate Navigation

Use your finger to navigate through the Slate.

Please do not use a stylus or sharp points as these will not function on the Slate and will damage the screen.
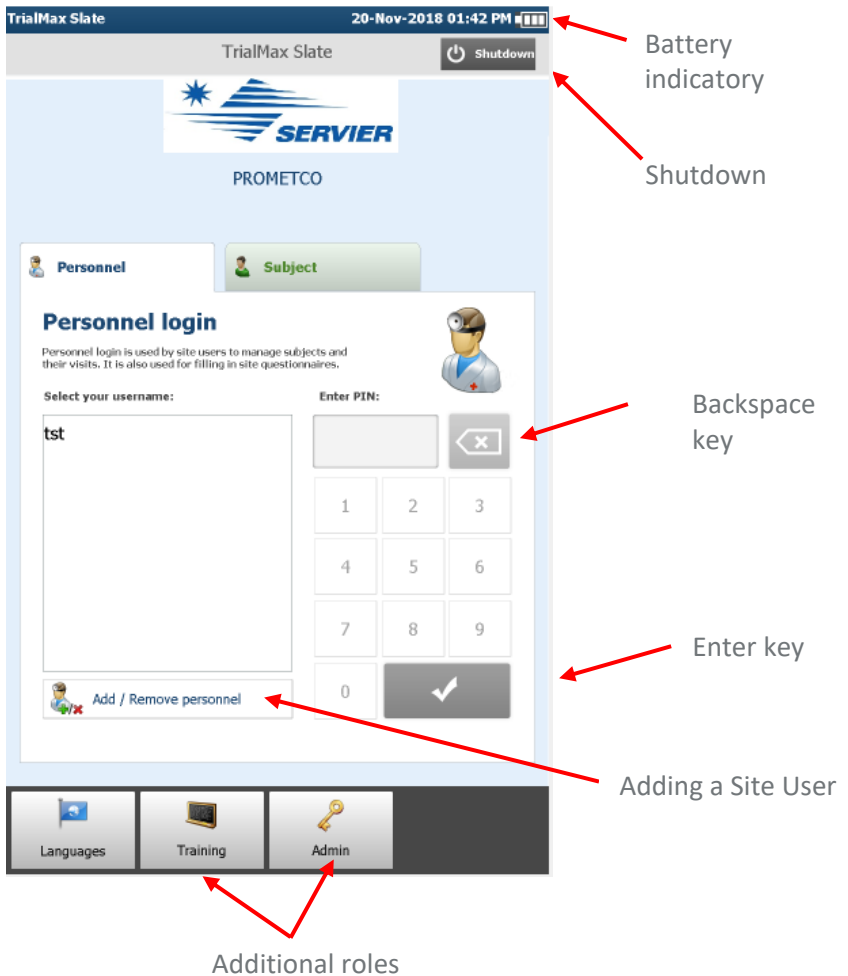
How to Log In

The Slate is set up with role assignments. Each role has unique functionality.

The site Personnel Manager must first be used to set up site user accounts on the device. Site user roles can be set up as Investigators or Study Coordinators on the device

The two main role types for the Slate are Site Personnel and Subjects. Thus, they are accessed on one of two tabs.

The user will select their tab and enter the corresponding PIN code, to use the TrialMax Slate.

Battery indicatory

Shutdown

Backspace key

Enter key

Adding a Site User

Additional roles

Slate Roles and PIN Codes

Role	PIN	Description
Personnel Manager	2356	Because some site personnel will be entering clinical data, each user is required to be set up on the device and create a unique PIN. This PIN code is used to set up and remove site personnel.
Investigator	Default 8899	All investigators at your site will use this same default PIN code in the initial login. Once the site user has updated their PIN they can set up subjects on the device, activate questionnaires and deactivate subjects. Refer to Section on Subject Setup for detailed instructions on creating a new subject.
Study Coordinator	Default 3865	All study coordinators will need to use this default PIN code in the initial login. Once the site user has updated their PIN they can set up subjects on the device, activate questionnaires and deactivate subjects. Refer to Section on Subject Setup for detailed instructions on creating a new subject.
Site Training	1245	This allows site personnel to practice setting up a subject, activating visits, and monitoring completion of questionnaires.
Train your Subjects	1233	This allows the Training Module to be opened during any site visit, for the site personnel to retrain the

Role	PIN	Description
		subject on the type of questions they will be asked to complete and how to provide a response. This can be accessed at any time during the study if the subject would like to be retrained on the TrialMax Slate.
Subject	Default 1234	The TrialMax Touch automatically creates the default PIN code when you set up a new subject (1234). A subject cannot access the Slate unless the site has set up the subject. The TrialMax Slate is then handed to the subject and they must choose a private PIN code to use throughout the study.

If the subject is having difficulty selecting a PIN code, suggest using the following:

- The first or last 4 digits of a telephone number
- The birth date of a friend or relative

A subject should not share their PIN code with anyone, not even with study staff. The new PIN code must remain confidential, with only the subject knowing the PIN code.

Likewise, the subject should never be given the site or training PINs.

If a subject forgets their PIN code, the site will need to contact the Helpdesk. The site should call the Helpdesk, request an interpreter (if required), and hand over the phone to the subject. The Helpdesk agents will then be able to reset the subject's PIN code by asking the subject the security question they had selected during the initial setup. Similarly, if a site user has forgotten their pin number they should contact the Helpdesk too.
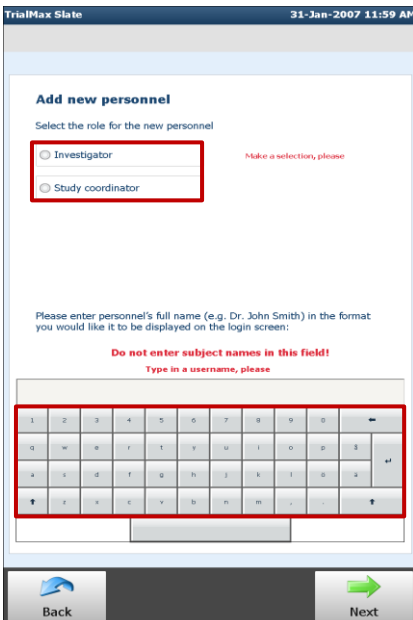
How to Set Up Site Users

Select the Personnel tab and tap the 'Add/Remove personnel' button.
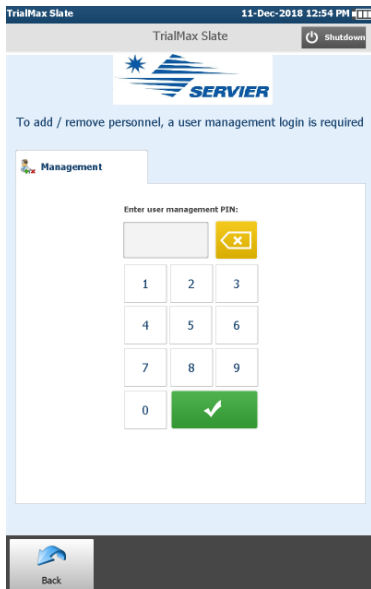
Enter the PIN code and upon initial login, site personnel will be asked to confirm the site number. If the site number is incorrect, please contact helpdesk.
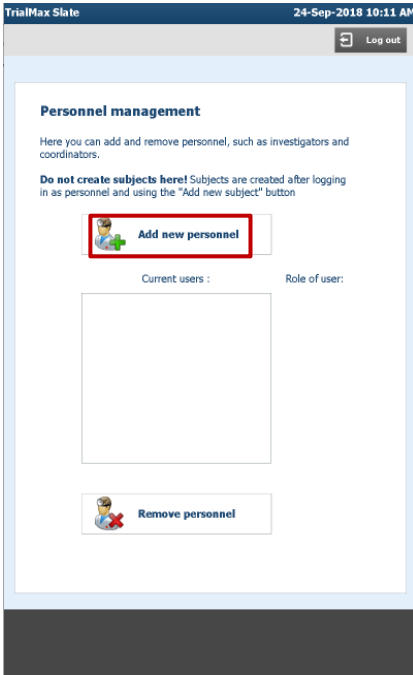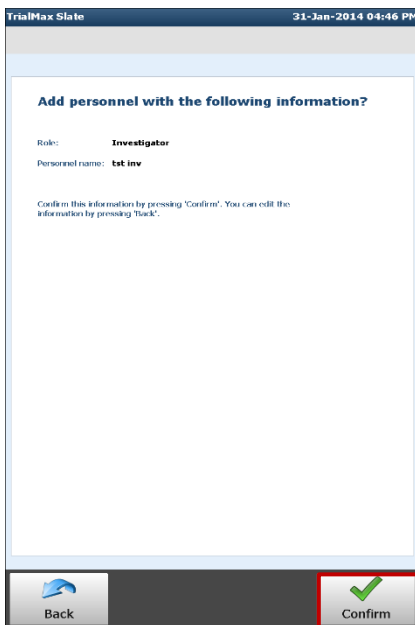
Select 'Add new personnel' to create a site user.

Enter the site user's screen name by entering a title and/or given name and surname (family name). Examples: Dr Nguyen, or Marie Salk. Note there is a 18-character limit for the user name.

Please note: the subject's name should NOT be entered here. Subjects' names should never be entered into the TrialMax Slate.

Once the site user's screen name has been entered, please select their role in the study. Please take care in selecting the correct role for the site user. All Investigators in the study must be assigned the "Investigator" role and all Study Coordinators will be assigned the "Study coordinator" role.

Then press 'Next.'

Note: The TrialMax Slate has a standard (QWERTY) keyboard. Please take care when entering the surname (family name).

Review the site user details that have been entered. If the details are correct, select 'Confirm' to proceed and finish the site user setup. If there is an item that is not correct, select the 'Back' button until the screen with the incorrect information has been reached and correct it. Once all details are confirmed as correct, select 'Confirm'.

User tst inv created successfully

Please find the site personnel's default PIN code below. Give this code to the site personnel for initial log in.

At first login the user will be instructed to change this PIN code.

PIN code: **4455**
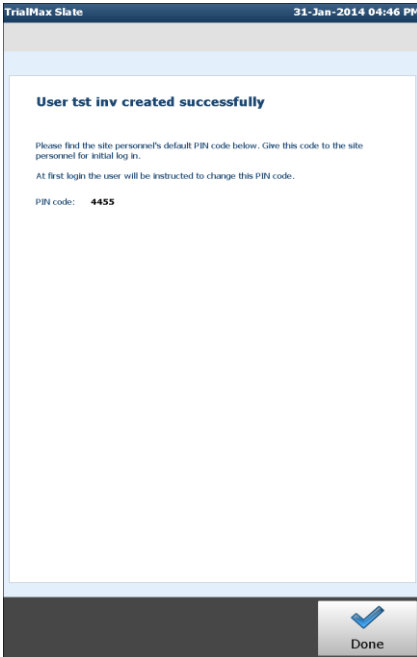
After tapping 'Confirm' a screen will display indicating the Site user was created successfully.

Note that the default PIN code for this new user displays on this page. The user will need this PIN code to log in for the first time

How to Remove Site Users
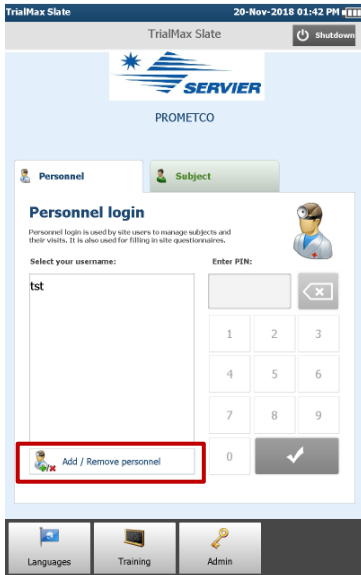
Select the Personnel tab and tap the 'Add/Remove personnel' button. Enter the PIN code.
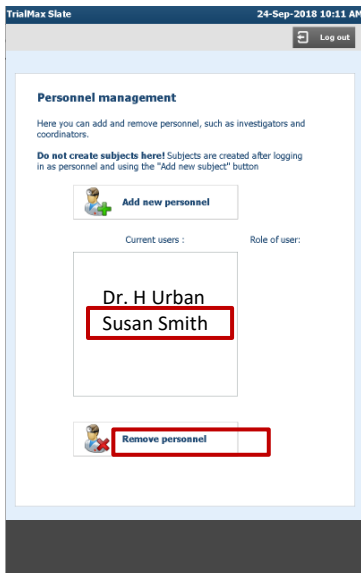
To remove a user, select their name from the list and click 'Remove personnel'.

This should be done for any site user that is no longer working on the study at the study site.

Setting up TrialMax Slate

Setup New Subject

A few days before the subject comes in for the first visit, log into the TrialMax Slate and check that it is working correctly.

Refer to Section How to set up a Replacement TrialMax Slate for detailed instructions on when and how to create a 'Replacement Setup.'
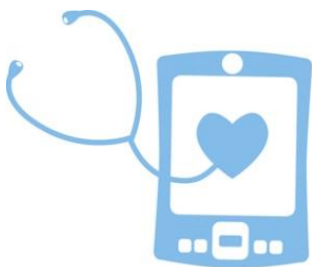
The TrialMax Slate must be set up for each new subject before being used for that subject.

Note: Please wait to go through the subject setup process until the subject is at the site. This will ensure the correct subject information is entered.

Prior to setting up the first subject, please go through the subject setup training, using the Site Personnel training PIN: 1233.

The following screens show the subject setup process in the TrialMax Slate:

Log into the TrialMax Slate by selecting the appropriate site username from the list of users and enter the unique PIN code. A menu as displayed to the left will appear.

Select 'Add new subject'.
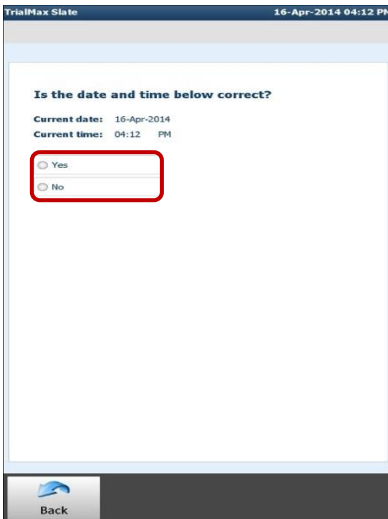
Confirm that the displayed date and time are correct. Select 'Yes' and then 'Next.'

If today's date and/or time is not correct, select 'No', press 'Next', and then follow the instructions provided on the screens to correct the date and/or time. The Helpdesk can also be contacted for assistance. This displayed time will be the local time at the site and will account for daylight savings, if applicable.

Setup subject for site 111

Is this a new subject or is this a replacement device for a subject that has been set up before?

○ New subject

○ Replacement device

Please enter the subject number by tapping on the arrow buttons:

▲ ▲ ▲ ▲
- - - -
▼ ▼ ▼ ▼

Please enter the subject's year of birth:

▲ ▲ ▲ ▲
1 9 8 0
▼ ▼ ▼ ▼

Back | Next

When creating a new subject, select the 'New subject' button.

Use the number spinner to enter the digits that comprise the subject's number. Please ensure the correct subject number is entered prior to selecting the "Next" button.

Answer the remaining prompts.

Add a subject with the following information?

Subject number: **1001**
Language: **English**
Birth year: **1980**
Subject type: **New subject**

Confirm this information by pressing 'Confirm'. You can edit the information by pressing 'Back'.

Back | Confirm

Review the subject details that were entered. If the details are correct, select 'Confirm' to proceed and finish the subject setup. If there is a particular item that is not correct, select the 'Back' button until the screen with the incorrect information is reached and correct it. Once all details are entered correctly, select 'Confirm.'

Answer the remaining prompts.

The subject default PIN code (**1234**) is shown in the above screen.

Once a subject has been set up in the TrialMax Slate, please remember to activate the visit to make the questionnaires available (refer to the Section Activate questionnaires at site visits in this manual).

How to set up a Replacement TrialMax Slate

If the TrialMax Slate is lost or broken, all existing subjects must be set up in the new TrialMax Slate as "Replacement device". The steps are similar to those for setting a new subject; however, there are additional screens.

Note: Please ensure subject is on site before setting them up on the device. It is vital the subject information is correct, and subject has agreed to participate before setting the subject on the device.

An auto-merge code should be used to link the subject's previous information to the new device. The Auto-merge code can be found in TrialManager (refer to section 'Subject Card' in this manual).

The following screens show the replacement process for subject setup in the TrialMax Slate. This process will need to be repeated for each replacement subject that needs to be set up in the TrialMax Slate.
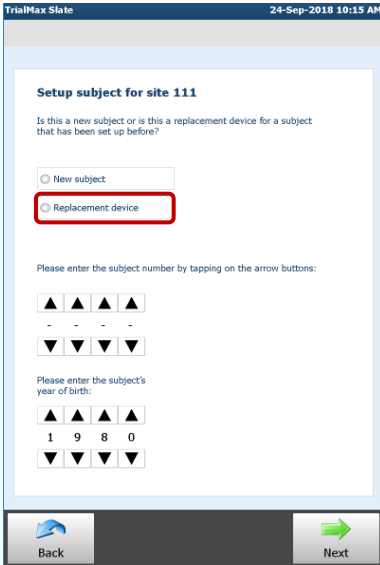
Once the date and time have been confirmed, select the 'Replacement device' button and use the number spinner to enter the digits that comprise the subject's number and Year of Birth.

Then press 'Next'.
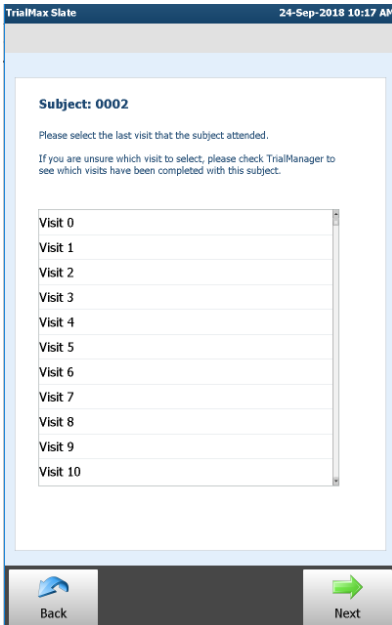
Select the subjects most recently **completed visit**

Note:
If a replacement device is necessary, data entered on the previous device will not be available on the new TrialMax Slate but can be viewed in TrialManager.

TrialMax Slate   22-Sep-2014 02:23 PM

Replacement device information

Do you have access to the automerge code for this subject? It can be found in TrialManager on the subject information screen for this subject.

- ● Yes
- ○ No

Please enter the 10-digit automerge code for this subject.

```
      [          ]  [⌫]

        1    2    3

        4    5    6

        7    8    9

             0
```

Back   Next

To link the subject's records, you will need to enter an 'auto-merge code' as found on the subject details page in TrialManager - **'Subject Card'**. If you do not have the auto-merge code, you will need to log a DCF to get the subjects records merged.

TrialMax Slate   24-Sep-2018 10:19 AM

Add a subject with the following information?

Subject number: **0002**
Language: **English**
Birth year: **1990**
Subject type: **Replacement device (Auto merge code not available)**
Last active visit: **Visit 5**

Confirm this information by pressing 'Confirm'. You can edit the information by pressing 'Back'.
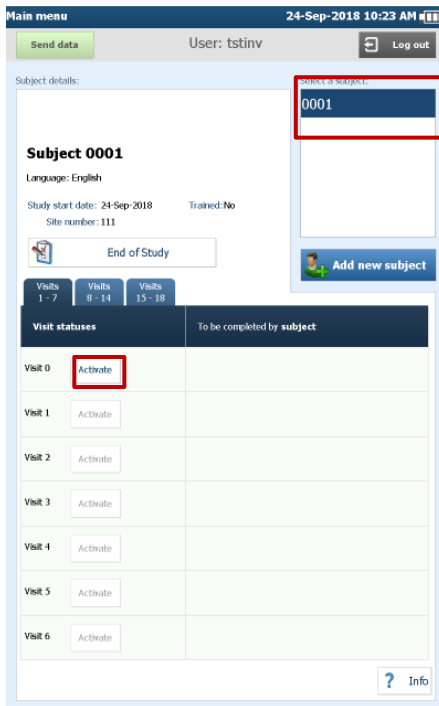
Back   Confirm

Confirm the details that you have entered during the replacement subject setup. If the information is correct, select 'Confirm' to continue.

If any information needs to be modified, select 'Back' and navigate to the proper screen.

Activate questionnaires at site visits

Once a subject's details have been confirmed during the subject set-up, and the subject has come in for their Visit 0, the site should activate Visit 0. For all subsequent visits, manual activation of the subject questionnaires is required on the Visit day in order for a subject to complete them.

After logging in with the Site User PIN code, select the target subject. Review the list of visits and activate the current visit by tapping the 'Activate' button. The available forms for that visit will then display.

Note: Once all questionnaires have been completed for a visit, the site will not be able to re-active the completed visit

Reactivating a Visit:

Reactivating a visit should only be done when a visit was activated by mistake by the site user, or if the subject has failed to attend a scheduled visit and the visit was rescheduled. When the subject comes in to complete their rescheduled visit, reactivate the visit to allow for the questionnaires to be completed.

You will need to select a reason for reactivation or activation of more than one visit on the same day.

IMPORTANT: Please ensure that the visit is only activated while the subject is at the clinic**.**

After the visit is activated, the subject questionnaires can be completed by tapping the 'Available' button in the column with the title 'To be completed by **subject**'. The following pop-up will display when the 'Available' button is pushed.

Subject Questionnaire

The subject questionnaires must be completed by the subject, who is required to log in with his or her own credentials. Do you wish to switch users to do this now?

Yes **No**

Press 'Yes' to logout of the TrialMax Slate if the subject is ready to enter the questionnaires. Otherwise, tap 'No' to go back to the Visit Management screen.

Remind subjects that their answers cannot be reviewed by site staff in any way as site users are blinded from seeing subject answers. Remind the subject to answer the questions as accurately as possible.

Once a subject has completed their questionnaires and clicked the 'Save' button the subject can no longer review or modify their answers. Remind the subject the importance of reviewing prior to 'saving' their answers.

Questionnaire Completion Verification

Once the subject has completed their questionnaires they will hand the device back to the site personnel.

Before the subject leaves your site, a site user must log back in, navigate to the visit selection screen as detailed in this section, and verify that all Subject questionnaires for that visit have been completed by the subject (completed questionnaires will be displayed with the green check mark illustrated below). If the subject failed to complete a required questionnaire for a visit, the site user must log out and hand the TrialMax Slate device back to the subject for them to complete it. Continue this verification process until all 3 required questionnaires have been completed by the subject for that visit.

If further information is needed regarding the icons on the Visit Management screen, please select the 'Info' button on the screen.

Tap the 'Back' button to return to the Visit Management button.
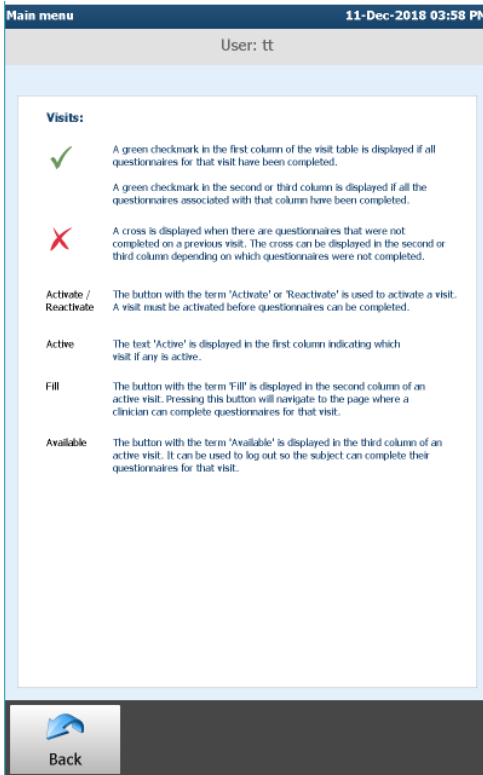
☑ This will be displayed if a questionnaire has been completed.

❌ This will be displayed when a questionnaire for a visit was not completed.

How to deactivate a subject
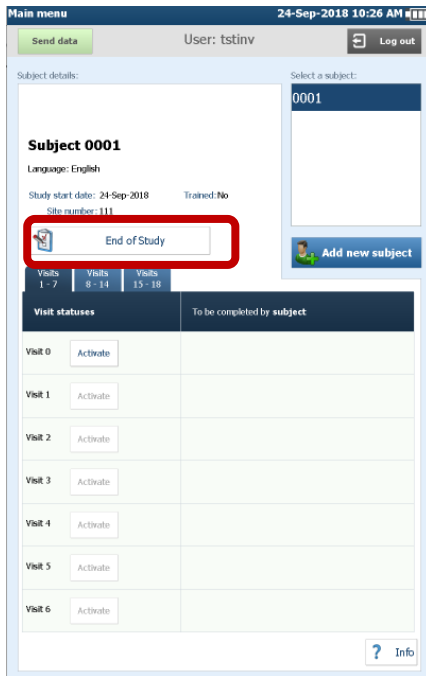
If the subject leaves the study for any reason, the deactivation process will need to be followed.

During the subject deactivation process, all unsent data in the TrialMax Slate should be sent to TrialManager, the data web portal.

How to send data from the TrialMax Slate

Site staff must ensure they are connected to the local WIFI. If your site requires a modem, please ensure the device is connected to the modem to assist with the data sending. Once the device is connected to the WIFI or modem, the TrialMax Slate is ready to send the answers to the study database (TrialManager). There is no cost to the site when the TrialMax Slate is used to send data. The site user should send data from the main menu, using the "Send data" button. Site users can send data at any time on the TrialMax Slate by logging in and selecting "Send data."

Remember to monitor TrialManager regularly to ensure all outstanding data has been sent.

How to send data via Wi-Fi

In order to send data using Wi-Fi, you need to connect to your local Wi-Fi.
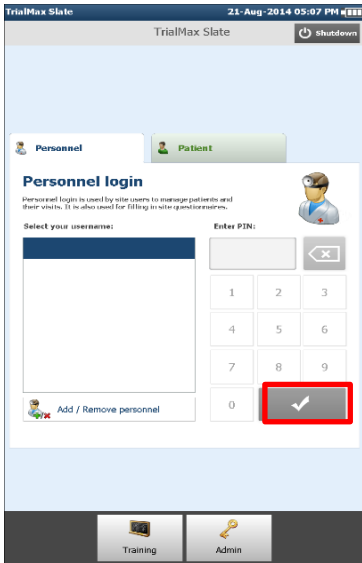
At the PIN code screen, enter the network settings codes:

• type in 00 then select the green tick

• then type 3644
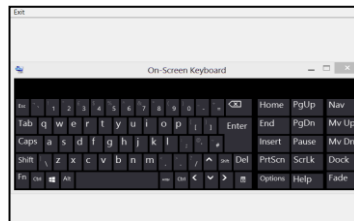
The keyboard will appear. Click, hold, and drag keyboard down the screen to see the menu options

Follow the instructions:
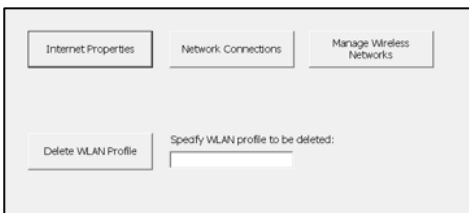
Select 'Network Connections'

If the status is "Disabled", double-click the "Wireless Network Connection" and a Pop up is shown with text, "Enabling…"
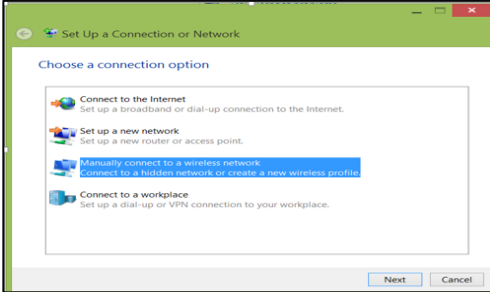
The Wireless Network Connections icon changes from, "Disabled" to "Not connected". Close this window and you will return to the start screen.

Select "Manage Wireless Networks".

Select "Set up a new connection or network".
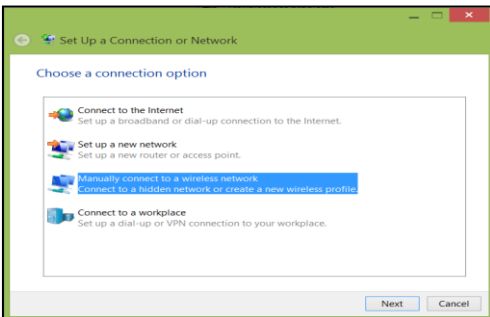
Select "Manually connect to a wireless network", then select next.

Fill in the Network name, Security type, Encryption type, Security Key and check the option "Start this connection automatically".
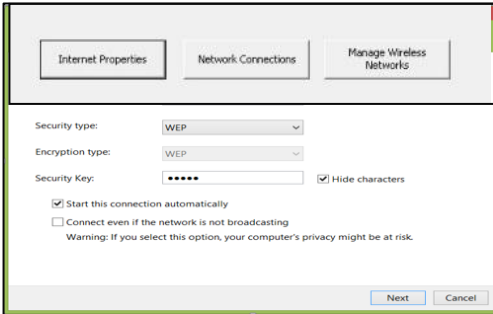
Note: The network name needs to be exact and is case-sensitive.

"Successfully added…" appears.
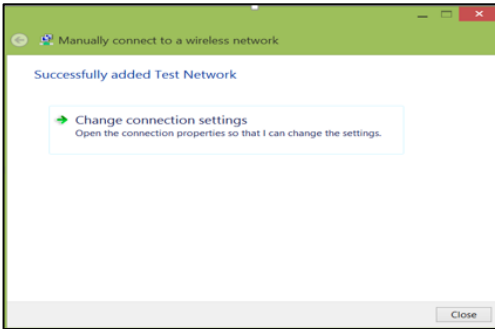
Select 'close'
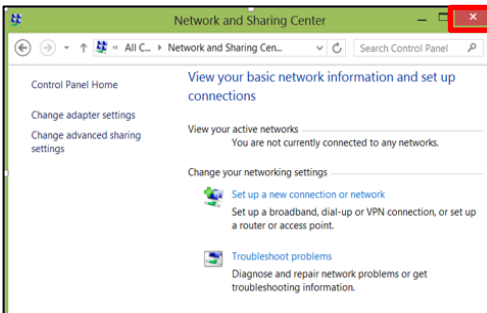
Select "X" to close out this window.
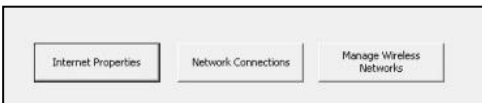
Now select "Network Connections"

Your wireless network should now appear marked with green tick.

To return to the PIN code screen, close this window

The WiFi connection is now set up.

How to send data wirelessly (ZTE MF971V)

If a site is having data sending issues using Wi-Fi, and Helpdesk have been contacted and cannot resolve the issue, a router can be requested. To request a ZTE MF971V router contact your appointed Monitor/CRA.
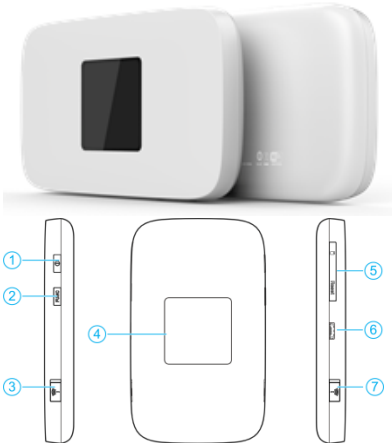
1. Power key
2. FUNC key
3. External antenna connector
4. LCD screen
5. micro-SIM card slot cover and reset hole
6. Charging/micro-USB jack
7. External antenna connector

Connecting to MIFI router Using Wi-Fi

1. Power on your router.
2. Ensure that your computer or other devices have enabled Wi-Fi, and search for available wireless networks.
3. Select the Wi-Fi name (SSID) of your router and click Connect.
4. Enter the Wi-Fi password if necessary and click OK.
5. Wait until the client device is connected to your router successfully.

Connecting to MIFI Router Using a USB Cable

1. Connect a computer to your router with a USB cable.

2. Power on your router. The operating system detects and identifies new hardware, and automatically installs the hardware.

3. Wait until the computer is connected to your router successfully.

Note: If the system does not automatically launch installation, you can Double-click the device installation icon in My Computer to install the software.

It is important to turn on the ZTE router first; then the TrialMax Slate, as this allows the device to pair to the ZTE.

Note: Please be sure to have the ZTE router is plugged into the power supply prior to sending data.

| Icon	Description
.ıll	Network signal strength
4G/3G/2G	Network type
R	The user is in roaming status.
⇅	Connected to the Internet.
✉	New message (s)
((ọ))	Wi-Fi status and the number of connected users
▭	Battery level

Data Sending Screens

Log in with the Site PIN code and select 'Send data.' Follow the directions on the screens that follow.
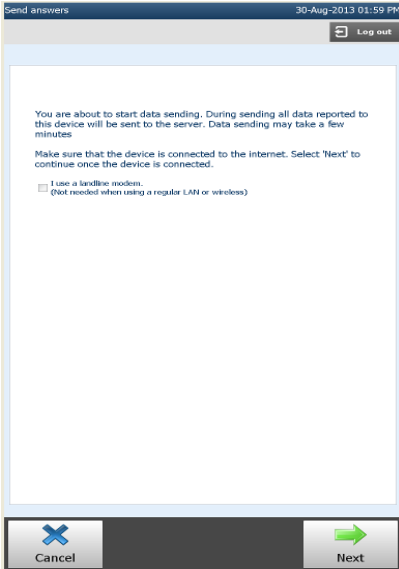
Once the site has selected to begin sending data, the site will have to indicate whether they will be using a landline connection or a wireless connection (either through WIFI setup or the ZTE MF971V router).

If landline is selected the site will need to confirm the prefix dial line in the screens below.
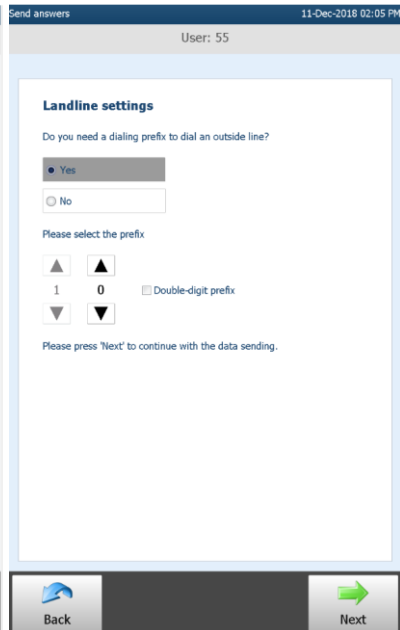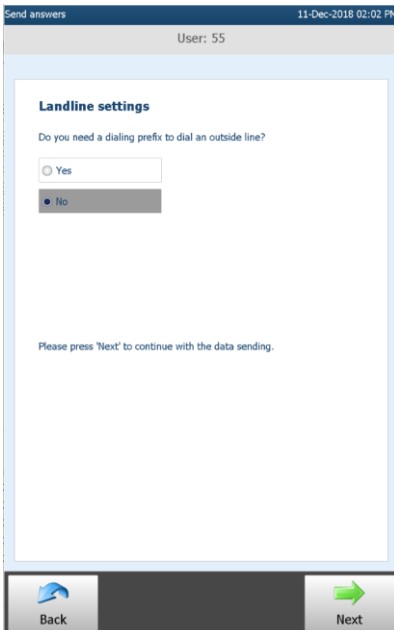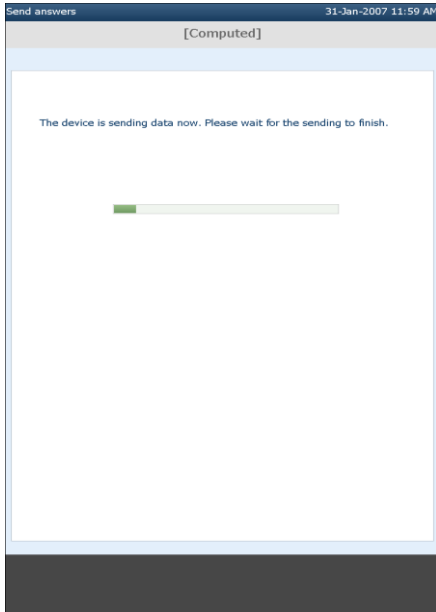
Once the data sending option has been selected, the following screen will appear notifying you to wait for sending to finish.
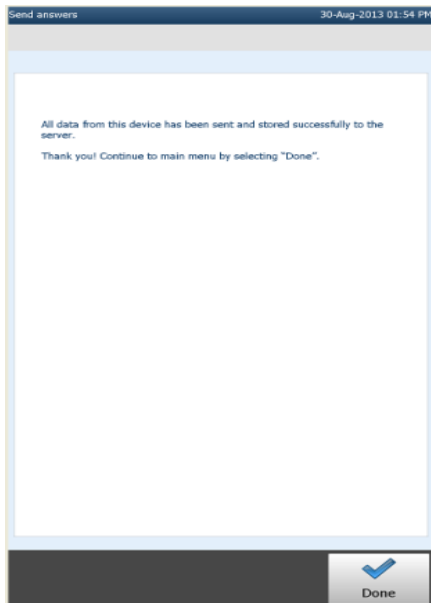
If data is sent successfully, a notice will display.

If data sending fails, please try again or contact the Helpdesk for assistance.

Software Online updates

An online update is an automatic software update that occurs after data is sent from the TrialSlate (Tablet) device. Once the online update is completed, each TrialSlate will contain an updated version of software. This update only needs to be applied once per TrialSlate.

It is imperative that you install the update prior to the next subject visit, as the device must have the latest version of software. If you do not install the update, it may impact your site's and/or subjects' accessibility to the full device functionality, and ability to comply with the study protocol requirements.

A memo will be provided by the CRF Health project team to inform sites of an upcoming online update.

How to install the online update

1. Log into your TrialMax Slate and send data.

2. When data sending has successfully completed, you should see a screen similar to the example below:
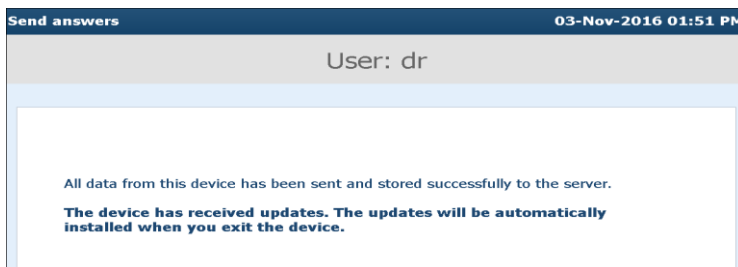
3. Select the '**Done**' button at the lower right-hand corner of the screen (not pictured here).

4. Log out of the TrialMax Slate and the software update(s) will automatically install. **Do not interfere with the device during installation.** Once installation is complete,

the device will automatically return to the main login screen.

5. Once the main login screen appears, repeat data sending a second time per step 1 above. This will allow CRF Health to remotely confirm if the update has been applied to your device.

6. There is no further action for you to take, and your device will be ready for next site/subject use.

If data sending is somehow interrupted (service connection lost, noted by an error message) or the TrialSlate is accidentally turned off during the update process, simply turn on the TrialSlate to restart it. You should then log in again and start the data sending process as described in the online update instructions above.

TrialManager

TrialManager is an online, internet-based application used by investigators, study coordinators, monitors and study personnel to view and monitor study progress. TrialManager enables the users to follow overall subject compliance and view the subject's diary data. TrialManager supports the following Internet browsers:

- Firefox 6 and up
- Internet Explorer 8 and up
- Chrome 13 and up

Accessing the TrialManager website

Your TrialManager username and initial password will be emailed to you. Each person will have separate access. You will be prompted to change this password at your first log in. Your new password needs to be a minimum of 8 characters and contain at least one capital letter and at least one number. Your TrialManager password has no relation to the Site personnel PIN codes on the TrialMax Touch.

Type the following address into your web browser.

https://trialmax.crfhealth.net/manager-6.0.0/A-1525-0006/login.faces

A login window will open.

How to request TrialManager access for new team members

In order to request TrialManager (TM) accounts for new team members, contact your appointed Monitor/CRA. Monitor/CRA should add their information into the Site Information List (SIL) and send the updated SIL to CRF Health team weekly.

Allow 3-5 business days to create new TM accounts/make updates.

Urgent TM requests can be requested via Helpdesk.

Functions of TrialManager

After answering the TrialMax Slate questions for the current day, the site will need to send their answers to the study database (TrialManager). Within minutes of sending data, you can view the data (and reports of the data) sent.

By using TrialManager, you can:

- Monitor subject compliance and other reports
- Monitor the number of days since the site has last sent data
- Raise DCFs (Data Clarification Forms)

Note: you should be logging in to TrialManager only with your own login details (which will be sent to your email) and do not share your password with your colleagues.

How to change your TrialManager password

The system will ask you to change your password the first time you log in to TrialManager to personalize it and make it secure. If you need to change the password later, select 'My settings' in the top right-hand corner of the screen. There you will find an option to change your password.

When you decide to change your password, you will be asked to type in your current password, your new password, and verify your new password by typing it in again. Click the 'Change' button to activate your new password.

Rules for creating new password:

- Must be at least 8 characters.
- Must contain at least one lower case character.
- Must contain at least one upper case character.
- Must contain at least one number.
- Must not contain Unicode characters.
- Special characters in password are not necessary.
- Must not contain spaces, line breaks or new lines.

How to navigate the TrialManager website

Investigators and Study Coordinators will see several tabs at the top of the screen. They are the 'Main Page', 'Reports', 'DCFs', and 'Study Information' tabs. These are selected by clicking on them.

Main Page Tab

When you select "Main page" the following screen appears:

1. Using this button, you are able to add new DCFs.

2. This section is called the DCF Notice Board and will display all DCFs for your site that require your action. Simply click on a particular DCF to see further details displayed. Note that all DCFs created by you or anyone else at the site will also need to be approved by a site user. CRF Health will be the ones to finally approve and implement the corrections requested in the DCFs.

3. The subject list section at the bottom of the screen will display all subjects at your site. You are able to sort by any of the column headings and can also filter by any of these by typing into the text boxes below the column headings. Clicking on a subject number will take you to more detailed information regarding that subject.

Subject Card

Upon clicking on a subject from the main page, the subject's information card will display:

Note: Site staff will not be able to review subject data information

This will show details for the subject, including: language, subject status, study start date, **and the subject's auto merge code, which is necessary for replacement subjects.**

How to review reports
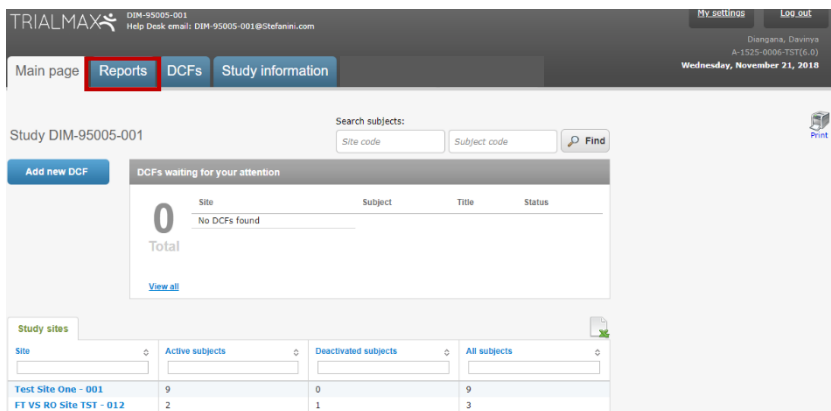
For monitoring purposes, you can view near real-time reports about the state of the study, right inside TrialManager. For example, you can verify the progress on resolving DCFs, or monitor subject compliance. Different reports will be available for different user groups based on tasks and responsibilities of these roles.

Reports Tab

The 'Reports' tab will contain reports for you to view. These reports should be reviewed on a regular basis to ensure the TrialSlate is being used correctly with good compliance. The following reports will be available for this study:

- **Compliance report -** This report provides an overview of the subjects completed and missed questionnaires. It provides a total compliance figure for the sites listed.

- **Questionnaire Compliance Report** – This report provides an overview of the Questionnaire Compliance. The report will show if a subject has completed or not completed questionnaires for a visit

- **Duplicate Subject Report** - The purpose of this report is to display a list of potential duplicate entries where subject number might need to be corrected

- **Active TrialDCF Overview Report** – This report provides a summary of all DCF's. If you see a red N in the Approved by Investigator column, please click on the Ref# hyperlink and

review then approve the DCF. Once CRF Health approves and implements the DCFs, the DCFs will no longer appear on this report.

- **DCF Ageing Report -** This report will provide information regarding the average number of days between DCF approval, verification and closure.

- **DCF Status Report:** The purpose of this report is to provide information regarding how many DCFs are in each TrialDCF lifecycle phase (E.g. lists how many are at status 'New', 'Approved', etc.).

- **Subject Information report:** The purpose of this report is to provide detailed information on each subject.

- **Inconsistency Report:** This report provides descriptions of the inconsistency results for subject data. This includes identifying any duplicate subject numbers set up on the TrialManager. It will also display any subjects that have completed more than one set of questionnaires for the visit selected. If an inconsistency is listed the data should be corrected via a DCF.

Data Clarification Forms (DCFs)

Introduction to Data Clarification Forms (DCF)

What is a DCF

TrialManager allows authorized personnel to modify certain data items via the DCF process. The data reported by the sites and subjects is considered to be the original electronic source data. This data is very rarely, if ever, changed. However, in some situations data changes needed to ensure the data is consistent with the rest of the study data. The DCF is the audit trail for data changes. Each DCF and its full history are available for review during the study via TrialManager and will be provided to the sites and client at the end of the study via site archive CD/DVD.

Note: Changing subject questionnaire data is not permitted

Where to create DCFs in TrialManager

There are 4 ways to create a DCF within TrialManager. The DCF process is initiated by selecting the 'Add new DCF' button.

This button can be found in multiple locations:

1. Main login page
2. Under the DCF tab
3. After selecting a site

4. Subject Level
   A DCF can also be created at the subject level. Once the subject has been selected, one can follow the 'Add new DCF' for this subject link

Creating standard DCFs

Begin by logging in to TrialManager and navigating to the DCF creation platform using the guidance provided in the section above, 'Where to create DCFs in TrialManager'.

All DCFs that are raised will include a set of steps that must be taken. These steps have been outlined below.

1. For certain DCFs, additional steps may be required to provide the necessary level of information. These steps will be outlined in the 'How to create various types of DCFs' section. **Select Site and Subject**

Note: If the DCF was raised at the subject level (noted above in '[Where to create DCFs in TrialManager](#)', number 4), entering the site and subject in the dropdown will not be necessary.

2. Select data to change

After selecting 'Next step', select the type of data to be changed. In this area, you will need to specify the type of DCF being raised. Depending on what is selected, the next steps to complete the DCF will change.

3. Specify details

As noted above, the specify details section will vary based on the selections made in step 2. These options are outlined in '<u>How to create various types of DCFs</u>' section below. The following DCF types will require this step.

- <u>Change Subject information</u>
- <u>Change subject status</u>
- <u>Mark Subject as removed</u>

For all other DCFs, steps 1, 2, 4, 5, and 6 listed here are the only steps required, although there is additional guidance for all DCF types below as well.

4. Describe the change

Fill in the 3 free text boxes to describe the change. When finished, click 'Next step':

a. **Title for the change:** Give the DCF a brief title that describes the change (*e.g. 'Update subject randomization number'*). This is what other users will see in the subject index.

b. **Reason for change:** **This field must be completed**. Describe the issue with as much details as possible. If this is not specific, processing may be delayed. This should not simply outline what change must be made but rather provide reason for the change explicitly. (*e.g. 'Subject number was entered incorrectly on the device'*)

c. **Requested changes:** This field must be completed. Detail the requested changes. Specify any values that need to be changed, including the original value and new value *(e.g. 'Please change X to Y.')*.

5. Confirm

When the DCF has been drafted, you will see a screen where you can review the information entered and click **'Save'** to save the information required; or press 'Previous Step' to return to the last step and amend the information.

You will get a confirmation that the DCF was created successfully. Select 'View DCF' to change the status of the DCF for processing by the CRF Health Data Management Team.

6. Approval

Approval is required from various levels before it can be implemented by CRF Health. These steps are outlined in the 'Approval of DCFs' section. Creating a DCF will not automatically add the approval. This must be completed separately once the DCF is created.

How to create various types of DCFs

The below selections begin at step 3 of the DCF process listed in 'Create standard DCFs' section above.

Subject Information related

Change subject information

This DCF is used to update subject information such as subject number (subject code), initials, period, date of birth, etc. Subject questionnaire data information is not permitted to be modified.

After you have selected this option and the 'Next step' button, you will then have to specify the subject information you would like to have updated. Be sure to select all that apply.

3 Specify the data that will be changed

▶ **Change subject information**
Please select the items that need to be changed from the list below.

	Field	Current value
☐	Screening code	
☐	Subject code	1001
☐	Initials	
☐	Period	Active
☐	Study start time	23-Nov-2016 20:19-05:00

Once this has been completed, you will be able to proceed with the DCF creation process outlined above in 'Create Standard DCFs' section starting at step 4.

Change subject status

This DCF is used to update subject status to completed, discontinued, active, etc.

DCFs of this type can be addressed using the 'Create standard DCFs' process outlined above. **Be sure to include the date of when the subject status has changed in step 4 (Describe the change). This DCF type cannot be processed without a date.**

Change subject's site number

This DCF is used to change the subject's site number in the event the site number associated with the subject is incorrect.

DCFs of this type can be addressed using the 'Create standard DCFs' process outlined above excluding step 3.

Mark a subject as removed

This DCF is used to remove the subject from reports and displaying in TrialManager. Subject related data will not be fully removed from the database.

If forms exist for this subject, specify if all forms can be removed as well.

DCFs of this type can be addressed using the 'Create standard DCFs' process outlined above excluding step 3.

Merge duplicate subjects (handle duplicate subjects)

This DCF is used to merge two duplicate subjects together so the data is associated with one subject. This will need to be used if a replacement subject was created and the auto-merge code was not used.

DCFs of this type can be addressed using the 'Create standard DCFs' process outlined above excluding step 3

DCF's related to Questionnaire Data like

Update visit number
Update date and time
Remove questionnaire

1. Sites must choose DCF Type "Change Subject information
2. Select subject Status

3. Title of DCF
4. Reason
5. Details

Add a new Data Clarification Form (DCF)

Step 4: Describe how the data will be changed

Title for the data change
A short and descriptive title helps following up on the data change until it is completed.
Update visit number

Reason for change
Describe why the data change is needed.
Site personnel accidentally activated the incorrect visit number.

Requested changes
Specify new values for the data.
questionnaires EQ 5D 5L, BFI and ACCEPT completed on 14FEB2019 are currently assigned to visit number 3- please update all these questionnaires to visit number 6.

Summary
You have chosen to **Change subject status.**
Site: **AA's Test Site TM05**
Subject: **1000**
Subject status: **Active**

1. Site must detail in the description box the date the questionnaire you require to be update, the questionnaire name, and visit number to be updated to.

2. Sites should be very specific which questionnaires they are referring to and ultimately if three questionnaires have been completed at the visit, site should detail all three questionnaires to be updated.

Remember all visits require three questionnaires to be completed therefore if you want to update the visit name for 1 questionnaire the other 2 should also be updated. Name all three questionnaires: EQ-5D-5L, BFI and ACCEPT.

DCFs must be approved once they have been created and confirmed to have all the necessary and required information. Creating a DCF will not automatically add the approval. This must be completed separately once the DCF is created. Before CRF Health can implement a DCF, it must first be approved by the Site

How to Approve DCFs

After selecting **'View DCF',** you will be taken directly to the page where the status of the DCF can be changed. If the DCF had been created earlier on, select the appropriate DCF from the DCF home page. The Filtering DCFs section describes how to select a DCF.

As noted previously, before the CRF Health Data Management Team can implement the DCF, it must be approved by the following levels:

> **Level 1 (Site):** The first level of approval is the Site/Investigator approval. Steps below describe how site personnel can approve DCFs.
>
> **Level 2 (Service):** The final approval level of approval will be the CRF Health Data Management Team approval. Once all approvals are received, CRF Health will implement the requested changes.

Follow the instructions below in order to ensure the DCF is approved for processing:

1. Navigate to the DCF that you wish to approve and select the 'Approve' button.

2. Next, a confirmation screen will appear which allows you to add a comment (*optional*) and approve the DCF. After entering your login credentials and password you can select approve.

3. At this point the DCF is now approved at the site level.

4. The DCF is now approved by the site. CRF Health can now implement the changes. (*Note: CRF Health may change the status and request additional information.*)

You can follow the progress by selecting the DCF and checking the status and comments.
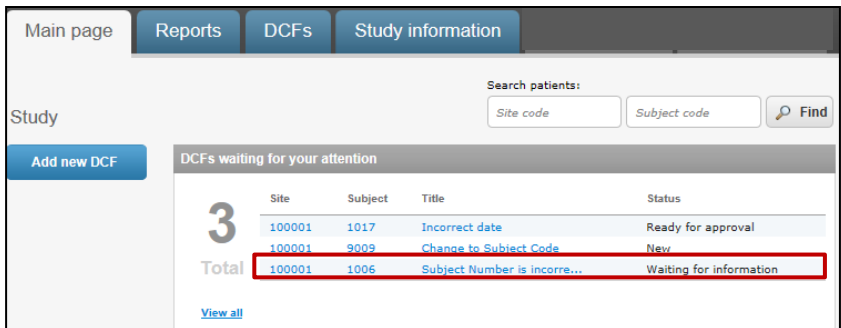
[Adding additional information](#)

How to Answer Comments: Waiting for Information

Sometimes, DCFs will need additional clarification and will be changed to the **'Waiting for information'** status. This means that there are questions regarding the DCF that the site will need to answer. The

DCFs waiting for information can be found on the 'Main page' tab of the TrialManager.

DCFs may be placed in a 'Waiting for information' status for the following reasons:

1. DCF wording is unclear
2. Wrong type of DCF was selected
3. There is missing information that needs to be confirmed before the change can be made

The following steps will be required in order to add comments to DCFs in a 'Waiting for information' status:

1. Click on the Title link to review and read the comment history for the DCF in the 'Waiting for information' status.

2. Review the comments that detail the information that needs to be clarified. Enter a clarifying comment in the 'Enter your comment…' text box. Try to respond to all questions raised with as much detail as possible. **If you are still unsure about what information is needed, please state this in your comment**. Press the 'Save comment' button when finished.

3. Once the necessary additional information has been added via a comment, **the DCF must be approved again**. Follow the steps outlined in the '[Approval of DCFs](#)' section above.

If you go back to the DCF Notice Board on the Main page, you will notice that the DCF no longer appears – meaning that no further action is needed on that DCF. Continue the process with all remaining DCFs in your notice board until no DCFs appear in the DCF Notice Board. **Note: The DCF may be moved to a 'Waiting for information' status a second time if the comments in the DCF are not clear or do not clearly answer the questions from the CRF Health Data Management Team.**

How to Modify DCFs
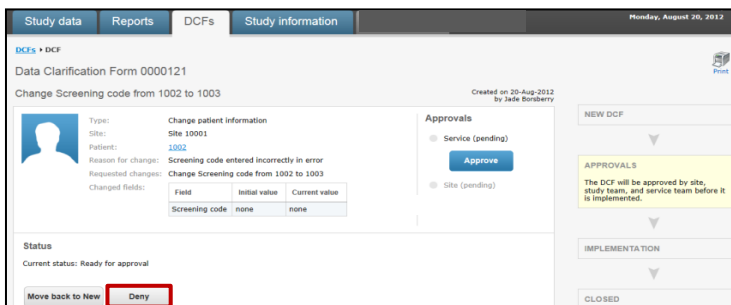
Until a DCF is either under 'Ready for approval' or any 'Approved' status, the site is able to modify the DCF. This can be accomplished by simply selecting the **'Modify DCF'** button on the DCF itself.

When making modifications, be sure to save all updates made to the DCF and move to 'Ready for approval' for processing.

How to Cancel/Deny DCFs

The site can cancel their entered DCF at any time prior to their first approval, by selecting the **'Deny'** button on the DCF page. By selecting

the 'Deny' button, this signals to the CRF Health Data Management Team that the DCF should not be processed.

Note: The CRF Heath Data Management Team may deny DCFs that are not applicable for your protocol or are duplicate requests.

DCF Timelines and Interim/Final Database lock

DCF Timelines

Once a DCF has both Site and Monitor approvals, CRF Health Data Management will review and implement within 5 working days. If a DCF must go to "Waiting for information" status, then the implementation time will restart on re-approval of the updated DCF.

Interim and Final DBL

Prior to interim/final database locks, it is important that all the data has been uploaded and cleaned. Please find below some important guidelines on best practices for interim/final database locks:

1. **It is highly important that data is reviewed and DCFs are raised and approved on an ongoing basis by Sites, Monitors**

and Study team to avoid high volumes of DCFs ahead of interim and final database locks.

2. Sites should continuously review any DCFs waiting for more information to provide CRF Health with the information required to implement prior to lock dates.
3. The Study team must inform CRF Health of upcoming interim/final database locks in advance to allow CRF Health to advise on DCF approval deadlines. For interim locks, notice of at least 2 months of the planned date is required and for final locks, notice of at least 3 months of the planned date is required.
4. Sites should ensure that all devices at site have sent data so that all data is uploaded.
5. CRF Health does not review data or raise DCFs.

How to request resupplies of TrialMax Slate

If a Site requires device re-supply, they can request it via Helpdesk (see Helpdesk phone number in section Helpdesk Support hours) or directly contacting your appointed Monitor/CRA to request resupply. The request has to be approved by Study Team.

Once approved, it will take 5 business days to prepare shipment and it will be shipped with 1-6-day delivery service.

Device Charging Tips

If the TrialMax Slate does not work properly, please check the following:

- Power cable: If the power cable is not properly connected to the electrical outlet, or if the TrialMax Slate is not properly connected, the TrialMax Slate will not charge properly.

Please contact the Helpdesk if your device is not working properly. The Helpdesk agents will assist you with technical questions.

How to return TrialMax Slate

At the end of the study, **all** devices have to be returned to CRF Health.

When returning devices to CRF Health, UPS will need to pick them up. If the site does not have a regular pickup, they will have to call their local UPS office for a pickup. The UPS number is different in each country. The UPS driver can bring a manual waybill to the site if they do not have one. Please see Appendix A UK Logistics and Appendix B US Logistics device returns instructions.

If you need to return a faulty device to CRF Health, make sure to include a completed Faulty Device Return Form (refer to CRF Health Project team for a form) with the return. Only devices with a Faulty Device Return Form included will be investigated for any unsent data.

Frequently Asked Questions

Q: Where can I get more help?

A: Please contact the CRF Health Helpdesk. The Helpdesk is available to assist you with any concerns about the TrialSlate or TrialManager. Please provide as much information as you can about the problem. Remember that every question is important. For protocol related questions, please contact your study monitor.

Q: How often should the TrialMax device be charged?

A: Please be sure to leave the TrialMax device plugged into the charger when not in use to keep it fully charged.

Q: What do I do if my TrialMax device does not switch on?

A: Charge the TrialMax device for two (2) hours. After charging, turn the TrialMax device on. If the PIN code screen does not appear, call the Helpdesk.

Q: The subject does not understand the questions. What should I do?

A: If the subject does not understand the questions in the TrialMax device, you may have to explain what is being asked. The Helpdesk cannot answer any health-related questions. For further assistance with the questions, please contact your study monitor.

Q: A subject forgot their PIN code and cannot use the TrialMax device. How can the PIN code be retrieved?

A: If subject PIN code for TrialMax Slate is forgotten, site member calls the helpdesk, requests interpreter (if needed) and hands over the phone for a subject.

Q: I forgot the site PIN code, and now I cannot get back into the TrialMax device. How can I find out what the PIN code is?

A: Call the Helpdesk. When you call the Helpdesk, you will be asked for the study number, site number and role in the study. The Helpdesk will then be able to give you your site personnel PIN code for the study; note the default PIN codes can also be found in this manual.

Q: Subject forgot to enter data on one day. Can that be added later on?

A: No. The subject can only enter data on the visit day. However, site personnel can reactivate the visit if a visit was rescheduled and questionnaires will be made available for the subject to complete on their reschedule visit day. Ensure you activate the visit on the visit day and remind subjects to complete all 3 questionnaires that day as they will be marked as missed if the visit day has passed midnight.

Q: What should be done if the TrialMax device is unable to send data?

A: If data cannot be sent, the site should not panic. The answers will be saved in the TrialMax device until the next time data is sent. The site should try sending again at a later time or from a different location. If the data-sending problem persists, the site should call the Helpdesk to report the problem.

Q: How do I obtain additional devices?

A: If you require additional devices at your site, please contact your CRA/monitor to request the additional Trialslate. Please allow for 5 business days for CRF Health to process the request.

Appendix A: UK Logistics device returns

UK Logistics Device Returns

- When returning devices to CRF Health, UPS will need to pick them up.
- If the site does not have a regular pickup, they will have to call their local UPS office for a pickup. The number is different in each country.
- When calling for a pickup, the site will need to provide the **CRF Health UPS account number 1F07X9 and postal code CT13 9FG** for the pickup charge to be billed on CRF Health's account. Sites with regular pickups will not have any issues with pickup charge.
- The UPS driver can bring a manual waybill to the site if they do not have one. Please complete the UPS Manual Waybill using the instructions below.

1 Shipper's UPS Account No.

2 Receiver's UPS account:
1F07X9

3 Contact Person:
UK Logistics

4 Company Name and Address:
CRF Health Logistics
Unit 2 (B819)
Hugin Lane, Discovery Park
Sandwich, UK. CT13 9FG

5 Telephone No:
+44 208 222 7467

6 Choose billing option:
Receiver

7 Choose billing option:
Receiver

8 Service Level:
UPS Standard

9 Reference No. 1:
Study Code / Protocol
(REQUIRED)

10 Reference No. 2:
Site Number (REQUIRED)
Number of Devices in pkg.

CRF Health UK Logistics Return Instructions
Version 6
20AUG2018

Appendix B: US Logistics device returns

US Logistics Device Returns

- When returning devices to CRF Health, UPS will need to pick them up.
- If the site does not have a regular pickup, they will have to call their local UPS office for a pickup. The number is different in each country.
- When calling for a pickup, the site will need to provide the **CRF Health UPS account number 37V198 and postal code 19462** for the pickup charge to be billed on CRF Health's account. Sites with regular pickups will not have any issues with pickup charge.
- The UPS driver can bring a manual waybill to the site if they do not have one. Please complete the UPS Manual Waybill using the instructions below.

① Shipper's UPS Account No.

② Receiver's UPS account:
37V198

③ Contact Person:
US Logistics

④ Company Name and Address:
CRF Health Logistics
5185 Campus Drive Suite 350
Plymouth Meeting,
PA 19462 U.S.A.

⑤ Telephone No:
+1 267-498-2365

⑥ Choose billing option:
Receiver

⑦ Choose billing option:
Receiver

⑧ Service Level:
UPS Standard

⑨ Reference No. 1:
Study Code / Protocol
(REQUIRED)

⑩ Reference No. 2:
Site Number (REQUIRED)
Number of Devices in pkg.

CRF Health US Logistics Return Instructions
Version 6
20AUG2018

Appendix C: Activation of Visit Questionnaires

This should only be used if the subject is unable to attend the clinic visits to complete their visit assessments on the TrialMax Slate.

Setting up a Subject on Web Diary

Using the TrialManager Portal, you will need to generate the subject credentials so that they can log in and complete their Clinic Visit Questionnaires.

Note: Subjects will need to log in to TrialMax Web within 48 hours of the subject being created, as the password will expire. If the password expires before the subject is able to log in, please have the subject contact the helpdesk and ask them to provide another temporary password.

1. When you select "Main Page", select the Subject for remote activation.

2. Select the "Activate web diary" button.

3. Complete the Web diary activation.

   a. Please take care when entering the Subject's Mobile Phone Number and/or Email address, then select 'Next'.

5. Confirm the subject information and select 'Confirm'.

   a. A pop-up screen is displayed to confirm the subject card containing the subject credentials have been delivered via email
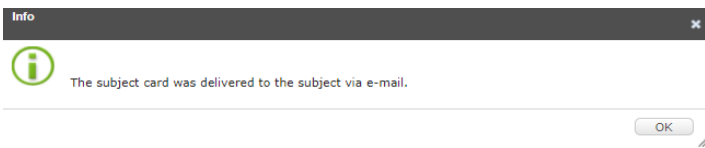
The Subject Card and Training:

Once the subject information has been confirmed, the Subject will receive the notification for their password. The Subject will log into the Web Diary and complete a short practice questionnaire on the Web Portal. The URL for the subject to log into the Web Diary is: https://trialmax.crfhealth.net/wd-6.0.0/A-1525-0006-PROD/diaryHomePage.faces

This training is mandatory for the Subjects.

Activate the Visit Questionnaires

Once a Subject's web diary has been activated, you will be required to activate the appropriate visit. Please ensure visit activation is completed prior to the subject logging onto the Web Diary to complete their visit questionnaires.

Go to the Management tab for the Subject.

Select the visit that that the Subject will need to complete (ensure you check the visit schedule)

Select the Questionnaires which need to be completed for that Subject.

▶ Visit activation

All questionnaires in the study will be listed once a visit is selected. Please select the correct questionnaires for the visit you are activating.
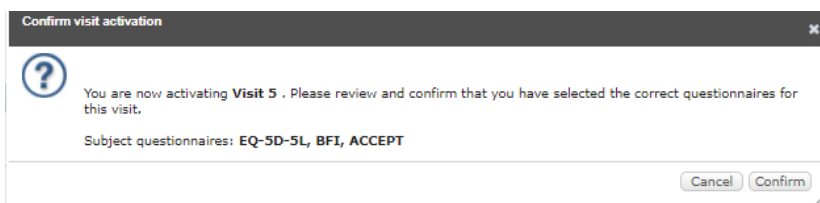
Select visit:

Visit 5 ▼

Select questionnaires:

EQ-5D-5L
BFI
ACCEPT

Activate

Select the Activate button.

Confirm visit activation   ✖

? You are now activating **Visit 5** . Please review and confirm that you have selected the correct questionnaires for this visit.

Subject questionnaires: **EQ-5D-5L, BFI, ACCEPT**

[Cancel] [Confirm]

⚠ The visit questionnaires will only be available to the Subject until the end of the day (Midnight of visit activation).

It is extremely important that the Subject completes their questionnaires during this time frame.

Once the Subject has completed their assessments, then you will be required to "End Visit" in the Management tab.

Subject Questionnaires

▸ **Visit information**

Active visit:	Subject questionnaires:
Visit 5 *Visit activation date:* **05-Feb-2021** **End visit**	EQ-5D-5L, BFI, ACCEPT

▸ **Visit activation**

Please end the currently active visit before activating a new one.

Please note that this visit will NOT be appear completed on the TrialMax Slate so you will need to check TrialManager prior to the Subject 's next visit to ensure the correct visit is activated on the TrialMax Slate.