Oracle® Health Sciences Mobile Clinical Research Associate Server

User's Guide

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Oracle Health Sciences Mobile Clinical Research Associate Server User's Guide, Release 1.3

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Preface

This guide provides information about how to use Oracle Health Sciences Mobile Clinical Research Associate (Mobile CRA) application.

This preface contains the following topics:

- Audience on page ix
- Documentation Accessibility on page ix
- Finding Information and Patches on My Oracle Support on page ix
- Finding Documentation on Oracle Technology Network on page xi
- Related Documents on page xi
- Conventions on page xii

Audience

This guide is intended for the following job classifications:

- Clinical Research Associates
- Lead Clinical Research Associate

Documentation Accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Access to Oracle Support

Oracle customers have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Health Sciences Mobile Clinical Research Associate is Oracle Support's self-service Web site, My Oracle Support (formerly MetaLink).

Before you install and use an Oracle software release, always visit the My Oracle Support Web site for the latest information, including alerts, release notes, documentation, and patches.

Creating a My Oracle Support Account

You must register at My Oracle Support to obtain a user name and password account before you can enter the Web site.

To register for My Oracle Support:

1. Open a Web browser to http://support.oracle.com.
2. Click the **Register here** link to create a My Oracle Support account. The registration page opens.
3. Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

1. Open a Web browser to http://support.oracle.com.
2. Click **Sign In**.
3. Enter your user name and password.
4. Click **Go** to open the My Oracle Support home page.

Searching for Knowledge Articles by ID Number or Text String

The fastest way to search for product documentation, release notes, and white papers is by the article ID number.

To search by the article ID number:

1. Sign in to My Oracle Support at http://support.oracle.com.
2. Locate the Search box in the upper right corner of the My Oracle Support page.
3. Click the sources icon to the left of the search box, and then select Article ID from the list.
4. Enter the article ID number in the text box.
5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

   The Knowledge page displays the results of your search. If the article is found, click the link to view the abstract, text, attachments, and related products.

In addition to searching by article ID, you can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus — On the Knowledge page, you can drill into a product area through the Browse Knowledge menu on the left side of the page. In the Browse any Product, By Name field, type in part of the product name, and then select the product from the list. Alternatively, you can click the arrow icon to view the complete list of Oracle products and then select your product. This option lets you focus your browsing and searching on a specific product or set of products.
- Refine Search — Once you have results from a search, use the Refine Search options on the right side of the Knowledge page to narrow your search and make the results more relevant.

- Advanced Search — You can specify one or more search criteria, such as source, exact phrase, and related product, to find knowledge articles and documentation.

Finding Patches on My Oracle Support

Be sure to check My Oracle Support for the latest patches, if any, for your product. You can search for patches by patch ID or number, or by product or family.

To locate and download a patch:

1. Sign in to My Oracle Support at http://support.oracle.com.
2. Click the **Patches & Updates** tab.

   The Patches & Updates page opens and displays the Patch Search region. You have the following options:

   - In the Patch ID or Number is field, enter the primary bug number of the patch you want. This option is useful if you already know the patch number.
   - To find a patch by product name, release, and platform, click the Product or Family link to enter one or more search criteria.
3. Click **Search** to execute your query. The Patch Search Results page opens.
4. Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.
5. Click **Download**. Follow the instructions on the screen to download, save, and install the patch files.

Finding Documentation on Oracle Technology Network

The Oracle Technology Network Web site contains links to all Oracle user and reference documentation. To find user documentation for Oracle products:

1. Go to the Oracle Technology Network at

   http://www.oracle.com/technetwork/index.html and log in.
2. Mouse over the Support tab, then click the **Documentation** hyperlink.

   Alternatively, go to Oracle Documentation page at

   http://www.oracle.com/technology/documentation/index.html
3. Navigate to the product you need and click the link.

   For example, scroll down to the Applications section and click Oracle Health Sciences Applications.
4. Click the link for the documentation you need.

Related Documents

Oracle Business Intelligence Enterprise Edition (OBIEE) Documentation

The Oracle Business Intelligence Suite Enterprise Edition Online Documentation Library 11.1.1.7.0 documentation set includes:

- *Oracle® Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)*

- *Oracle® Fusion Middleware Metadata Repository Builder's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)*
- *Oracle® Fusion Middleware System Administrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)*
- *Oracle® Fusion Middleware Scheduling Jobs Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)*
- *Oracle® Fusion Middleware Security Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)*
- *Oracle® Fusion Middleware Developer's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)*
- *Oracle® Fusion Middleware Integrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)*

Siebel Clinical Documentation

The Siebel Clinical documentation set includes:

- *Siebel Life Sciences Guide*
- *Siebel Data Model Reference for Industry Applications*

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

1 Introduction

This chapter contains the following topics:

- Section 1.1, "Overview"
- Section 1.2, "What Can I Do Using Oracle Health Sciences Mobile Clinical Research Associate?"

1.1 Overview

The Mobile CRA mobile application supports the clinical research associate (CRA) in conducting and monitoring site visits. It provides the CRA with alerts or notifications sent to the mobile device, location capture vis-a-vis the sites, the ability to view the status of a site-at-a-glance, and access the trip report.

The theme of Mobile CRA is to consolidate the CRA's view of the trial, collecting data from clinical data management systems, clinical trial management systems, drug supply systems, randomization systems and other systems, through an open API or Web services model.

The current version of the system has been designed to interact with Oracle Health Sciences Clinical Data Analytics (CDA), Siebel Clinical Trial Management System (CTMS), and third party systems for receiving KPIs and alerts with subscriptions.

1.2 What Can I Do Using Oracle Health Sciences Mobile Clinical Research Associate?

During site visits within any clinical trial, the CRA has to track any number of important attributes of the study or of a study site. Events such as patient enrollment, study drug supplies running low, or a high percentage of screen failures at the site maybe of interest to the CRA as they monitor sites.

CRAs typically do not have easy access to high performance internet connections as they travel from site to site. Having key site events delivered to their mobile device will relieve the CRA from having to log on to a study analytic tool such as Oracle Health Sciences Trail Center or CDA.

Following are the main features of Mobile CRA:

- Trip Report Checklist Completion - You can create a trip report in CTMS, download it to the mobile device, enter data for the trip report items, and upload the results to CTMS. Once uploaded, the trip report can be submitted to the CTMS approval workflow

- Alerts and Notifications - You can subscribe and receive alerts and notifications about various attributes, tracking progress of the study and sites. The alerts can be from OCDA and/or any 3rd party external sources.
- Adaptive Site-at-a-Glance (SAAG) - You can view the site performance information in terms of various Key Performance Indicators (KPIs) arranged in multiple configurable pages, view key site contacts, and entry points to other features like trip reports, alerts, subscriptions, and so on.
- CTMS Contacts Integration - Mobile CRA pulls out the contact details for each site from the CTMS. These can be used to store on the native device and then making calls as well.
- Geolocation Services - The CRA may indicate that they have arrived at the site by capturing their Geolocation.

Table 1–1 Mobile CRA Features

Feature	Android Tablet or Phablet	Android Smartphone
Alerts and Notifications	X	X
CTMS Contacts integration	X	X
Site Check-in	X	X
Reconcile Checkins		X
Site at a Glance	X	
Trip Reports	X	

Part I

Using Oracle Health Sciences Mobile Clinical Research Associate Server on Android Tablet or Phablet

This part of the Oracle Health Sciences Mobile Clinical Research Associate Server User Guide describes how to use Mobile CRA on the Android Tablet or Phablet.

Part I contains the following chapters:

- Chapter 2, "Accessing the Application"
- Chapter 3, "Alerts"
- Chapter 4, "Trip Reports"
- Chapter 5, "Contacts"
- Chapter 6, "GeoLocation Services"
- Chapter 7, "Offline Services"

2

Accessing the Application

This chapter contains the following topics:

- Section 2.1, "Logging into Oracle Health Sciences Mobile Clinical Research Associate"
- Section 2.2, "Oracle Health Sciences Mobile Clinical Research Associate Server Landing Page"
- Section 2.3, "Site-at-a-Glance"
- Section 2.4, "Settings"

Note: The appearance of the user interface that you see in the application may vary from the figures displayed in the subsequent sections.

2.1 Logging into Oracle Health Sciences Mobile Clinical Research Associate

Note: Ensure that Mobile CRA has been installed on your Android Tablet or Phablet before proceeding with this section. For more information on installing Mobile CRA, refer to the *Oracle Health Sciences Mobile Clinical Research Associate Server Installation Guide*.

The login screen is presented on startup and in situations where an active session does not exist. Perform the following steps to log into Mobile CRA from your Android Tablet or Phablet:

1. Tap the Mobile CRA launch icon.

Figure 2–1 Mobile CRA Launch Icon

2. The following login screen is displayed:

Figure 2–2 Login Screen

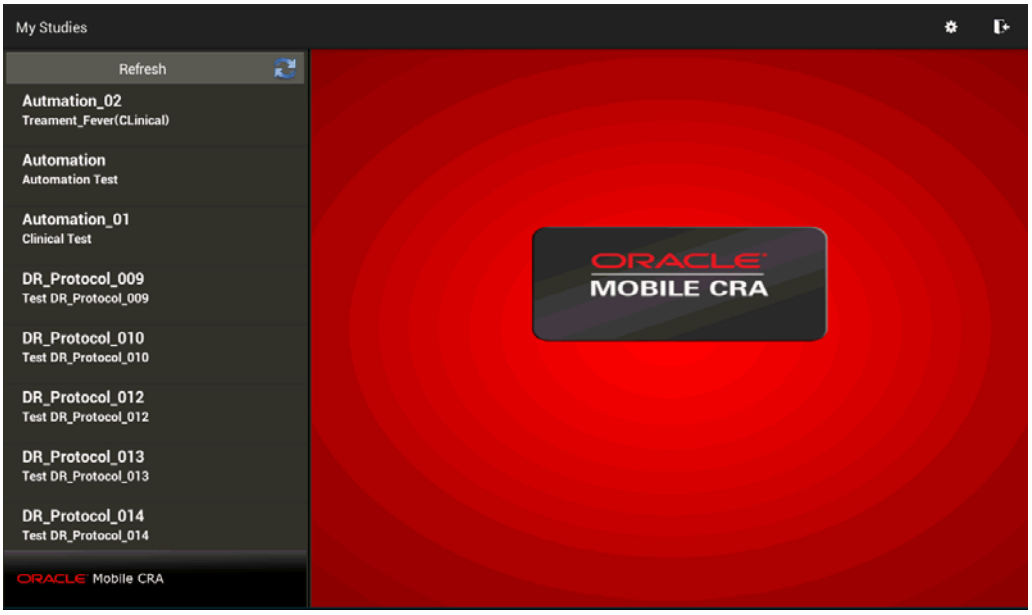
Enter the following details:

- **Server** - Enter the Mobile CRA server address. This is a one-time entry and once done, this field will not appear again during login. If you want to change it, double-tap anywhere on the login screen to invoke the server address field, and make the necessary modifications.
- **User Name** - Enter your user name

- **Password** - Enter your password

3. Tap **Login**. The **My Studies** page is displayed.

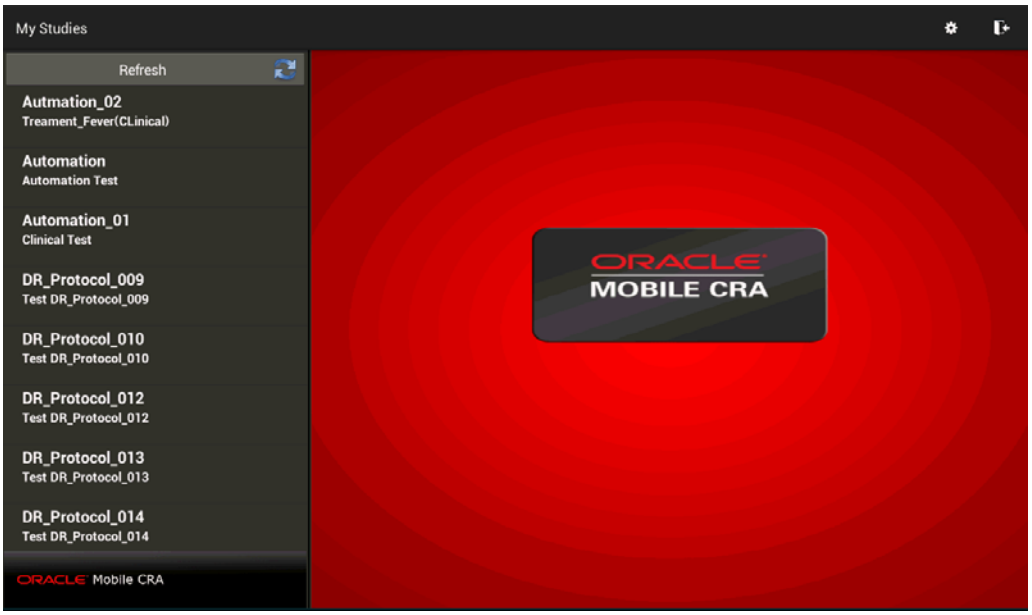
Figure 2–3 My Studies Page



2.2 Oracle Health Sciences Mobile Clinical Research Associate Server Landing Page

When you log into Mobile CRA, the following landing page appears by default. It provides access to studies from where you can drill down to details such as study and site information, alerts, subscription, and trip reports.

Figure 2–4 Landing Page



The landing page consists of the following components:

- **My Studies** pane - This pane consists of a list of studies that you are involved in. The list displays the protocol number and the study title as entered in CTMS. You can tap a study to view its details, which include its sites, key contacts and site metrics.

  To update the My Studies pane, on the left pane, tap **Refresh**. The system makes a call to the server and fetches the latest information from CTMS.

- **Log out** option - This option, present on the top right-hand corner, lets you log out of Mobile CRA.

Figure 2–5 Logout Icon

- **Settings** options - This option, present on the top right-hand corner, lets you view and change the application settings.

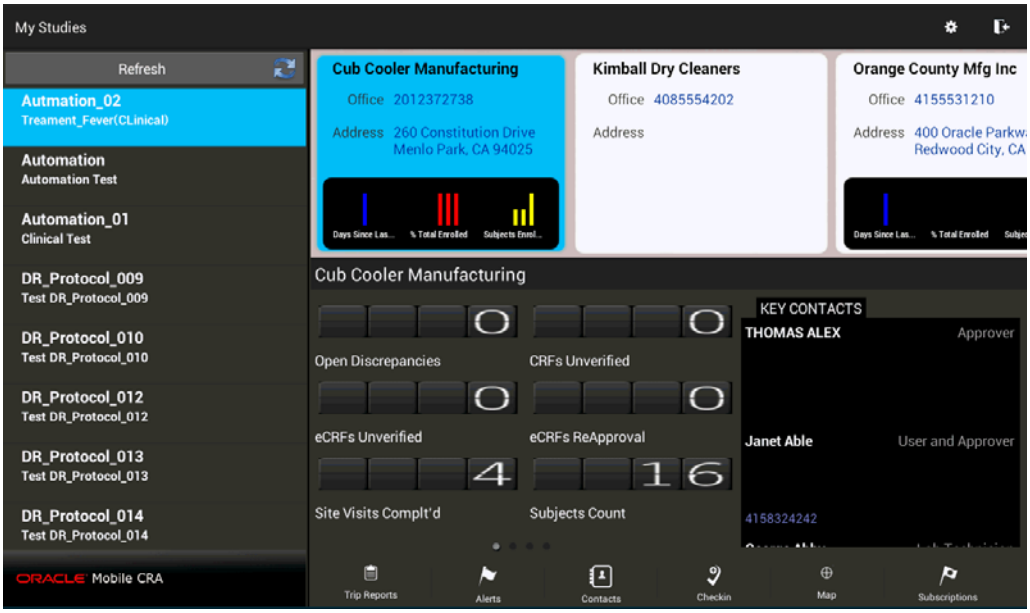
Figure 2–6 Settings Icon

2.3 Site-at-a-Glance

This feature displays overview information about the study sites, including a dashboard where you can view multiple pages of KPIs (6, 9, or 12 displayed at once), performance graphs, and launch various other components. The application displays a maximum of eight digits for the KPI value.

The first three KPIs defined in the Admin UI is used for the trending graphs, which is displayed on the site carousel.

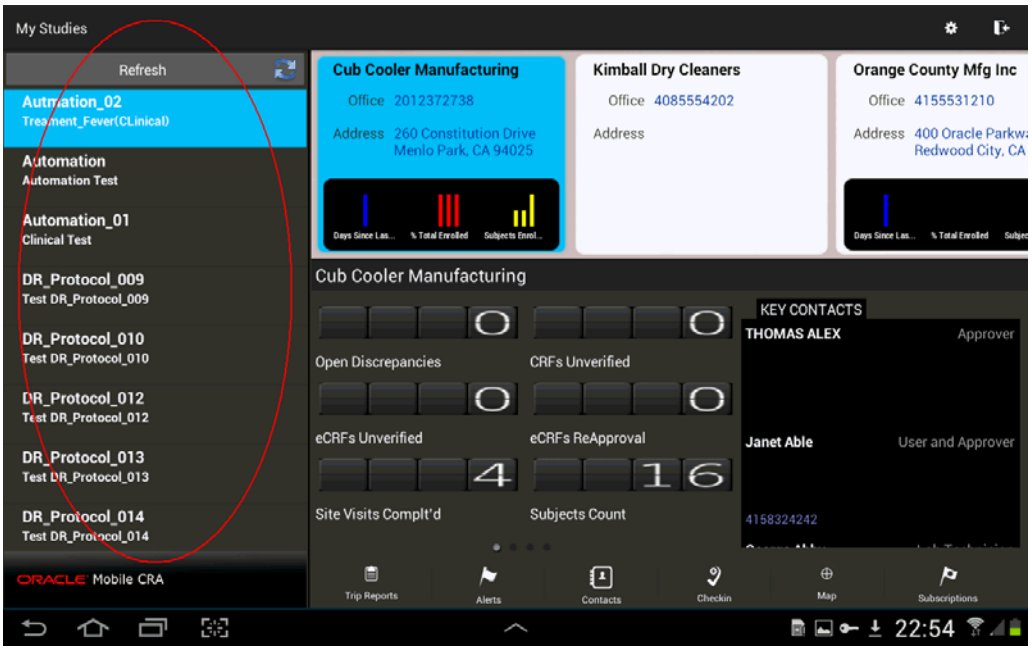
Figure 2–7 Sites for a Study



The page contains the following areas:

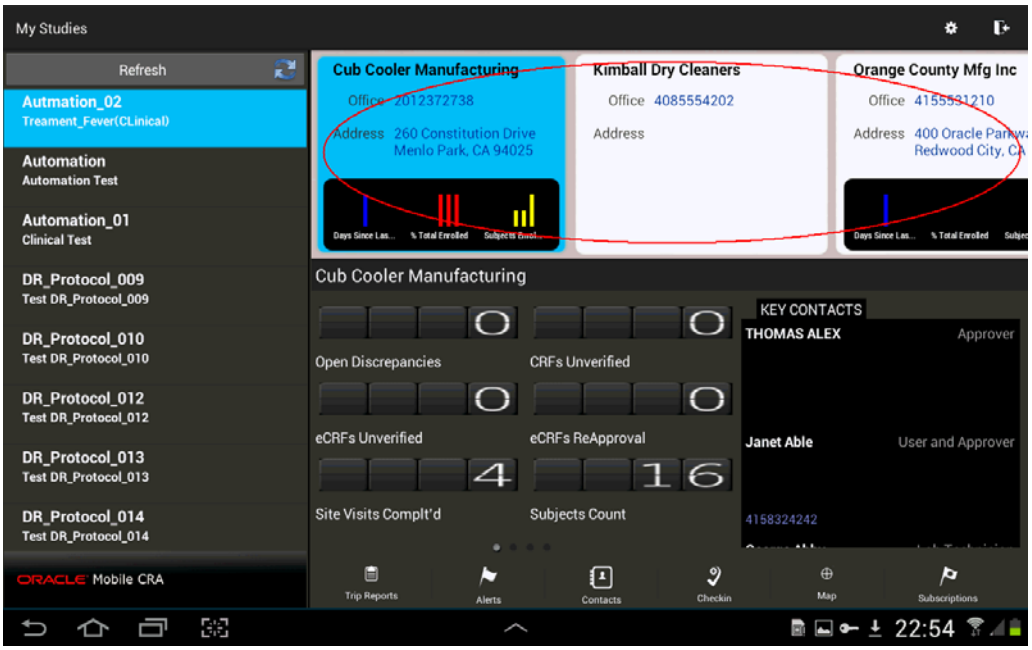
- The study selection bar on the left, which displays all sites that the user has permission to view in CTMS.

Figure 2–8 Study Selection Bar



- The site selector slide on top. Tapping an unselected site will display its details.

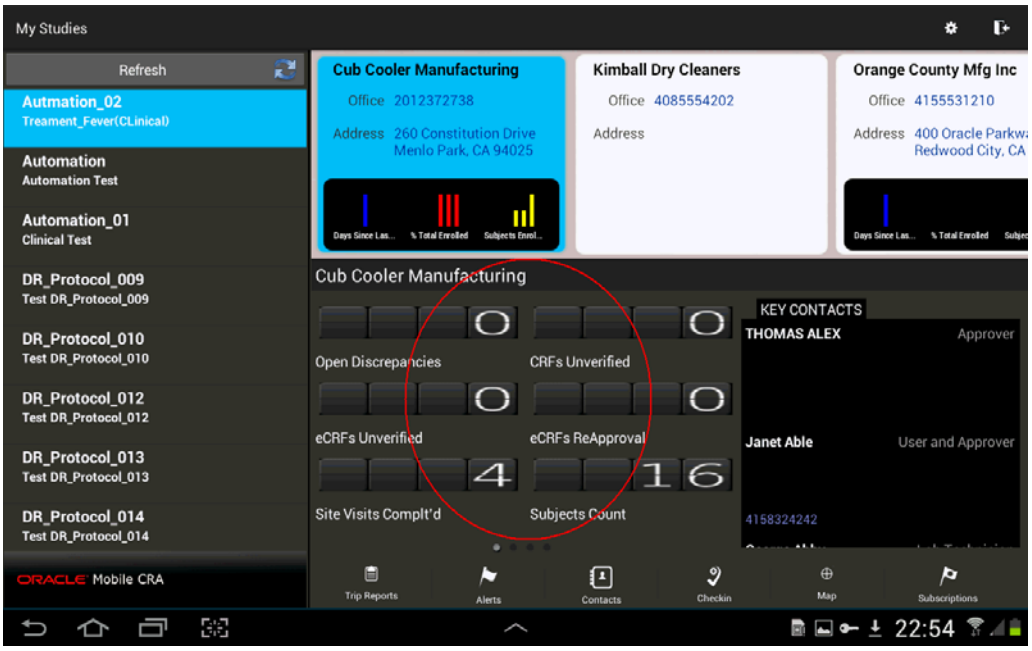
Figure 2–9 Site Selector Slide



- The list of site metrics consists of one of the following:

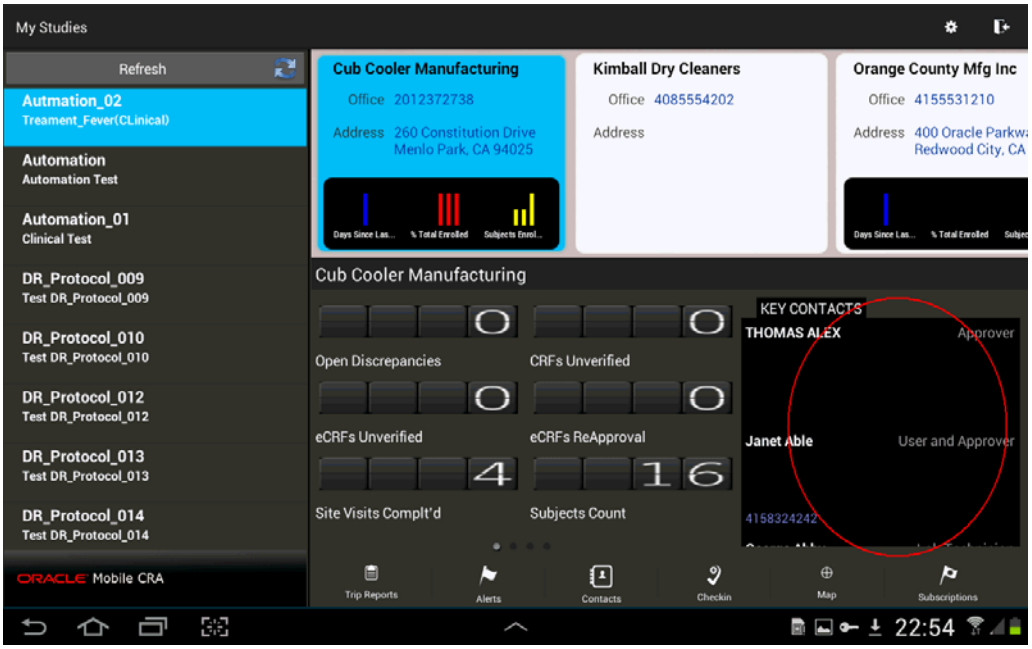
- OCDA KPIs selected at the time of MCRA implementation or default KPIs coming as a part of the Admin UI.
- External KPIs that the company has selected to display to the CRAs. The study-site KPIs are listed first, followed by the study KPIs, and then the generic KPIs.

Figure 2–10 Site Metrics Area



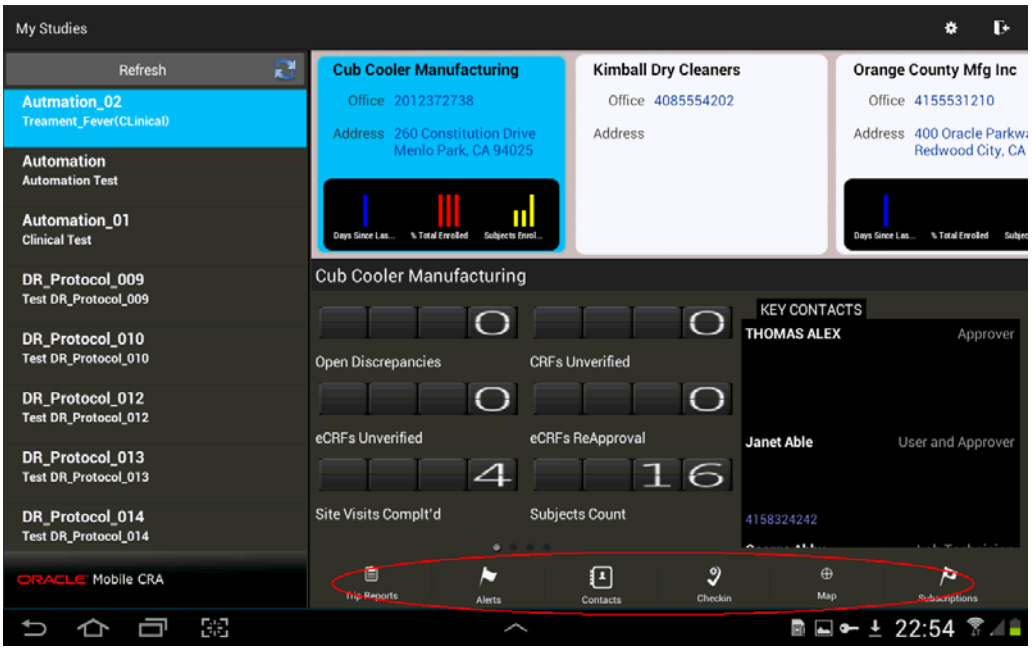
- Key contacts, which contains both site addresses and staff address, as captured in CTMS. You can scroll through to view the list.

Figure 2–11 Key Contacts



- The feature access bar at the bottom, which lets you navigate to trip reports, alerts, contacts, checkin, map and subscriptions.

Figure 2–12 Feature Access Bar



2.3.1 Accessing the Site-at-a-Glance Display

To view the site-at-a-glance display, perform the following steps:

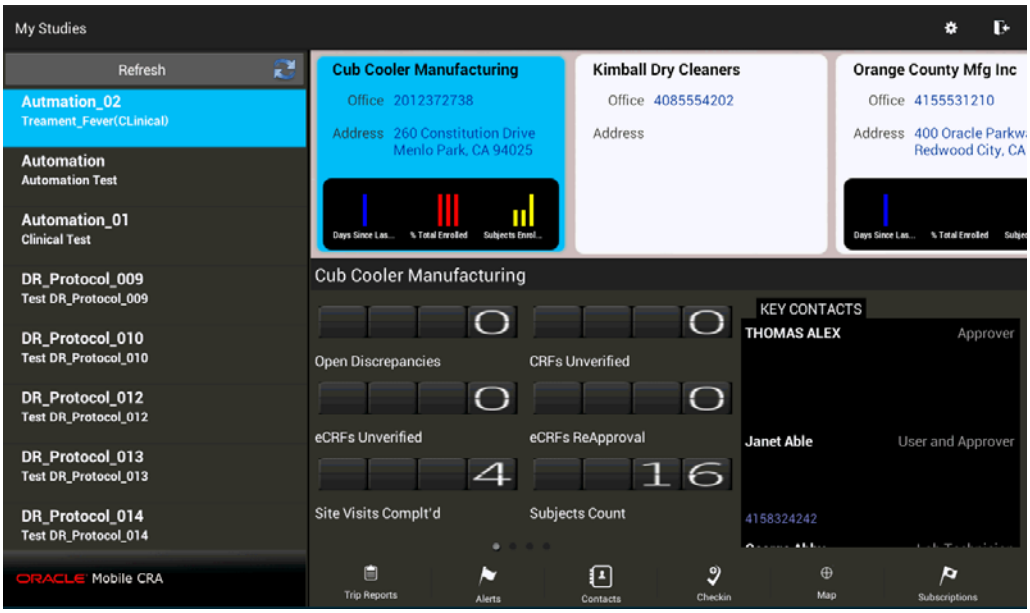
1. Tap a study to view all the study sites under it.
2. Tap a study site to view its details.

   For each site, the following details are displayed:

   - The primary contact phone number and primary address for the site.
   - The key contacts for the site, with addresses and phone numbers.
   - An overview of the site information from CDA or external source, with both trend graphs and up-to-date statistics on study progress.
   - Swipe left or right across the page to view the KPIs.

   Note: The number of KPIs displayed depends on the **Site Metrics (KPIs) to be displayed per page** value.

Figure 2–13 Sites for a Study

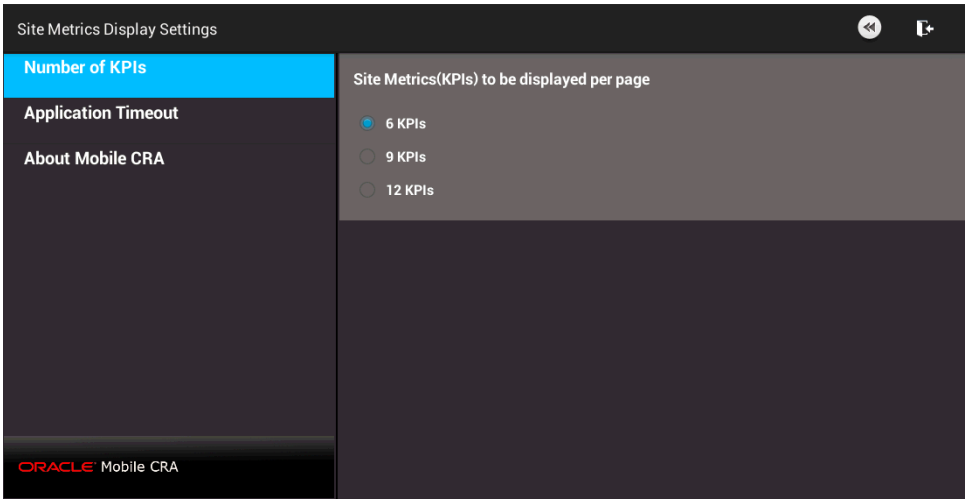


2.4 Settings

You can modify the Mobile CRA settings. Perform the following steps to modify the settings:

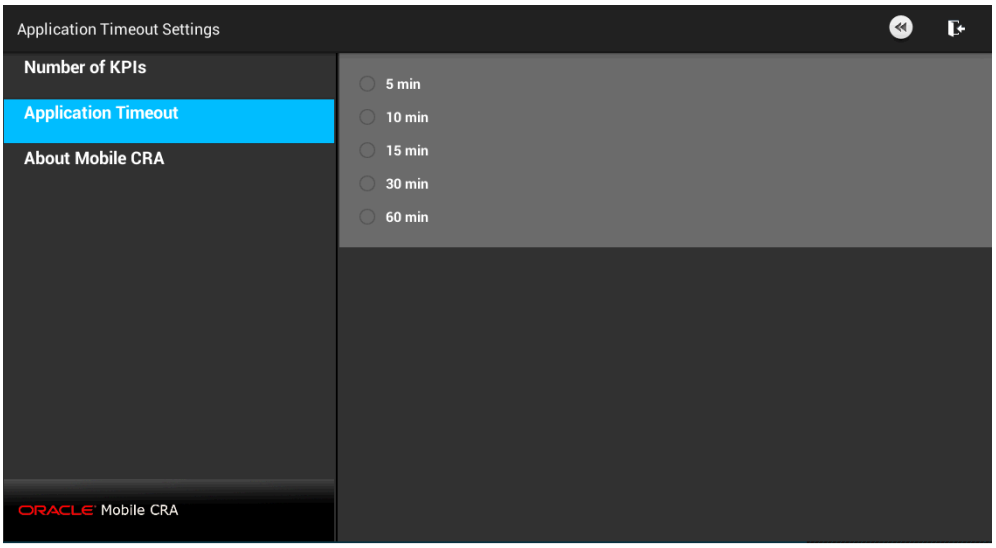
1. Tap **Settings** on your Android Tablet or Phablet Menu.

Figure 2–14 Android Tablet or Phablet Menu



2. The following settings are displayed:

Figure 2–15 Mobile CRA Settings

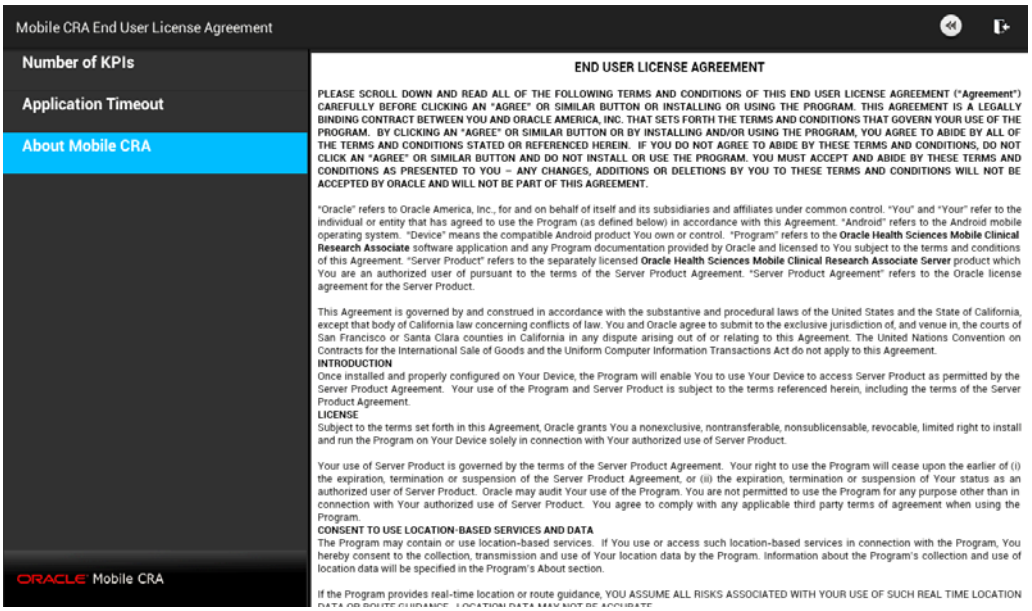


- **Number of KPIs** - You can select either of the following options:
  - 6 KPIs - This option displays six KPIs per page. This is the default value set. The cells will be arranged in a 2x3 matrix, that is two columns and three rows.
  - 9 KPIs - This option displays nine KPIs per page. The cells will be arranged in a 3x3 matrix that is, three columns and three rows.
  - 12 KPIs - This option displays 12 KPIs per page. The cells will be arranged in 3x4 matrix that is, three columns and four rows.

  Note: The setting will be applicable for all the pages of the SAAG. In case there are a total of 26 KPIs defined, the application would display 12 KPIs on the first page, 12 KPIs on the second page, and two KPIs on the third page. The cells will be arranged in 3*4 matrix.

- **Application Timeout** - You can set the idle time for a session. Once this specified amount of time has passed, you will be logged out from the Mobile CRA session.
- **About Mobile CRA** - You can access the end user license agreement.

Figure 2–16 License Agreement



3 Alerts

This chapter contains the following topics:

- Section 3.1, "Introduction to Alerts"
- Section 3.2, "Viewing Alerts"
- Section 3.3, "Subscribing to an Alert"
- Section 3.4, "Predefined Alerts"
- Section 3.5, "Resetting Alerts"
- Section 3.6, "Marking an Alert as Important"
- Section 3.7, "Unmarking an Alert as Important"
- Section 3.8, "Alerts While Application is Closed"

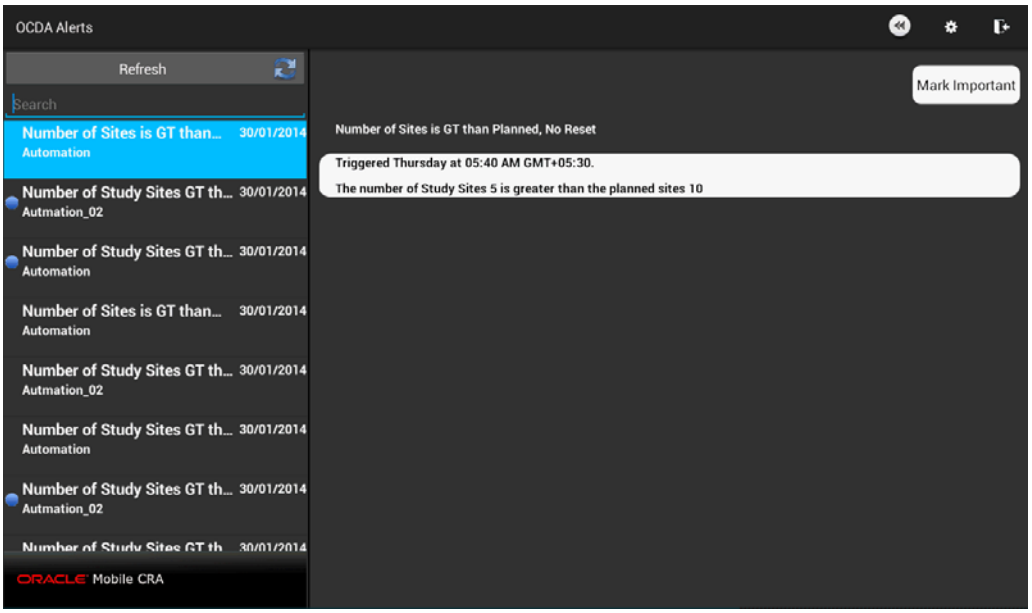
3.1 Introduction to Alerts

As a CRA on the move, you will have to be notified about various aspects of studies and site visits, including their progress, performance, and so on. Mobile CRA lets you create alert rules through the administrator user interface and then subscribe to one or more of them. These will then show up on the device as alert subscriptions, which you can then subscribe to. Once subscribed, you will receive notifications every time the subscription criteria is met. The Alert Rules run on the OCDA and external system for the triggering process. The alert inbox will display all the alerts. For more information on creating alerts in the administrator's user interface, refer to the *Oracle Health Sciences Mobile Clinical Research Associate Server Administrator's Guide*.

You can also flag an alert as 'Important'. This ensures that alerts carrying important information of your interest or those requiring your attention are flagged. Alerts can be generated for a study or for a study-site.

The following is an example of an alert:

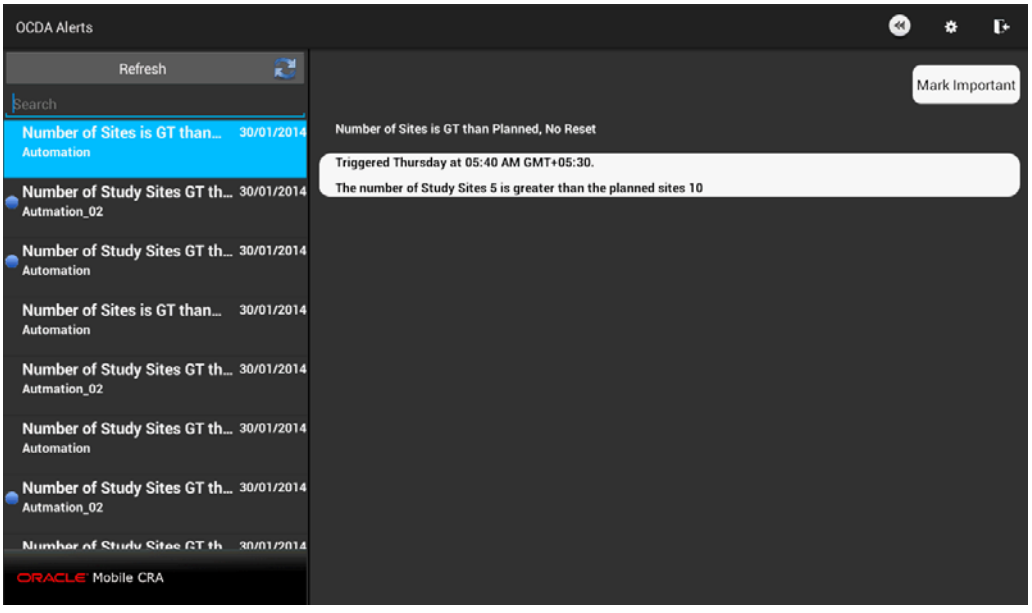
Figure 3–1 An Alert



An alert includes the following details, in order from top to bottom:

- The name of the alert
- The timestamp for when the alert was triggered
- The details and text of the alert
- Unread alerts will display a blue circle next to them in the list of alerts. Once you view the alert, the circle is removed as shown in Figure 3–2.

Figure 3–2 Viewed Alerts

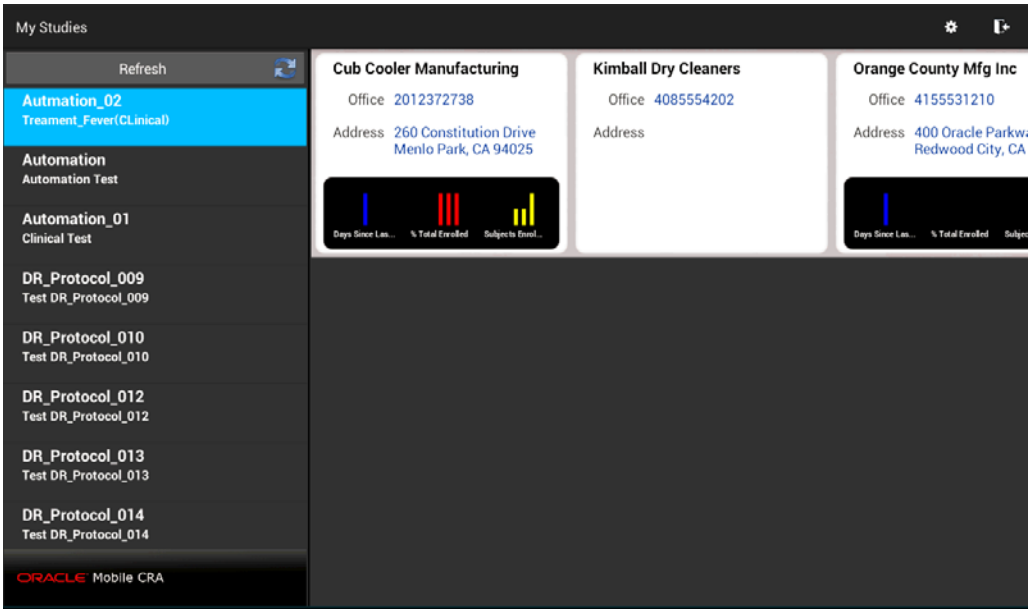


3.2 Viewing Alerts

Perform the following steps to view alerts:

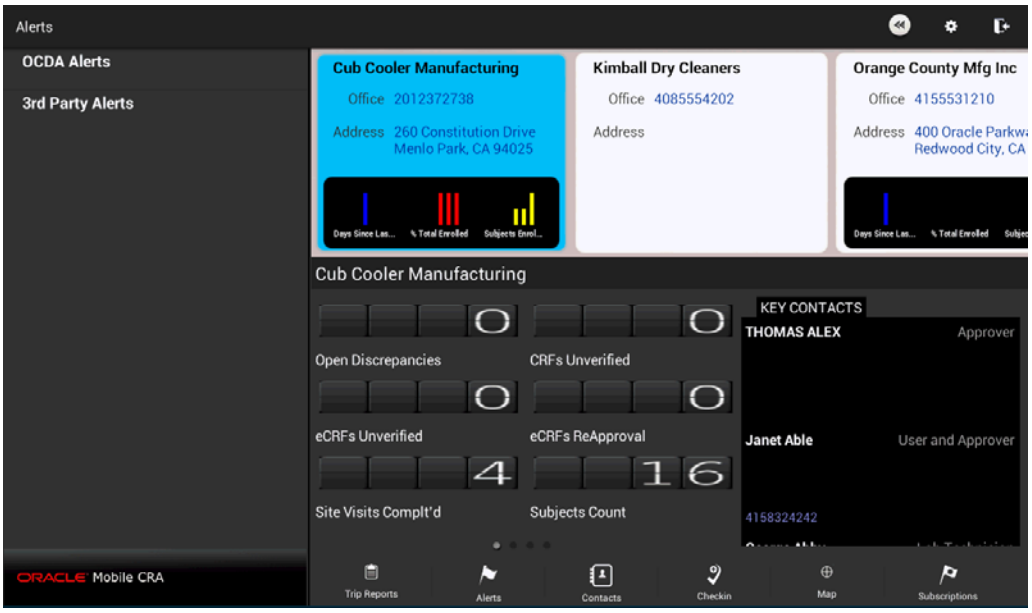
1. In the **My Studies** pane, tap a study to select it.
2. Tap a study-site to view its details.

Figure 3–3 View an Alert



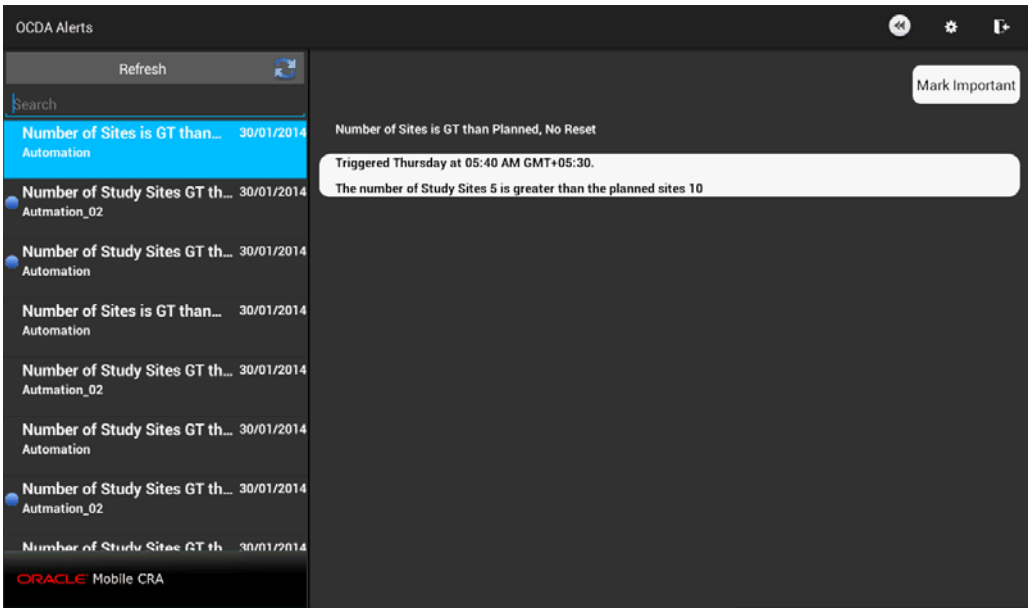
3. Tap **Alerts**. The following screen is displayed:

Figure 3–4 Alerts Screen



4. In the Subscriptions pane, tap a notification to select it. The list of alerts for the study is displayed, with the most recent alerts on top.

Figure 3–5 Alerts for a Study



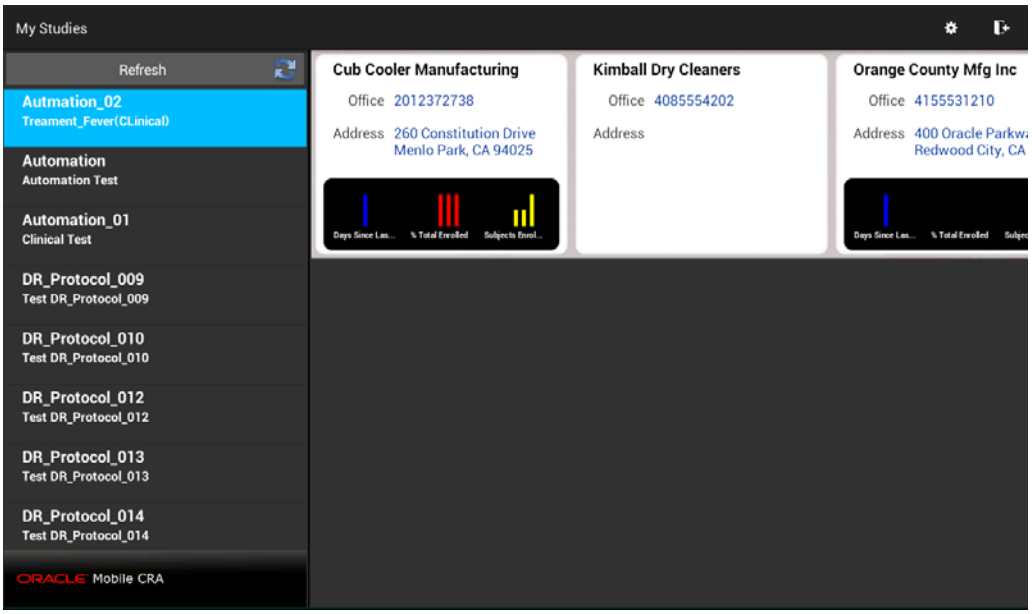
Note: To update the list of alerts, tap **Refresh** on the left.

3.3 Subscribing to an Alert

Before subscribing to an alert, ensure that Mobile CRA has been downloaded, registered, and all administrative tasks have been completed. Perform the following steps to subscribe to an alert from your mobile device:

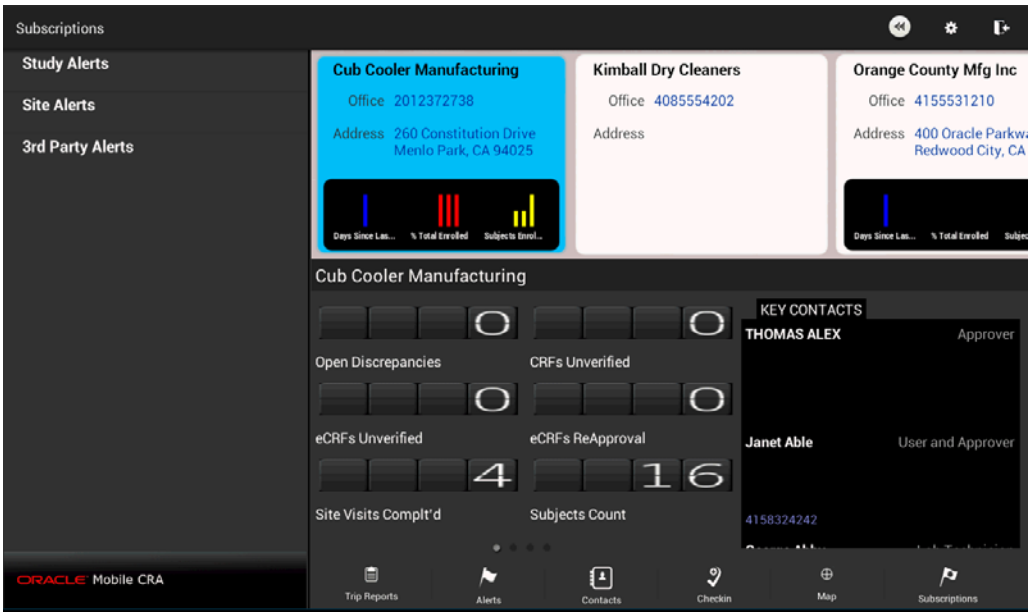
1. In the **My Studies** pane, tap a study to select it.
2. Tap a study-site to select it.

Figure 3–6 Select a Study-Site



3. Tap **Subscription**. The following screen is displayed:

Figure 3–7 Subscriptions for a Study

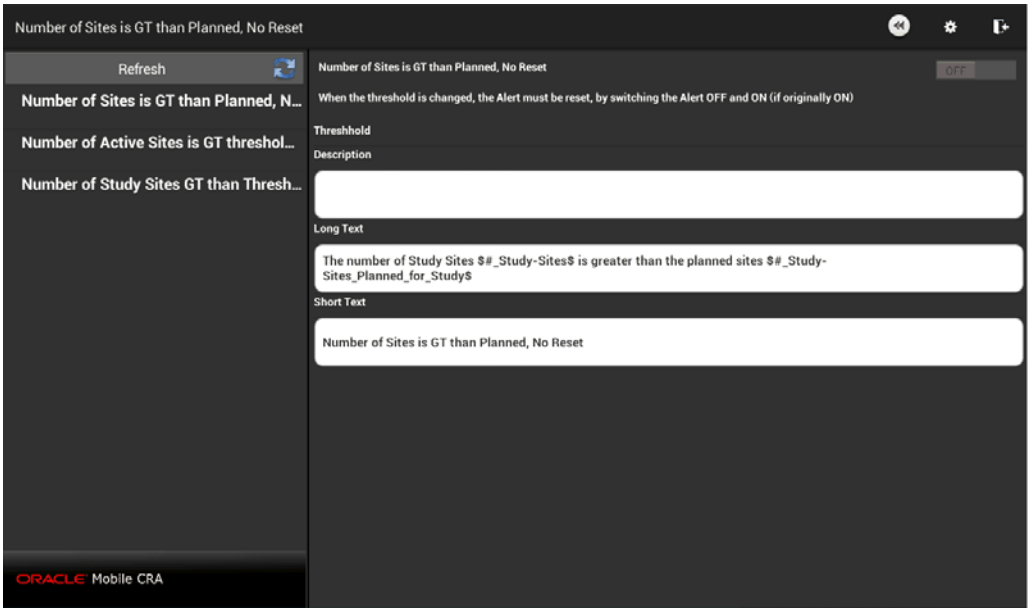


4. Select the alert category (Study Alerts, Site Alerts, and 3rd Party Alerts) to view the alerts in it. The details defined in the Admin UI will be displayed.

> **Note:** If Adaptive SAAG is not configured, the 3rd Party Alerts option will not be available.

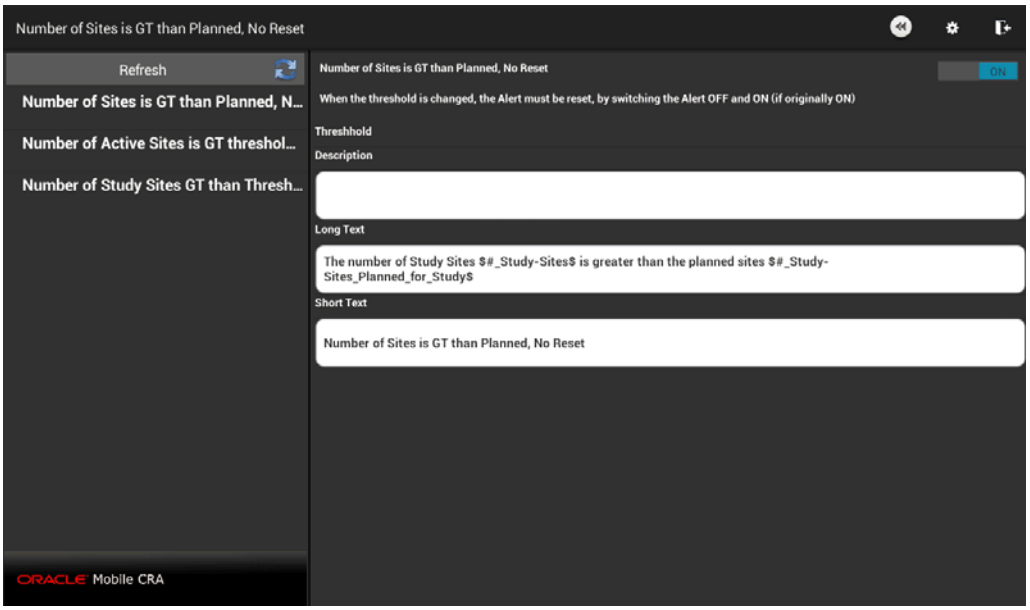
5. Select the alert you want to subscribe to.

Figure 3–8 Select an Alert



6. If necessary, modify the default threshold. For more details, see Section 3.3.2.
7. Tap **OFF** on the top-right corner. It changes to **ON** and you will be subscribed to the alert.

Figure 3–9 Subscribe to an Alert

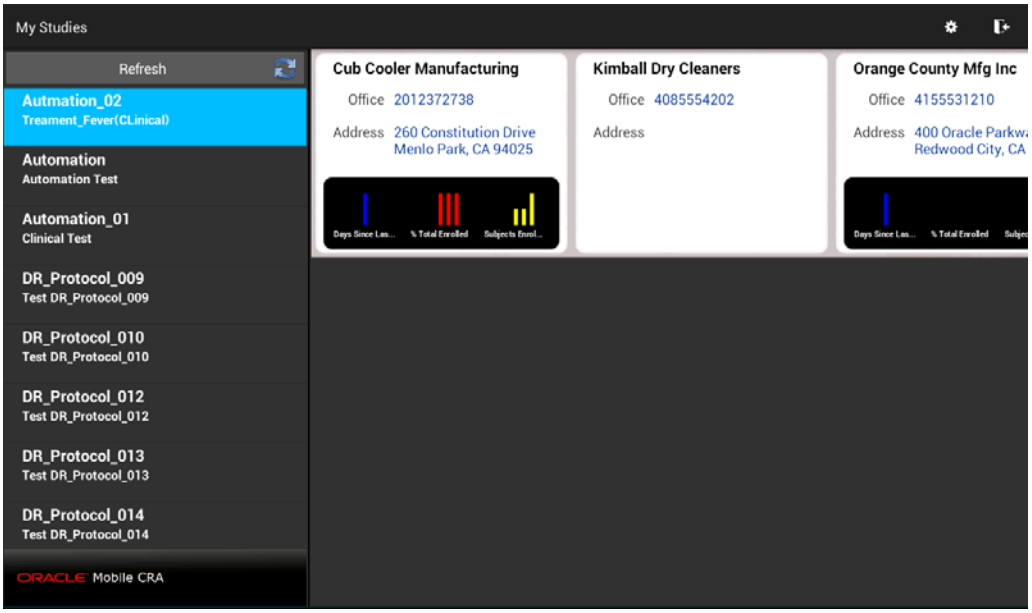


3.3.1 Unsubscribing from an Alert

Perform the following steps to unsubscribe from an alert from your mobile device:

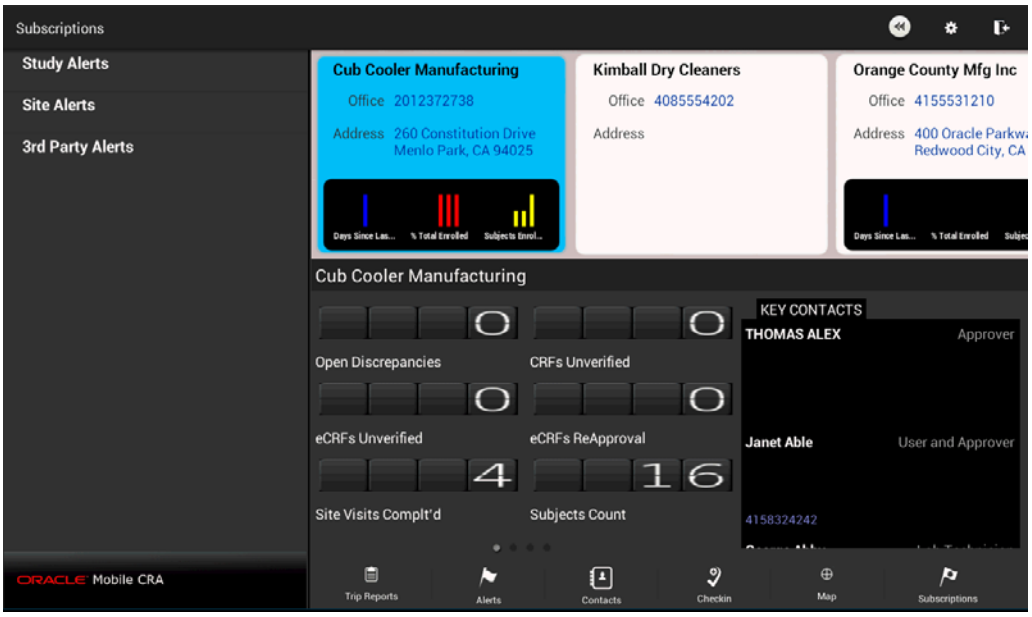
1. Open the Mobile CRA application and log in with your user name and password.
2. In the **My Studies** tab, tap a study to view its details.

Figure 3–10 Select a Study



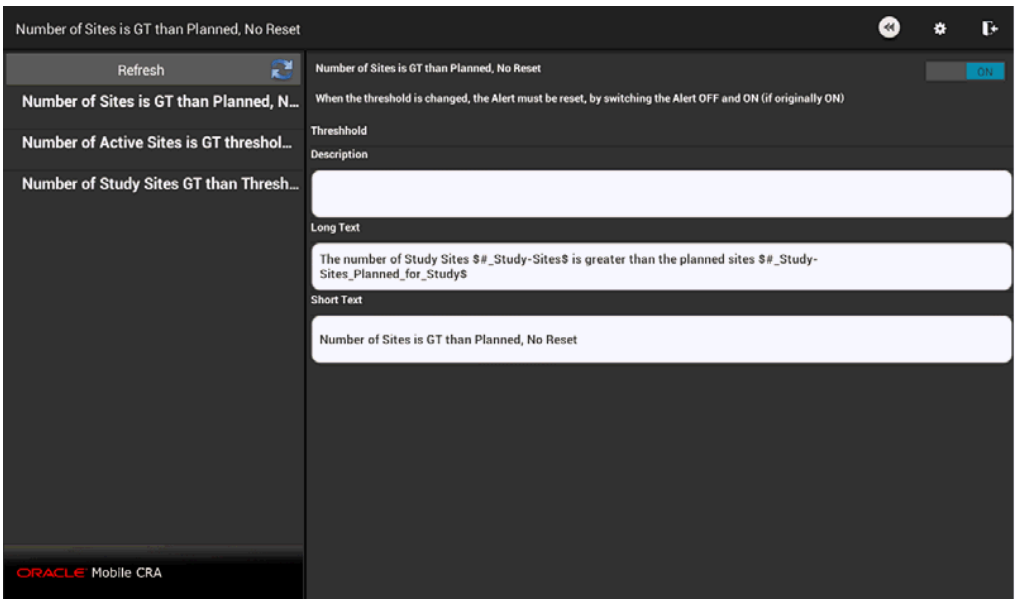
3. Tap **Subscription**. The following screen is displayed:

Figure 3–11 Alerts for a Study



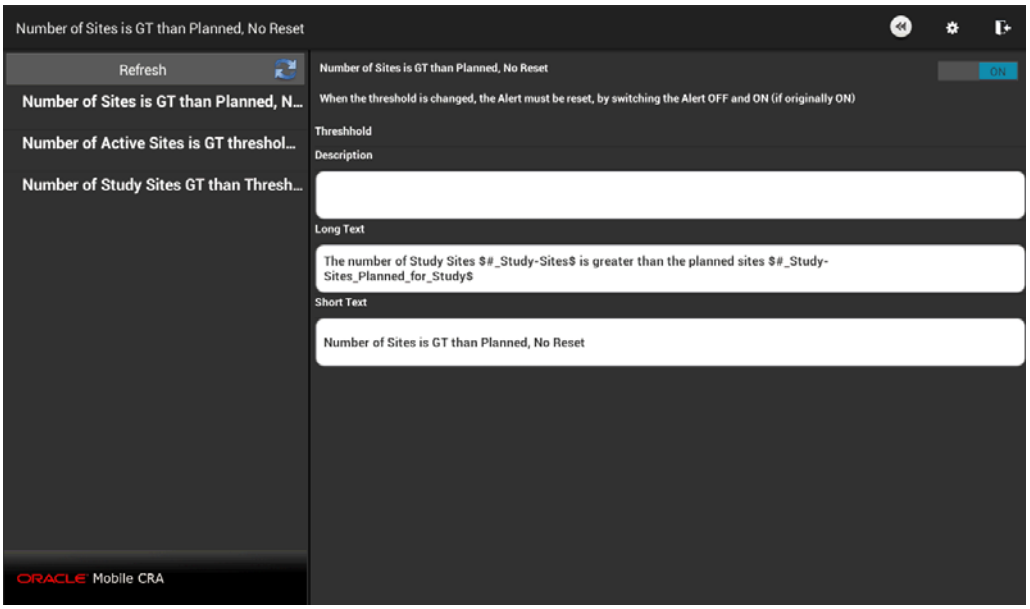
4. Select the alert category to view the alerts in it. In the graphic below, **Study Alerts** have been selected.

Figure 3–12 Study Alerts



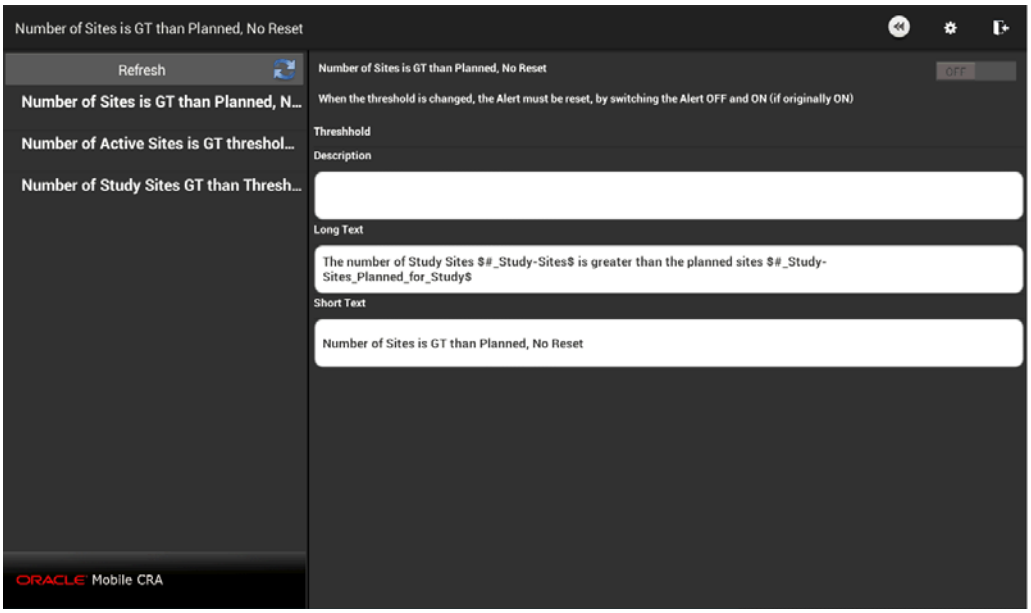
5. Select the alert you want to unsubscribe from.

Figure 3–13 Subscribe to an Alert



6. Tap **ON** on the top-right corner. It changes to **OFF** and you will be unsubscribed from the alert.

Figure 3–14 Select an Alert



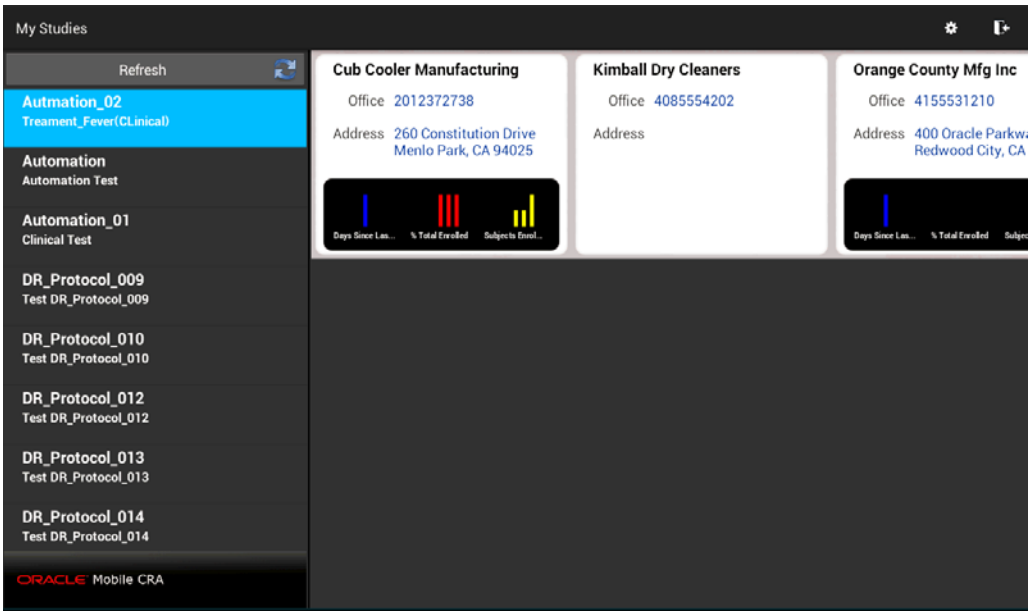
3.3.2 Modifying an Alert Subscription

Perform the following steps to modify an alert from your mobile device:

Modify an Alert Subscription for a Study-Site

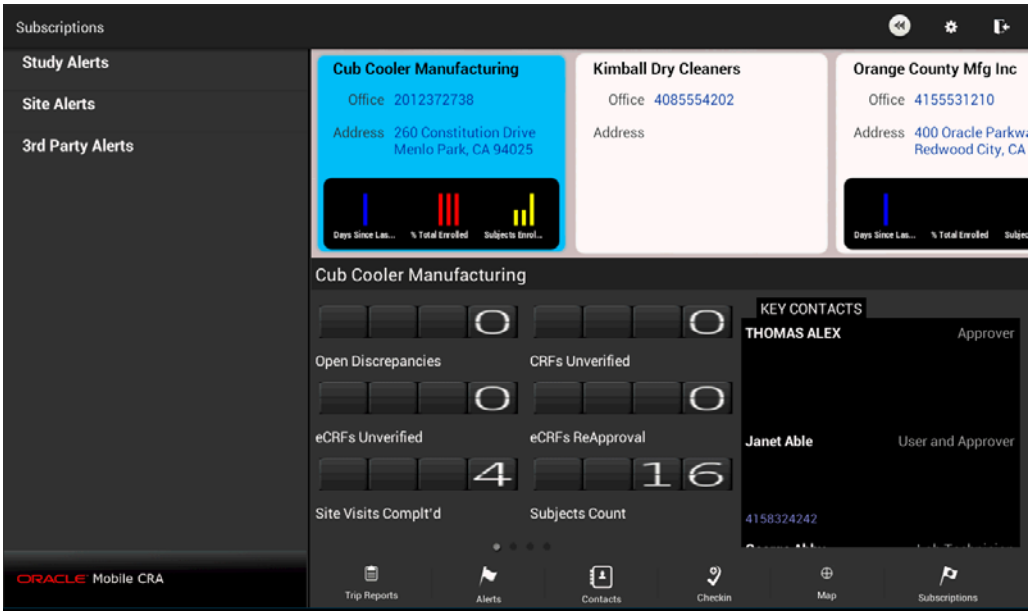
1. Open the Mobile CRA application and log in with your user name and password.
2. In the **My Studies** tab, tap a study to select it.

Figure 3–15 Select a Study



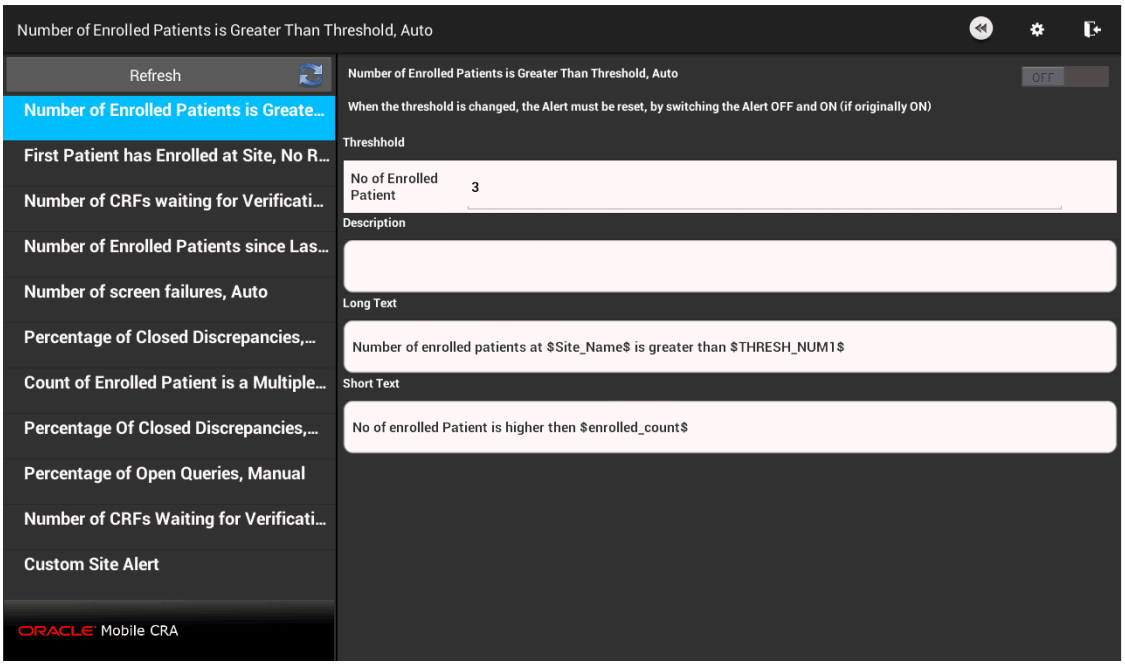
3. Tap **Subscription**. The following screen is displayed:

Figure 3–16 Alerts for a Site



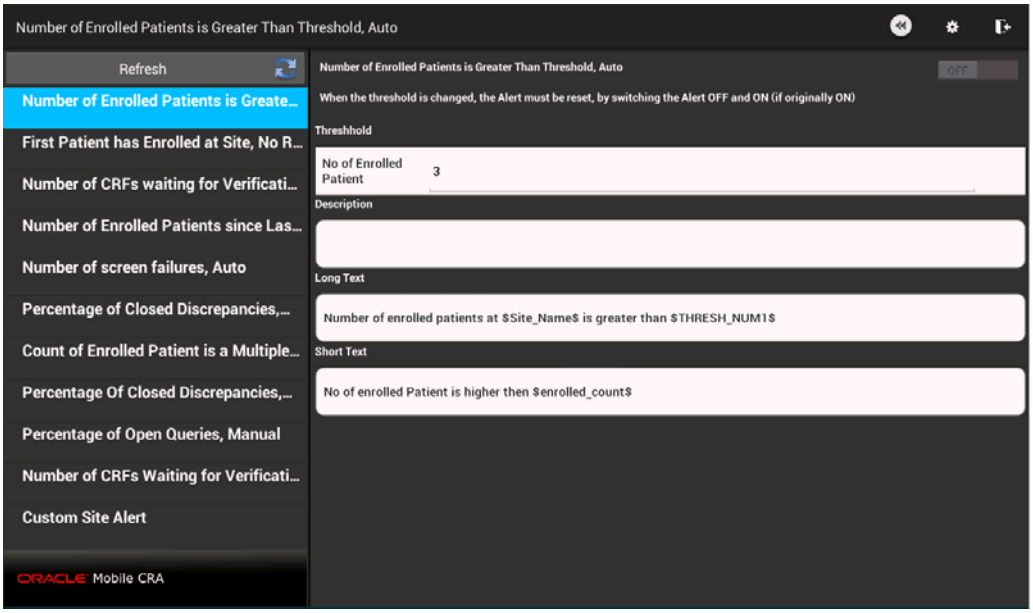
4. Select **Site Alerts** to view a list of study-site alerts.

Figure 3–17 Site Alerts



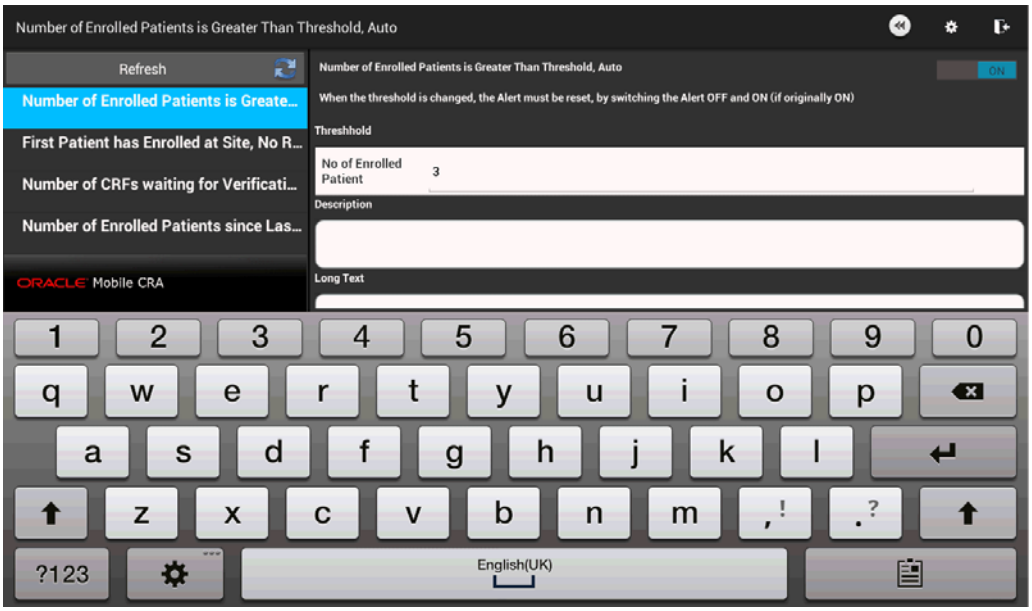
5. Select the alert whose subscription you want to modify.

Figure 3–18 Site Alerts



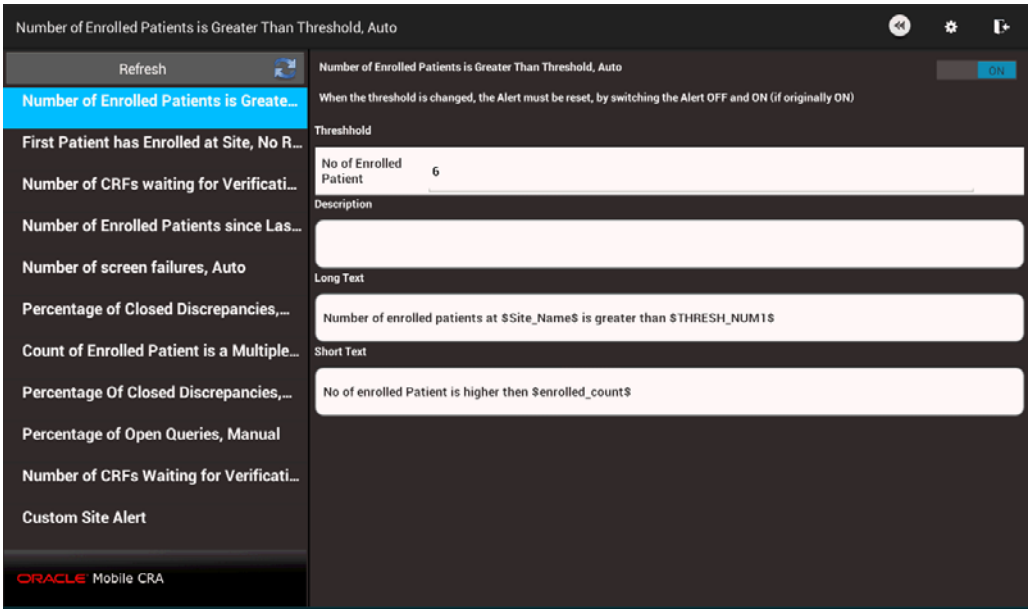
6. Tap **Threshold** to edit it.

Figure 3–19 Edit the Study-Site Alert Subscription



7. After editing, tap **Done** on the top-right corner to save your changes.

Figure 3–20 Threshold Modified



Important: To propagate the threshold changes to CTMS, reset the alert by switching it **OFF** and then **ON** again (if it was originally **ON**).

Similarly, you can modify the threshold value for a Study alert.

3.4 Predefined Alerts

Oracle Health Sciences Mobile CRA system will ship with a set of predefined alerts for data available from CDA. All predefined alerts will generate a notification in the following format:

You have received an alert for <*Study X*> regarding <*Site Y*>.

The following is a list of predefined alerts in the system:

Table 3–1 Predefined Alerts

Predefined Alert	Description
Number of CRFs waiting for verification	Number of CRF pages ready for source verification at the site
First patient has enrolled at site	The first patient has been enrolled at site
Number of enrolled patients is greater than threshold	The number of enrolled patients at a study site is greater than the preset threshold value
Count of enrolled patient is a multiple of five	Number of patients enrolled in list
Percent of open queries	The number of open queries at a study site is greater than the preset threshold percentage
Percent of closed discrepancies	Percent of discrepancies that are closed as Irresolvable is greater than the preset threshold percentage
Number of screen failures	Screen failures is greater than the preset threshold value
Number of enrolled patients since last site visit	Count of enrolled patients since last site visit
Visit reports waiting approval	The number of trip reports pending approval
Number of active sites is greater than threshold	Count of active sites is greater than the threshold
Number of sites greater than planned	The number of study sites that exceed the planned sites
Number of study sites is greater than threshold	Count of study sites is greater than the threshold

3.5 Resetting Alerts

Manual Reset

You can manually reset an alert to trigger again on the same conditions. Before resetting an alert, ensure that you are connected to the server. If you try to reset an alert when offline, an error is displayed.

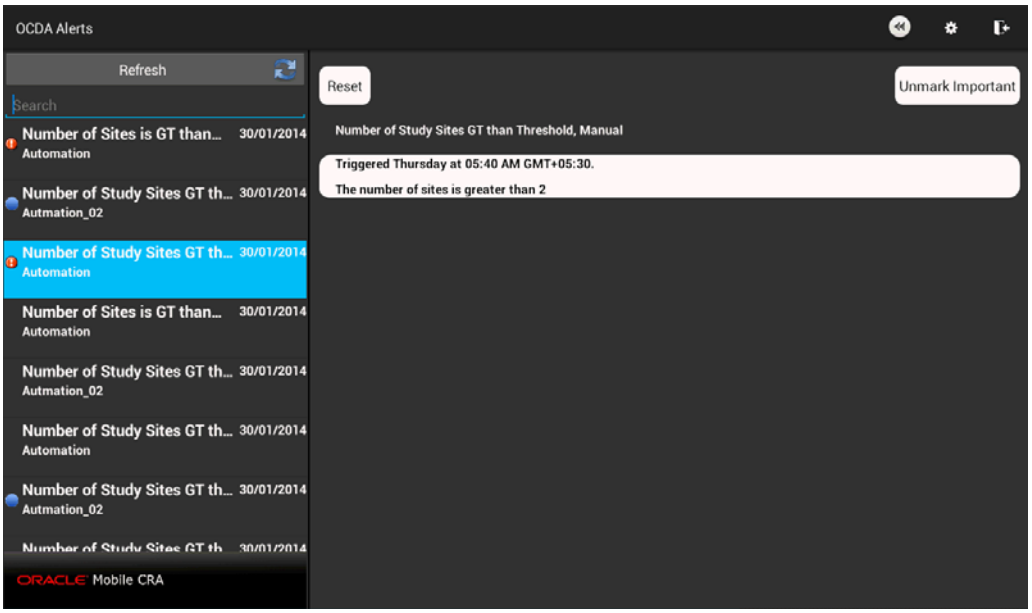
Note: The **Reset** option is not available for external notifications.

Perform the following steps to reset an alert:

1. In the **My Studies** pane, tap a study to select it.
2. Tap a study-site to select it.
3. Tap **Alerts** to view a list of alerts for a study or study-site.

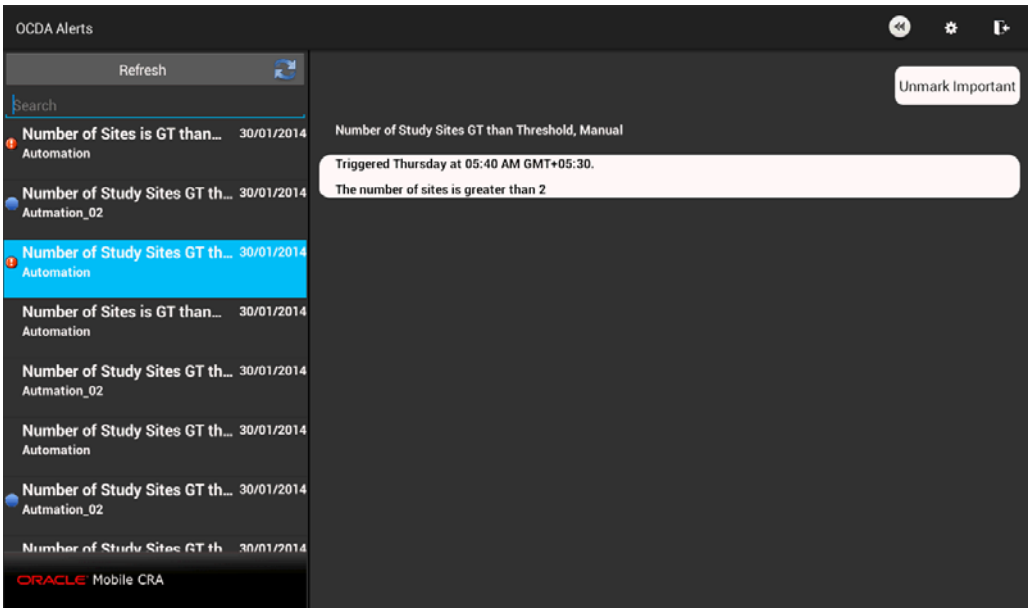
4. Tap the alert to view its details.

Figure 3–21 Alert Details



5. Tap **Reset**. A reset message is sent to the mobile server and the alert will be reset.

Figure 3–22 Alert Reset



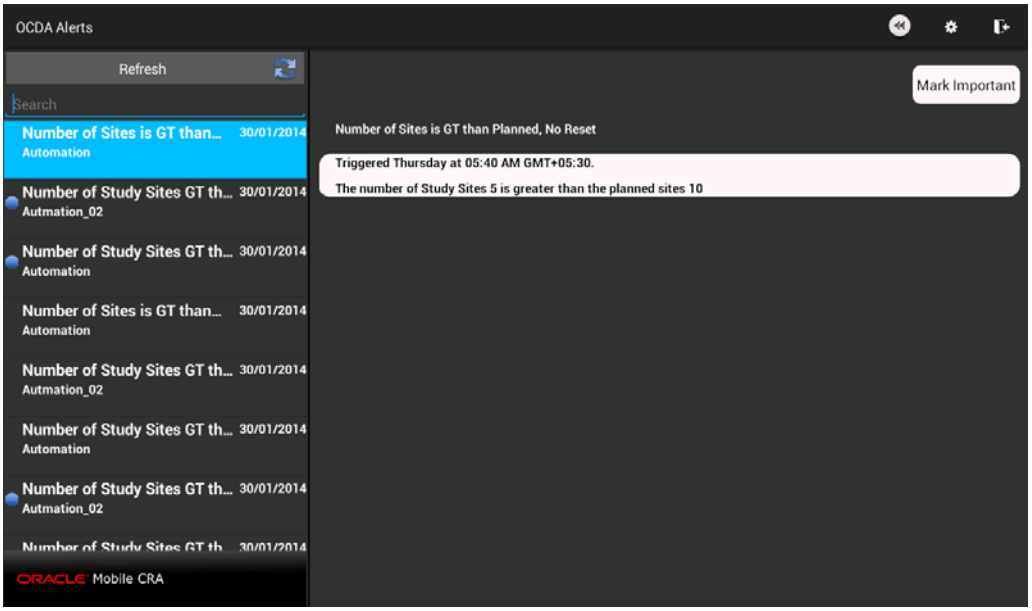
3.6 Marking an Alert as Important

You can also mark an alert as important. An important alert is indicated by a red exclamation mark icon. Perform the following steps to mark an alert as important:

1. In the **My Studies** pane, tap a study to select it.

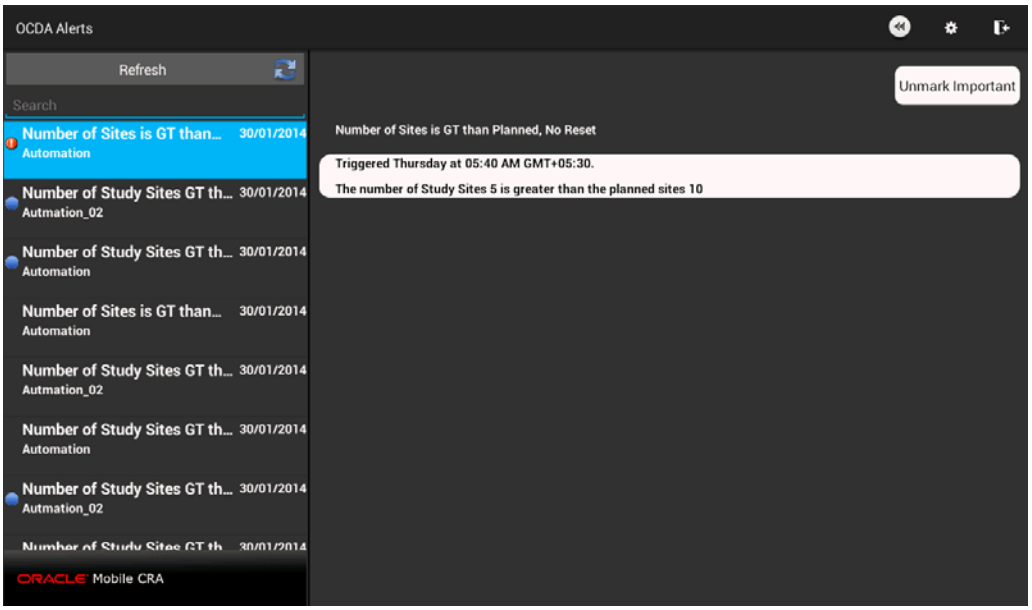
2. Tap a study-site to select it.
3. Tap **Alerts** to view a list of alerts for a study or study-site.
4. Tap an alert to view its details.

Figure 3–23 Alert Details



5. Tap **Mark Important** on the top right. The alert will be marked as important and a red exclamation mark icon appears next to it.

Figure 3–24 Alert Marked Important

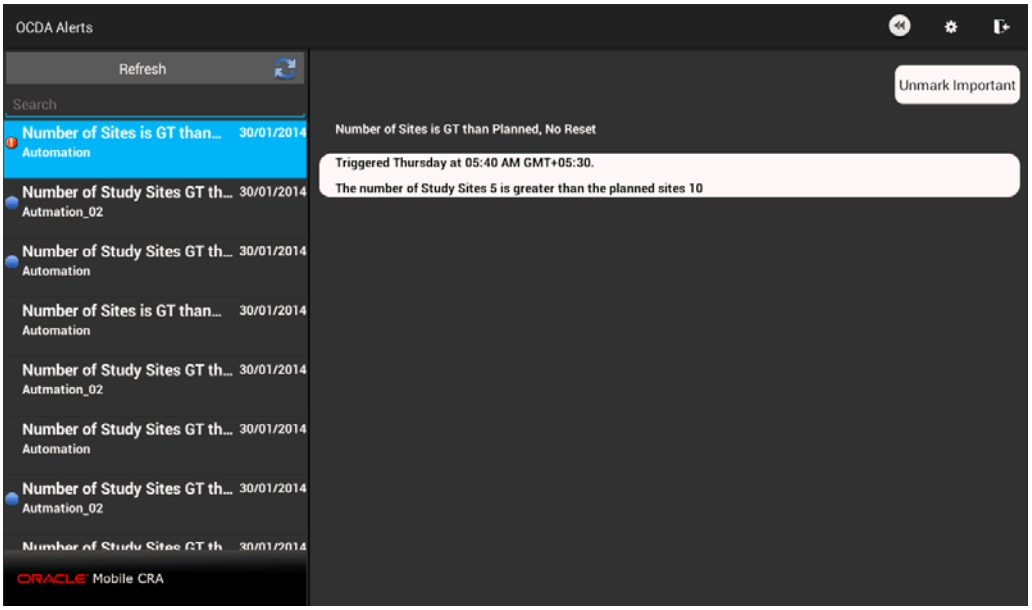


3.7 Unmarking an Alert as Important

Perform the following steps to clear the importance flag on an alert:

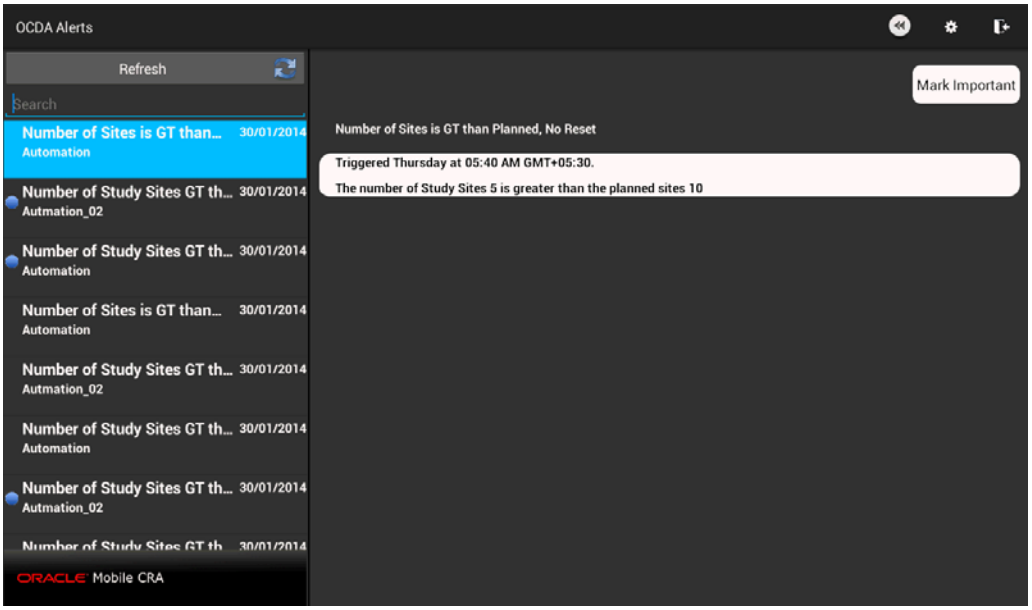
1. In the **My Studies** pane, tap a study to select it.
2. Tap a study-site to select it.
3. Tap **Alerts** to view a list of alerts for a study or study-site.
4. Tap the alert marked important to view its details. Alerts marked important will display a red exclamation mark icon.

Figure 3–25 Important Alert



5. Tap **Unmark Important**. The important flag for the alert will be cleared.

Figure 3–26 Alert Marked Not Important



3.8 Alerts While Application is Closed

When the application is closed or running in the background, the Android system sends a notification when an alert is triggered.

4

Trip Reports

This chapter describes how to work with trip reports. It contains the following topics:

- Section 4.1, "Introduction to Trip Reports"
- Section 4.2, "Trip Report Fields"
- Section 4.3, "Trip Report Status Icons"
- Section 4.4, "Creating a Trip Report"
- Section 4.5, "Adding Attendees to a Trip Report"
- Section 4.6, "Adding an Item to the Trip Report Check List"
- Section 4.7, "Modifying an Item in the Trip Report Check List"
- Section 4.8, "Creating Follow up Items in a Trip Report"
- Section 4.9, "Creating a Trip Report Summary"
- Section 4.10, "Saving Trip Report Data to Oracle Siebel Clinical Trial Management System"
- Section 4.11, "Submitting a Trip Report for Approval"
- Section 4.12, "Viewing an Approved Trip Report"

4.1 Introduction to Trip Reports

Mobile CRA will display trip reports that are on the device or in CTMS. If the trip report is not on the device, the system will automatically fetch it.

You can create a trip report visit by entering a site visit date and selecting a site visit template. You can perform the following activities in relation to trip reports:

- Access the trip reports already created in CTMS
- Create a trip report
- Add attendees to the trip report
- Complete trip report activities by changing status, adding comments, and filling out custom fields
- Depending on your implementation, add trip report activities to check list
- Alter user-created trip report activities
- Create trip report follow up items
- Review previous trips reports

- Review final trip report
- Submit trip report to work flow for approval

Prerequisites

To create a Trip Report on Mobile CRA, you must:

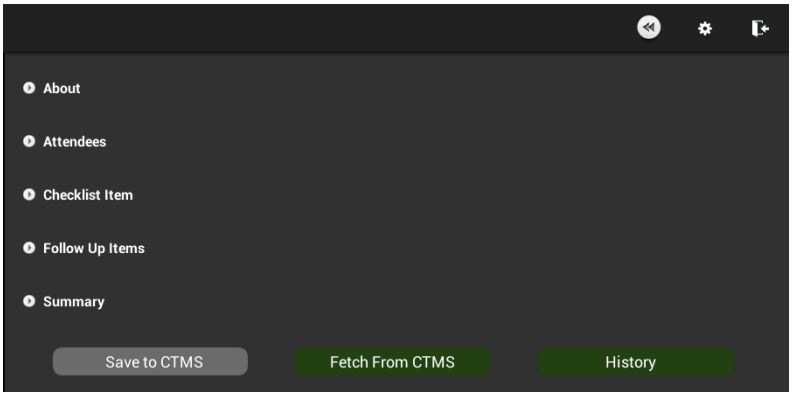
1. have access to the study and site in question.
2. create a site visit record when you schedule the site visit.

4.2 Trip Report Fields

Every organization has different views of how trip reports should be structured. Mobile CRA supports each of the above modules out of the box. Your organization's configuration may result in different elements.

The following is an example of a trip report:

Figure 4–1 Trip Report Example



A trip report consists of the following four main areas:

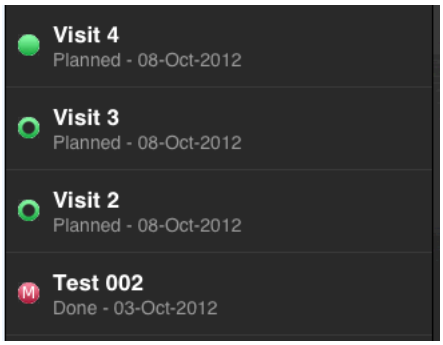
- **About** - This section contains details of the trip report like individuals working on it, the protocol it is related to, different dates associated and so on.
- **Attendees** - This section lists all the people associated with a particular site.
- **Checklist Items** - This section displays the list of tasks to be accomplished for a visit.
- **Follow Up Items** - This section displays the subsequent tasks to be performed before a visit can be completed.
- **Summary** - This section displays comments, summary of the site visit, or additional comments that is applicable for the entire trip report

For more information on the various fields in each section, refer to the *Oracle Siebel Clinical Trial Management System User's Guide*.

4.3 Trip Report Status Icons

Following are the possible status icons for a trip report:

Figure 4–2 Trip Report Icons



- The green filled circle indicates the trip report is on the device.
- The green open circle indicates that the trip report is not on the mobile device.
- The red filled circle with an **M** indicates that the trip report has been modified and not saved to the device.

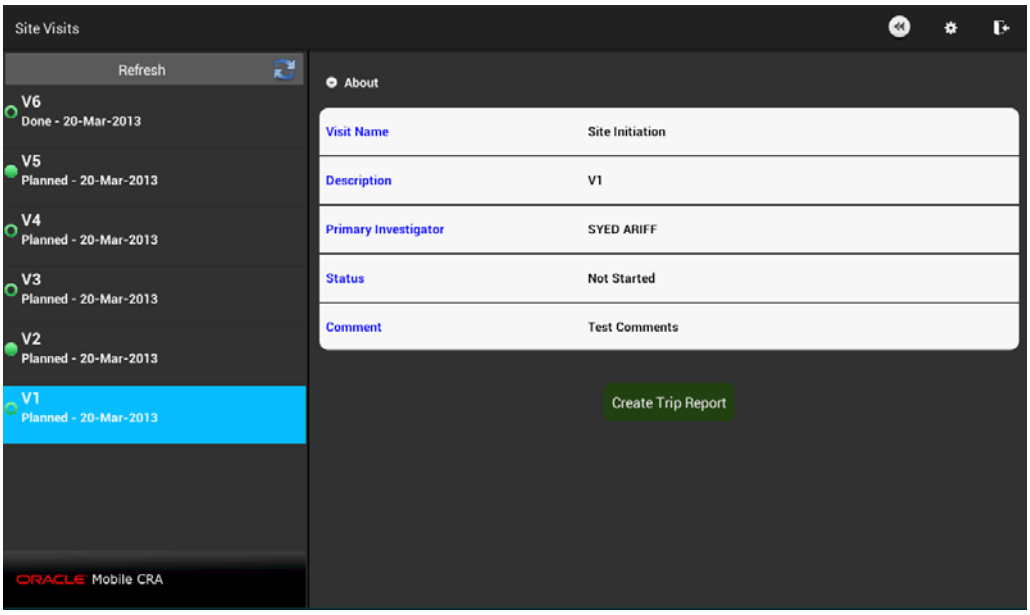
4.4 Creating a Trip Report

If the trip report has not been created for a site visit, the trip report creation screen is displayed. If the trip report is on the device, you can use it immediately, in on-line or disconnected mode.

Perform the following steps to create a trip report:

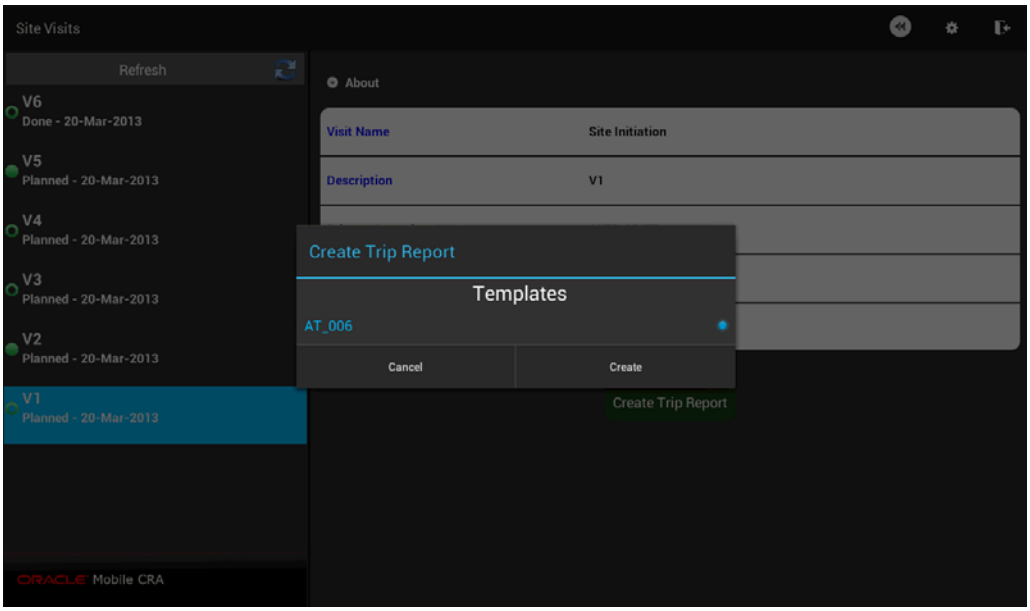
1. In the **My Studies** pane, tap a study to view all the sites under it.
2. Tap a site to view all its details.
3. Tap **Trip Reports**. The site visits displayed.
4. Tap a visit to view its details.

Figure 4–3 Visit Task List



5. Tap **Create Trip Report**. A list of trip report templates is displayed.

Figure 4–4 Trip Report Templates

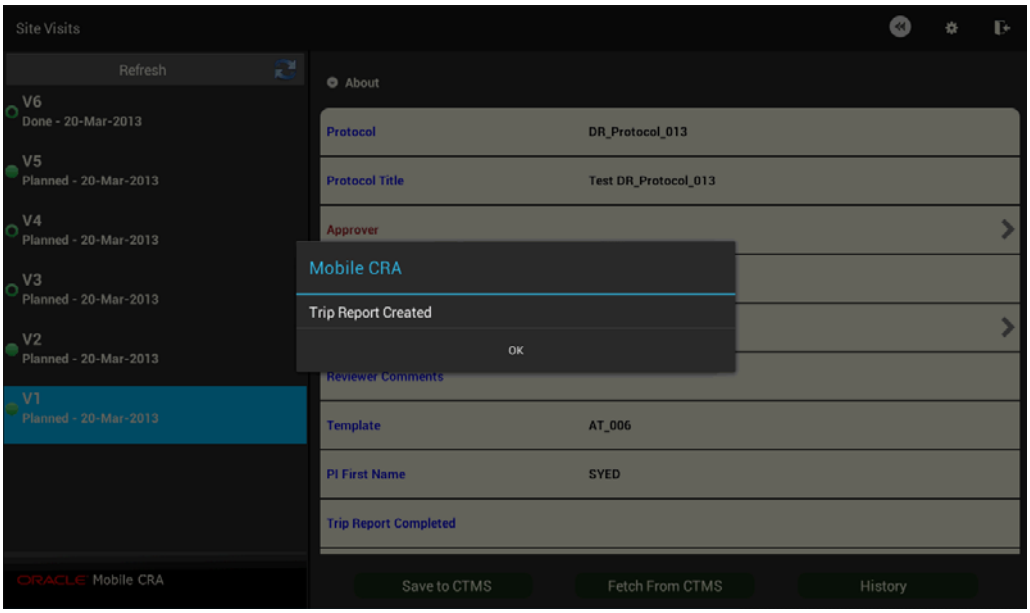


6. Select a template and tap **Create**.

> **Note:** To exit the trip report creation process, tap **Cancel** on the top right.

7. A trip report is created and a confirmation screen is displayed.

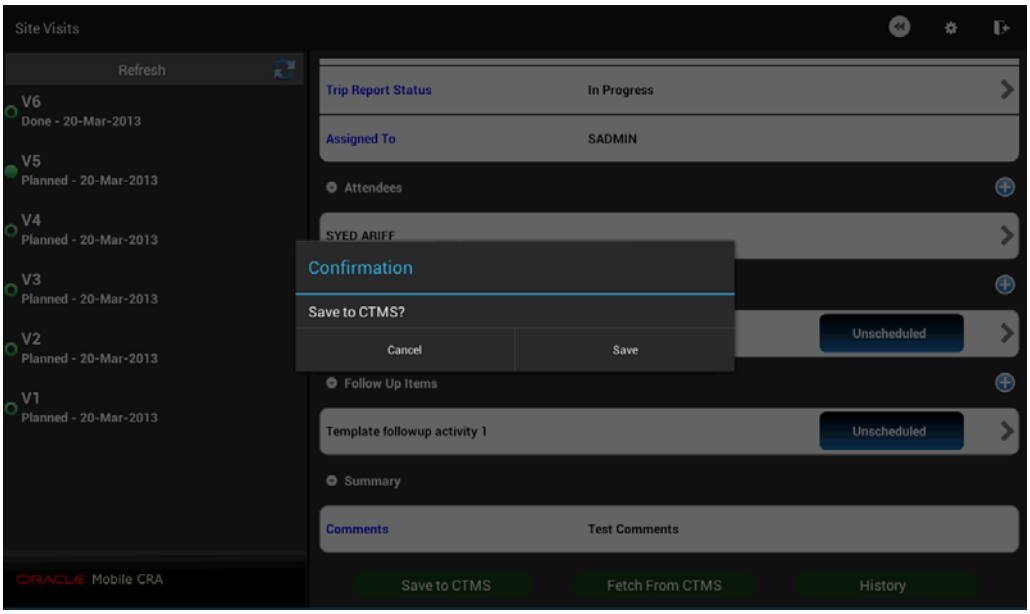
Figure 4–5 Confirmation Screen



8. Click **OK** to view the trip report.

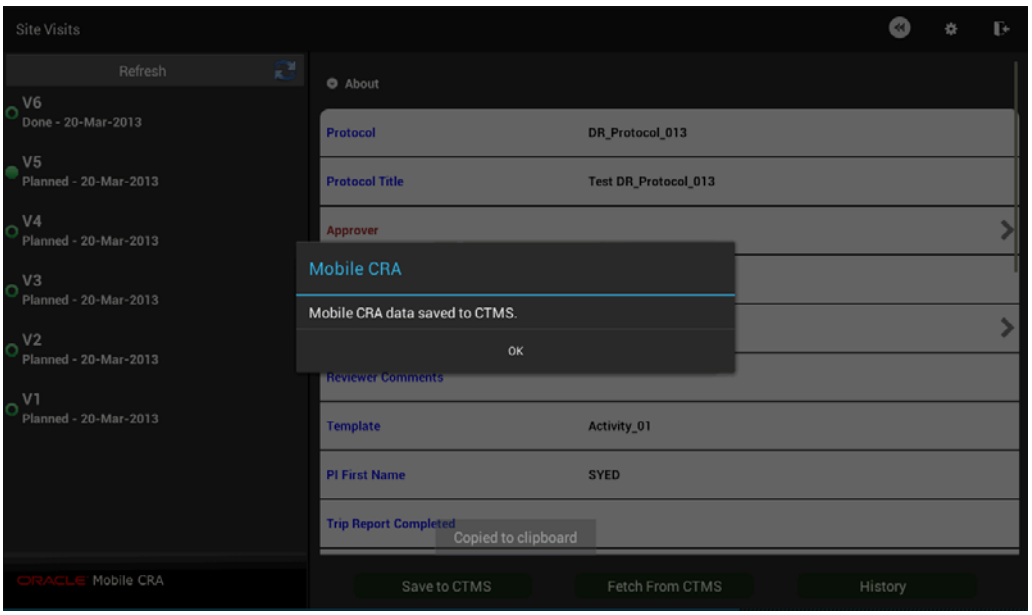
9. Edit the appropriate trip report fields and tap **Save to CTMS**.

Figure 4–6 Saving the Trip Report



10. Tap **Save**. Your report will be saved to CTMS and the status will change to completed. The following confirmation will be displayed:

Figure 4–7 Trip Report Saved to CTMS



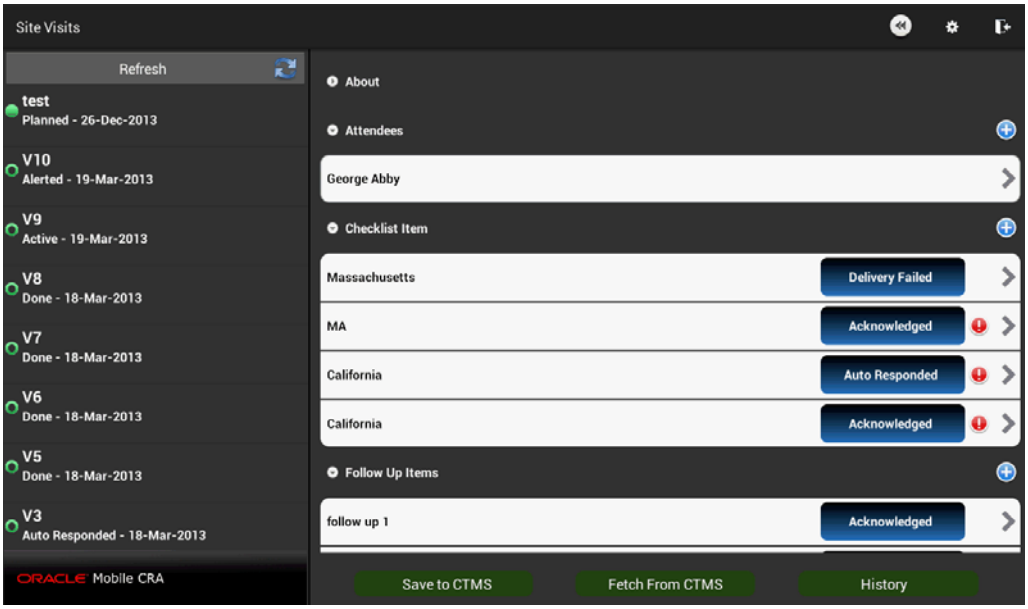
4.5 Adding Attendees to a Trip Report

You can add attendees to the trip report by selecting a contact from your Mobile CRA contact list. Perform the following steps to add attendees to your trip report:

1. In the **My Studies** pane, select a study and study-site.

2. Tap **Trip Reports**.
3. Select a trip report.

Figure 4–8 Trip Report

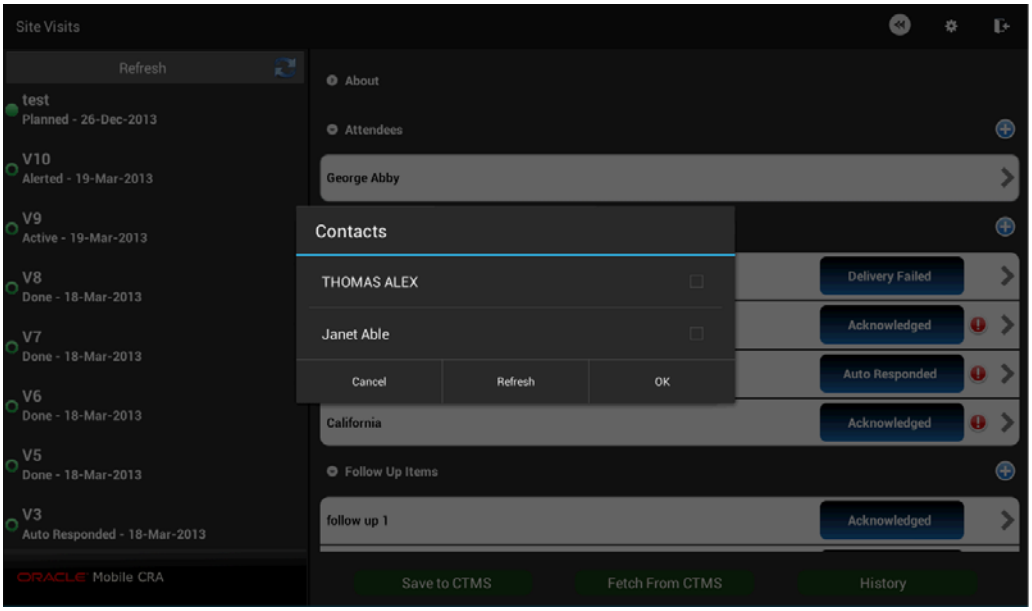


4. Open the attendee list for that trip report. Tap the following icon to add attendees.

Figure 4–9 Add Icon

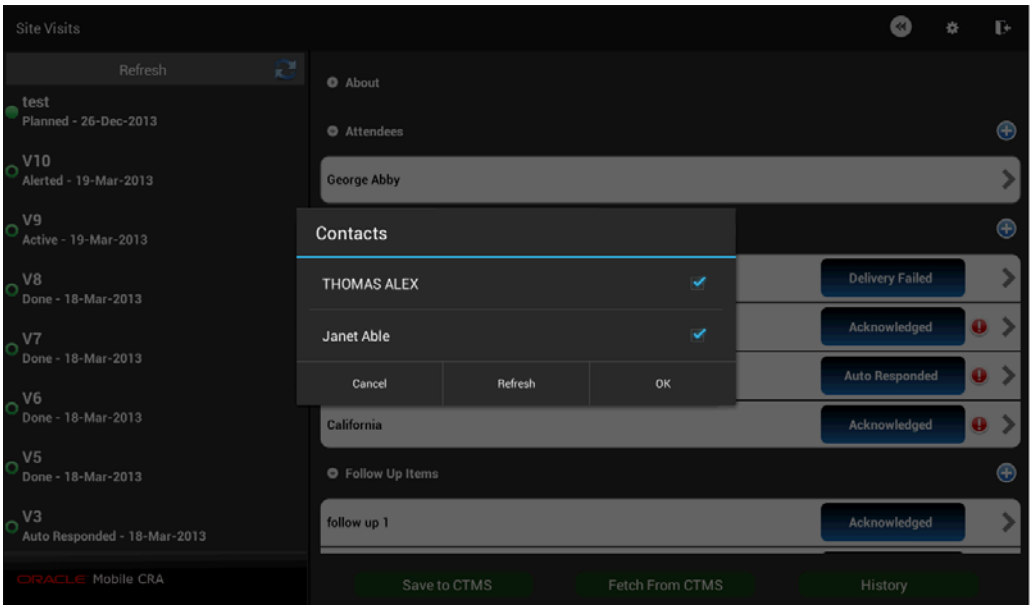
5. Your Mobile CRA contacts associated with the study-site will be displayed.

Figure 4–10 Mobile CRA Contacts



6. Tap the contact you want to add to the attendee list.

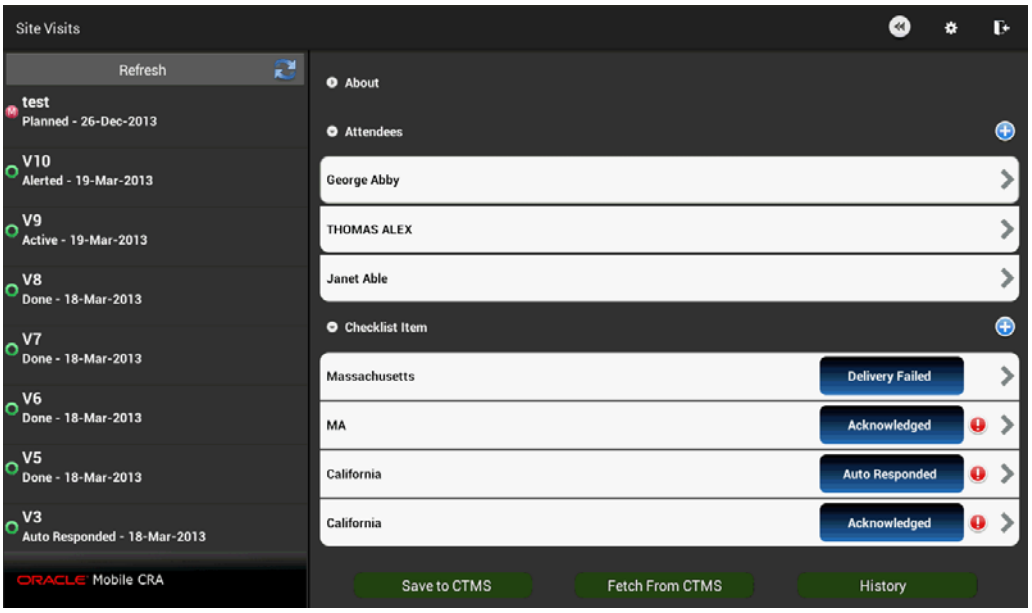
Figure 4–11 Select Contact



Note: You can add multiple contacts by selecting them at once.

7. Tap **Done** on the top left. The contact will be added.

Figure 4–12 Attendee Added to Trip Report

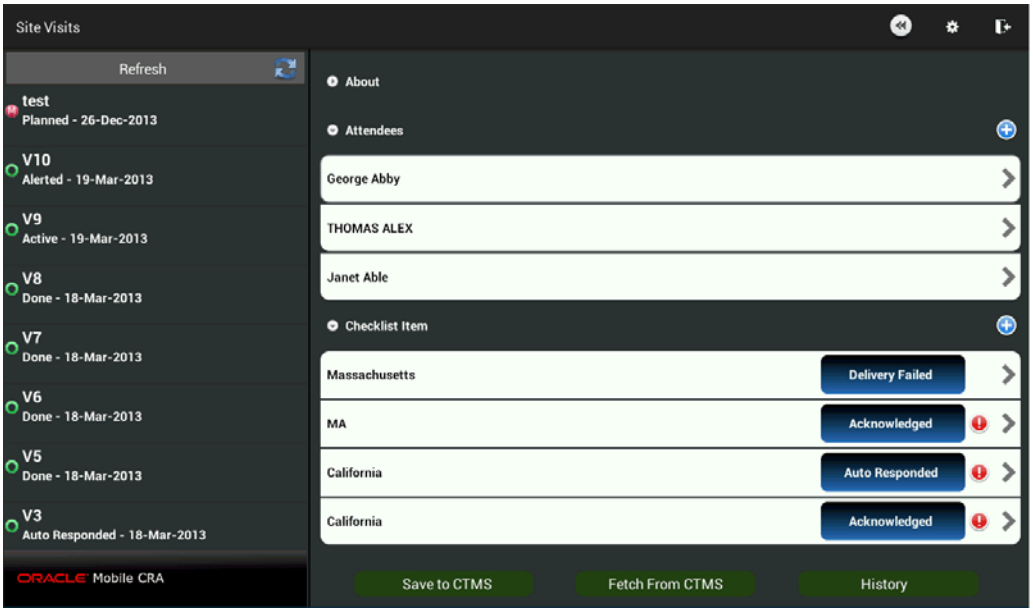


4.6 Adding an Item to the Trip Report Check List

Perform the following steps to add an item to the trip report check list:

1. In the **My Studies** pane, select a study and study-site.
2. Tap **Trip Reports**.
3. Select a trip report.

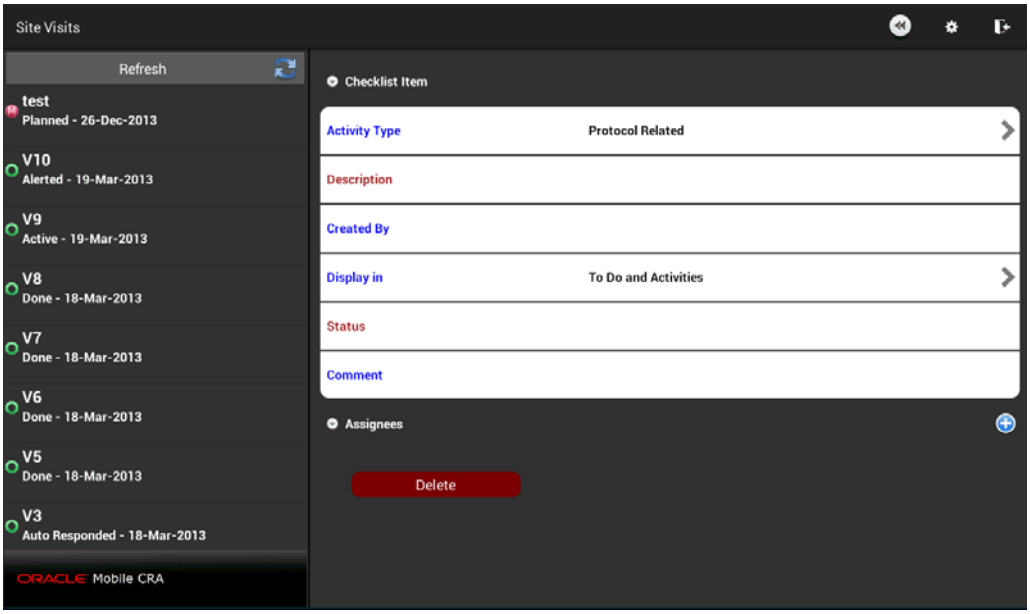
Figure 4–13 Trip Report



4. Tap the icon below to add a checklist item.

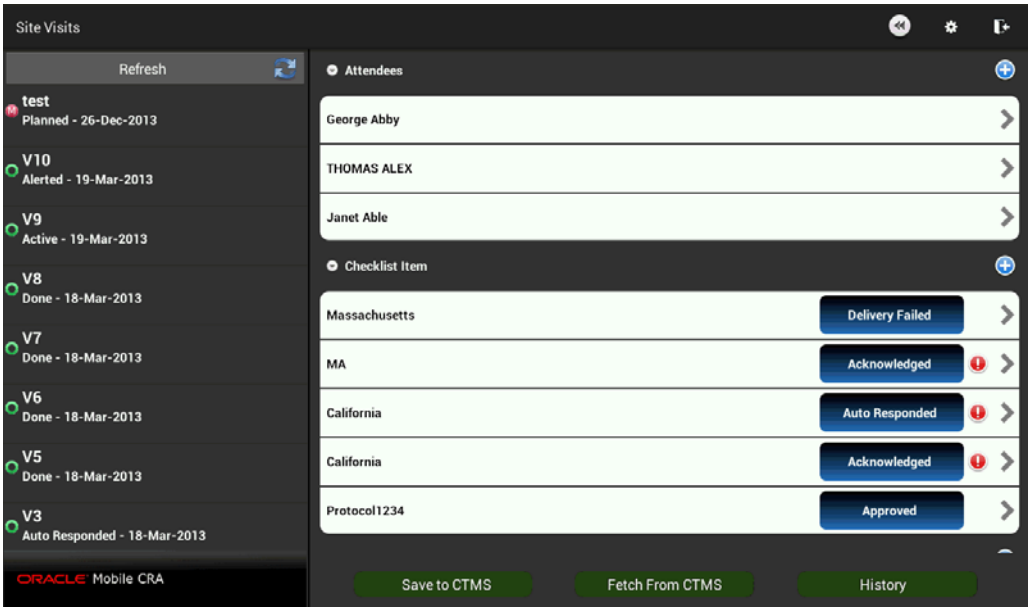
Figure 4–14 Add Icon

Figure 4–15 New Checklist Item



5. Edit the required fields.
6. Navigate back to the trip report. The checklist item will be added.

Figure 4–16 Checklist Item Added



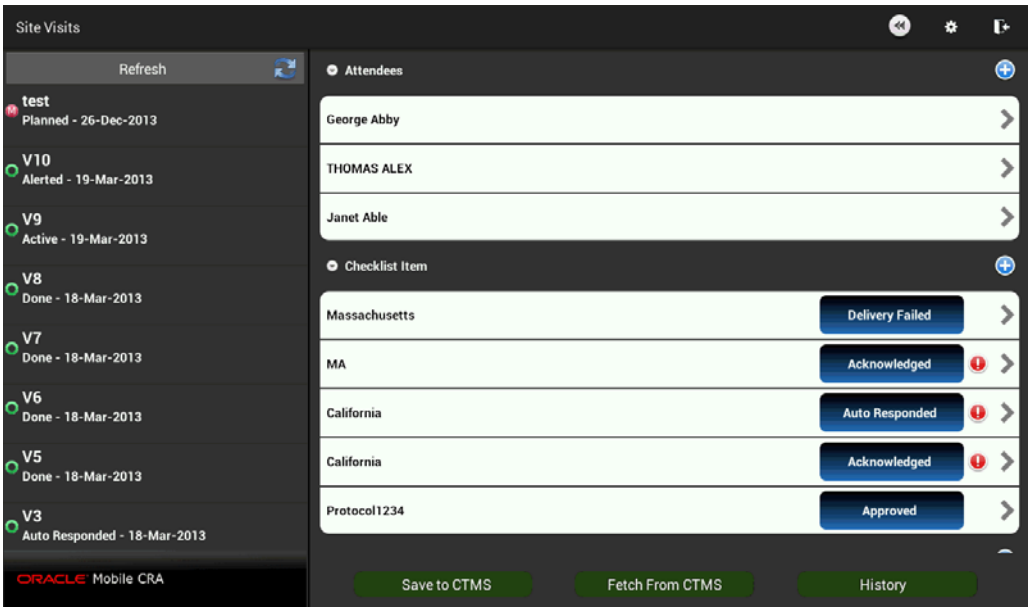
4.7 Modifying an Item in the Trip Report Check List

Perform the following steps to add an item to the trip report check list:

> **Note:** You cannot modify an item that originated in CTMS. Doing so will display an error message.

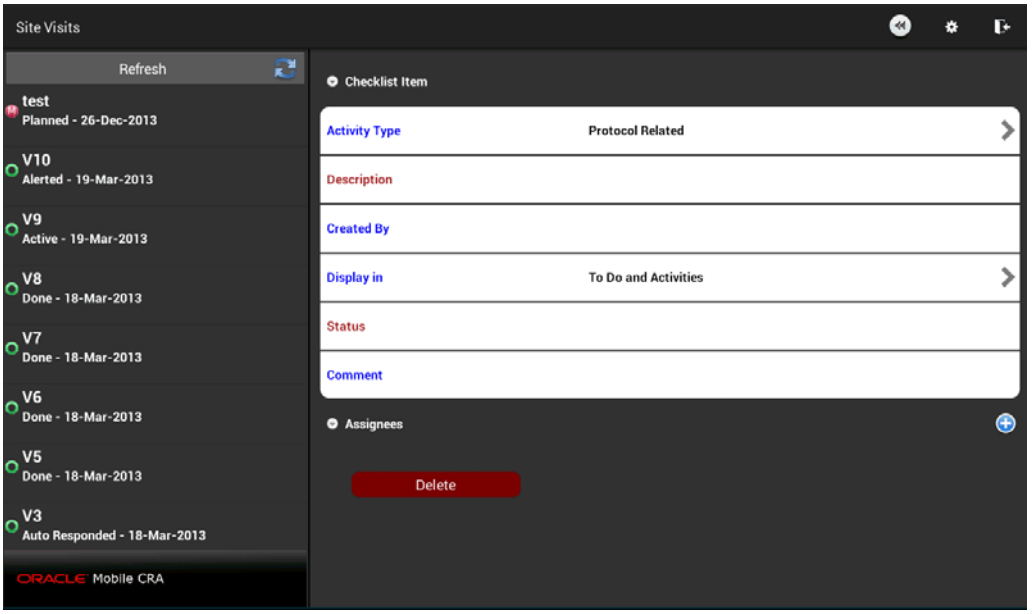
1. In the **My Studies** pane, select a study and study-site.
2. Tap **Trip Reports**.
3. Select a trip report.

Figure 4–17 Trip Report



4. Tap the checklist item you want to modify.

Figure 4–18 Checklist Item



5. You can modify the type, display location, comments and status. You can also add an assignee. Make the modifications you require.

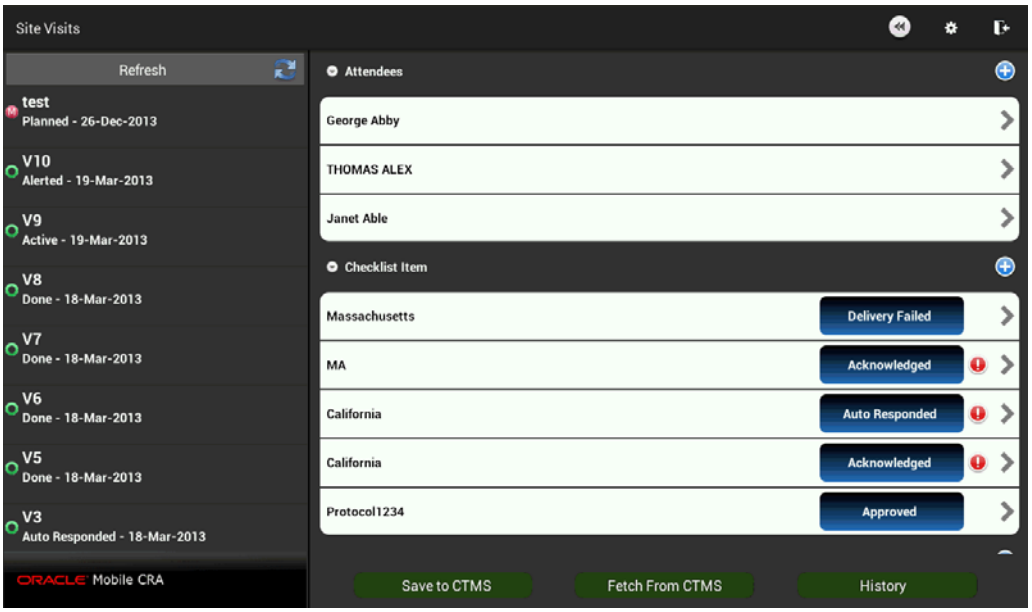
> **Note:** You can also change the **Status** of the checklist item at the top level.

4.8 Creating Follow up Items in a Trip Report

You can edit a follow up item for completeness until it is submitted. You can add a due date to the item and add it to the Task Calendar. Perform the following steps to add an item to the trip report check list:

1. In the **My Studies** pane, select a study and study-site.
2. Tap **Trip Reports**.
3. Select a trip report.

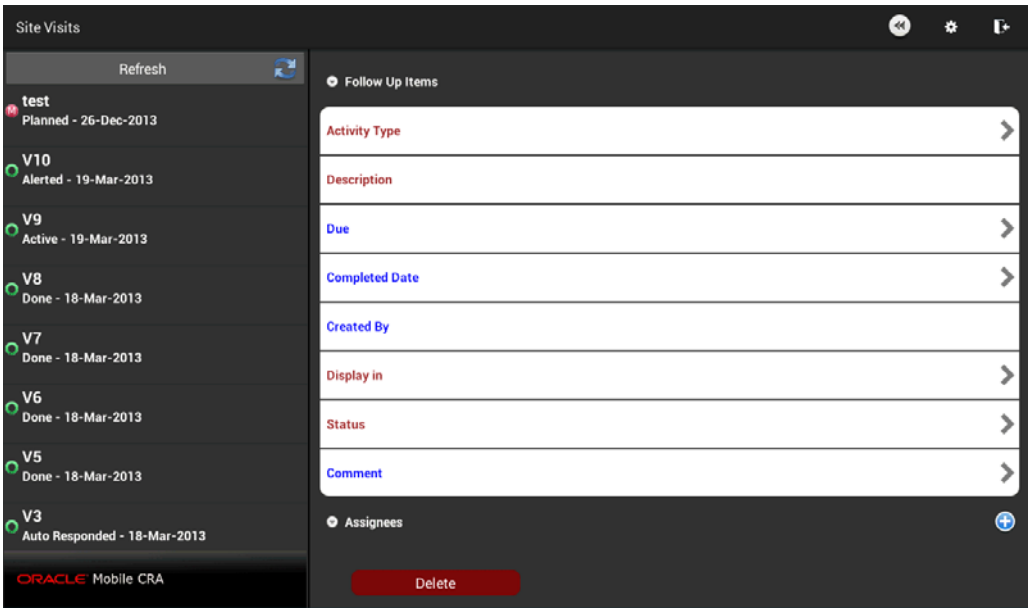
Figure 4–19 Trip Report



4. Tap the icon below to add a follow up item.

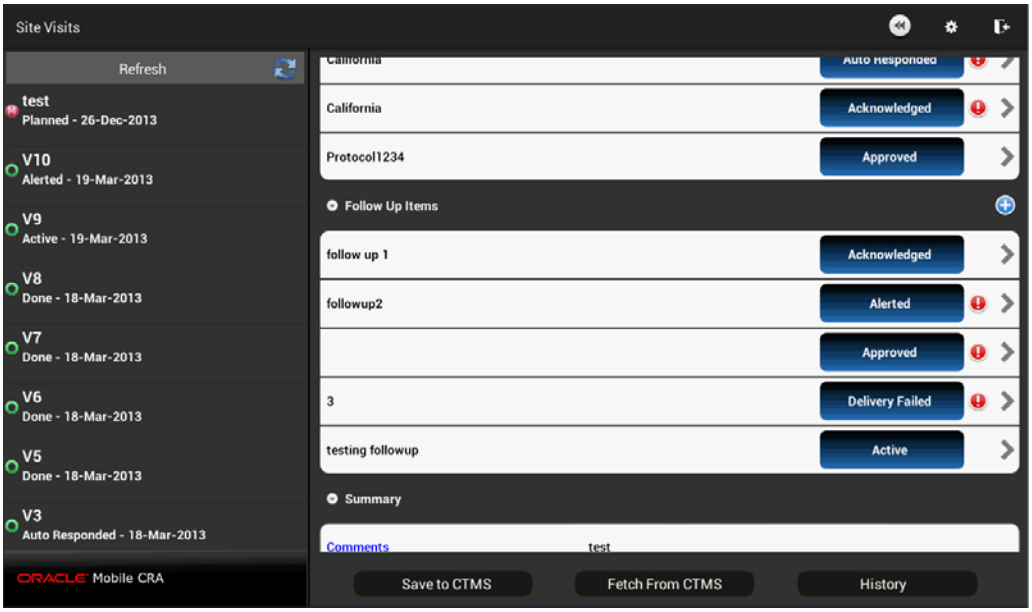
Figure 4–20 Add Icon

Figure 4–21 New Follow Up Item



5. Navigate back to the trip report, the follow up item will be added to it.

Figure 4–22 Follow up Item Added

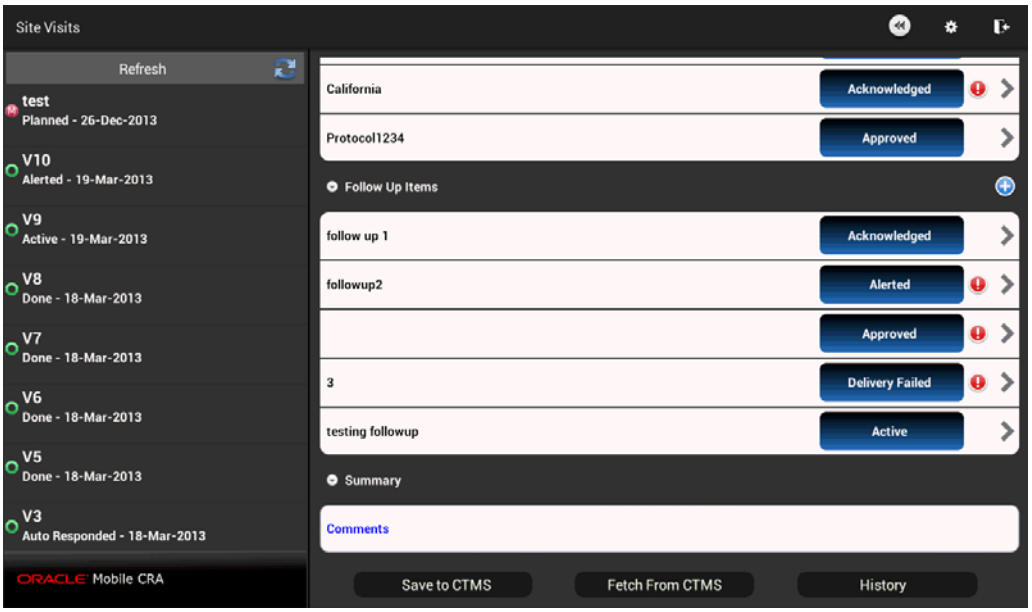


4.9 Creating a Trip Report Summary

Perform the following steps to add an item to the trip report check list:

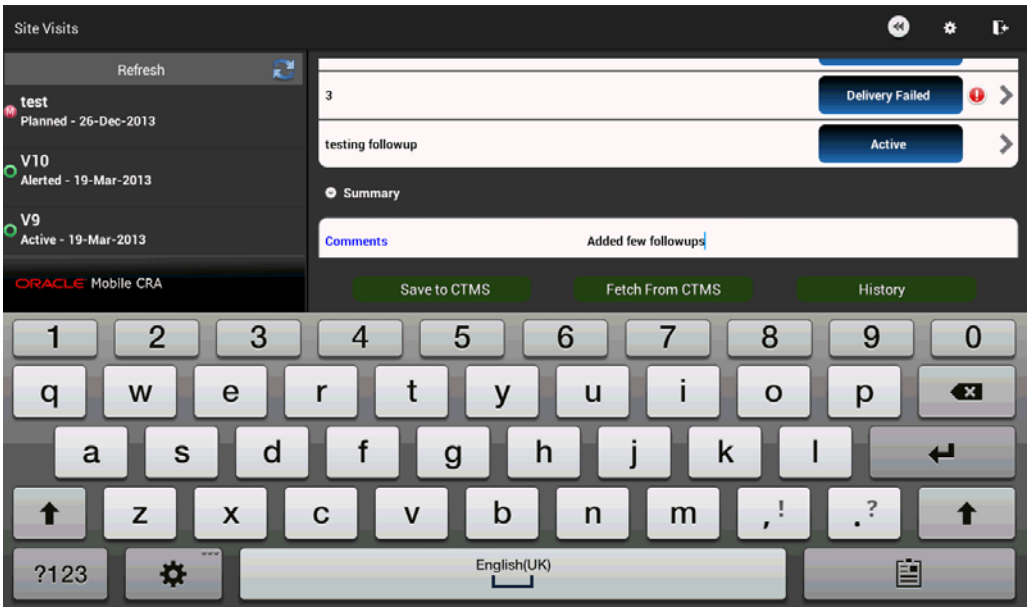
1. In the **My Studies** pane, select a study and study-site.
2. Tap **Trip Reports**.
3. Select a trip report.

Figure 4–23 Trip Report



4. Tap the field below **Summary** to add comments.

Figure 4–24 Trip report Summary



5. Type your comments. They will be added to the trip report. To save your changes to CTMS, refer to Section 4.10.

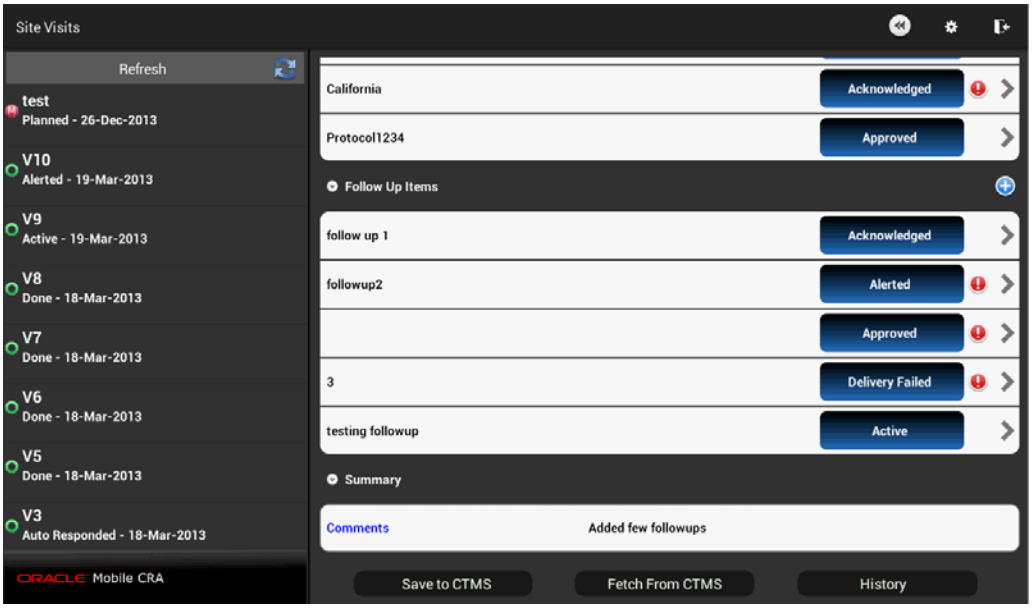
4.10 Saving Trip Report Data to Oracle Siebel Clinical Trial Management System

Perform the following steps to add an item to the trip report check list:

1. Tap a study to view all the sites under it.

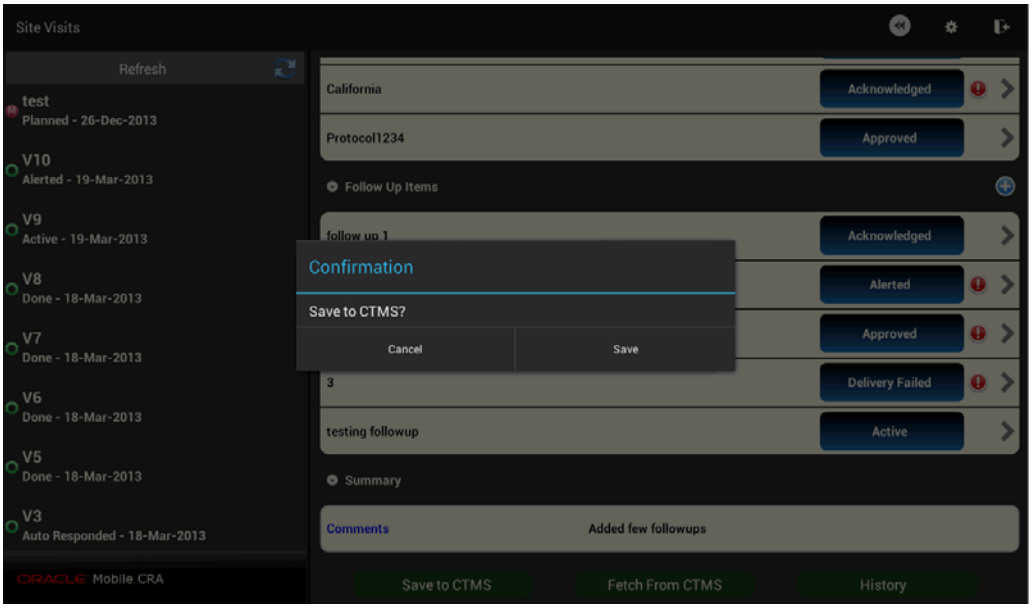
2. Tap a site to view all its details.
3. Tap **Trip Reports**. A list of visits is displayed.
4. Select a trip report for which you want to save data. Visits containing unsaved data are displayed with a red M icon next to them.

Figure 4–25 Trip Report



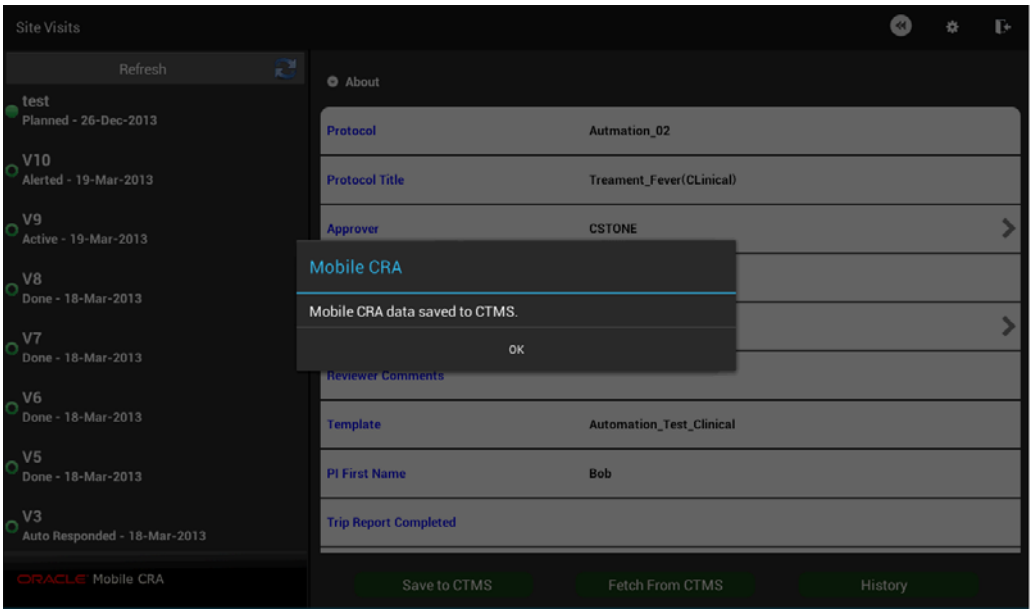
5. Tap **Save to CTMS**.

Figure 4–26 Save to CTMS Prompt



6. Tap **Save**. Your changes will be saved to CTMS and the red M icon is cleared from the visit list.

Figure 4–27 Trip Report Saved to CTMS

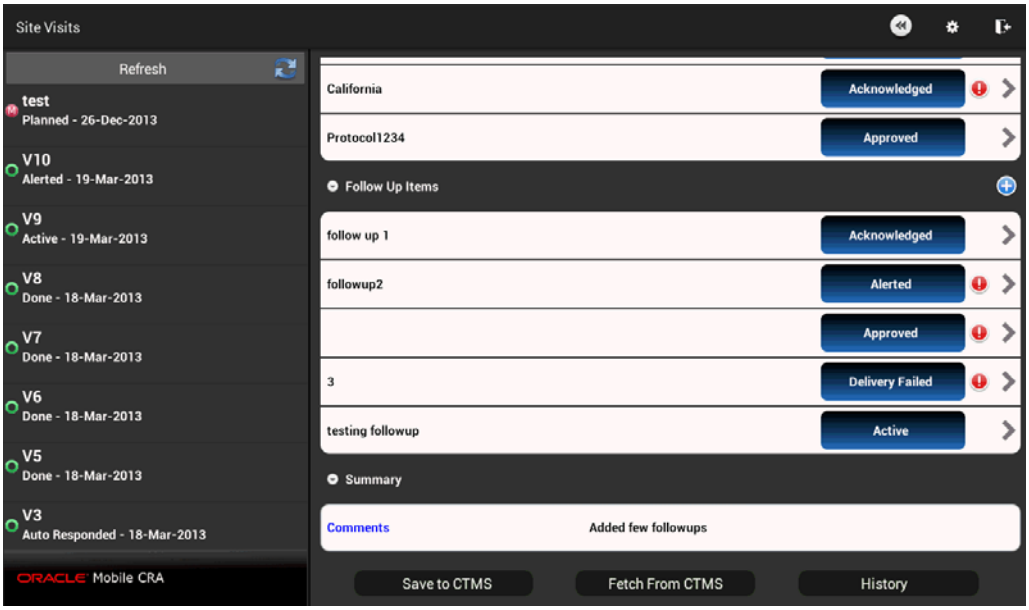


Fetching Data from Siebel Clinical Trial Management System

You can reset your trip report data by downloading data available on CTMS. Perform the follow steps to reset your trip report data.

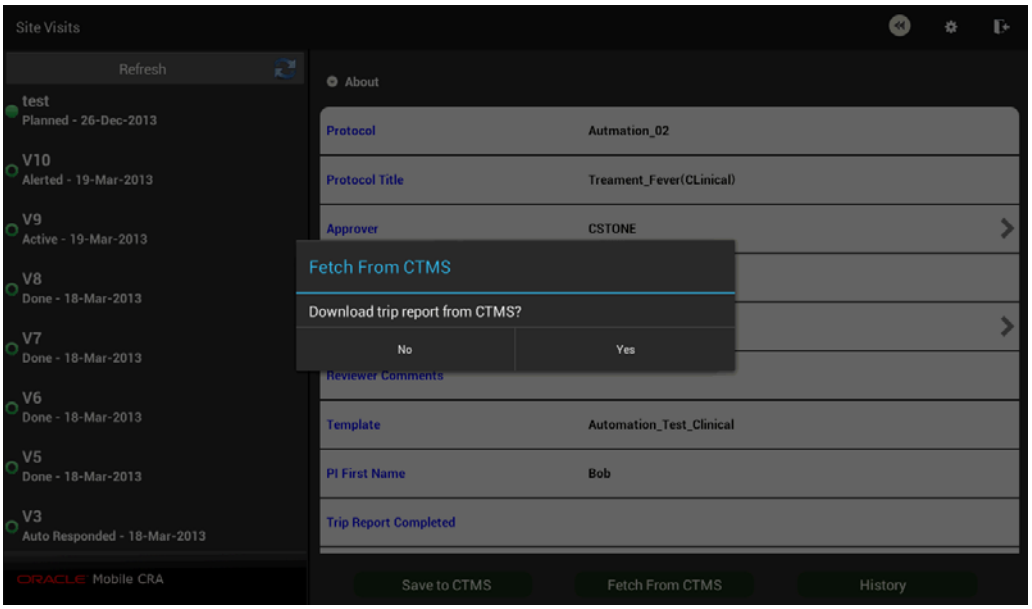
1. Tap a study to view all the sites under it.
2. Tap a site to view all its details.
3. Tap **Trip Reports**. A list of visits is displayed.
4. Select the trip report for which you want to reset data.

Figure 4–28 Trip Report



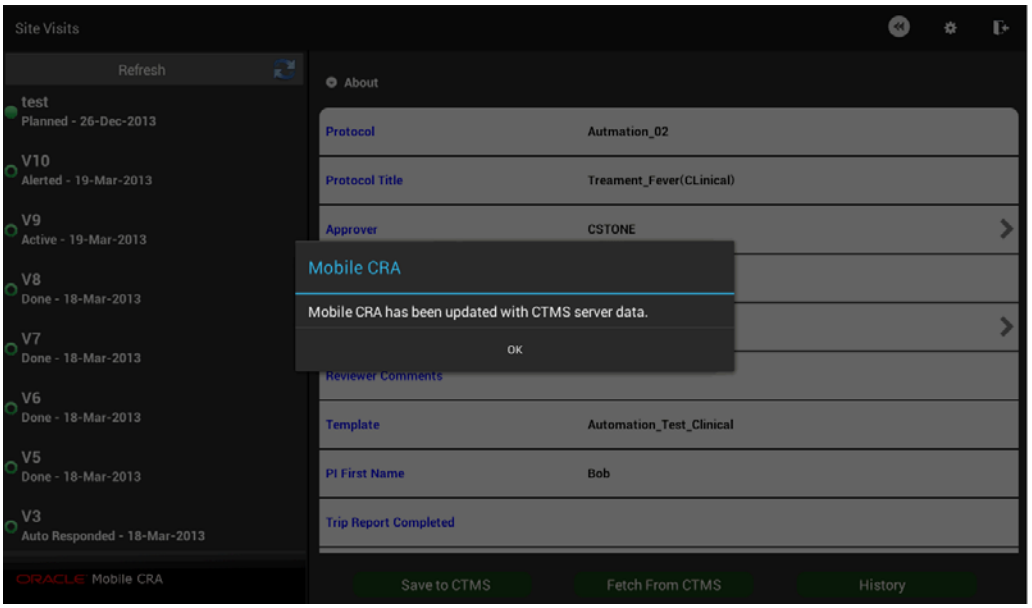
5. Tap **Fetch from CTMS**.

Figure 4–29 Fetch from CTMS Prompt



6. Tap **Yes**.

Figure 4–30 Trip Report Data Fetched from CTMS



4.11 Submitting a Trip Report for Approval

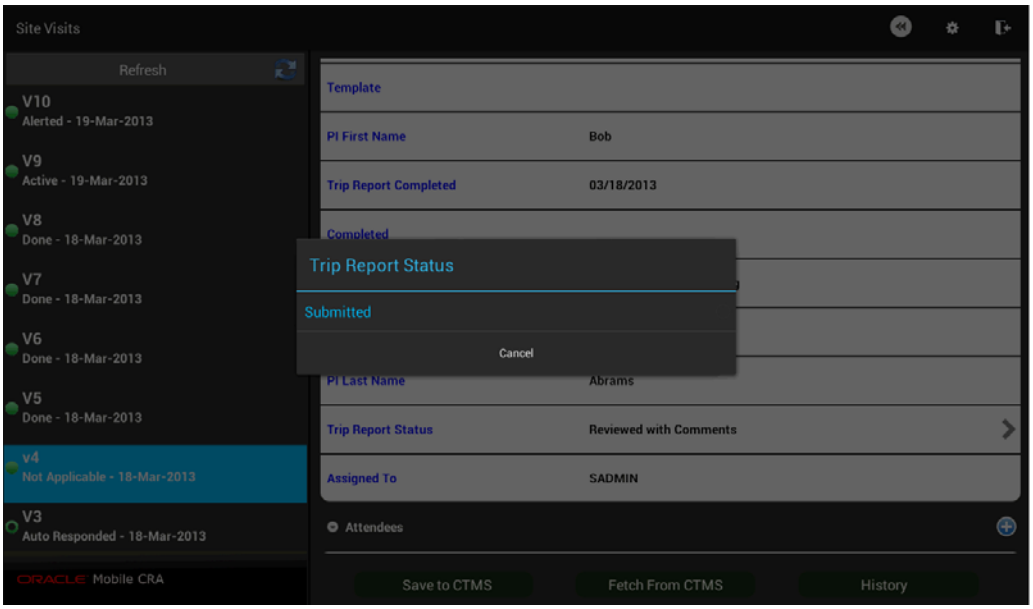
The work flow process in CTMS can be configured in Mobile CRA. For more information on your status flows, consult with your configuration teams. CTMS lets you select the reviewer and approvers for the Trip Report. Currently, this activity must be done in CTMS, and the result fetched to Mobile CRA, in order to submit from Mobile CRA to the work flow.

Perform the following steps to submit your trip report:

Note: If multiple reports are submitted for the same visit, CTMS will only display the latest report.

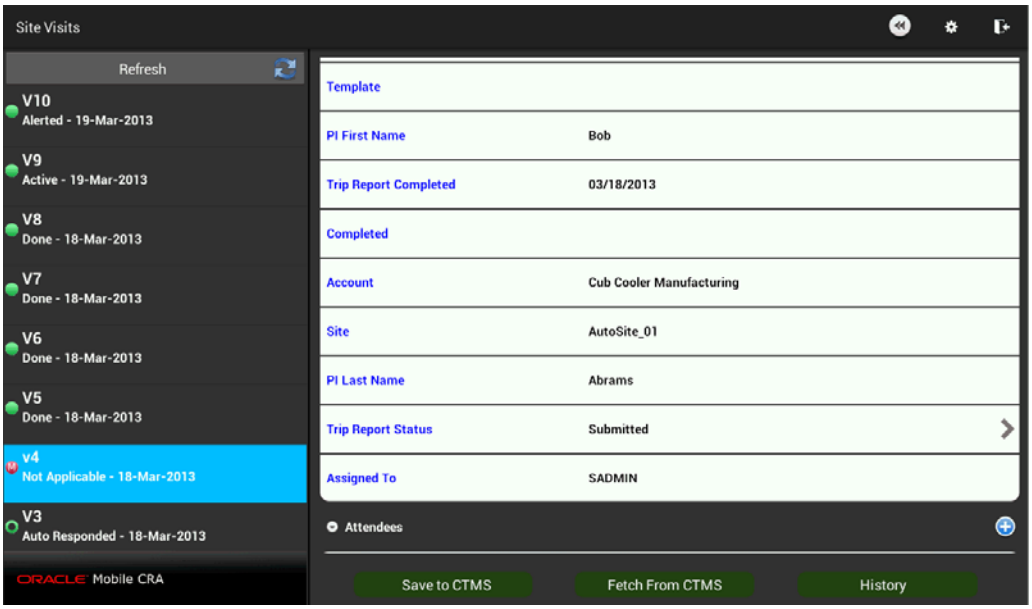
1. In the **My Studies** pane, tap a study to view all the sites under it.
2. Tap a site to view all its details.
3. Tap **Trip Reports**. The site visits displayed.
4. Select the visit whose report you want to submit. The trip report saved on CTMS is displayed.
5. in the About section, tap **Trip Report Status**. The following options are displayed:

Figure 4–31 Trip Report Status



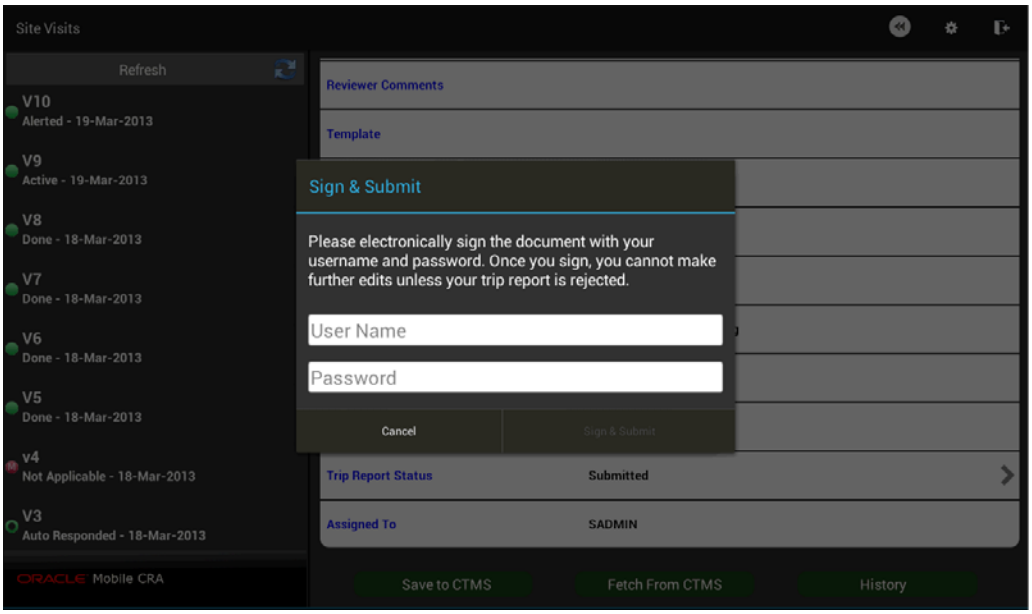
6. Tap **Submitted**. The trip report status will be changed to submitted.

Figure 4–32 Trip Report Status Changed



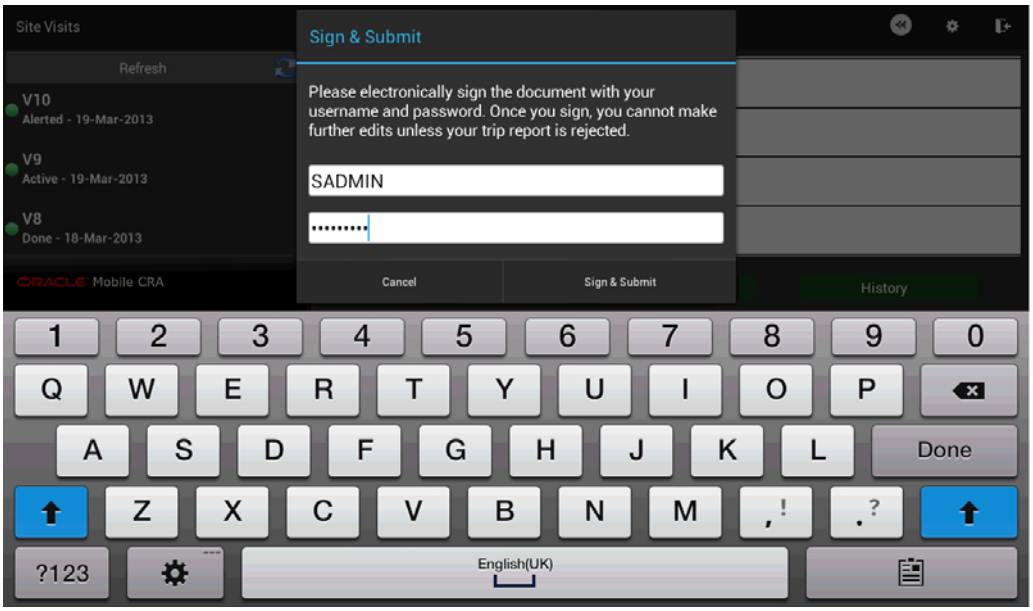
7. Tap **Save to CTMS**. The **Sign and Submit** screen is displayed.

Figure 4–33 Sign and Submit



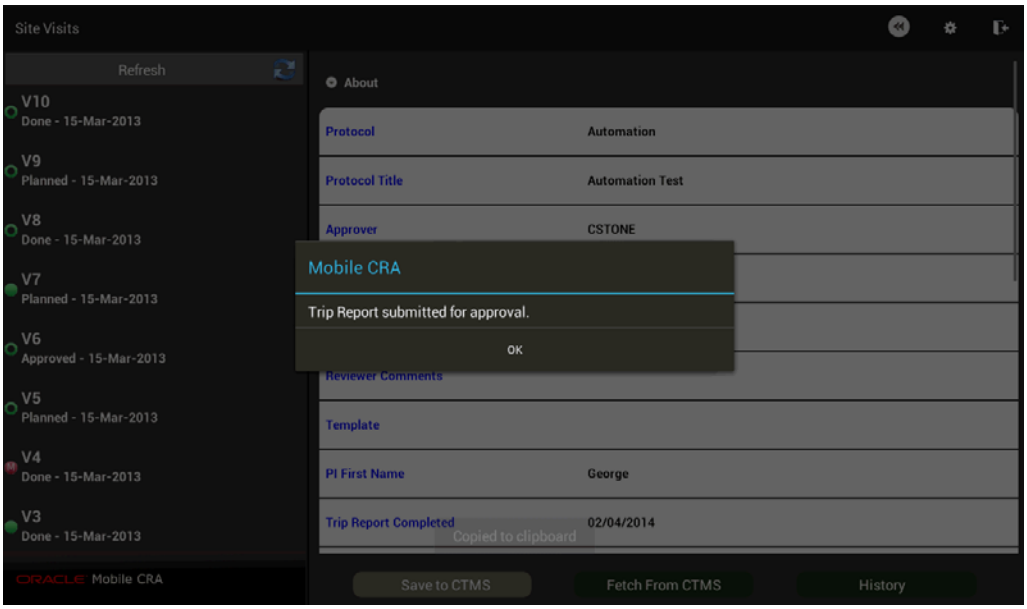
8. Enter your user name and password and tap **Sign & Submit**.

Figure 4–34 Submit Trip Report



9. Your trip report will be submitted for approval and you will receive a confirmation.

Figure 4–35 Submitted for Approval



4.12 Viewing an Approved Trip Report

Perform the following steps to view an approved trip report:

1. Tap a study to view all the sites under it.
2. Tap a site to view all its details.
3. Tap **Trip Reports**. A list of visits is displayed.

4. Select an approved trip report.
5. You can review all findings in the trip report. However, you may not modify it.

5 Contacts

This section describes how to work with contacts on Mobile CRA. It contains the following topics:

- Section 5.1, "Contacts Integration"
- Section 5.2, "Integrating Contacts with Siebel Clinical Trial Management System"

5.1 Contacts Integration

Mobile CRA lets you can access a lot of pertinent CTMS information on your Tablet or Phablet, including the contact details of study-sites. The following is what you can do using the application:

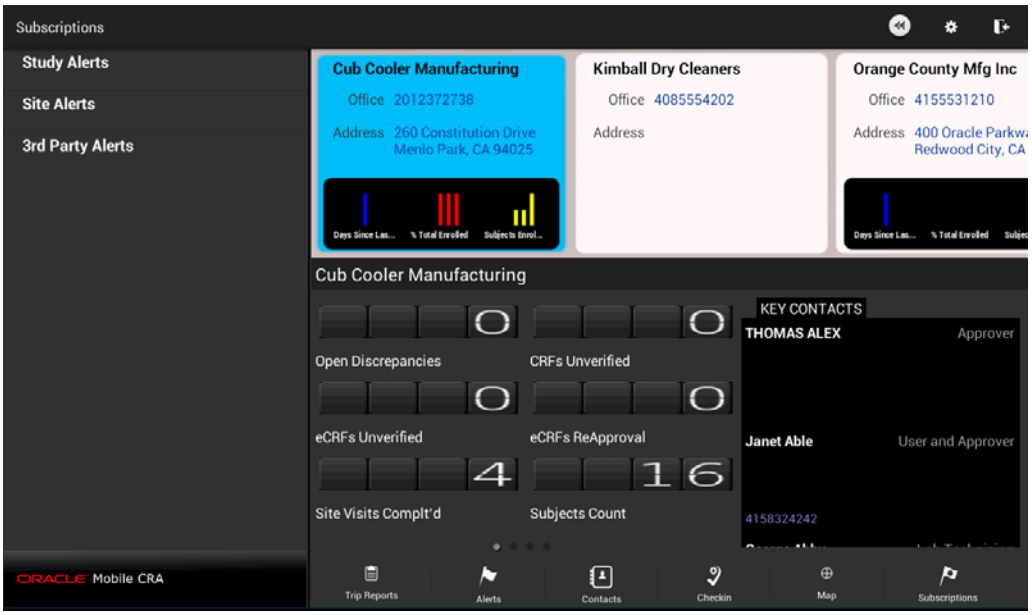
- Synchronize contacts from CTMS — You can view contact details of sites assigned to you.
- Export contacts to native device — Mobile CRA displays the contacts from CTMS and you can export the contacts to your devices. You can later edit them or make calls.
- Synchronize contacts from Mobile CRA to Tablet or Phablet — Contacts on the application can be synchronized with the contacts that are already available on your Tablet or Phablet.
- Synchronize in offline mode — Mobile CRA lets you synchronize contacts from the application to the device without an active internet connection. However, synchronizing from the CTMS to Mobile CRA requires an active internet connection.

5.2 Integrating Contacts with Siebel Clinical Trial Management System

Perform the following steps to integrate contacts with CTMS:

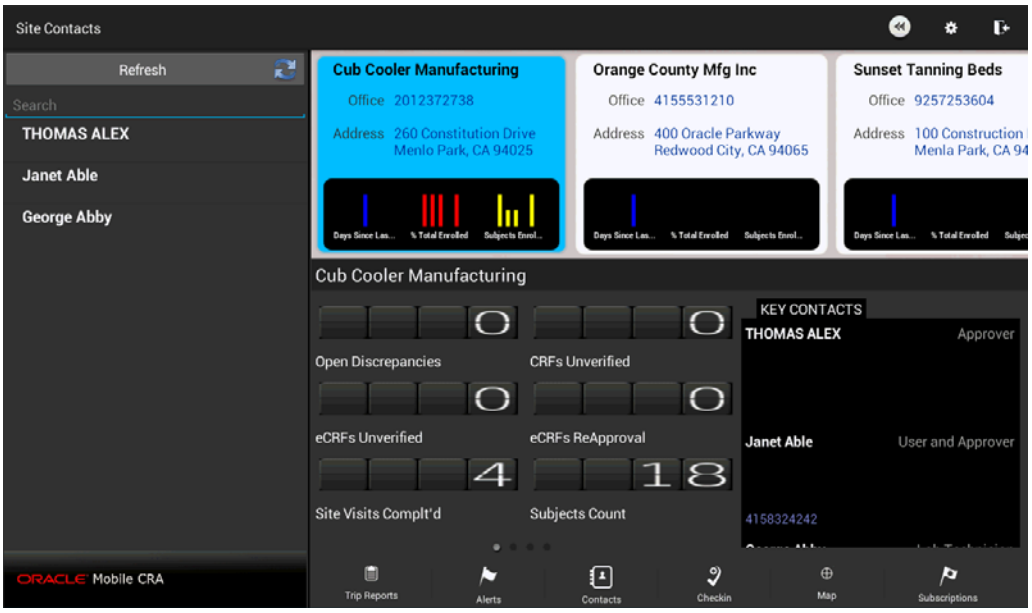
1. Tap a study to view all the sites under it.
2. Tap a site to view all its details.

Figure 5–1 Sites for a Study



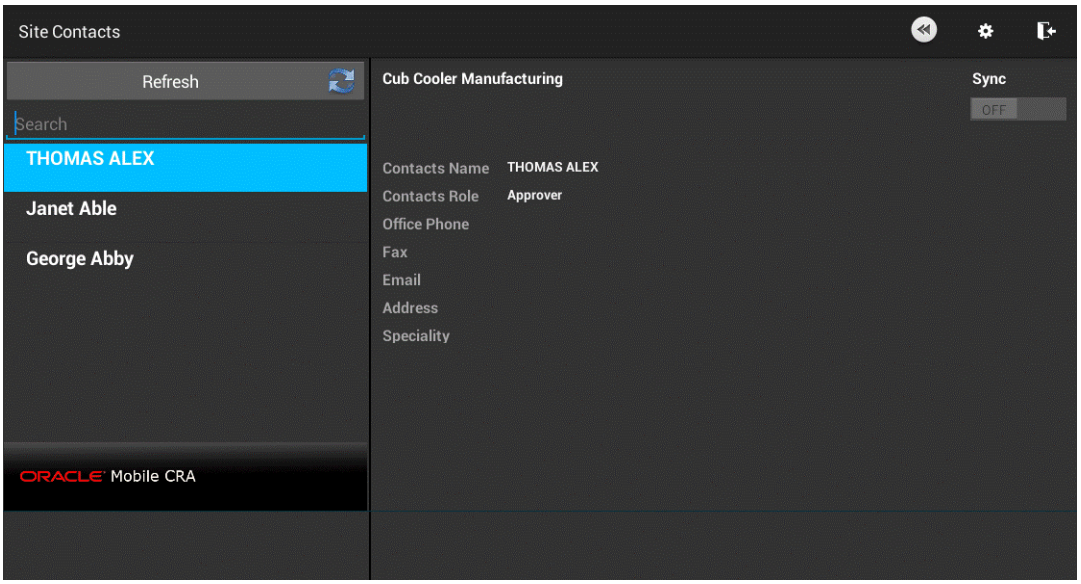
3. Tap **Contacts** at the bottom of the screen. All the site contacts will be displayed on the left.

Figure 5–2 Site Contacts



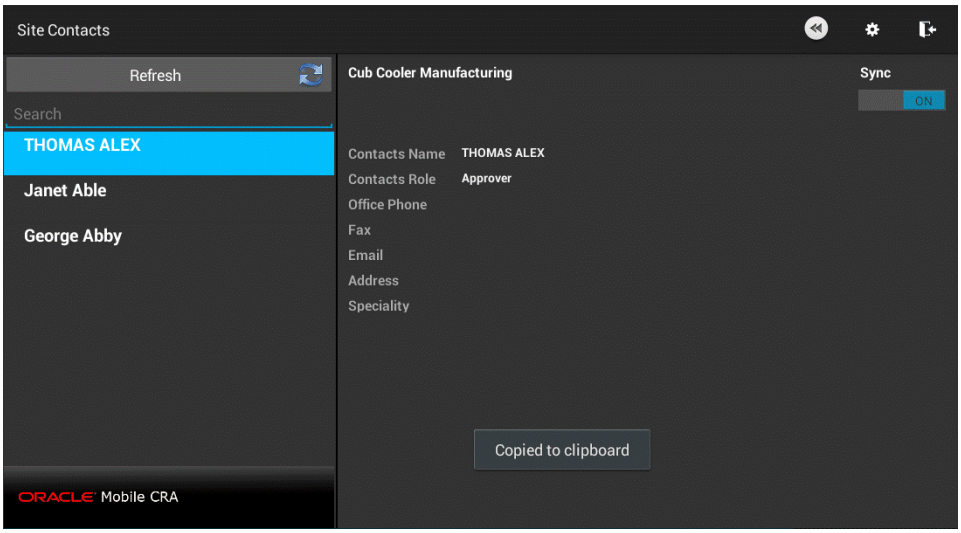
4. Tap a contact to view the details.

Figure 5–3 Contact Details



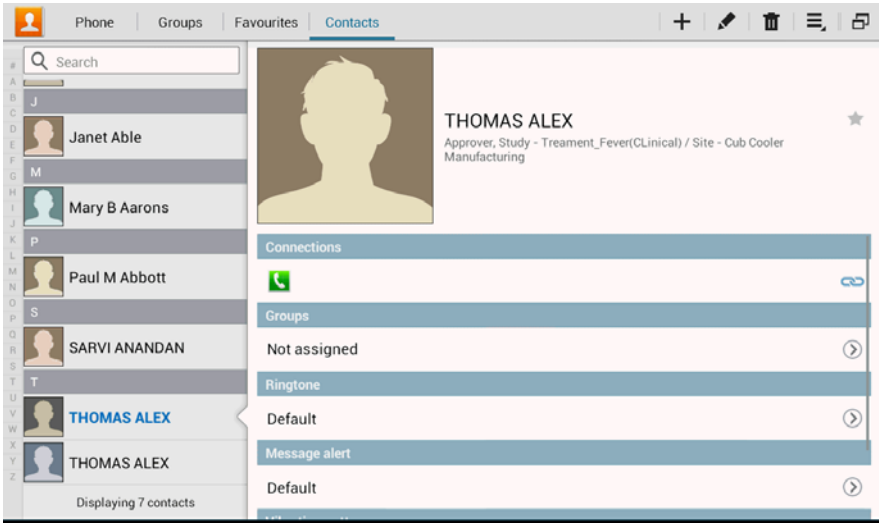
5. Check if the **Sync** button is set to **OFF.** If yes, tap it to turn it on.

Figure 5–4 Synchronize Contacts



6. The contact will now be available in your device contact list.

Figure 5–5 Contact Available on Device Contact List



6

GeoLocation Services

This section contains the following topics:

- Section 6.1, "Introduction"
- Section 6.2, "Registering a Site Visit"
- Section 6.3, "Map"

6.1 Introduction

When visiting a site, or any other location, you can register your location against a site visit currently in the system. You can also capture a geographic location (geolocation) and publish it to a community map, which shows the location of all CRAs in the system.

The Geolocation services will be set to **Off** at installation. If you attempt to access the Geolocation services while it is turned off, an error message is displayed. To use the services you will have to set it to **On** and Mobile CRA lets you turn it off, while retaining all other connected services.

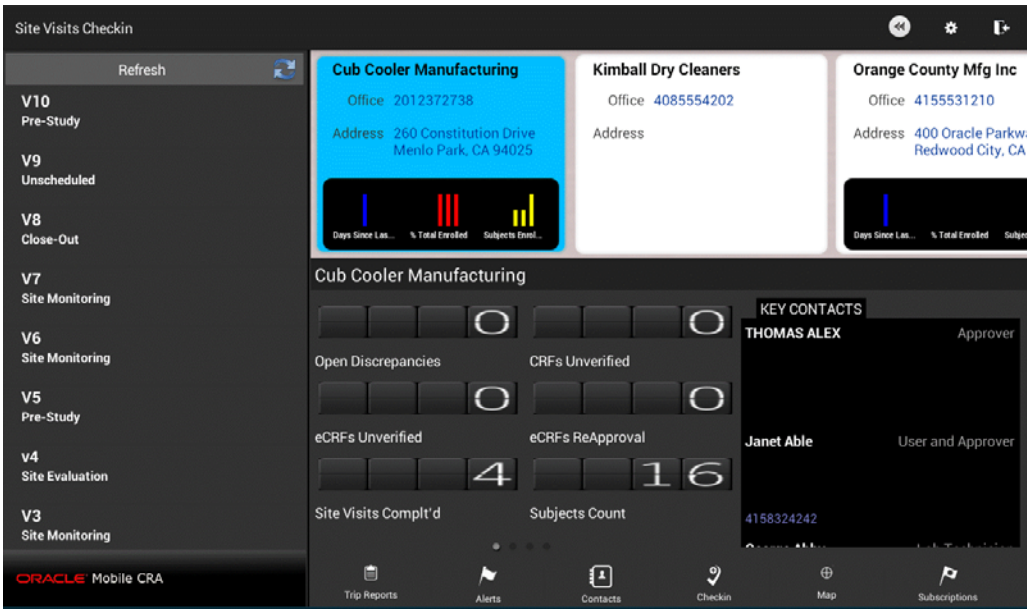
6.2 Registering a Site Visit

You can capture your geolocation from your Tablet or Phablet against a list of site visits beginning with the visit closest to the current date. Mobile CRA will capture the date, timestamp, latitude, and longitude. If you do not accept the geolocation, you can request another capture. Once a site visit geolocation is completed, it will be sent to CTMS and applied to the site visit record.

Perform the following steps to register your location and attach the location to a site visit record:

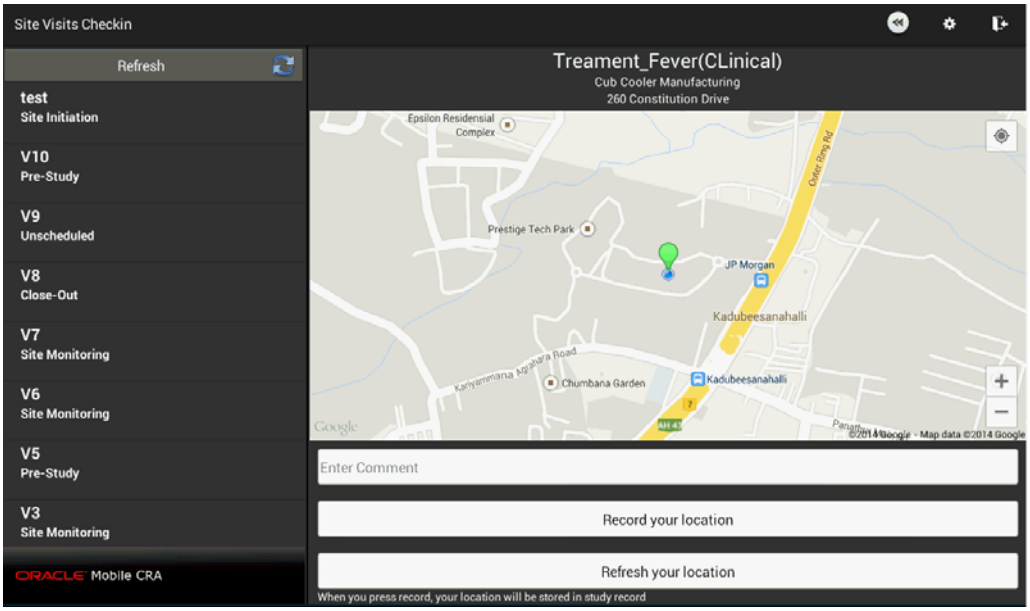
1. In the My Studies pane, select a study.
2. Select a study-site. Tap **Checkin**.

Figure 6–1 Checkin for a Study-Site



3. Tap a visit to select it. A map of the location capture and site location is displayed.

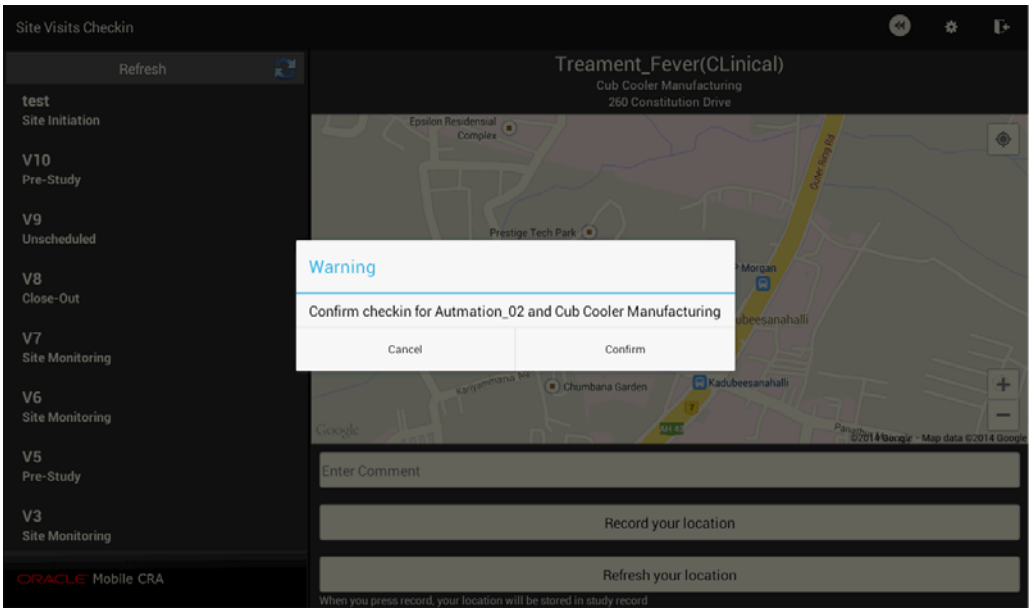
Figure 6–2 Location Capture Map



4. Select **Record your location**. You will be prompted to check in the site visit for the study-site.

Note: If you have moved from one location to another, the **Refresh your location** option will refresh the map and indicate your current location.

Figure 6–3 Checkin Prompt



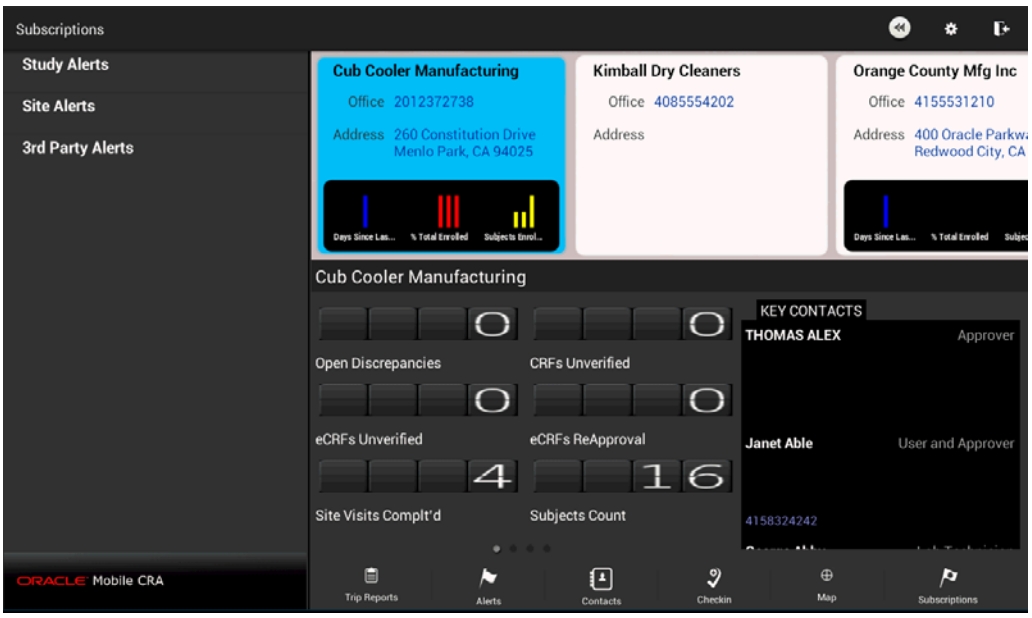
5. Tap **Confirm** to checkin. Your will be checked in and your location will be captured on OBIEE and CTMS.

6.3 Map

The Map option lets you view the various sites for a study. Perform the following steps to view all the sites for a study:

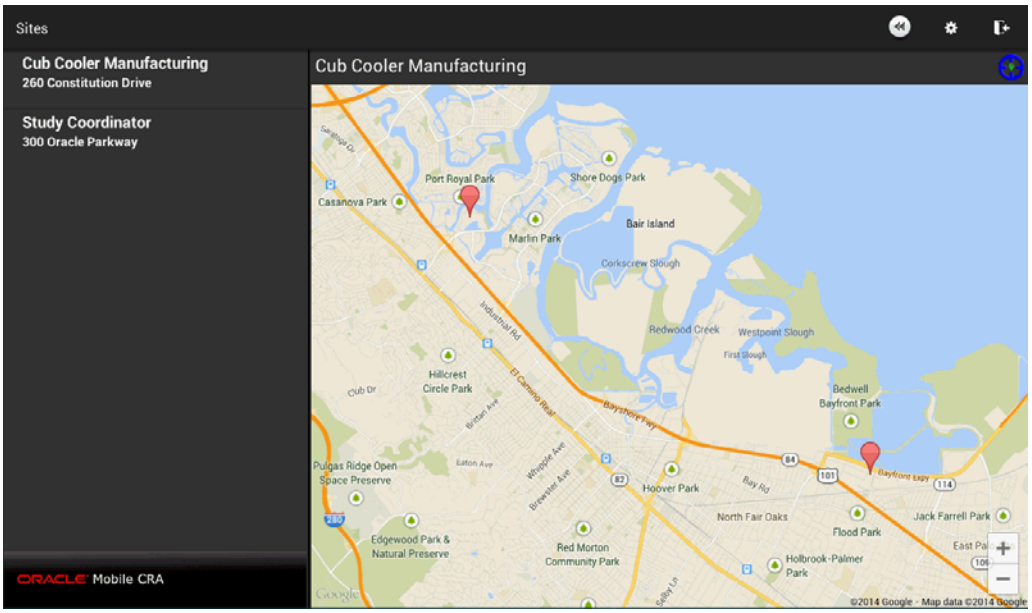
1. In the **My Studies** pane, tap a study to view all the sites under it.
2. Tap a site to view all its details.

Figure 6–4 Study and Site Details



3. Tap **Map**. A map indicating site locations will be displayed. Tap each site to view its details.

Figure 6–5 Map with Site Locations



7

Offline Services

When visiting a site, or any other location, your device might not be able to connect to the application server. In such cases, you can work on the information currently on the mobile device, making changes to the data. You can update the central repository when your device is able to connect to the server. This chapter contains the following topics:

- Section 7.1, "Offline Functionality"

7.1 Offline Functionality

The following are the details of offline services:

- Notifications will not be received.
- Notifications that have been delivered and marked as favorites, will be available for review.
- Notifications that have been delivered to the device, viewed but not marked as favorite, will not be stored on the mobile device for review.
- You cannot create, modify or delete subscriptions to alerts.
- You cannot modify alert thresholds.
- Location capture functionality is not available.
- Contact synchronization from CTMS to Mobile CRA will not be available. However, contact synchronization from Mobile CRA to device contact application will be available.
- While the mobile device should be connected to the Mobile CRA server to create, download, and submit trip report items, while offline, you can add attendees to the trip report, modify the status of the trip report checklist activities, modify the trip summary text, create a follow up item.
- You cannot upload or save data to CTMS. This will only occur when you request it.

Part II

Using Oracle Health Sciences Mobile Clinical Research Associate Server on Android Smartphone

This part of the Oracle Health Sciences Mobile Clinical Research Associate Server User Guide describes how to use Mobile CRA on the Android Smartphone.

- Chapter 8, "Accessing the Application"
- Chapter 9, "Alerts"
- Chapter 10, "Contacts"
- Chapter 11, "GeoLocation Services"
- Chapter 12, "Offline Services"

8

Accessing the Application

This chapter contains the following topics:

- Section 8.1, "Logging into Oracle Health Sciences Mobile Clinical Research Associate"
- Section 8.2, "Oracle Health Sciences Mobile Clinical Research Associate Server Menu"
- Section 8.3, "Settings"
- Section 8.4, "Logging Out of Oracle Health Sciences Mobile Clinical Research Associate"

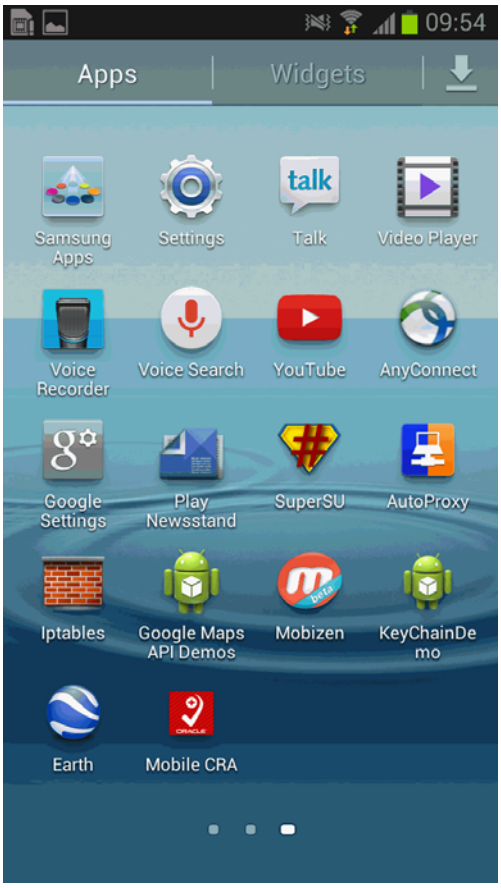
> **Note:** The appearance of the user interface that you see in the application may vary from the figures displayed in the subsequent sections.

8.1 Logging into Oracle Health Sciences Mobile Clinical Research Associate

The login screen is presented on startup and in situations where an active session does not exist. Perform the following steps to log into Mobile CRA from your Android Smartphone:

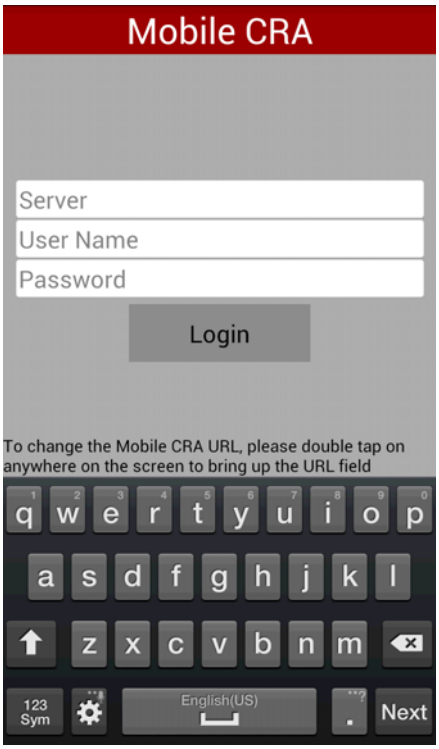
1. Tap the Mobile CRA launch icon on your Smartphone.

Figure 8–1 Mobile CRA Application Icon



2. The following login screen is displayed:

Figure 8–2 Mobile CRA Login Screen

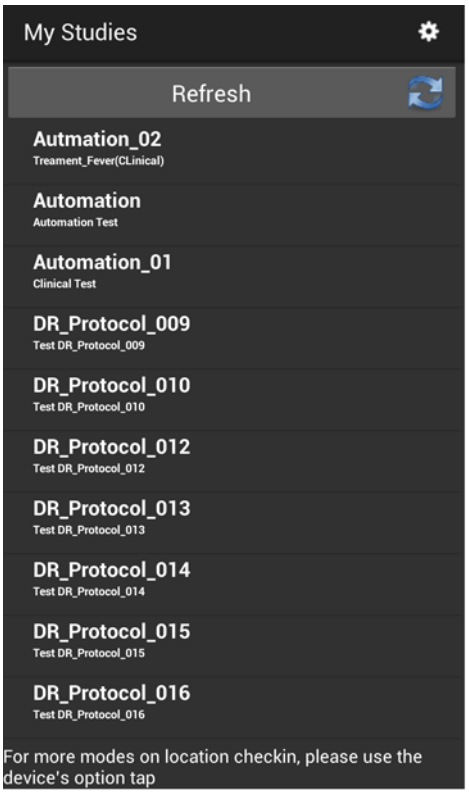


Enter the following details:

- **Server** - Enter your Mobile CRA server URL
- **User Name** - Enter your user name
- **Password** - Enter your password

3. Tap **Login**. The My Studies screen is displayed.

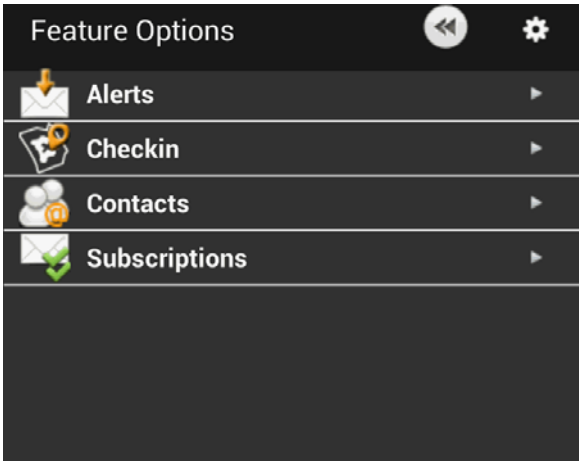
Figure 8–3 My Studies Screen



8.2 Oracle Health Sciences Mobile Clinical Research Associate Server Menu

Upon selecting a study and site, various functions are displayed in a list. Selecting a feature displays the related pages.

Figure 8–4 Mobile CRA Menu (After Selecting a Study and Site)



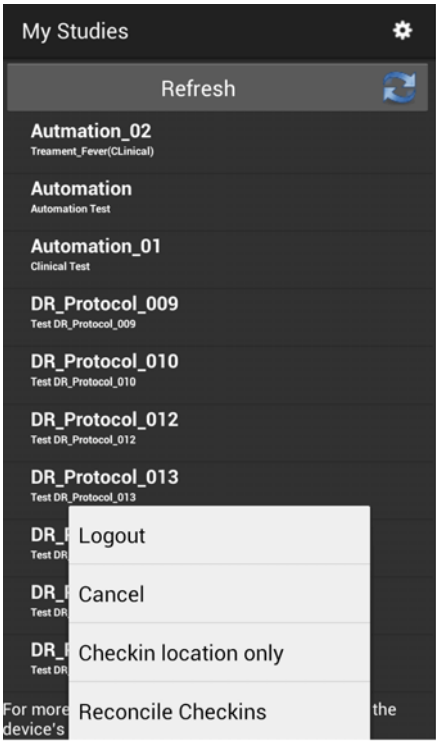
The following is a description of the available menu icons:

- **Alerts** - navigates to the alert list. For more details, see Chapter 9.
- **Checkin** - launches a check-in.

- **Contact** - lets you view the CTMS contacts which have been synchronized with your phone.
- **Subscriptions** - lets you subscribe to alerts and notifications for studies and sites.

In the Study list page, if you tap **Options** on your smartphone, another set of features or options are displayed:

Figure 8–5 Mobile CRA Options from the Phone Menu



The following is a description of the available menu icons:

- **Logout** - lets you log out of the application.
- **Cancel** - lets you come out of the tap or menu.
- **Checkin location only** - lets you record your location even without selecting a study-site-site visit combination.
- **Reconcile Checkins** - lets you connect unrelated check-ins to site visits.
- **Settings** - launches the settings page. For more details, Section 8.3.

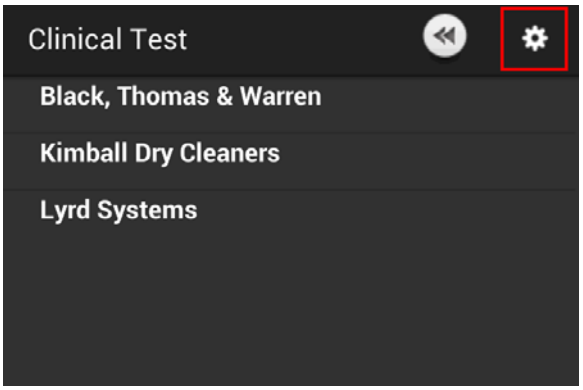
8.3 Settings

Perform the following steps to modify Mobile CRA settings.

Device Settings

1. Select a study and tap **Settings** on your Smartphone menu as shown.

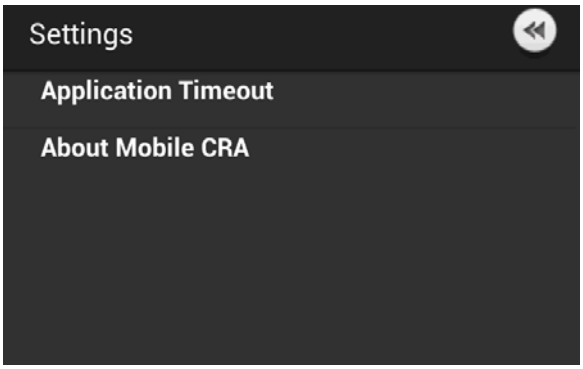
Figure 8–6 Device Menu



The Settings screen is displayed.

2. You can add or modify the settings for the Mobile CRA server here.

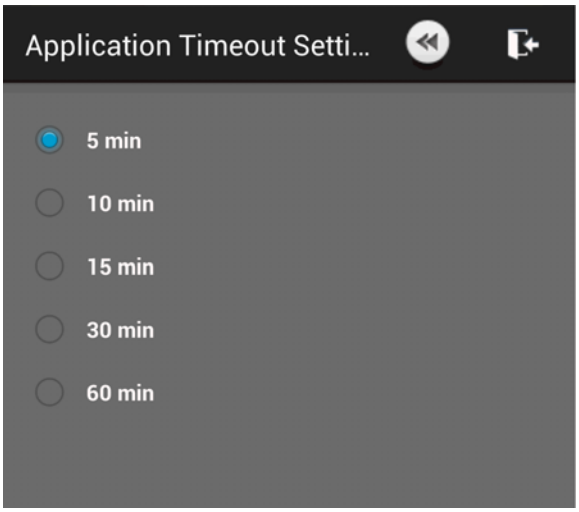
Figure 8–7 Mobile CRA Settings



This screen contains the following fields:

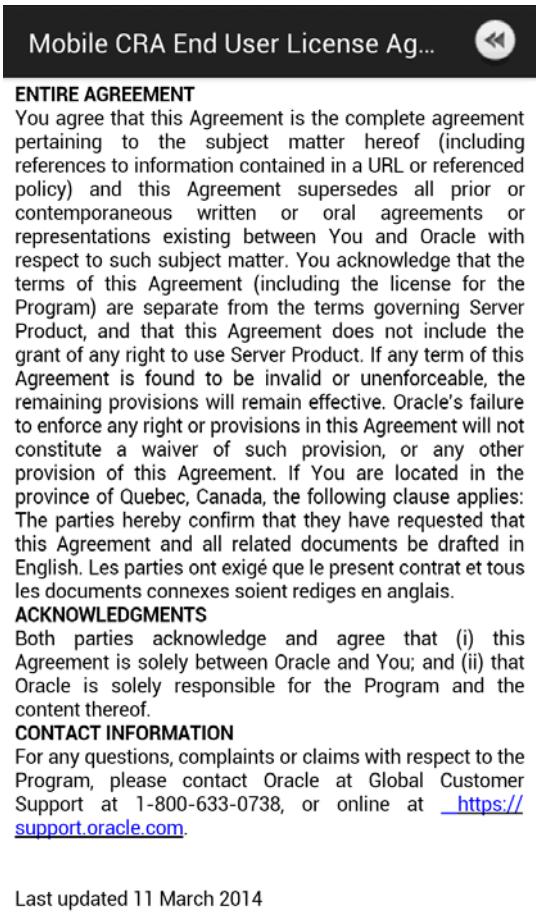
- **Application Timeout** - This lets you set the idle time for a session. Once this specified amount of time has passed, you will be logged off from your Mobile CRA session. Tap the option you want to set.

Figure 8–8 Timeout Options



- **About Mobile CRA** - This lets you access the end user license agreement.

Figure 8–9 License Agreement



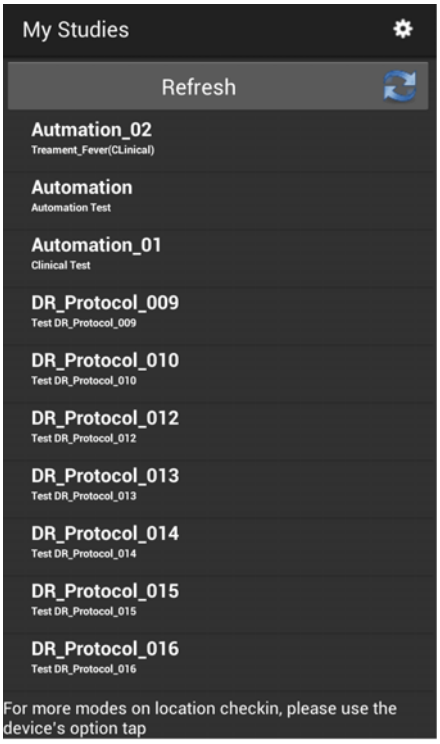
8.4 Logging Out of Oracle Health Sciences Mobile Clinical Research Associate

The logout option is present on the bottom left side of the main menu.

Perform the following steps to log out of Mobile CRA:

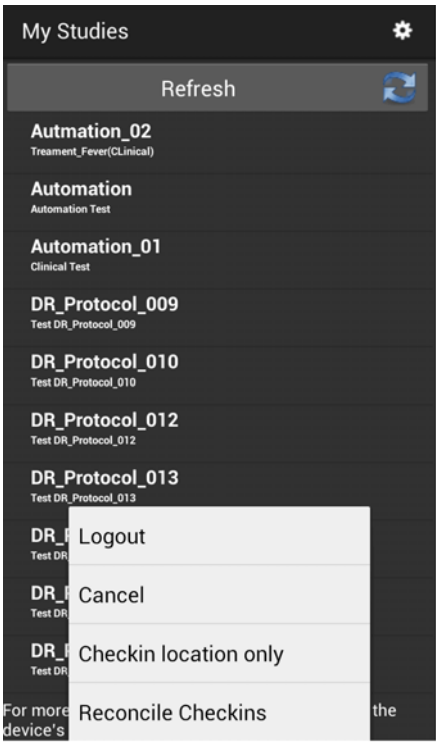
1. Navigate to the main screen.

Figure 8–10 Mobile CRA Main Screen



2. Tap on your Smartphone menu key on the bottom-left side. The following options will be displayed:

Figure 8–11 Menu Options



3. Tap **Logout**. You will be logged out of Mobile CRA.

> **Note:** If you do not want to logout, tap **Cancel**. The Mobile CRA menu will be displayed.

9 Alerts

This chapter provides details on alerts. It contains the following topics:

- Section 9.1, "Introduction to Alerts"
- Section 9.2, "Viewing Alerts"
- Section 9.3, "Searching for Alerts"
- Section 9.4, "Alerts Subscription"
- Section 9.5, "Predefined Alerts"
- Section 9.6, "Resetting Alerts"
- Section 9.7, "Marking an Alert as Important"
- Section 9.8, "Alerts while Application is Closed"

9.1 Introduction to Alerts

When on the move, you will have to be notified about various aspects of studies and site visits, including their progress, performance, and so on. Mobile CRA lets you create alerts through the administrator user interface and then subscribe to one or more of them. Once subscribed, you will receive notifications every time the subscription criteria is met. The alert inbox will display all the alerts logically categorized based on the site. For more information on creating alerts in the Administrator user interface, refer to the *Oracle Health Sciences Mobile Clinical Research Associate Server Administrator's Guide*.

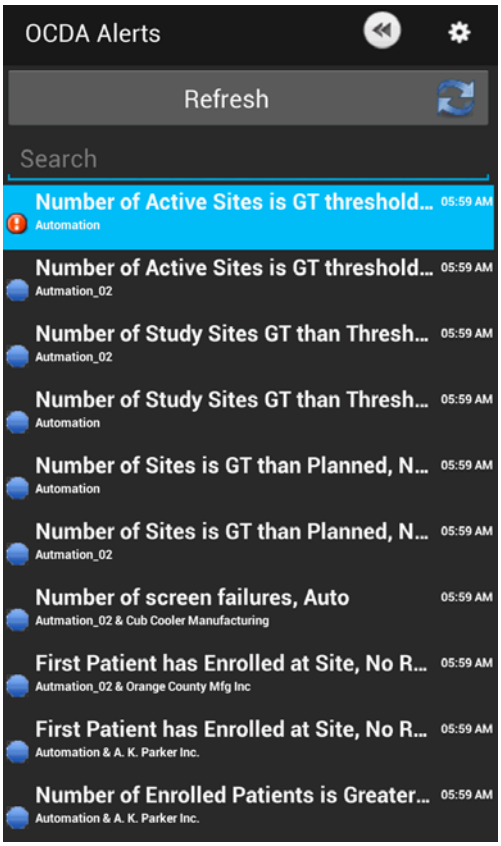
You can also flag an alert as 'Important'. This ensures that alerts carrying important information of your interest or those requiring your attention are flagged.

9.1.1 Alert Views

Alerts can be generated for a study, study-site, or 3rd party. Alerts are displayed in the following two views:

Alert List View

Figure 9–1 Alert List View



For each alert, the following information is displayed:

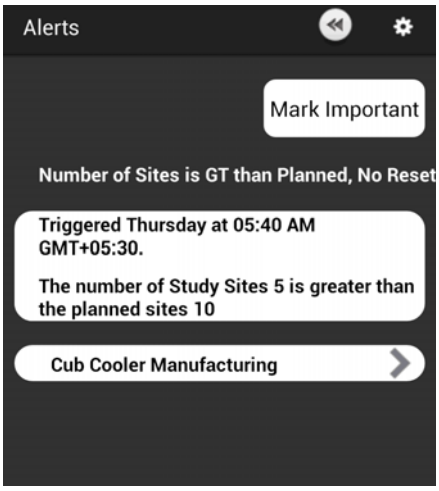
- The alert name
- The site name
- The study name
- The timestamp for the alert. If the alert was triggered in the last 12 hours the time the alert was triggered is shown. If the alert was triggered more than 7 days earlier, the date is shown in localized format taken from a global setting on the Smartphone.
- If an alert has been marked important, a red exclamation mark icon is also present.

Alert Details View

The Alert Detail View displays a single alert that has been selected through the Alert List View. Perform the following steps to view the alert details:

1. Tap the alert in the list to display its details.

Figure 9–2 Alert Details View



For each alert, the following information is displayed:

- The site name
- The study name
- The alert title
- The timestamp for the alert
- The details and text of the alert
- The importance of the alert

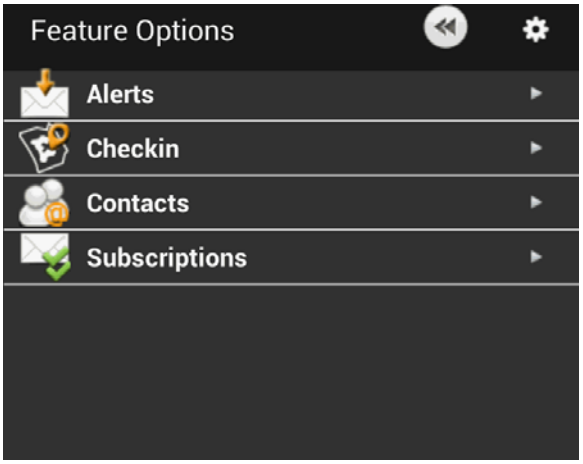
You can scroll up or down to view all details of the alert. When alert details are viewed, its receipt is confirmed. The **Mark as important** button lets you mark an alert as important. For more information on marking alerts as important, refer to Section 9.7.

9.2 Viewing Alerts

Perform the following steps to view alerts:

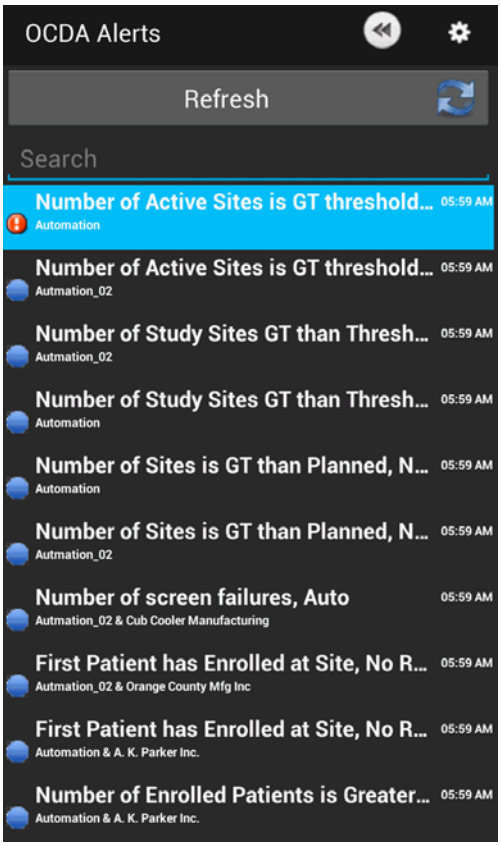
1. Navigate to the Mobile CRA menu.

Figure 9–3 Mobile CRA Menu



2. Tap **Alerts**. The list of alerts will be displayed. The 50 most recent alerts available from the Mobile CRA Server will be listed.

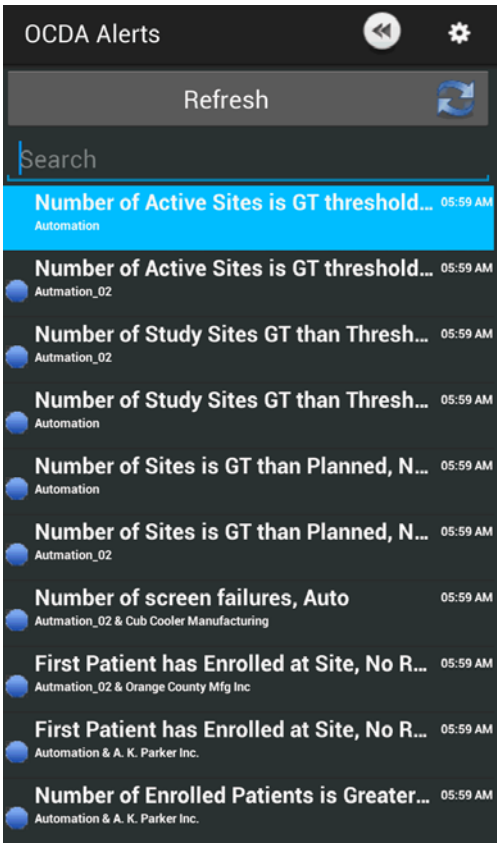
Figure 9–4 Alerts List



9.3 Searching for Alerts

A search bar is provided at the top of the alerts list view. When the search field is tapped, a keyboard is displayed and the search bar occupies the title bar space as shown below. You can then enter your search text in the search bar. The list is updated with the search results as you type in the search text.

Figure 9–5 Search for Alerts



You can search for an alert based on the following:

- Site name
- Study name
- Alert title

9.4 Alerts Subscription

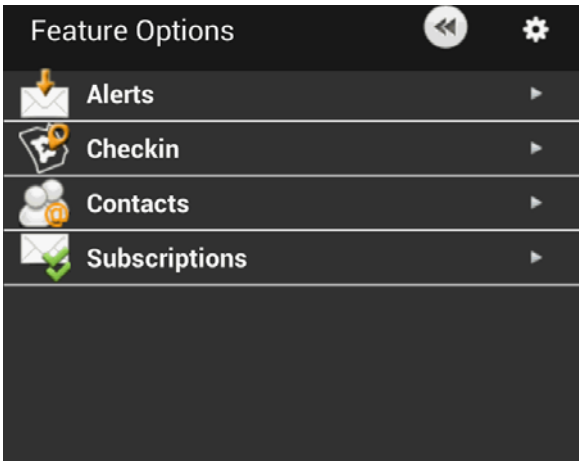
9.4.1 Subscribing to an Alert

Before subscribing to an alert, ensure that Oracle Health Sciences Mobile CRA has been downloaded, registered, and all administrative tasks have been completed. Perform the following steps to subscribe to an alert from your mobile device:

Subscribing to an Alert for a Study

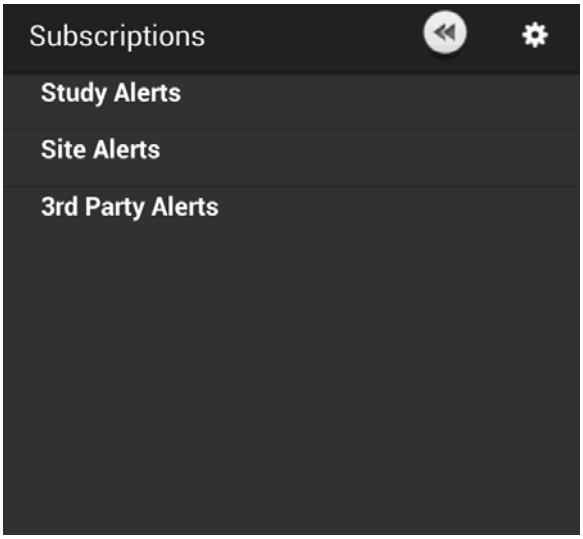
1. In the Mobile CRA menu, tap **Subscriptions**. A list of studies is displayed.

Figure 9–6 Mobile CRA Menu



2. Tap the study you want to subscribe alerts from.

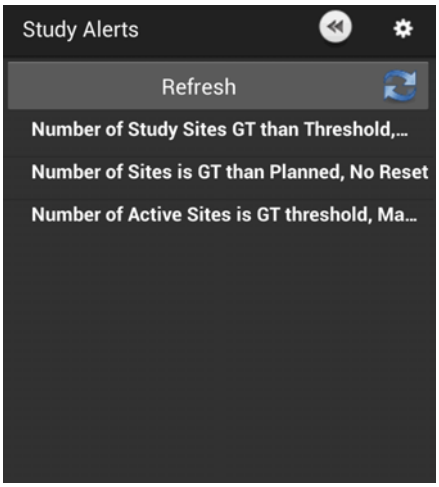
Figure 9–7 List of Alerts



3. Tap **Study Alerts**.

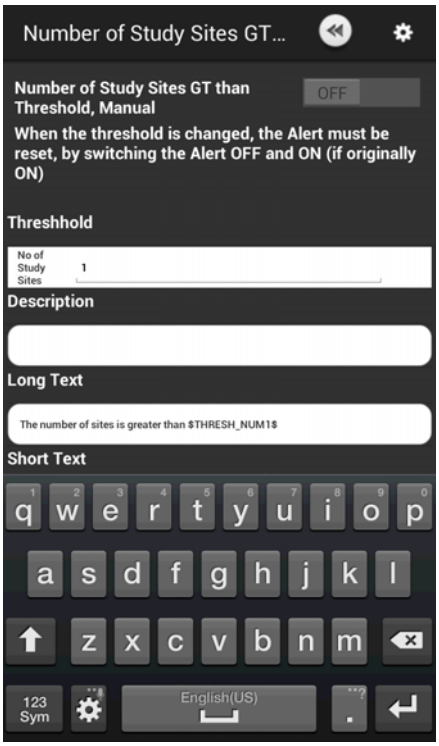
   A list of alerts for the study is displayed.

Figure 9–8 List of Alerts for a Study



4. Tap the alert you want to subscribe to and view its details.

Figure 9–9 Alert Details



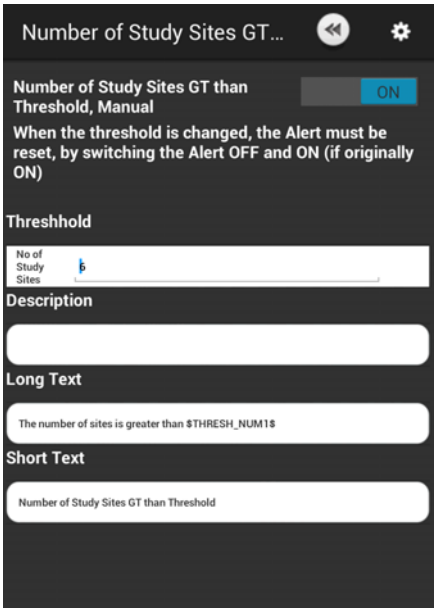
5. If you want, modify the threshold value by tapping **Threshhold**.

Figure 9–10 Modify the Threshold

6. If the alert is set to **OFF** on the top right, tap it to turn it on and subscribe to it.

> **Important:** To propagate the threshold changes to CTMS, reset the alert by switching it **OFF**, and then **ON** again (if it was originally **ON**).

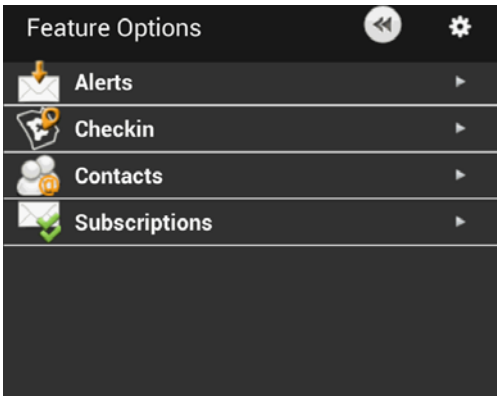
Figure 9–11 A Subscribed Alert



Subscribing to an Alert for a Site

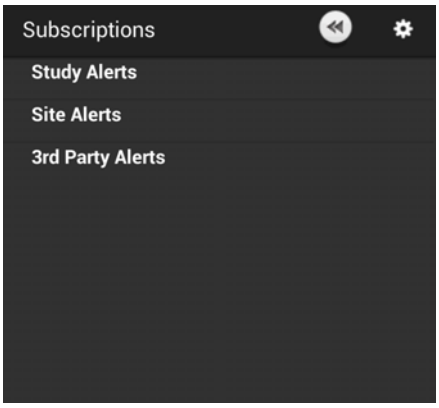
1. In the Mobile CRA menu, tap **Subscriptions**. A list of studies is displayed.

Figure 9–12 Mobile CRA Menu



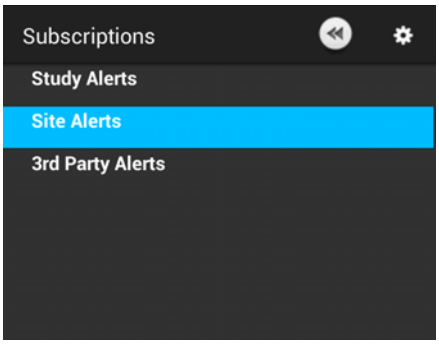
2. Tap the study you want to subscribe alerts from.

Figure 9–13 List of Alerts



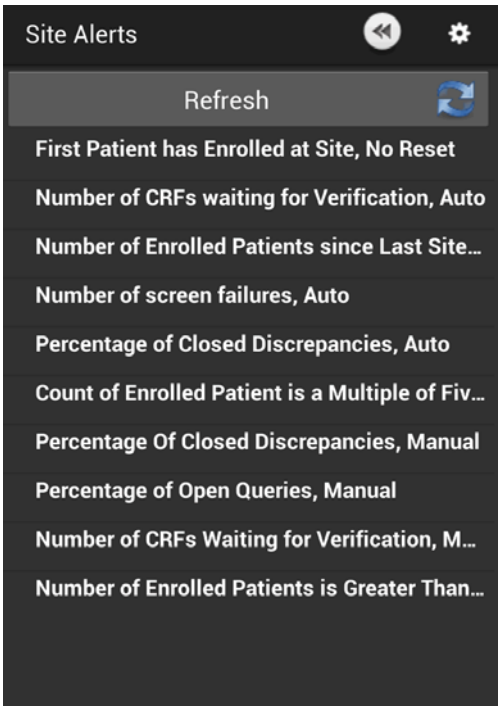
3. Tap **Site Alerts**.

Figure 9–14 Site Alerts



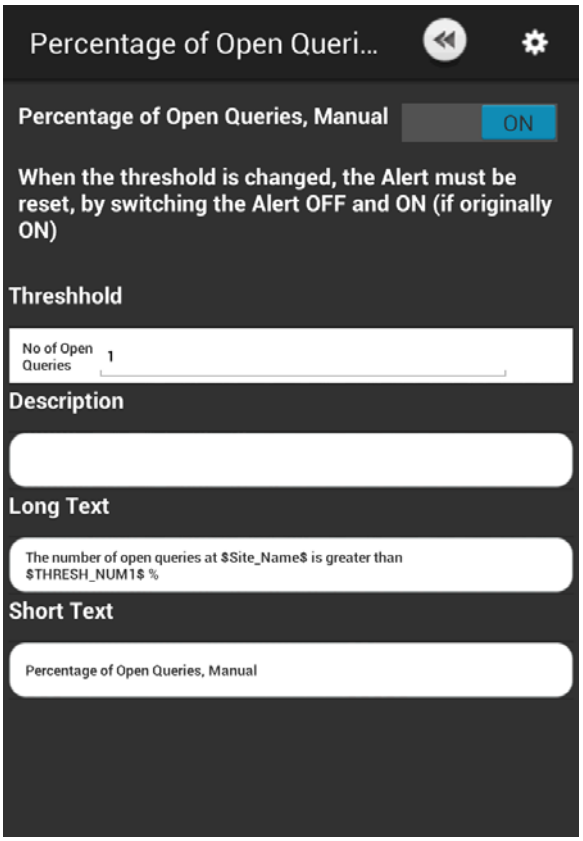
4. A list of alerts is displayed.

Figure 9–15 List of Alerts for a Site



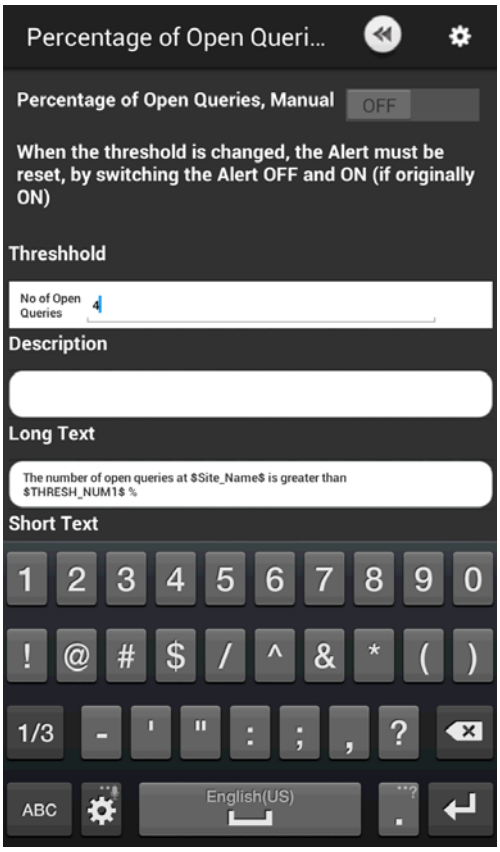
5. Tap the alert you want to subscribe to and view its details.

Figure 9–16 Alert Details



6. If you want, modify the threshold value by tapping on **Threshold**.

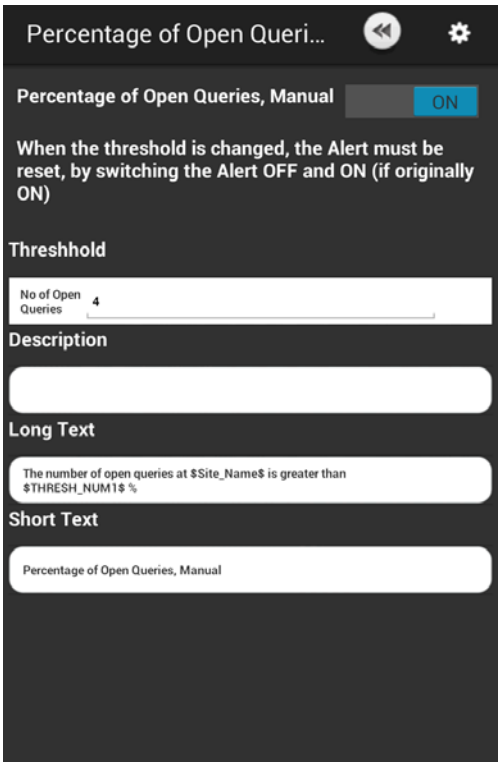
Figure 9–17 Modify the Threshold



7. If the alert is set to **OFF** on the top right, tap it to turn it on and subscribe to it.

Important: To propagate the threshold changes to CTMS, reset the alert by switching it **OFF**, and then **ON** again (if it was originally **ON**).

Figure 9–18 Turn an Alert ON



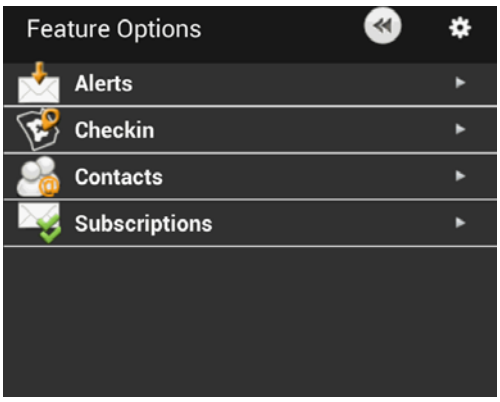
9.4.2 Unsubscribing an Alert

Before unsubscribing from an alert, ensure that Oracle Health Sciences Mobile CRA has been downloaded, registered and all administrative tasks have been completed. Perform the following steps to unsubscribe from an alert from your mobile device:

Unsubscribe an Alert for a Study

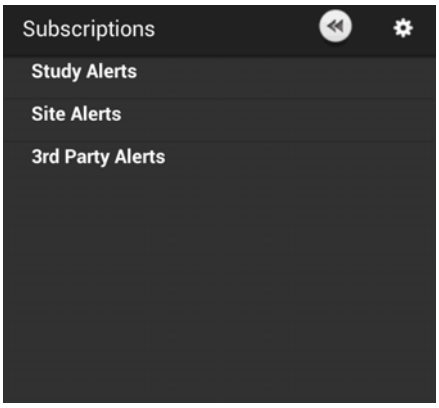
1. In the Mobile CRA menu, tap **Subscriptions**.

Figure 9–19 Mobile CRA Menu



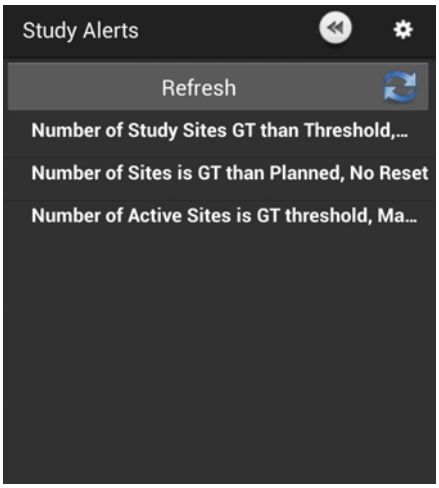
2. A list of alerts is displayed. Tap the study for which you want to unsubscribe an alert.

Figure 9–20 List of Studies



3. Tap **Study Alerts**. A list of alerts is displayed.

Figure 9–21 Alerts for Study



4. Tap the alert that you want to modify.
5. Tap **ON** on the top right hand corner. It switches off the alert and you will be unsubscribed.

Figure 9–22 Turn an Alert OFF

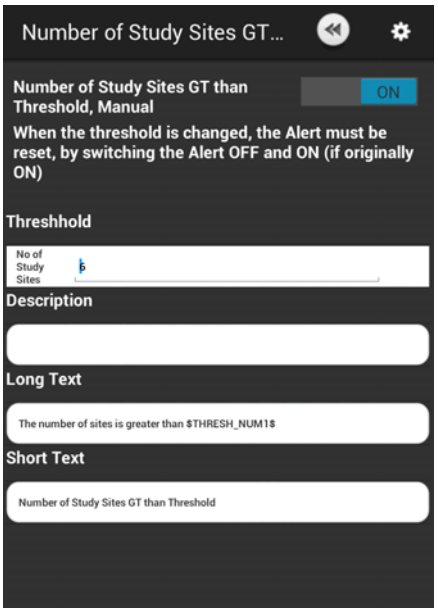
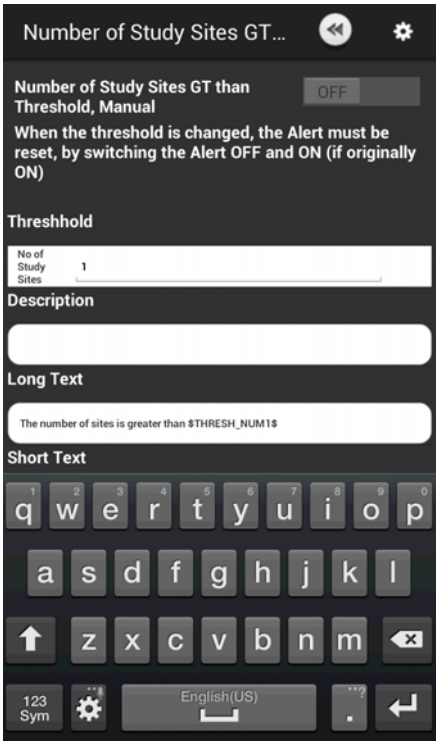


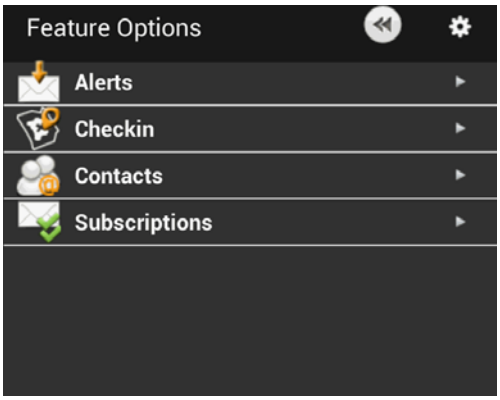
Figure 9–23 Alert Details



Unsubscribe an Alert for a Site

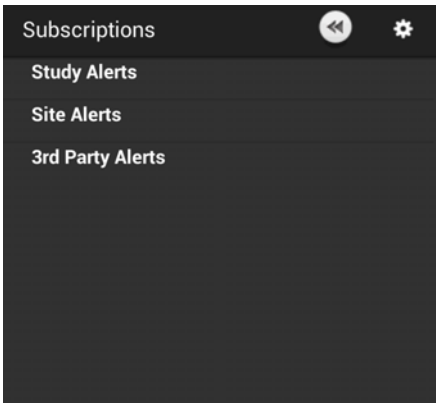
1. In the Mobile CRA menu, tap **Subscriptions**. A list of studies is displayed.

Figure 9–24 Mobile CRA Menu



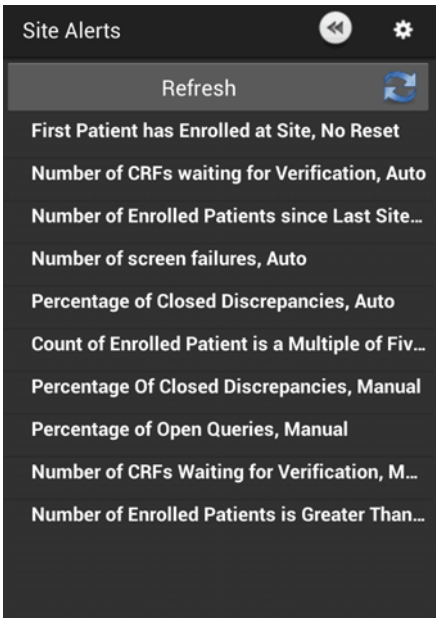
2. Tap the study you want to unsubscribe alerts from.

Figure 9–25 List of Alerts



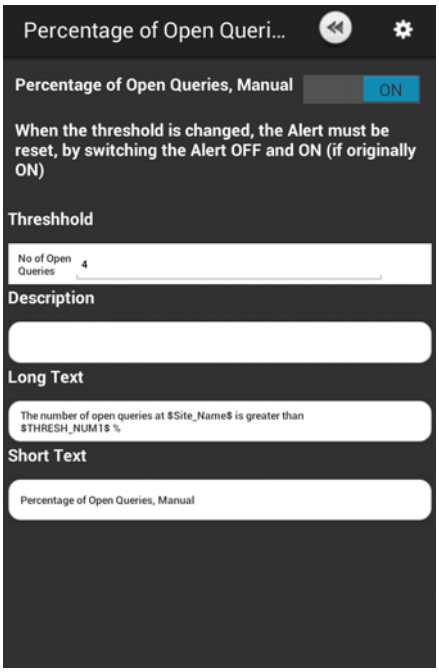
3. Tap **Site Alerts**.
4. A list of alerts is displayed.

Figure 9–26 List of Alerts for a Site



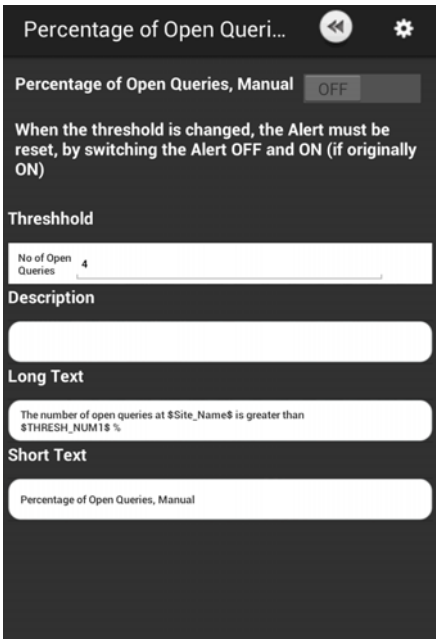
5. Tap the alert you want to unsubscribe and view its details.

Figure 9–27 Alert Details



6. Tap **ON** on the top right, to switch off the alert. You will be unsubscribed.

Figure 9–28 Alert Details

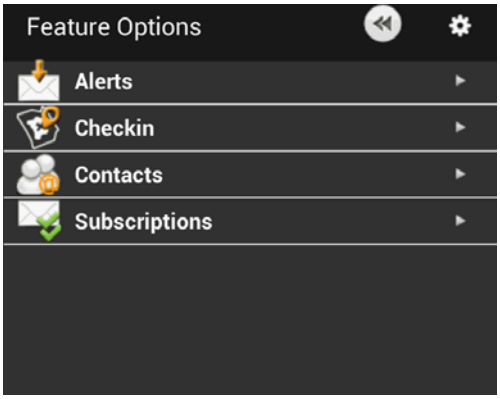


9.4.3 Modifying an Alert Subscription

Before modifying a subscription, ensure that Oracle Health Sciences Mobile CRA has been downloaded, registered, and all administrative tasks have been completed. Perform the following steps to modify an alert from your mobile device:

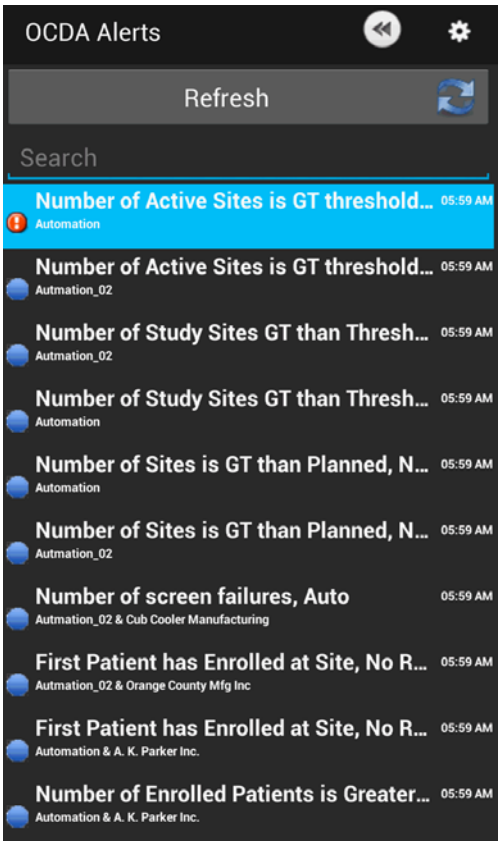
1. Navigate to the Mobile CRA menu.

Figure 9–29 Mobile CRA Menu



2. Tap **Alerts**. The list of alerts will be displayed. The 50 most recent alerts available from the Mobile CRA Server will be listed.

Figure 9–30 List of Alerts



3. Tap the alert you want to modify.
4. Tap **Threshhold** to modify the threshold value.
5. Tap **Done** on the top right. If you do not want to save your changes, tap **Cancel** to go back to the alert details.

9.5 Predefined Alerts

Oracle Health Sciences Mobile CRA system will ship with a set of predefined alerts for data available from CDA. All predefined alerts will generate a notification in the following format:

You have received an alert for <*Study X*> regarding <*Site Y*>.

Following is a list of predefined alerts in the system:

Table 9–1 Predefined Alerts

Predefined Alert	Description
Number of CRFs waiting for verification	Number of CRF pages ready for source verification at the site
First patient has enrolled at site	The first patient has been enrolled at site
Number of enrolled patients is greater than threshold	The number of enrolled patients at a study site is greater than the preset threshold value
Count of enrolled patient is a multiple of five	Number of patients enrolled in list

Table 9–1 (Cont.) Predefined Alerts

Predefined Alert	Description
Percent of open queries	The number of open queries at a study site is greater than the preset threshold percentage
Percent of closed discrepancies	Percent of discrepancies that are closed as Irresolvable is greater than the preset threshold percentage
Number of screen failures	Screen failures is greater than the preset threshold value
Number of enrolled patients since last site visit	Count of enrolled patients since last site visit
Visit reports waiting approval	The number of trip reports pending approval
Number of active sites is greater than threshold	Count of active sites is greater than the threshold
Number of sites greater than planned	The number of study sites that exceed the planned sites
Number of study sites is greater than threshold	Count of study sites is greater than the threshold

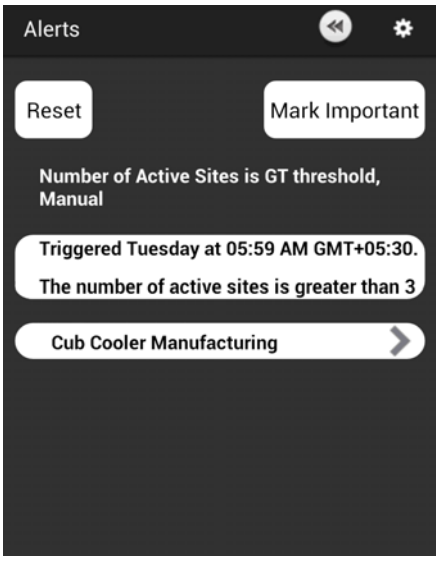
9.6 Resetting Alerts

You can manually reset an alert to trigger again on the same conditions. Before resetting an alert, ensure that you are connected to the server. If you try to reset an alert when offline, an error will be displayed. Perform the following steps to reset an alert:

Note: The **Reset** option is not available for external notifications.

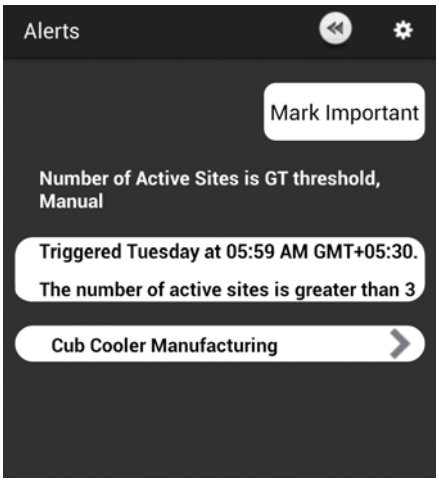
1. Tap the alert to view its details.

Figure 9–31 Alert Details



2. Click **Reset**. A reset message is sent to the mobile server and the reset option is not visible.

Figure 9–32 Reset an Alert

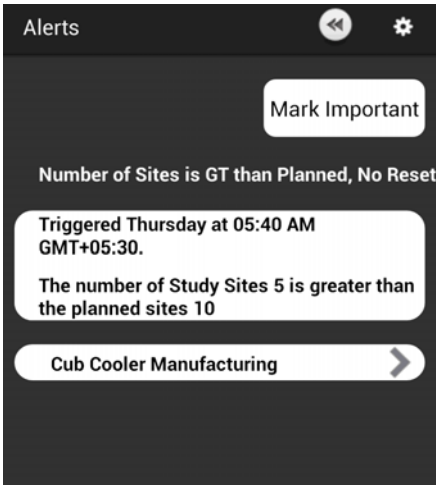


9.7 Marking an Alert as Important

You can also mark an alert as important. An important alert is indicated by a red exclamation mark icon. Perform the following steps to mark an alert as important:

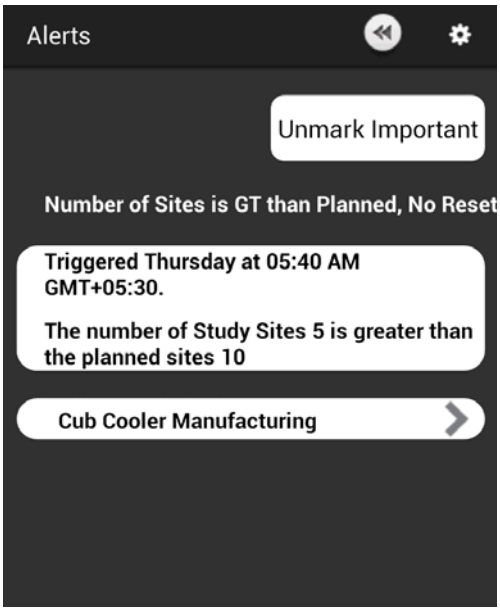
1. Tap an alert to view its details.

Figure 9–33 Alert Details



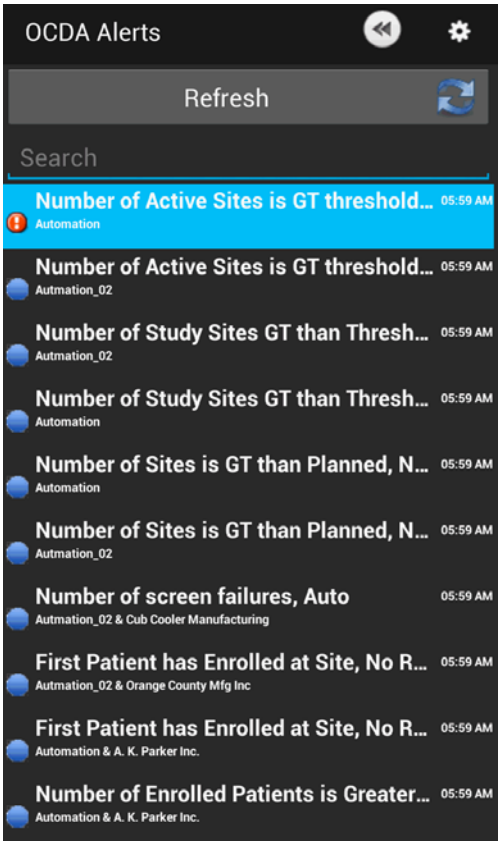
2. Tap **Mark important**. The alert will be marked as important and the button changes to **Mark unimportant**.

Figure 9–34 Alert Marked Important



3. In the alerts list, a red exclamation mark icon will be displayed next to the alert.

Figure 9–35 Important Alerts in the List

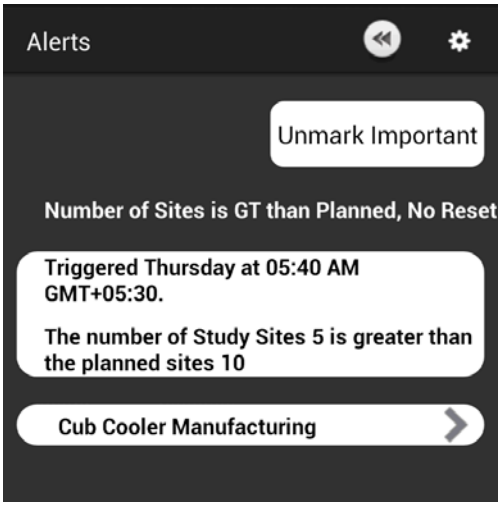


9.7.1 Clearing the Important Flag for an Alert

Perform the following steps to clear the importance flag on an alert:

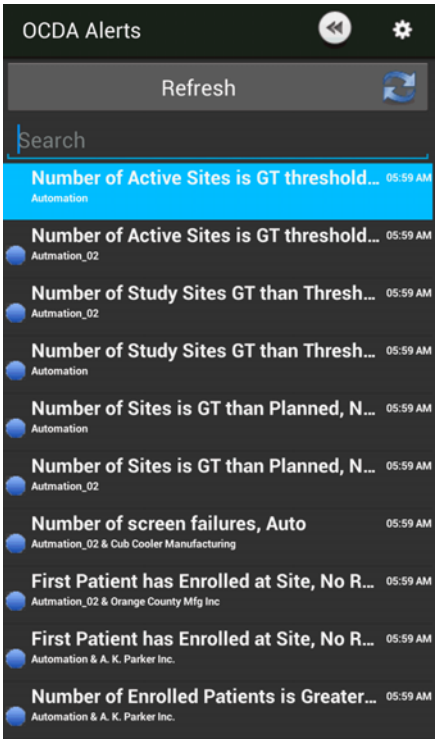
1. Tap the alert, marked important, to view its details.

Figure 9–36 Mark Alert Unimportant



2. Tap **Unmark Important**.
3. The important flag will be cleared in the list of alerts.

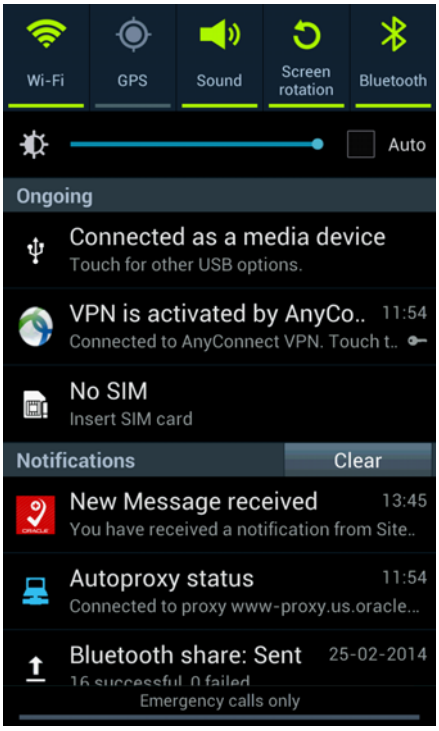
Figure 9–37 Important Icon Removed



9.8 Alerts while Application is Closed

When the application is closed or running in the background, the Android system sends a notification when an alert is triggered.

Figure 9–38 Alert Signal in the Android Notification Menu



Tapping on the Mobile CRA notification proceeds to open the application and then the alerts to view.

10 Contacts

This chapter describes how to work with Mobile CRA contacts. It contains the following topics:

- Section 10.1, "Introduction to Contacts"
- Section 10.2, "Linking an Alert to a Contact"
- Section 10.3, "Removing Contact from Site"

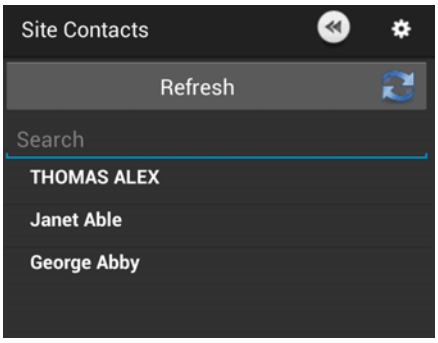
10.1 Introduction to Contacts

Mobile CRA maintains a contact list separate from your Smartphone contacts. The contact list within the Mobile CRA application will synchronize with the CTMS contact list. The CTMS contacts delivered to Mobile CRA will be the contacts associated with your assigned sites, where you are on the study team. All contacts will be read only. You can set a user preference to control the frequency of contact synchronization, and the time at which the synchronization occurs.

The following steps describe how to navigate within CRA contacts:

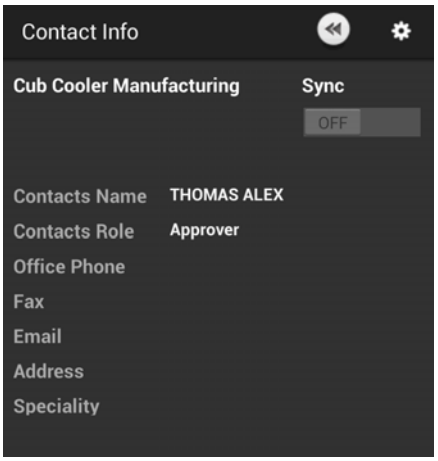
1. Tap **Contacts** in the Mobile CRA menu. A list of studies is displayed.
2. Tap a study to view the contacts for it.

Figure 10–1 Contact List for a Study



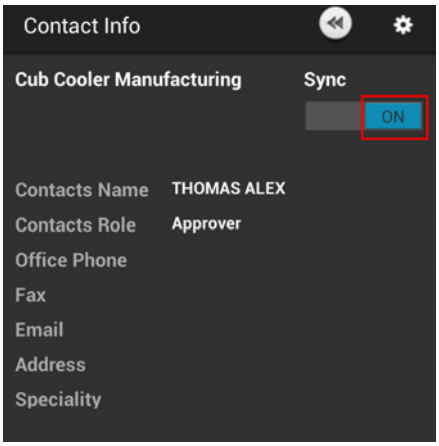
3. Tap a contact to view the details.

Figure 10–2 Contact Details



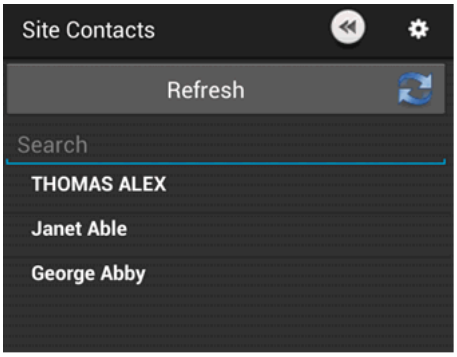
4. To synchronize the Mobile CRA contacts with your device contacts, tap **Sync** on the top right of the contact details.

Figure 10–3 Synchronize CRA Contacts with Device Contacts



5. To synchronize Mobile CRA contacts with CTMS contacts, tap **Refresh** on the top-right corner.

Figure 10–4 Synchronize CRA Contacts with CTMS



10.2 Linking an Alert to a Contact

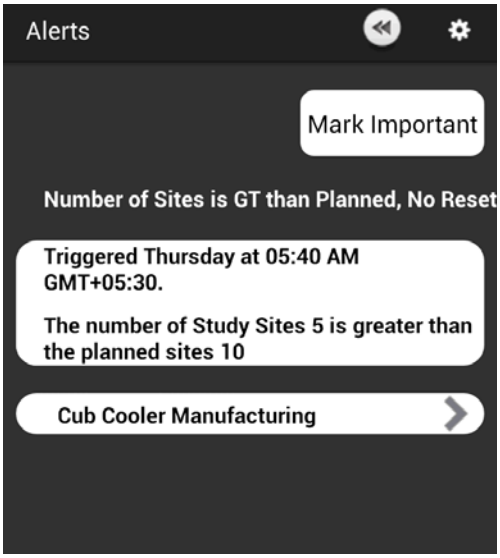
You can link an alert to a contact either by dialing a new number from your phone or by selecting an existing number in your Smartphone phonebook.

10.2.1 Linking an Alert to a New Number

Perform the following steps to link an alert to a new number:

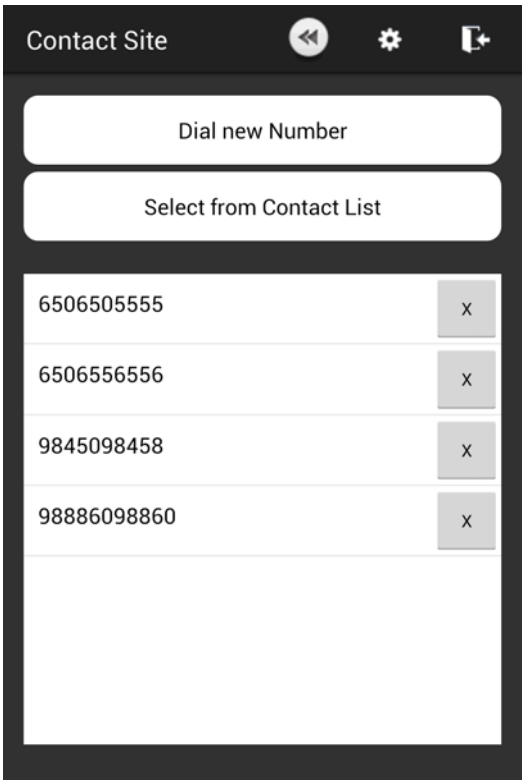
1. Tap the alert to view its details.

Figure 10–5 Alert Details



2. Tap the site name to display its contact details.

Figure 10–6 View Site Contact Details



3. Tap **Dial new number**. Your Smartphone dialing pad is displayed.
4. Tap the number you want to call. Once a call is initiated, the phone number is associated with the site.

Figure 10–7 Dial a New Number

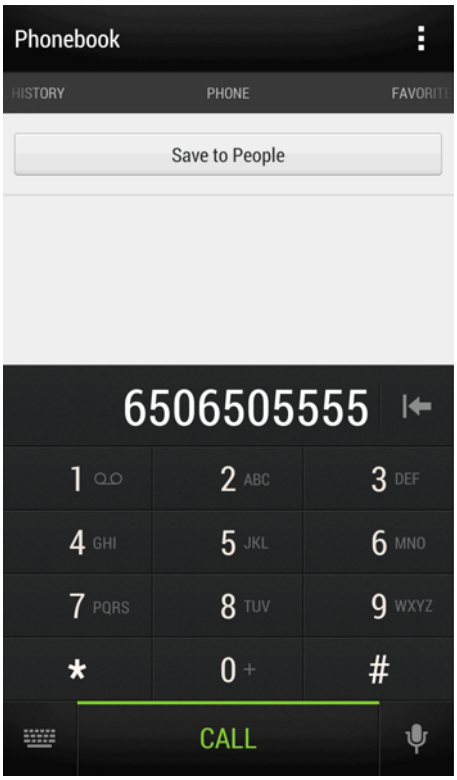
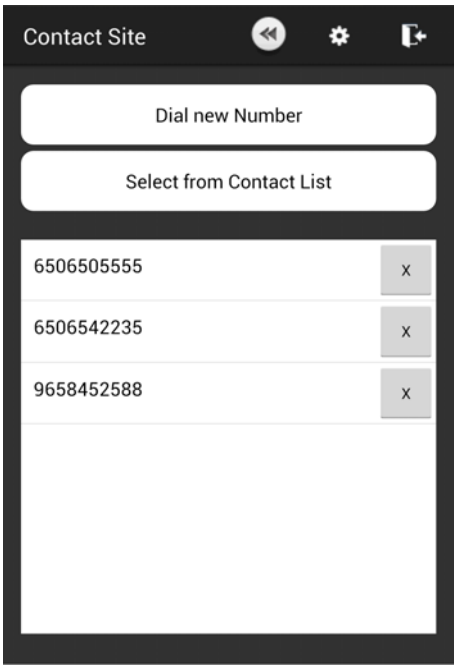


Figure 10–8 Contact Associated with Site



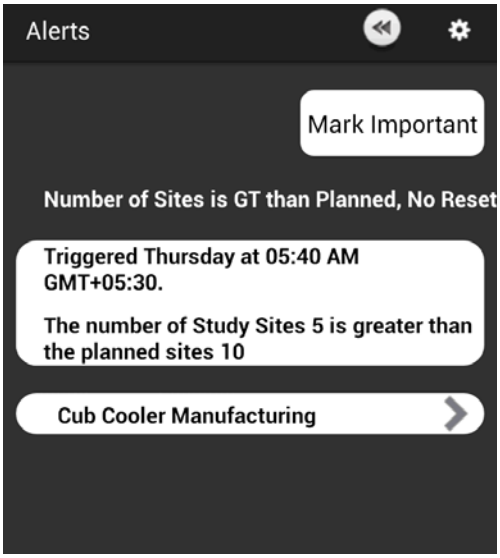
If you dial more than one number, they all will be linked to one site.

10.2.2 Linking an Alert to a Phonebook Number

Perform the following steps to link an alert to an existing number in your device phonebook:

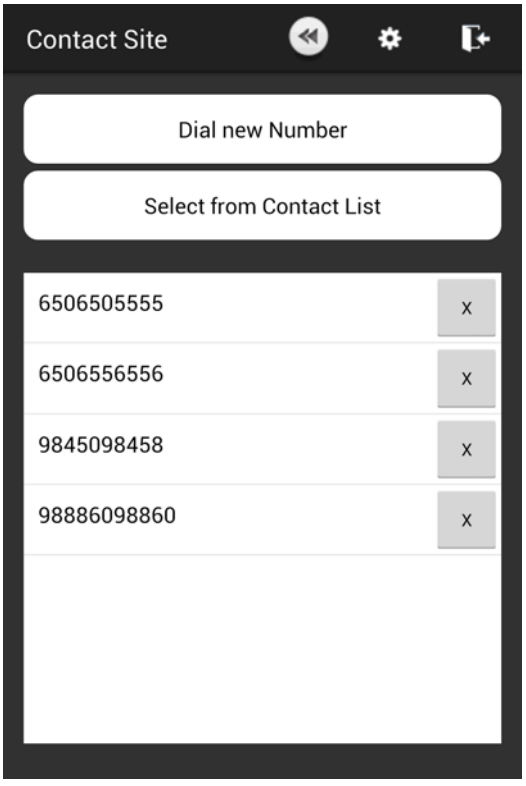
1. Tap the alert to view its details.

Figure 10–9 Alert Details



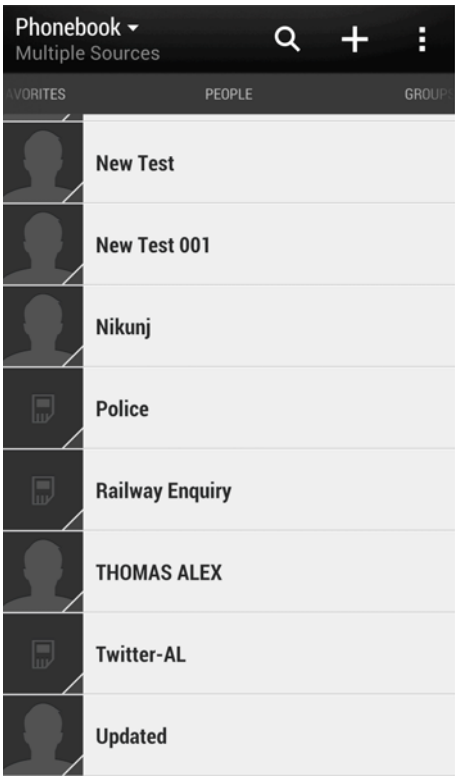
2. Tap the site name to display its contact details.

Figure 10–10 View Site Contact Details



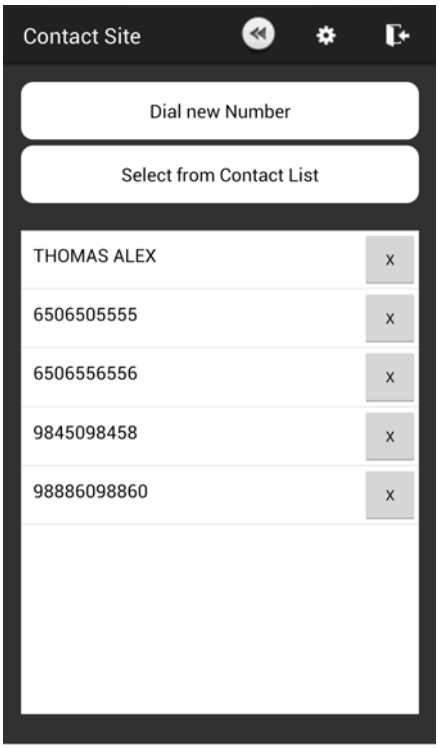
3. Tap **Select from Contact List**. Your Smartphone contact list is displayed.

Figure 10–11 Select Number from Contact List



4. Tap the contact you want to associate with the site.
5. Once the call is initiated the name and number are associated with the site.

Figure 10–12 Select Number from the Contact List



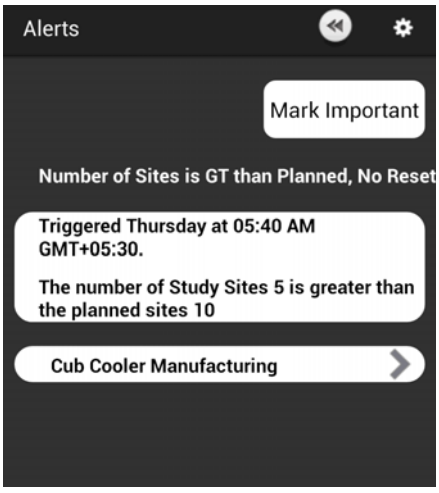
You can link more than one phonebook contact to the same site by following the above steps.

10.3 Removing Contact from Site

You can dissociate a contact from a site. Perform the following steps to remove a contact from a site:

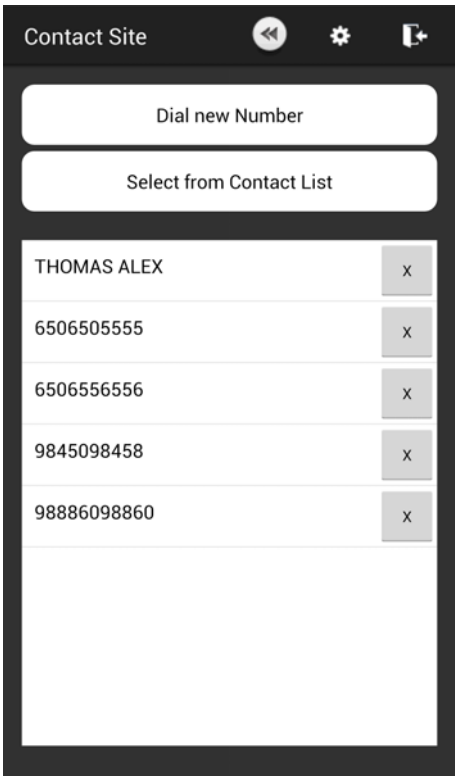
1. Tap a site to view its details.

Figure 10–13 Alert Details



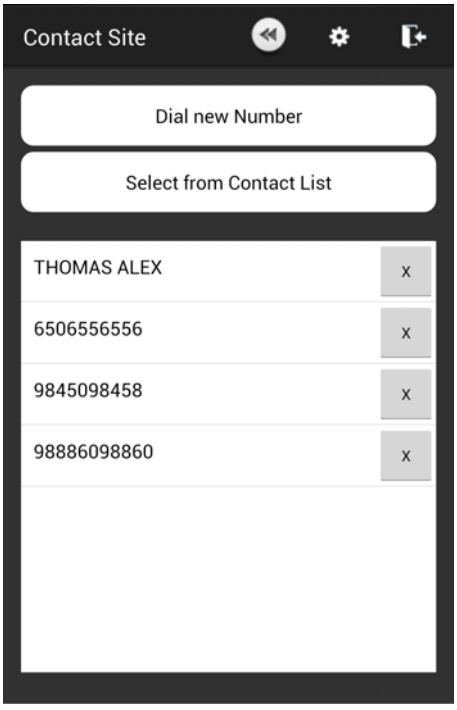
2. Tap the site name to display its contact details.

Figure 10–14 View Site Contact Details



3. Tap the x icon in the contact to remove it from a site.

Figure 10–15 Delete Contact



11

GeoLocation Services

This chapter contains the following topics:

- Section 11.1, "Introduction"
- Section 11.2, "Registering a Site Visit"
- Section 11.3, "Capturing Location Without Selecting a Study-Site Pair"
- Section 11.4, "Reconcile Check In"

11.1 Introduction

When visiting a site, or any other location, you can register your location against a site visit currently in the system. You can also capture a geographic location (geolocation) and publish it to a community map, which shows the location of all CRAs in the system.

The Geolocation services will be set to **Off** at installation. If you attempt to access the Geolocation services while it is turned off, an error message is displayed. To use the services you will have to set it to **On** and Mobile CRA lets you turn it off, while retaining all other connected services.

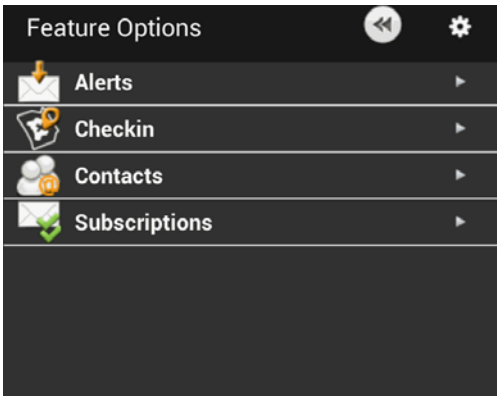
11.2 Registering a Site Visit

You can capture your geolocation from your Smartphone against a list of site visits beginning with the visit closest to the current date. Mobile CRA will capture the date, timestamp, latitude, and longitude. If you do not accept the geolocation, you can request another capture. Once a site visit geolocation is completed, it will be sent to CTMS and applied to the site visit record.

Perform the following steps to register your location and attach the location to a site visit record:

1. Tap **Check-In** on the Mobile CRA menu. A list of studies is displayed.

Figure 11–1 Mobile CRA menu

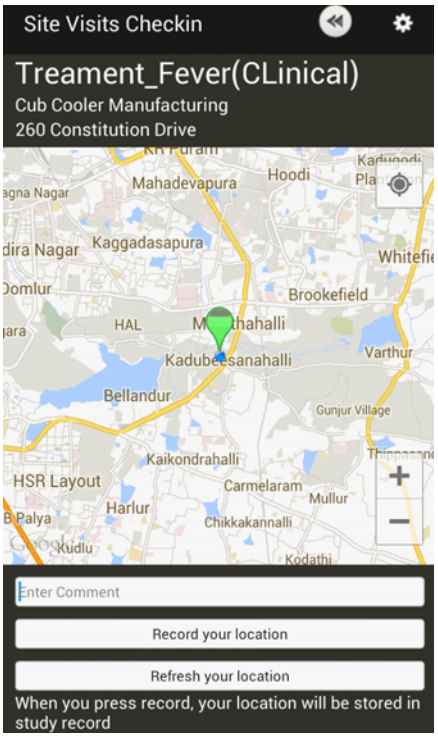


2. Tap the study-site pair for which you want to register a visit.

Figure 11–2 Select a Study Site Pair

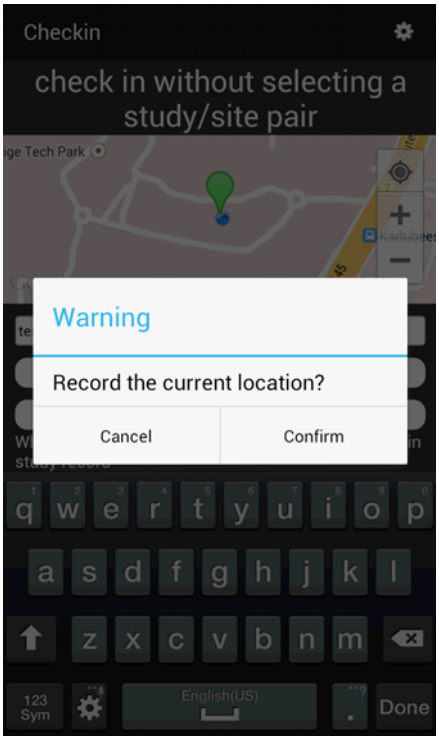
3. An area map with your location is displayed. Tap **Record your location**.

Figure 11–3 Record Your Location



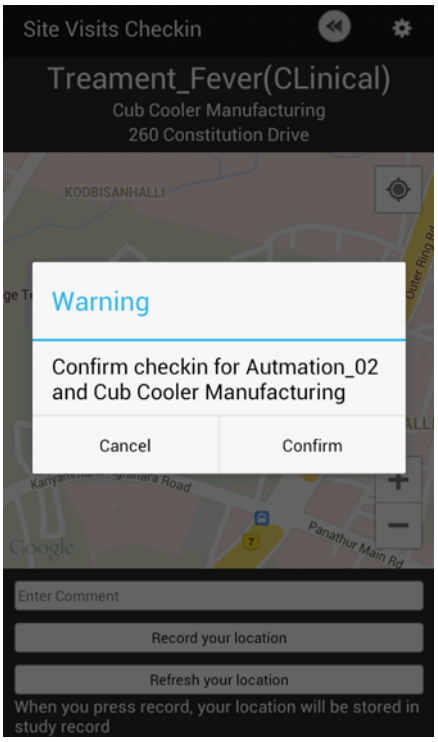
4. A list of study-sites is displayed. Select the site for which you want to check in.

Figure 11–4 Approve Location



5. Tap **Confirm Check In**. Your location will be recorded in CTMS.

Figure 11–5 Checking In



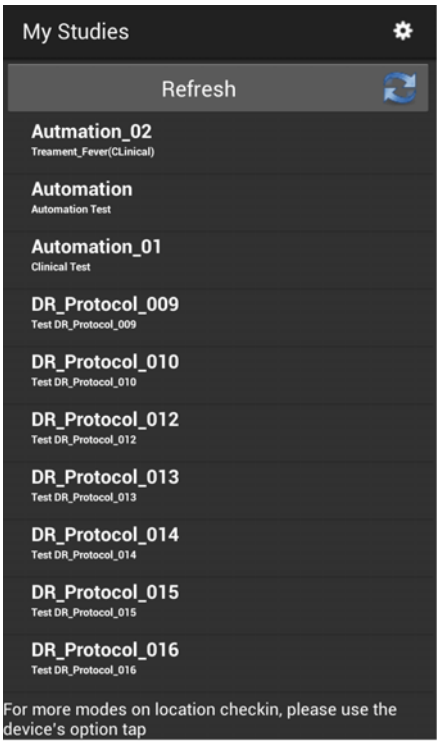
6. If you want to check in later, tap **Cancel**. Your location will be stored as an unlinked location capture. For more information refer to Section 11.4, "Reconcile Check In" on page 11-7.

11.3 Capturing Location Without Selecting a Study-Site Pair

Perform the following steps to capture your location without selecting a study-site pair:

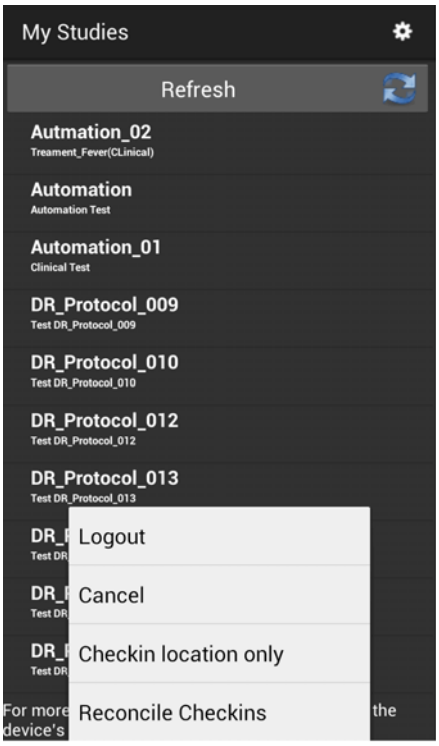
1. Tap on your Smartphone menu key on the bottom-left side.

Figure 11–6 Mobile CRA menu



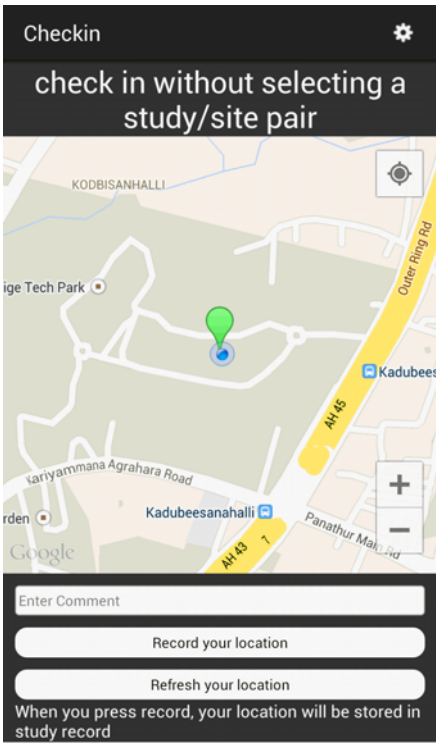
2. Tap **Checkin location only**.

Figure 11–7 Select the Checkin location only Option



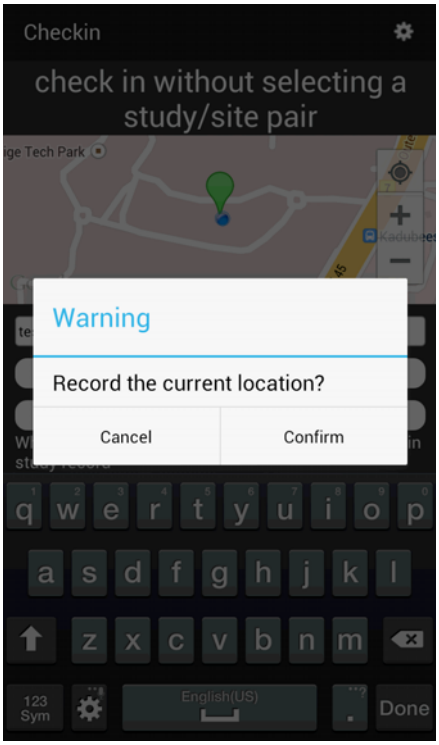
3. Tap **Record Your Location**.

Figure 11–8 Record Your Location



4. You will be checked in. You can associate this unlinked location capture with a study-site by reconciling the check in. For more details, refer to Section 11.4.

Figure 11–9 Approve Location



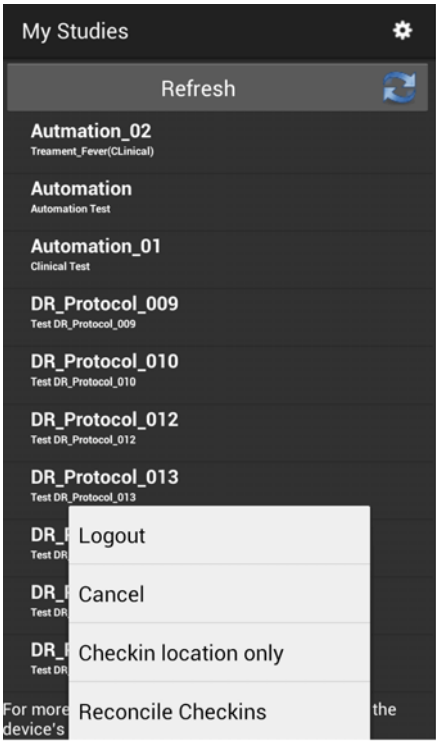
11.4 Reconcile Check In

All unlinked location captures are stored under the reconcile check in option. You can later link it to a study or site. After you check in a visit using this option, the visit will still be displayed. Refresh the list to remove the entry. In case, you cannot view your unlinked capture in the list, refresh to get the latest data.

Perform the following steps to assign a location capture to a site visit:

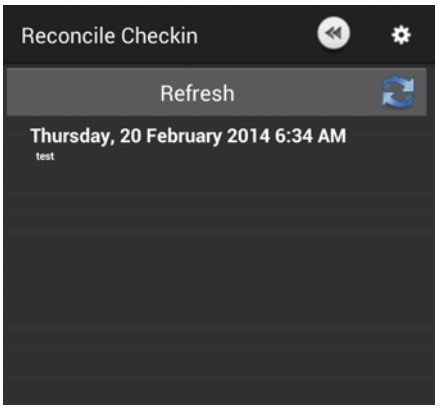
1. Tap **Reconcile Checkins** on the Mobile CRA menu.

Figure 11–10 Mobile CRA Menu



2. A list of unlinked location captures is displayed.

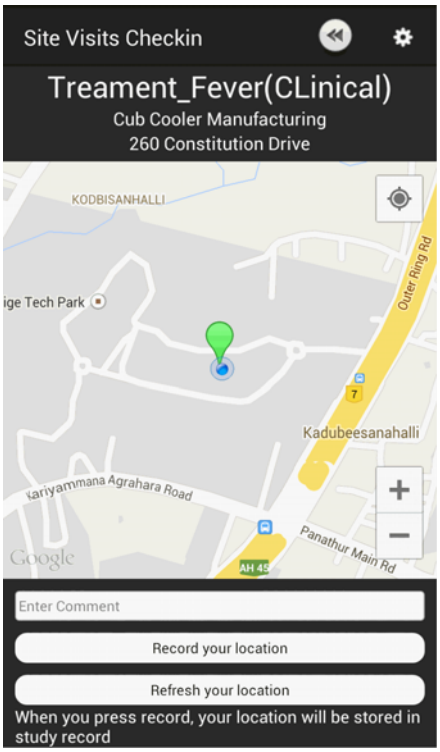
Figure 11–11 Unlinked Location Capture



3. Select a study, site and site visit. The location map is displayed.

4. The map is displayed. Tap **Record your location**.

Figure 11–12 Record Location



12

Offline Services

When visiting a site, or any other location, your device might not be able to connect to the application server. In such cases, you can work on the information currently on the mobile device, making changes to the data. You can update the central repository when your device is able to connect to the server. This chapter contains the following topics:

- Section 12.1, "Offline Functionality"

12.1 Offline Functionality

The following are the details of offline services:

- Notifications will not be received or stored.
- Creating, modifying or deleting subscriptions to alerts is disabled.
- Modifying alert thresholds is disabled.
- Location based alerts will not process.
- Location capture functionality is not available.
- Contact synchronization from CTMS to Mobile CRA will not be available. However, contact synchronization from Mobile CRA to device contact application will be available.
- If the password is changed on the device when you are offline, the device application will synchronize passwords with the mobile server at the highest priority (before all other synchronization tasks) when connection is established.
- You cannot upload or save data to CTMS. This will only occur when you request it.

Glossary

Alert

Alert is the actual definition of the decision rule and the notification.

Badge Icon

The icon representing the Oracle Health Sciences Mobile CRA application on the mobile device can be modified to include a badge icon.

Badge Number

The badge can display a numeric character to indicate the number of unviewed notifications on the Mobile server.

Clinical Data

Data pertaining to the medical characteristics or status of a patient or subject.

Clinical Research Organization

A company or organization that conducts all or part of a clinical trial under contract to a Clinical Trial sponsor.

Clinical Research Team Leader

Typically is an experienced CRA that manages a team of CRAs. The Clinical Research Team Leader is primarily responsible for conducting a trial, managing the Trial CRA team, checking over budgeting and compliance.

Clinical Study

See **Clinical Trial**.

Clinical Trial

Before a pharmaceutical or biotech company can initiate testing on humans, it must conduct extensive pre-clinical or laboratory research. This research typically involves years of experiments on animal and human cells. The compounds are also extensively tested on animals. If this stage of testing is successful, a pharmaceutical company provides this data to the Food and Drug Administration (FDA), requesting approval to begin testing the drug on humans. This is called an Investigational New Drug application (IND). A clinical trial is a carefully designed investigation of the effects of drug, medical treatment, or device on a group of patients (also called Subjects).

CRA

Clinical Research Associate. An employee of the Sponsor, responsible for getting a site prepared to conduct a trial and getting cleaned data back from the site to the Sponsor.

Google Notification Service

The Google Notification Service will send brief messages to a mobile device. For the purposes of this application, the notification service will inform the user that a notification has been received.

Sponsor

The organization funding the clinical trial. This is typically the Pharmaceutical company whose product is being tested with the clinical trial.

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