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 1.0

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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 11.1.1.5 documentation set includes:

• Oracle® Fusion Middleware User's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)

- Oracle® Fusion Middleware Metadata Repository Builder's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware System Administrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Scheduling Jobs Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Security Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Developer's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)
- Oracle® Fusion Middleware Integrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1)

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.

Introduction

This chapter contains the following topics:

- Overview on page 1-1
- What Can I Do Using Oracle Health Sciences Mobile Clinical Research Associate? on page 1-1

1.1 Overview

The Mobile CRA mobile application supports the clinical research associate (CRA) in conducting and monitoring site visits. This release 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) and Siebel Clinical Trial Management System (CTMS).

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.

- Site at a Glance You can view information about a study site, including a site of study progress measures.
- 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.

Feature	iPad	iPhone	
Alerts and Notifications	Х	Х	
CTMS Contacts integration	Х	Х	
Site Check-in	Х	Х	
Site at a Glance	Х		
Trip Reports	Х		

Table 1–1 Mobile CRA Features for iPad and iPhone

Part I

Using Oracle Health Sciences Mobile Clinical Research Associate Server on Apple iPad

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

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"

Accessing the Application

This chapter contains the following topics:

- Logging into Oracle Health Sciences Mobile Clinical Research Associate on page 2-1
- Oracle Health Sciences Mobile Clinical Research Associate Server Landing Page on page 2-4
- Settings on page 2-13

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 iPad 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 Apple iPad:

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 Address Enter the CRA server address. This is a one-time entry and once done, this field will not appear again during login. You can also enter the server URL in iOS Settings > Mobile CRA.
- 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.

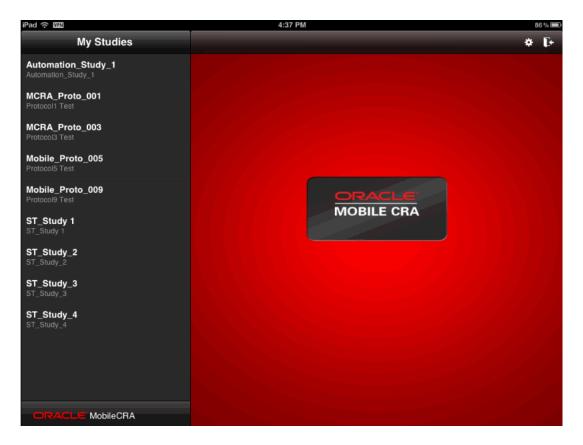


Figure 2–4 Landing Page

The landing page consists of the following components:

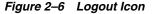
 My Studies pane - This pane consists of a list of studies that you are involved in. The list displays the protocol number and the study title as entered in CTMS. You can tap a study to view its details, which include its sites, key contacts and site metrics.

When you pull down the left pane as shown in Figure 2–5, "Updating the My Studies Pane" on page 2-6, the system makes a call to the server and fetches the latest information from CTMS.

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My Studies		٠	ŀ
Release to update Last updated: 09/10/12 11:49 AM			
Automation_Study_1			
MCRA_Proto_001 Protocol1 Test	ORACLE!		
MCRA_Proto_003 Protocol3 Test	MOBILE CRA		
Mobile_Proto_005 Protocol5 Test			
Mobile_Proto_009 Protocol9 Test			
ST_Study 1 ST_Study 1			
ST_Study_2 ST_Study_2			
ST_Study_3 ST_Study_3			
ST_Study_4			

Figure 2–5 Updating the My Studies Pane

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





2.3 Site-at-a-Glance

This feature displays overview information about the study sites, including a configurable dashboard where you can view eleven site metrics (6 displayed at once), performance graphs and launch various other components.

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My Studies	M_Study_2 - S	Sites 🔹 🕏
Automation_Study_1 Automation_Study_1	Bay General Hospital Office 9980098761	
MCRA_Proto_001 Protocol1 Test	Address 300 Oracle Parkway Redwood City, CA 94065	
MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLMENT	
MCRA_Proto_004 Protocol4 Test	discrepancie records/wk subjects/wk	
MCRA_Proto_008 Protocol8 Test	Bay General Hospital	
M_Study_1 cardiac research	0 0	KEY CONTACTS Mary Aarons Site Coordinator 400 Oracle Parkway
M_Study_2 vaccination research	Subjects Enrolled Irresolvable Discrepancies	Redwood City, CA 94065 9257253609
Mobile_Proto_005 Protocol5 Test		Janet Able Exhibit Coordinator 300 Oracle Parkway
Mobile_Proto_009 Protocol9 Test	Open Discrepancies Unverified CRFs	Redwood City, CA 94065 4158324242
ST_Alert Study Alerts	Completed Site Visits Days since Last Enrollment	George Abby Principal Investigator 500 Oracle Parkway Redwood City, CA 94065
ST_Study 1 ST_Study 1	Days since Last Entoiment	9980098761 Pharmacy
	Trip Reports Alerts Contacts C	? 🕀 🎘 Sheckin Map Subscription

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.

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My Studies		M_Study_2 - S	Sites	* 6
Automation_Study_1 Automation_Study_1	Bay General Hospital Office 9980098761			· · · · · · · · · · · · · · · · · · ·
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MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLME	NT		
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Mobile_Proto_009 Protocol9 Test		verified CRFs	Redwood City, CA 94065 4158324242	
ST_Alext Study Alerts	Completed Site Visits Date	ys since Last Enrollment	George Abby Principal Inve 500 Oracle Parkway Redwood City, CA 94065	stigator
ST_Study 1 ST_Study 1			9980098761 Pharmacy	
	Trip Reports Alerts	Contacts C	Ŷ ⊕ heckin Map Si	A ubscription

Figure 2–8 Study Selection Bar

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

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My Studies	M_Study_2 - Site	s 🏾 🏶 🖡
Automation_Study_1 Automation_Study_1	Bay General Hoopital Office 9980098761	
MCRA_Proto_001 Protocol1 Test	Address 300 Oracle Parkway Redwood City, CA 94065	
MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLMENT	
MCRA_Proto_004 Protocol4 Test	discrepancie Navarte/Wk subjects/Wk	
MCRA_Proto_008 Protocol8 Test	Bay General Hospital	
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M_Study_2 vaccination research	Subjects Enrolled Irresolvable Discrepancies Re	0 Oracle Parkway dwood City, CA 94065 57253609
Mobile_Proto_005 Protocol5 Test	30	net Able Exhibit Coordinator 0 Oracle Parkway
Mobile_Proto_009 Protocol9 Test	41	dwood City, CA 94065 58324242
ST_Alert Study Alerts	50	orge Abby Principal Investigator 0 Oracle Parkway dwood City, CA 94065
ST_Study 1 ST_Study 1	99	armacy
	Trip Reports Alerts Contacts Checki	n Map Subscription

Figure 2–9 Site Selector Slide

- Key Site Metrics, including:
 - Subjects Enrolled
 - Open Discrepancies
 - Completed Site Visits
 - Irresolvable Discrepancies
 - Unverified CRFs
 - Number of Days since Last Enrollment



Figure 2–10 Site Metrics Area

- Three progress bars for each site, displaying the following data from CDA:
 - Open Discrepancies
 - Forms ready for SDV
 - Patient Enrollment

Figure 2–11 Progress Bars for Site



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

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My Studies	M_St	tudy_2 - Sites 🛛 🌣 🖡
Automation_Study_1 Automation_Study_1	Bay General Hospital Office 9980098761	
MCRA_Proto_001 Protocol1 Test	Address 300 Oracle Parkway Redwood City, CA 94065	
MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLMENT	
MCRA_Proto_004 Protocol4 Test	discrepancie records/wk subjects/wk	
MCRA_Proto_008 Protocol8 Test	Bay General Hospital	
M_Study_1 cardiac research	0	KEY CONTACTS Mary Arrons Site Coordinator 400 Oracle Parkway
M_Study_2 vaccination research	Subjects Enrolled Irresolvable Dis	
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Mobile_Proto_009 Protocol9 Test	Open Discrepancies Unverified CRF	41)8324242
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ST_Study 1 ST_Study 1	Completed One Visits Days since Last	9980099761 Pharmacy
	Trip Reports Alerts Contac	ts Checkin Map Subscription

Figure 2–12 Key Contacts

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

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My Studies	M_Study_2 -	Sites 🗰 🗱 🖡
Automation_Study_1 Automation_Study_1	Bay General Hospital Office 9980098761	
MCRA_Proto_001 Protocol1 Test	Address 300 Oracle Parkway Redwood City, CA 94065	
MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLMENT	
MCRA_Proto_004 Protocol4 Test	discrepancie records/wk subjects/wk	
MCRA_Proto_008 Protocol8 Test	Bay General Hospital	
M_Study_1 cardiac research	0 0	KEY CONTACTS Mary Aarons Site Coordinator
M_Study_2 vaccination research	Subjects Enrolled Irresolvable Discrepancies	400 Oracle Parkway Redwood City, CA 94065 9257253609
Mobile_Proto_005 Protocol5 Test		Janet Able Exhibit Coordinator 300 Oracle Parkway
Mobile_Proto_009 Protocol9 Test	Open Discrepancies Unverified CRFs	Redwood City, CA 94065 4158324242
ST_Alert Study Alerts	Completed Site Visits Days since Last Enrollment	George Abby Principal Investigator 500 Oracle Parkway Redwood City, CA 94065
ST_Study 1 ST_Study 1		9980098761 Pharmacy
	Trip Reports Alerts Contacts (Image: Sheckin Map Subscription

Figure 2–13 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, with both trend graphs and up to date statistics on study progress.

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My Studies	M_Study_2	- Sites 🛛 🏶 🖡
Automation_Study_1 Automation_Study_1	Bay General Hospital Office 9980098761	
MCRA_Proto_001 Protocol1 Test	Address 300 Oracle Parkway Redwood City, CA 94065	
MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLMENT	
MCRA_Proto_004 Protocol4 Test	discrepancie records/wk subjects/wk	
MCRA_Proto_008 Protocol8 Test	Bay General Hospital	
M_Study_1 cardiac research	0 0	KEY CONTACTS Mary Aarons Site Coordinator 400 Oracle Parkway
M_Study_2 vaccination research	Subjects Enrolled Irresolvable Discrepancie	Redwood City, CA 94065 9257253609
Mobile_Proto_005 Protocol5 Test		Janet Able Exhibit Coordinator 300 Oracle Parkway
Mobile_Proto_009 Protocol9 Test	Open Discrepancies Unverified CRFs	Redwood City, CA 94065 4158324242
ST_Alert Study Alerts	Completed Site Visits Days since Last Enrollme	George Abby Principal Investigator 500 Oracle Parkway nt Redwood City, CA 94065
ST_Study 1 ST_Study 1		9980098761 Pharmacy
	Trip Reports Alerts Contacts	? ⊕ ⊅ Checkin Map Subscription

Figure 2–14 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 iPad Menu.

Figure 2–15



2. Tap Mobile CRA. CRA settings will be displayed.

Figure 2–16

iPad 🗢 🕅	2:09 PM	66 % 🔳
Settings	Mobile CRA	
wessayes		
🗾 Music	Mobile CRA Server	
Video	Time out 1500	
Photos	DebugFlag	OFF
Motes	Server Address	
Store		
Apps		
O AccuWeather		
🕢 App Cooker		
BBC News		
Envia Forms		
💟 iBooks		
Mobile CRA		
Organize HD		
🚳 Paper		
Skype		
Xavier		

The following settings can be modified:

- **Time out** 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.
- **Debug Flag** This option pertains to Mobile CRA logs. To enable detailed logs, switch this option **ON**.
- Server Address This is the Mobile CRA server address.

This chapter contains the following topics:

- Introduction to Alerts on page 3-1
- Viewing Alerts on page 3-3
- Subscribing to an Alert on page 3-6
- Predefined Alerts on page 3-22
- Resetting Alerts on page 3-23
- Marking an Alert as Important on page 3-25
- Unmarking an Alert as Important on page 3-27

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 CDA 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.

Following is an example of an alert:

Figure 3–1 An Alert

iPad 🔶 💵		11:22	AM	100% 💶
Automation_Study_1 Alerts		Automation_Study_1 - Sites	Amvax Pharmaceuticals	
Q Search				
Number of Enroll MCRA_Proto_002 &	29/10/12 >			Unmark Important
Number of Enroll MCRA_Proto_002 &	29/10/12 >	Number of Enrolled F	Patients is Greater Than Thre	eshold, Auto
Number of Enroll MCRA_Proto_002 &	29/10/12 >	Triggered Wednese	day at 4:48 PM.	
Number of Enroll MCRA_Proto_002 &	29/10/12 >	Number of enrolled	l patients at Amvax Pharm	aceuticals is greater than 3
Number of Enroll MCRA_Proto_002 &	29/10/12 >			
Number of Enroll MCRA_Proto_002 &	29/10/12			
Number of Enroll MCRA_Proto_002 &	29/10/12			
Number of Enroll MCRA_Proto_002 &	29/10/12			
Number of Enroll MCRA_Proto_002 &	29/10/12 >			
MUMber of Enroll MCRA_Proto_002 &	29/10/12 >			

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.

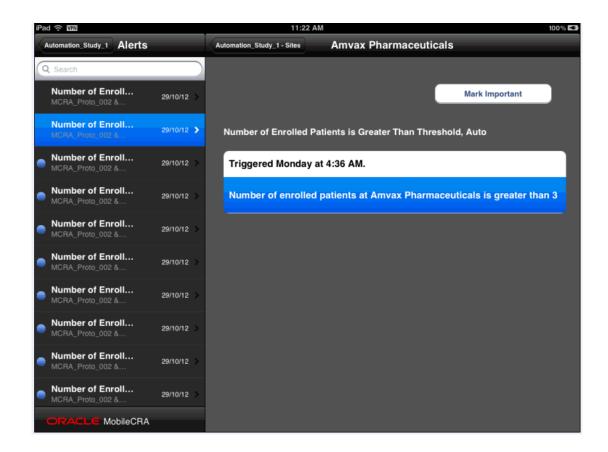


Figure 3–2 Viewed Alerts

3.2 Viewing Alerts

The Mobile CRA menu contains the Alerts icon with a badge to show the number of unread alerts in the list.



Figure 3–3 Alert Icon with Badge

The application icon also displays this badge.





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 3–5 View an Alert

3. Tap **Alerts**. The list of alerts for the study is displayed, with the most recent alerts on top.

iPad 🔶 VPN		11:2	9 AM	100% 📼
AMXN 9374 Alerts		AMXN 9374 - Sites	MCRA_Proto_002	
Q Search				
Number of Enroll MCRA_Proto_002 &	07/11/12 >		(Mark Important
Number of Sites MCRA_Proto_025	07/11/12 >	Number of Study Si	tes GT than Threshold, Manua	ı
Number of Sites MCRA_Proto_002	07/11/12 >	Triggered Wedne	sday at 4:48 PM.	
Number of Study MCRA_Proto_002	07/11/12 >	The number of si	tes is greater than 2	
Number of Study MCRA_Proto_002	07/11/12 🔉			
Number of Enroll MCRA_Proto_002 &	07/11/12 >			
Number of Enroll MCRA_Proto_002 &	29/10/12 >			
Number of Enroll MCRA_Proto_002 &	29/10/12			
Number of Enroll MCRA_Proto_002 &	29/10/12 >			
Number of Enroll MCRA_Proto_002 &	29/10/12 >			

Figure 3–6 Alerts for a Study

=

Note: Swipe the Alerts panel, on the left, downwards as shown in Figure 3–7 to update the list of alerts.

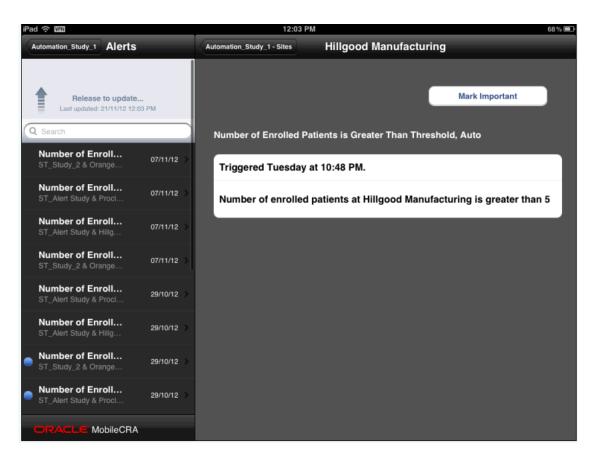


Figure 3–7 Update the Alerts List

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.

iPad 🔶 🕅	2:32 PM		100 % 📟
My Studies	Aut	omation_Study_1 - Sites	* F•
Automation_Study_1 Automation_Study_1	Amsterdam Memorial Hospital Office 4131000000	Jones, Johnson and Jefferson, LLC Office 4085554202	
MCRA_Proto_001 Protocol1 Test	Address 1 Barcelona Ln.	Address	
MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLMENT		
MCRA_Proto_004 Protocol4 Test	discrepancie records/wk subjects/wk		
MCRA_Proto_008 Protocol8 Test	Amsterdam Memorial Hospital		
M_Study_1 cardiac research	0	Frederick Aaron	
M_Study_2 vaccination research	SubjectEnrollCnt Irresolv	4046733748	
Mobile_Proto_005 Protocol5 Test		James Aaron Princi	pal Investigator
Mobile_Proto_009 Protocol9 Test	OpenDiscCnt UnVeri	fyCRFCnt 4152065351	
ST_Alert Study Alerts	CompSitevisitCnt NumDa	avsSinceLastEnroll	
ST_Study 1 ST_Study 1		Granite City, CA 9564	43
	Trip Reports Alerts	Contacts Checkin Map	Subscription

Figure 3–8 Select a Study-Site

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

iPad 奈 VFN	12:04 PM		68 % 💷
Automation_Study_1 Subscriptions	Auto	omation_Study_1 - Site	es ≄[+
Study Alerts	Amsterdam Memorial Hospital Office 4131000000	Jones, Johnson and Jefferson, L Office 4085554202	
Site Alerts	Address 1 Barcelona Ln. 	Address	
	OPEN DISCR SV READY ENROLLMENT discrepancie records/wk subjects/wk		
	Amsterdam Memorial Hospital		
		()	ONTACTS k Aaron Evaluator
	SubjectEnrollCnt Irresolv	eDiscCnt 4046733 James A	748 aron Principal Investigator
	OpenDiscCnt UnVeri	lyCRFCnt 4152065 Investig 1 Health	ator
	CompSitevisitCnt NumDa	ssinceLastEnroll	City, CA 95643
	Trip Reports Alerts	Contacts Checkin	Map Subscription

Figure 3–9 Subscriptions for a Study

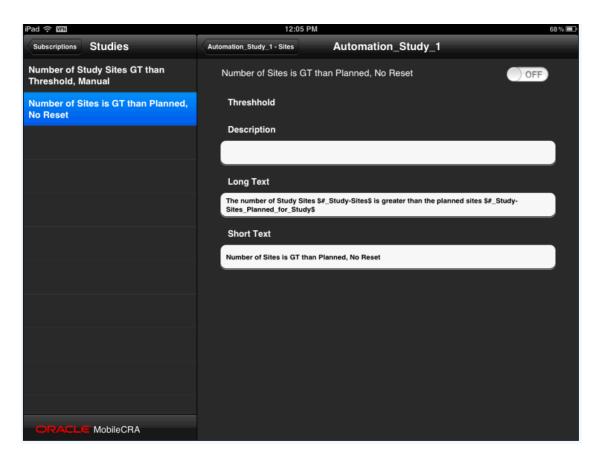
4. Select the alert category to view the alerts in it. In the graphic below, **Study Alerts** have been selected.

iPad 奈 VFN	12:05 PI	N		68 % 🂻
Subscriptions Studies		Automation_Study	_1 - Sites	* [·
Number of Study Sites GT than Threshold, Manual	Amsterdam Memorial Hospit Office 4131000000	tal Jones, Johnson and Office 408555		
Number of Sites is GT than Planned, No Reset	Address 1 Barcelona Ln. 	Address		
	OPEN DISCR SV READY ENROLLI discrepancie records/Wk subjects/v			
	Amsterdam Memorial Hosp	pital		
	0	0	KEY CONTA	
	SubjectEnrollCnt Ir		4046733748 James Aaron	Principal Investigator
	OpenDiscCnt U		4152065351 Investigator 1 Health Way	
	CompSitevisitCnt N	lumDaysSinceLastEnroll	Granite City, C	A 95643
	Trip Reports Alerts	Contacts C		Map Subscription

Figure 3–10 Category of Alerts

5. Select the alert you want to subscribe to.

Figure 3–11 Select an Alert



- **6.** If necessary, modify the default threshold. For more details, refer to section Modifying an Alert Subscription on page 3-16.
- **7.** Tap **OFF** on the top right corner. It changes to **ON** and you will be subscribed to the alert.

iPad 🔶 VEX	12:05 PM 68%	
Subscriptions Studies	Automation_Study_1 - Sites Automation_Study_1	
Number of Study Sites GT than Threshold, Manual	Number of Study Sites GT than Threshold, Manual	
Number of Sites is GT than Planned, No Reset	Threshhold Count of Sites in a Study 2	>
	Description	
	Long Text	
	The number of sites is greater than \$THRESH_NUM1\$	
	Short Text	
	Number of Study Sites GT than Threshold	

Figure 3–12 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 username and password.
- 2. In the My Studies tab, tap a study to view its details.

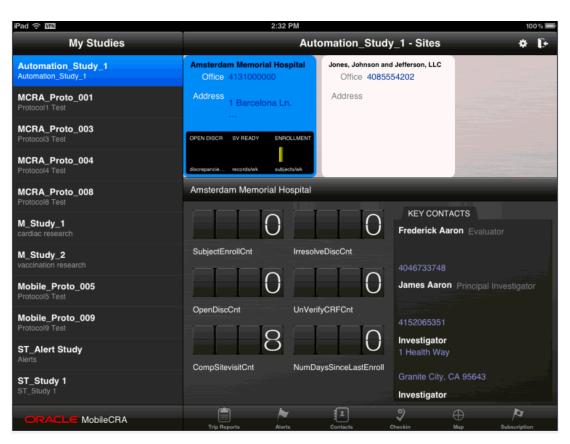


Figure 3–13 Select a Study

3. Tap **Subscription**. The following screen with the study and site alerts is displayed.

iPad 🎅 VFN	12:04 PM		68 % 🔳
Automation_Study_1 Subscriptions	Aut	omation_Study_1 - Sites	* D-
Study Alerts	Amsterdam Memorial Hospital Office 4131000000	Jones, Johnson and Jefferson, LLC Office 4085554202	
Site Alerts	Address 1 Barcelona Ln.	Address	
	OPEN DISCR SV READY ENROLLMENT discrepancie records/wk subjects/wk		
	Amsterdam Memorial Hospital		
		KEY CONT/ Frederick Aa	ACTS ron Evaluator
	SubjectEnrollCnt Irresolv	4046733748 James Aaron	Principal Investigator
	OpenDiscCnt UnVeri	fyCRFCnt 4152065351 Investigator 1 Health Way	
		aysSinceLastEnroll Granite City, (Investigator	CA 95643
	Trip Reports Alerts	Contacts Checkin	Map Subscription

Figure 3–14 Alerts for a Study

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

iPad 奈 VFN	12:05 PM		68 % 💷
Subscriptions Studies	Auto	omation_Study_1 - Sites	* (•
Number of Study Sites GT than Threshold, Manual	Amsterdam Memorial Hospital Office 4131000000	Jones, Johnson and Jefferson, LLC Office 4085554202	
Number of Sites is GT than Planned, No Reset	Address 1 Barcelona Ln. 	Address	
	OPEN DISCR SV READY ENROLLMENT		
	discrepancie records/wk subjects/wk		
	Amsterdam Memorial Hospital		
	0	KEY CONT Frederick Aa	ACTS ron Evaluator
	SubjectEnrollCnt Irresolv	4046733748	
	\mathbf{O}	James Aaron	Principal Investigator
	OpenDiscCnt UnVeri	fyCRFCnt 4152065351	
		Investigator 1 Health Way	
	CompSitevisitCnt NumDa	aysSinceLastEnroll Granite City,	CA 95643
		Investigator	
	Trip Reports Alerts	Contacts Checkin	Map Subscription

Figure 3–15 Study Alerts

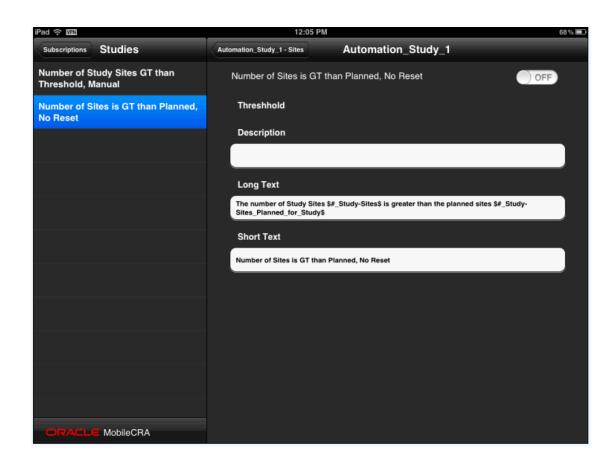
5. Select the alert you want to unsubscribe from.

iPad 🔶 🕅	12:05	PM	68 % 🔳
Subscriptions Studies	Automation_Study_1 - Sites	Automation_Study_1	
Number of Study Sites GT than Threshold, Manual	Number of Study Site	s GT than Threshold, Manual	
Number of Sites is GT than Planned, No Reset	Threshhold Count of Sites in a Study 2		>
	Description		
	Long Text		
	The number of sites is gr	eater than \$THRESH_NUM1\$	
	Short Text Number of Study Sites G	T than Threshold	

Figure 3–16 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 3–17 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 username and password.
- 2. In the My Studies tab, tap a study to select it.

iPad 🙃 VFN	2:32 PM		100% 🚍
My Studies	Aut	omation_Study_1 - Sites	* D-
Automation_Study_1 Automation_Study_1	Amsterdam Memorial Hospital Office 4131000000	Jones, Johnson and Jefferson, LLC Office 4085554202	
MCRA_Proto_001 Protocol1 Test	Address 1 Barcelona Ln.	Address	
MCRA_Proto_003 Protocol3 Test	OPEN DISCR SV READY ENROLLMENT		
MCRA_Proto_004 Protocol4 Test	discrepancie records/wk subjects/wk		
MCRA_Proto_008 Protocol8 Test	Amsterdam Memorial Hospital		
M_Study_1 cardiac research	0	KEY CONTA Frederick Aar	
M_Study_2 vaccination research	SubjectEnrollCnt Irresol	veDiscCnt 4046733748	
Mobile_Proto_005 Protocol5 Test	0		Principal Investigator
Mobile_Proto_009 Protocol9 Test	OpenDiscCnt UnVeri	4152065351	
ST_Alert Study Alerts		Investigator 1 Health Way	
ST_Study 1 ST_Study 1	CompSitevisitCnt NumD	aysSinceLastEnroll Granite City, C Investigator	A 95643
	Trip Reports Alerts		Map Subscription

Figure 3–18 Select a Study

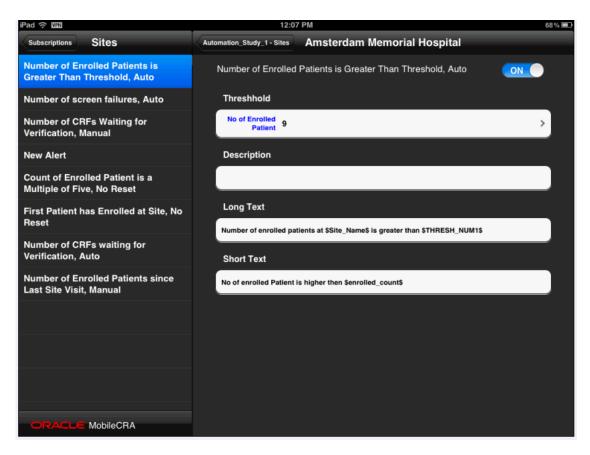
3. Tap **Subscription**. The following screen with the study and site alerts is displayed.

iPad 🔶 VFN	12:04 PM	68%
Automation_Study_1 Subscript	ions Autom	ation_Study_1 - Sites 🔹 🕏
Study Alerts	Amsterdam Memorial Hospital Jo Office 4131000000	ones, Johnson and Jefferson, LLC Office 4085554202
Site Alerts	Address 1 Barcelona Ln.	Address
	OPEN DISCR SV READY ENROLLMENT discrepancie records/wk subjects/wk	
	Amsterdam Memorial Hospital	
		KEY CONTACTS Frederick Aaron Evaluator
	SubjectEnrollCnt IrresolveDis	scCnt 4046733748 James Aaron Principal Investigator
	OpenDiscCnt UnVerifyCF	AFCnt 4152065351 Investigator 1 Health Way
	CompSitevisitCnt NumDaysS	SinceLastEnroll Granite City, CA 95643 Investigator
		Contacts Checkin Map Subscription

Figure 3–19 Alerts for a Site

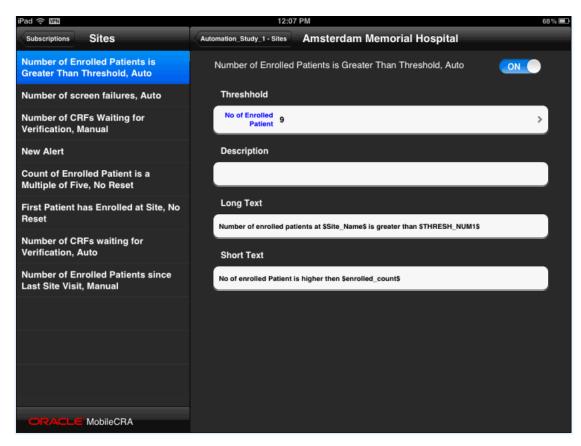
4. Select **Site Alerts** to view a list of study-site alerts.

Figure 3–20 Site Alerts



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

Figure 3–21 Site Alerts



6. Tap Threshhold to edit it.

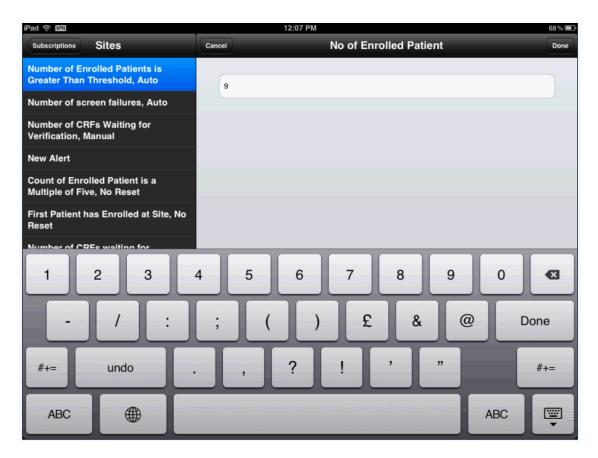
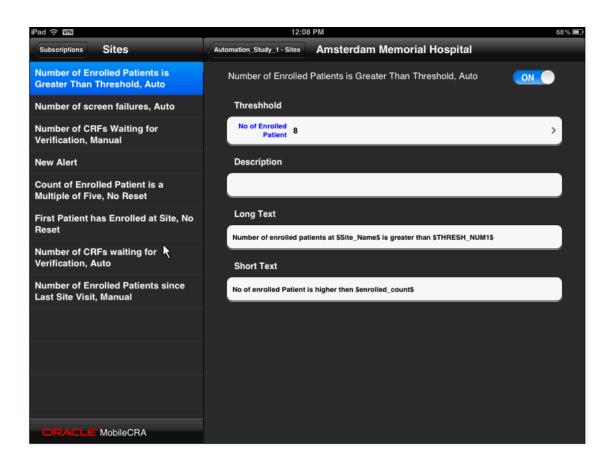


Figure 3–22 Edit the Study-Site Alert Subscription

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

Figure 3–23 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>*.

Following is a list of predefined alerts in the system:

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

Table 3–1 Predefined Alerts

Predefined Alert	Description
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

 Table 3–1 (Cont.) Predefined Alerts

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. 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.

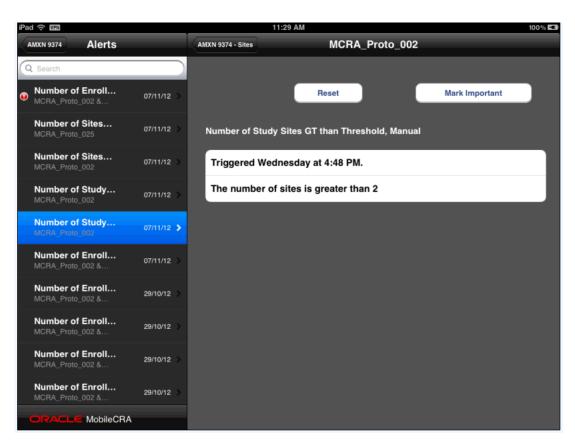


Figure 3–24 Alert Details

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

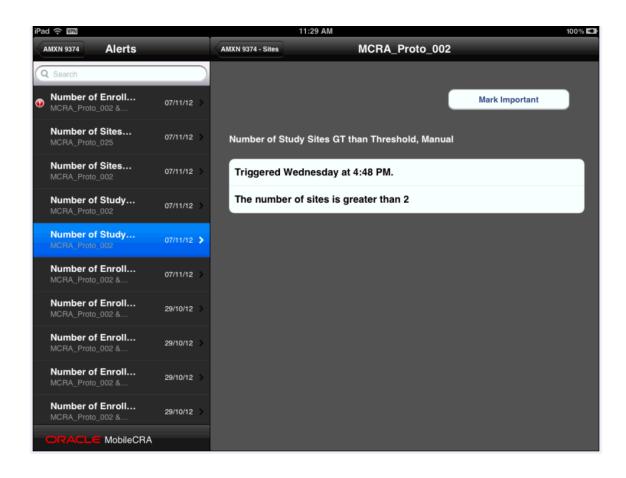


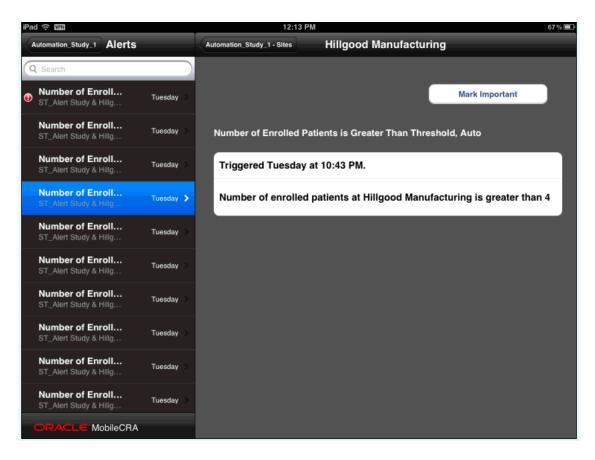
Figure 3–25 Alert Reset

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 3–26 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.

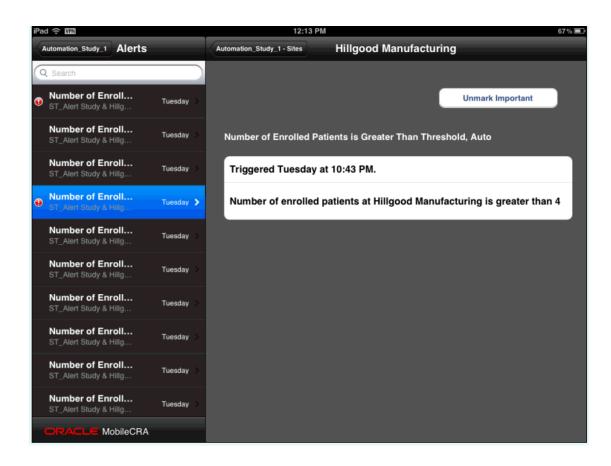


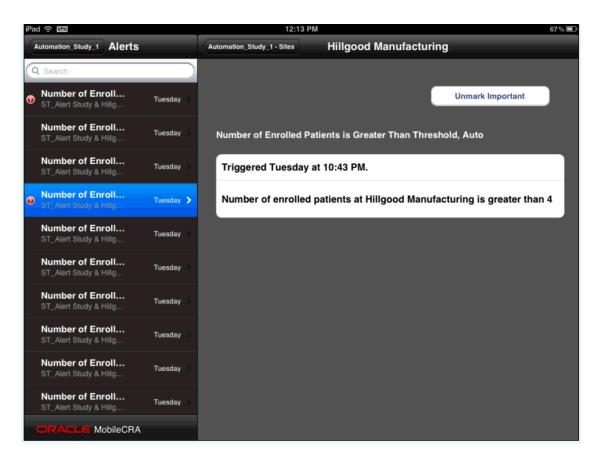
Figure 3–27 Alert Marked Important

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.





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

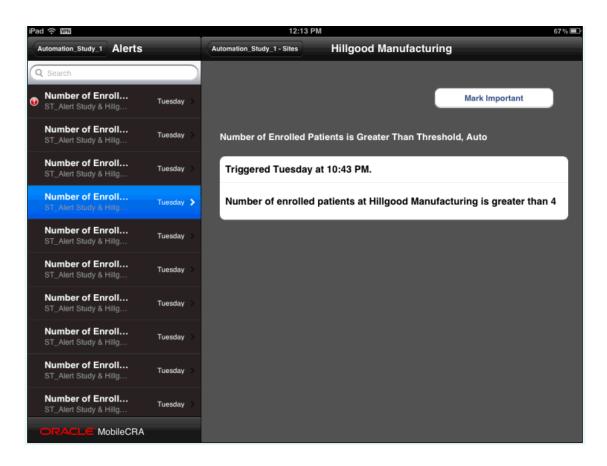


Figure 3–29 Alert Marked Not Important

4

Trip Reports

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

- Introduction to Trip Reports on page 4-1
- Trip Report Fields on page 4-2
- Trip Report Status Icons on page 4-3
- Creating a Trip Report on page 4-3
- Adding Attendees to a Trip Report on page 4-8
- Submitting a Trip Report for Approval on page 4-29
- Adding an Item to the Trip Report Check List on page 4-12
- Modifying an Item in the Trip Report Check List on page 4-15
- Creating Follow up Items in a Trip Report on page 4-17
- Creating a Trip Report Summary on page 4-20
- Viewing an Approved Trip Report on page 4-34

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.

Following is an example of a trip report:

ST_Study_4 - Sites	Visit G1		Ŀ
About			
• Attendees			③
Frederick Aaron			>
Janet Able			>
Checklist Items	i i i i i i i i i i i i i i i i i i i	the second	③
Checklist 1		Unscheduled	>
Follow Up Items		 A start of the second se	(
Follow up 1			>
Save to CTMS	Fetch From CTMS		
In the provide state of the pr			
Processing Process			

Figure 4–1 Trip Report Example

A trip report consists of the following four main areas:

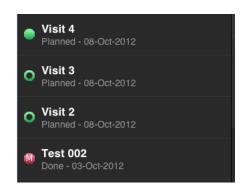
- **About** This section contains details of the trip report like individuals working on it, the protocol it is related to, different dates associated and so on.
- Attendees This section lists all the people associated with a particular site.
- Checklist Items This section displays the list of tasks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

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.

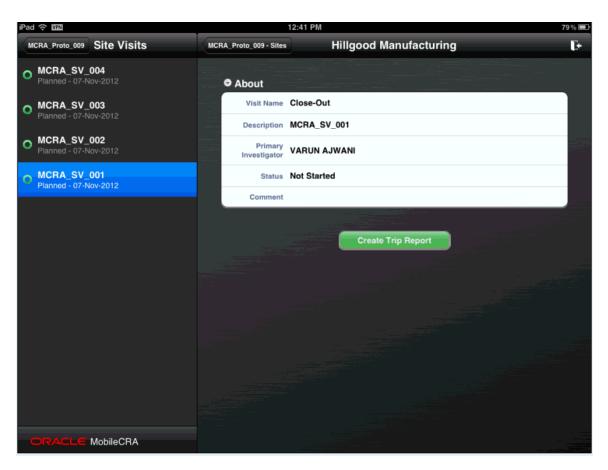


Figure 4–3 Visit Task List

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

iPad 🔶 🔤	12:41	12:41 PM	
MCRA_Proto_009 Site Visits	MCRA_Proto_009 - Sites	Hillgood Manufacturing	Ŀ
O MCRA_SV_004 Planned - 07-Nov-2012	About		
O MCRA_SV_003 Planned - 07-Nov-2012	Visit Name Clos Description MCR		
O MCRA_SV_002 Planned - 07-Nov-2012	Create Tri		
O MCRA_SV_001 Planned - 07-Nov-2012	Template	_	
	MCRA_AT1	8 ip Report	
	Crea	ate and a second s	

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.

iPad 🔶 📼		12:41 PM	79 % 🔳
MCRA_Proto_009 Site Visits	MCRA_Proto_009 - Sites	Hillgood Manufacturing	Ŀ
O MCRA_SV_004 Planned - 07-Nov-2012	C About		
O MCRA_SV_003 Planned - 07-Nov-2012		MCRA_Proto_009	
O MCRA_SV_002 Planned - 07-Nov-2012	Protocol Title Approver	Protocol9 Test	
MCRA_SV_001 Planned - 07-Nov-2012	Approver Comments Reviewer		
	Trip Report	obile CRA Report Created. MCRA_AT18 OK	
	Completed	Hillgood Manufacturing	
	Site	MCRA_Site_002	
	PI Last Name	AJWANI	
	Trip Report Status	In Progress	>
	Assigned To	CWALKER	

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**.

iPad 🔶 📼	12:42 PM		79 % 🔳
MCRA_Proto_009 Site Visits	MCRA_Proto_009 - Sites Hillgood Manufactu	ring	Ę.
MCRA_SV_004	PI Last Name AJWANI		
Planned - 07-Nov-2012	Trip Report Status Completed		
O MCRA_SV_003 Planned - 07-Nov-2012	Assigned To CWALKER		
O MCRA_SV_002 Planned - 07-Nov-2012	Attendees		Ð
	VARUN AJWANI		
MCRA_SV_001 Planned - 07-Nov-2012	Checklist Items	 A second s	
	Anto	Unscheduled	>
	Save to CTMS		
	Save Cancel	Unscheduled	•
	Follow Up Items		Ð
	Act3	Unscheduled) >
	Act4	Unscheduled) >
	Summary		
	Comments		
	Save to CTMS Fetch From 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.

iPad 奈 四	12:42 PM	79 % 🔳
MCRA_Proto_009 Site Visits	MCRA_Proto_009 - Sites Hillgood Manufacturing	Ŀ
O MCRA_SV_004 Planned - 07-Nov-2012	Pi Last Name AJWANI Trip Report Status	
O MCRA_SV_003 Planned - 07-Nov-2012	Assigned To CWALKER	
O MCRA_SV_002 Planned - 07-Nov-2012	• Attendees	Ð
MCRA_SV_001 Planned - 07-Nov-2012	VARUN AJWANI	
	Checklist Items Act2 Mobile CRA Mobile CRA data saved to CTMS. OK Follow Up Items	
	Act3 Unscheduled	⊇ >
	Act4 Unscheduled) >
	Summary	
	Comments	
	Save to CTMS Fetch From CTMS	

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.

iPad 🤶 🕅	10:15 AM			80% 💷
ST_Study_4 Visits - Site 88-2KKA0	ST_Study_4 - Sites	Visit G1		Ę.
Planned - 10-Oct-2012	About			
O Visit G Done - 10-Oct-2012	• Attendees			(
O V6 Done - 09-Oct-2012	Frederick Aaron Janet Able			> >
Visit 5 Planned - 08-Oct-2012	Checklist Items			•
O Visit 4 Planned - 08-Oct-2012	Checklist 1		Unscheduled	`
• Visit 3 Planned - 08-Oct-2012	Follow Up Items Follow up 1		1 March 2014 Constraints and a second	€
Visit 2 Done - 08-Oct-2012				
O Visit 1 Planned - 08-Oct-2012	Save to CTMS	Fetch From CTMS		

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

\bigcirc

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

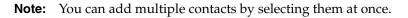
iPad 🔶 VEN		10:15 AM		80% 💻
ST_Study_4 Visits - Site 88	ST_Study_4 - Sites		Visit G1	Ŀ
Visit G1 Planned - 10-Oct-2012	Done	Contacts	Cancel	
O Visit G Done - 10-Oct-2012	A George Abby		AB	Ð
• V6 Done - 09-Oct-2012	Joshua Aarons		C D E	>
O Visit 5 Planned - 08-Oct-2012				•
O Visit 4 Planned - 08-Oct-2012				Unscheduled >
O Visit 3 Planned - 08-Oct-2012			L M N	•
• Visit 2 Done - 08-Oct-2012			0 P 0	
O Visit 1 Planned - 08-Oct-2012				
		-		and the second

Figure 4–10 Mobile CRA Contacts

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

iPad	🔶 VPN				10:15 AM				80% 🔳
s	T_Study_4	Visits - Site 88	-2KKA0	ST_Study_4 - Sites		Visit G1			Ę.
•	Visit G1 Planned -	10-Oct-2012	Done	_	Contacts	_	Cancel		
0	Visit G Done - 10		A George A	Abby			A B		(
0	V6 Done - 09		Joshua /	arons			✓ D E		> >
0	Visit 5 Planned -								Ð
0	Visit 4 Planned -							Unscheduled	>
0	Visit 3 Planned -								•
0	Visit 2 Done - 08								
0	Visit 1 Planned -								
	DRAC								

Figure 4–11 Select Contact



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

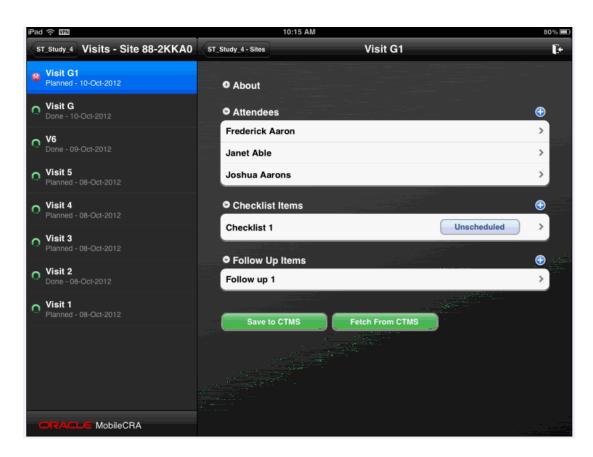


Figure 4–12 Attendee Added to Trip Report

4.6 Adding an Item to the Trip Report Check List

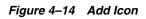
Perform the following steps to add an item to the trip report check list:

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

iPad 🔶 🔤			11:27 AM	100% 💶
AMXN 9374 Visi	ts - Site 88-2IJI9	AMXN 9374 - Sites	Lab Evaluation	ŀ
O v1 Planned - 19-Oc		Reviewer Comments		
e Lab Evaluati		Template	TR_ProtocolTrip_En_001	
Done - 25-Sep-2	2012	PI First Name	CHRISTINA	
		Trip Report Completed	10/05/2012	
		Completed	10/05/2012 19:04:27	
		Account	Oregon State College	
		PI Last Name	ANTHONY	
		Trip Report Status	Completed	>
		Assigned To	SADMIN	
		• Attendees		
		CHRISTINA A	NTHONY	>
		Checklist I		•
		Follow Up	Items	
		Save to C	TMS Fetch From CTMS	
ORACLE'N	MobileCRA			

Figure 4–13 Trip Report

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



(

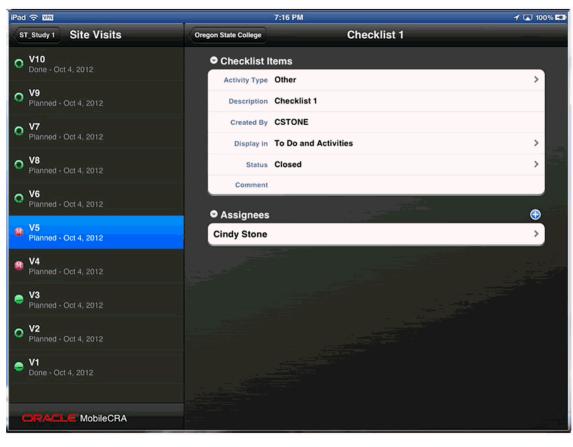


Figure 4–15 New Checklist Item

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

iPad 중 WWW	7:11 PM		10	0% 🖘
ST_Study 1 Site Visits	ST_Study 1 - Sites	Oregon State College		ŀ
• V10 Done - Oct 4, 2012	About			
• V9 Planned - Oct 4, 2012	• Attendees		Ð	
• V7 Planned - Oct 4, 2012	Michael Aaron Janet Able		>	8
O V8 Planned - Oct 4, 2012	Checklist Items		•	
• V6 Planned - Oct 4, 2012	Checklist 2		Approved >	- 77 i
V5 Planned - Oct 4, 2012	Checklist 1	and the second s	Closed >	ļ
V4 Planned - Oct 4, 2012	 Follow Up Items Follow up 1 	—: 	Active >	
V3 Planned - Oct 4, 2012	Summary			
O V2 Planned - Oct 4, 2012	Comments)
V1 Done - Oct 4, 2012	Save to CTMS	Fetch From CTMS		_

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.

iPad 🗢 🏧	7:11 PM		1 🗖	100% 📼
ST_Study 1 Site Visits	ST_Study 1 - Sites	Oregon State College		Ŀ
O V10 Done - Oct 4, 2012	About			
• V9 Planned - Oct 4, 2012	• Attendees		6	
O V7 Planned - Oct 4, 2012	Michael Aaron Janet Able			> > //////////////////////////////////
O V8 Planned - Oct 4, 2012	Checklist Items	-		
• V6 Planned - Oct 4, 2012	Checklist 2		Approved	> ==
W5 Planned - Oct 4, 2012	Checklist 1		Closed	
V4 Planned - Oct 4, 2012	Follow Up Items Follow up 1	(Active)
V3 Planned - Oct 4, 2012	Summary		ang	
© V2 Planned - Oct 4, 2012	Comments			
Done - Oct 4, 2012	Save to CTMS	Fetch From CTMS		

Figure 4–17 Trip Report

4. Tap the checklist item you want to modify.

iPad 🗢 🚥		7:16 PM	100% 📼
ST_Study 1 Site Visits	Oregon State College	Checklist 1	_
O V10 Done - Oct 4, 2012	Checklist I	tems	
○ V9	Activity Type	Other	>
O Planned - Oct 4, 2012	Description	Checklist 1	
0 ^{V7}	Created By	CSTONE	
Planned - Oct 4, 2012	Display in	To Do and Activities	>
• V8 Planned - Oct 4, 2012	Status	Closed	>
• V6 Planned - Oct 4, 2012	Comment Assignees		•
V5 Planned - Oct 4, 2012	Cindy Stone		>
V4 Planned - Oct 4, 2012			
S V3 Planned - Oct 4, 2012			
• V2 Planned - Oct 4, 2012			
V1 Done - Oct 4, 2012			

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 on the iPad. 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.

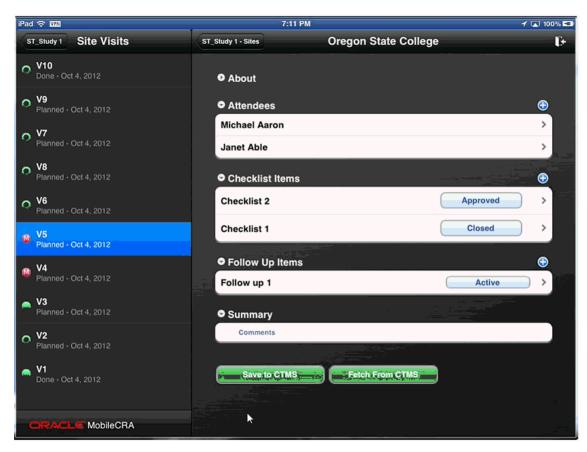
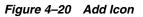


Figure 4–19 Trip Report

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





iPad 🙃 💵	11:27 AM 100% 🛙
AMXN 9374 Visits - Site 88-2IJI9	Lab Evaluation
Planned - 19-Oct-2012	Follow Up Items
M Lab Evaluation	Created By
Done - 25-Sep-2012	Completed Date
	Assigned To
	Status Required value
	Due
	Comment
	Description Required value
	Activity Type Required value
	Display In Required value

Figure 4–21 New Follow Up Item

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

iPad 奈 💵			11:27 AM	100% 📼
AMXN 9374	Visits - Site 88-2IJI9	AMXN 9374 - Sites	Lab Evaluation	ŀ
O v1 Planned -	19-Oct-2012	Completed	10/05/2012 19:04:27	
		Account	Oregon State College	
Done - 25	aluation 5-Sep-2012	PI Last Name	ANTHONY	
		Trip Report Status	Completed	>
		Assigned To	SADMIN	
		Attendees		•
		CHRISTINA A	ANTHONY	>)
		Checklist I	tems	
		Follow Up	Items	•
				•
				•
			R. (
		Save to C	TMS Fetch From CTMS	
ORAC	LE MobileCRA			

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.

iPad 🗢 VPN		11:24 AM	1	00% 르
Automation Visits - Site 88-2IU	Automation_Study_1 - S	Sites Visit 1		ŀ
Wisit 1 Planned - 27-Sep-2012	Account	Amsterdam Memorial Hospital		
	Site	Automation_Site_1		
	PI Last Name	Aaron		
	Trip Report Status	In Progress	>	
	Assigned To	SADMIN		
	Attendees			
	James Aaron	1	>	
	Mary Aaron		>	
	Frederick Aa	ron	>	-
	Checklist I	tems		
	Checklist act	tivity 1	Delivery Failed >	
	Summary			
	Comments			
	Save to C	CTMS Fetch From CTMS		a kin sta

Figure 4–23 Trip Report

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

iPad 🔶 VFN	11:25 AM	100% 💶
Automation Visits - Site 88-2IU	Visit 1	ŀ
Visit 1	James Aaron	>
Planned - 27-Sep-2012	Mary Aaron	>
	Frederick Aaron	>
	Checklist Items	•
×		Q >
	Checklist activity 1	very Failed >
	Summary	
	Comments Trip report comments	
Q W E	RTYUIO	P 🗳
A S D	FGHJKL	return
	С V В N М !,	? . ↔
.?123		.?123

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 Saving Trip Report Data to Oracle Siebel Clinical Trial Management System on page 4-22.

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.

iPad 🔶 WEN	12:17 PM		96 % 💻
Automation Visits - Site 88-2IU	Automation_Study_1 - Sites	Test 002	Þ
Planned - 26-Oct-2012	Trip Report Status Completed		>
AV1 Planned - 19-Oct-2012	Assigned To CSTONE		
Visit G4 Done - 10-Oct-2012	• Attendees		•
Visit G2 Done - 10-Oct-2012	James Aaron Frederick Aaron		> ==== >
Visit GA1 Done - 10-Oct-2012	Checklist Items		••••••••••••••••••••••••••••••••••••••
Visit 5 Planned - 08-Oct-2012	Checklist activity 1	2	Active >
Visit 4 Planned - 08-Oct-2012	 Follow Up Items Test 		In Progress
O Visit 3 Planned - 08-Oct-2012	Comment1		In Progress >
O Visit 2 Planned - 08-Oct-2012	Followup activity 1	 Marcine and Administration of the second seco	Unscheduled >
Test 002 Done - 03-Oct-2012	Summary Comments	(a) An Alfred Markov, Song Y. S.	
O Test 001 Done - 03-Oct-2012	Save to CTMS	Fetch From CTMS	

Figure 4–25 Trip Report

5. Tap Save to CTMS.

iPad 🔶 🖾	12:18 PM			96 % 🚍
Automation Visits - Site 88-2IU	Automation_Study_1 - Sites	Test 002		Ę.
Planned - 26-Oct-2012	Trip Report Status Completed			
AV1 Planned - 19-Oct-2012	Assigned To CSTONE			
Visit G4 Done - 10-Oct-2012	• Attendees		e	•
	James Aaron			
Visit G2 Done - 10-Oct-2012	Frederick Aaron			
O Visit GA1 Done - 10-Oct-2012	Checklist Items	A construction of the second sec		Ð
Visit 5 Planned - 08-Oct-2012	Checklist Save to CTMS		Active	
Visit 4 Planned - 08-Oct-2012	Foll Save Item Car	ncel	In Progress	
O Visit 3 Planned - 08-Oct-2012	Comment1			
O Visit 2 Planned - 08-Oct-2012	Followup activity 1		Unscheduled	
Test 002	Summary			
Done - 03-Oct-2012	Comments			
O Test 001 Done - 03-Oct-2012	Saus to OTMO	Falah From 0740		
	Save to CTMS	Fetch From 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.

iPad 🙃 🗤	12:18 PM	96 % 📟
Automation Visits - Site 88-2IU	Automation_Study_1 - Sites Test 00	2 🖡
Planned - 26-Oct-2012	Trip Report Status Completed	>
AV1 Planned - 19-Oct-2012	Assigned To CSTONE	
Visit G4 Done - 10-Oct-2012	• Attendees	Ð
• Visit G2 Done - 10-Oct-2012	Frederick Aaron James Aaron	> >
Visit GA1 Done - 10-Oct-2012	Checklist Items	Ð
Visit 5 Planned - 08-Oct-2012	Checklist activity 1 Mobile CRA data saved to CTMS.	Active
Visit 4 Planned - 08-Oct-2012	Follow Up Ite OK	In Progress >
Visit 3 Planned - 08-Oct-2012	Comment1	In Progress >
O Visit 2 Planned - 08-Oct-2012	Followup activity 1	Unscheduled >
Test 002 Done - 03-Oct-2012	© Summary Comments	
O Test 001 Dane - 03-Oct-2012	Save to CTMS Fetch From C	

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.

iPad 🔶 🕅	12:17 PM	96%
Automation Visits - Site 88-2IU	Automation_Study_1 - Sites	Test 002 📭
Planned - 26-Oct-2012	Trip Report Status Completed	>
AV1 Planned - 19-Oct-2012	Assigned To CSTONE	and the second
Visit G4 Done - 10-Oct-2012	C Attendees	⊕
Visit G2 Done - 10-Oct-2012	James Aaron Frederick Aaron	> >
O Visit GA1 Done - 10-Oct-2012	• Checklist Items	•
Visit 5 Planned - 08-Oct-2012	Checklist activity 1	Active
Visit 4 Planned - 08-Oct-2012	 Follow Up Items Test 	In Progress
• Visit 3 Planned - 08-Oct-2012	Comment1	In Progress >
Visit 2 Planned - 08-Oct-2012	Followup activity 1	Unscheduled
Test 002 Done - 03-Oct-2012	Summary Comments	
• Test 001 Done - 03-Oct-2012	Save to CTMS Fetc	ch From CTMS

Figure 4–28 Trip Report

5. Tap **Fetch from CTMS**.

iPad	u ⇔ man	12:20 PM		95 % 💻
A	utomation Visits - Site 88-2IU	Automation_Study_1 - Sites	Test 002	F
		Trip Report Status Completed		*
•	AV1 Planned - 19-Oct-2012	Assigned To CSTONE		
•	Visit G4 Done - 10-Oct-2012	• Attendees		Ð
•	Visit G2 Done - 10-Oct-2012	Frederick Aaron James Aaron		> >
0	Visit GA1 Done - 10-Oct-2012	Checklist Items		Ð
•	Visit 5 Planned - 08-Oct-2012	Checkli Fetch From CTMS Download trip report from CTM	MS?	ive >
•	Visit 4 Planned - 08-Oct-2012	Yes No Test		rogress >
0	Visit 3 Planned - 08-Oct-2012	Comment1		rogress >
•	Visit 2 Planned - 08-Oct-2012	Followup activity 1	Unsc	heduled >
•	Test 002 Done - 03-Oct-2012	Summary Comments		
	Test 001 Done - 03-Oct-2012	Save to CTMS	Fetch From CTMS	
(Save to CTMS	Petch From CTMS	

Figure 4–29 Fetch from CTMS Prompt

6. Tap **Yes**.



Figure 4–30 Trip Report Data Fetched from CTMS

If your trip report has unsaved changes and you try to fetch data from CTMS, the following warning will be displayed. Tap **Yes** to fetch data and **No** to exit.

iPad 🔶 🖾	12:18 PM	96 % 🥅
Automation Visits - Site 88-2IU	Automation_Study_1 - Sites Test 0	02 📭
Planned - 26-Oct-2012	Trip Report Status Completed	>
Planned - 19-Oct-2012	Assigned To CSTONE	
Visit G4 Done - 10-Oct-2012	Attendees	•
Visit G2 Done - 10-Oct-2012	James Aaron Frederick Aaron	~ ~ ~
• Visit GA1 Done - 10-Oct-2012	Chee Fetch From CTMS	•
Visit 5 Planned - 08-Oct-2012	WARNING! The trip report contains unsaved changes and will be replaced by the CTMS version. Are	Active
Visit 4 Planned - 08-Oct-2012	you sure? Test Yes No	In Progress >
Visit 3 Planned - 08-Oct-2012	Comment1	In Progress >
O Visit 2 Planned - 08-Oct-2012	Followup activity 1	Unscheduled >
Test 002 Done - 03-Oct-2012	© Summary Comments	E La Carla de La C
• Test 001 Done - 03-Oct-2012	Save to CTMS Fetch From	CTMS
	Save to Crists Potch From	C HIG

Figure 4–31 Warning Displayed

4.11 Submitting a Trip Report for Approval

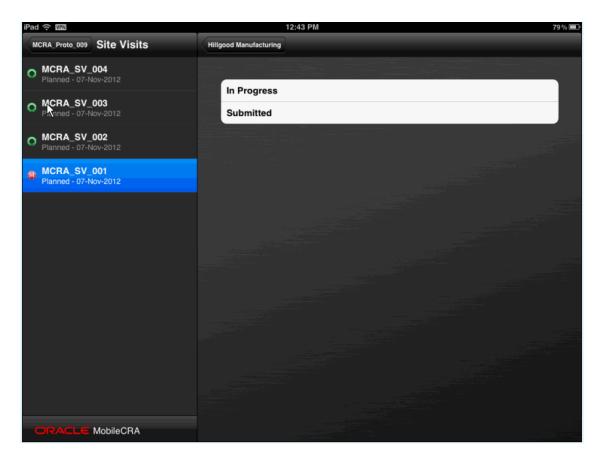
The work flow process in CTMS can be configured in Mobile CRA. For more information on your status flows, consult with your configuration teams. CTMS lets you select the reviewer and approvers for the Trip Report. Currently, this activity must be done in CTMS, and the result fetched to Mobile CRA, in 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 4–32 Trip Report Status



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

iPad 🗢 VPN		12:43 PM		79 % 🔳
MCRA_Proto_009 Site Visits	MCRA_Proto_009 - Sites	Hillgood Manufacturing		Þ
Planned - 07-Nov-2012	Template	MCRA_AT18		
O MCRA_SV_003	PI First Name	VARUN		
Planned - 07-Nov-2012	Trip Report Completed	11/26/2012		
O MCRA_SV_002 Planned - 07-Nov-2012		11/26/2012 07:12:10		
MCRA_SV_001	Account	Hillgood Manufacturing		
Planned - 07-Nov-2012	Site	MCRA_Site_002		
	PI Last Name	AJWANI		
	Trip Report Status	Submitted	>	
	Assigned To	CWALKER		
	Attendees			
	VARUN AJW	ANI	>	
	Checklist I	tems		
	Act2	(Unscheduled >	
	Act1	(Unscheduled >	J
	• Follow Up	tems	•	

Figure 4–33 Trip Report Status Changed

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

iPad 🎅 WEN	12:43 PM	79	9% 🔳
MCRA_Proto_009 Site Visits	MCRA_Proto_009 - Sites Hillgood Manufacturing		₽.
MCRA_SV_004 Planned - 07-Nov-2012 MCRA_SV_003	PI Last Name AJWANI Trip Report Status Submitted	>	
Planned - 07-Nov-2012	Assigned To CWALKER		
O MCRA_SV_002 Planned - 07-Nov-2012	Sign & Submit	()	
MCRA_SV_001 Planned - 07-Nov-2012	Please electronically sign the document with your username and password. Once you sign, you cannot make further edits unless your trip report is rejected.	Ð	
	User Name	>	
	Password	>	
	Sign & Submit Cancel	Ð	
	Unscheduled) >	
	Unscheduled) >	
	Summary		
	Comments		
	Save to CTMS Fetch From CTMS		

Figure 4–34 Sign and Submit

8. Enter your username and password and tap Sign & Submit.

iPad 🤶 🕬	12:44 PM	79 % 🔳
MCRA_Proto_009 Site Visits	Sign & Submit	nufacturing
MCRA_SV_004 Planned - 07-Nov-2012 MCRA_SV_003 Planned - 07-Nov-2012	Please electronically sign the document with your username and password. Once you sign, you cannot make further edits unless your trip report is rejected.	>
MCRA_SV_002 Planned - 07-Nov-2012	CWALKER	Đ
MCRA_SV_001 Planned - 07-Nov-2012	Sign & Submit Cancel	
		Unscheduled
	Act1	Unscheduled >
1 2 3	4 5 6 7	8 9 0 🛯
- / :	; () £	& @ return
#+= undo	. , ? !	, , ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,,
ABC		ABC

Figure 4–35 Submit Trip Report

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

iPad 🔶 🚾	12:44 PM	79 % 🔳
MCRA_Proto_009 Site Visits	MCRA_Proto_009 - Sites Hillgood Manufacturing	Ę.
O MCRA_SV_004 Planned - 07-Nov-2012	PI Last Name AJWANI Trip Report In Review	
MCRA_SV_003 Planned - 07-Nov-2012	Assigned To CWALKER	
O MCRA_SV_002 Planned - 07-Nov-2012	Attendees	
MCRA_SV_001 Planned - 07-Nov-2012	VARUN AJWANI	
	Checklist Items Act2 Mobile CRA Unscheduled Trip Report submitted for approval. OK Unscheduled	
	Follow Up Items Act3 Unschedulee	
	Act4 Unscheduler	
	• Summary	
	Comments	
	Save to CTMS Fetch From CTMS	

Figure 4–36 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.

Contacts

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

- Contacts Integration on page 5-1
- Integrating Contacts with Siebel Clinical Trial Management System on page 5-1

5.1 Contacts Integration

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

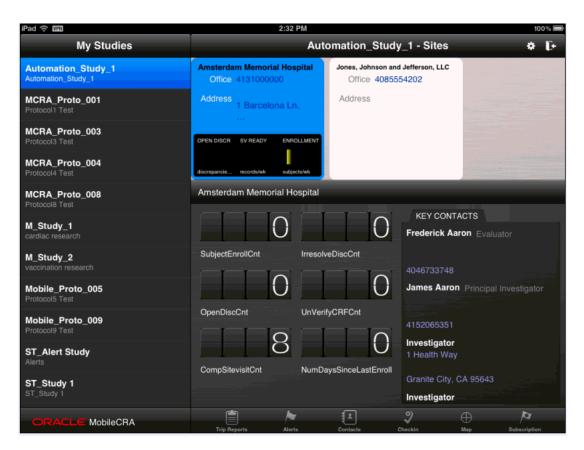
- Synchronize contacts from CTMS You can view contact details of sites assigned to you.
- Export contacts to native device Mobile CRA displays the contacts from CTMS and you can export the contacts to your devices. You can later edit them or make calls.
- Synchronize contacts from Mobile CRA to iPad Contacts on the application can be synchronized with the contacts that are already available on you iPad.
- 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.





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

iPad 🔶 🔤			11:58 AM				89 % 🔳
Automation_Study_1	Site Contacts	Automation_Study_1	Aut	omation_	_Study_	1 - Sites	Ę.
A Frederick Aaron	A 8	Amsterdam Memoria Office 415206535		na i presidente de la companya de la			
James Aaron		Address 1 Barcelor	na Ln.				
		Amsterdam Memori	ial Hospital			KEY CONTACTS	
		SubjectEnrollCnt		veDiscCnt		Frederick Aaron E	
		OpenDiscCnt		fyCRFCnt		James Aaron Print 4152065351	
		CompSitevisitCnt	5 NumDa	aysSinceLas	tEnroll	1 Health Way Granite City, CA 95	543
	obileCRA	Trip Reports	Alerta	Contacts		9 🕀	Subscription

Figure 5–2 Site Contacts

4. Tap a contact to view the details.

iPad 🗇 💵	11:58 AM			89 % 🔳
Automation_Study_1 Site Contacts	Automation_Study_1 - Sites	Contact Info		
A	James R Aaron		Synchronize to Device	OFF
Frederick Aaron B	Principal Investigator		Synchronize to Device	OIT
James Aaron				
	Address			
	Address			
	Email jaaron@bayside.c	om		
	Fax 4155553974			
	Office Phone 4152065351			

Figure 5–3 Contact Details

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

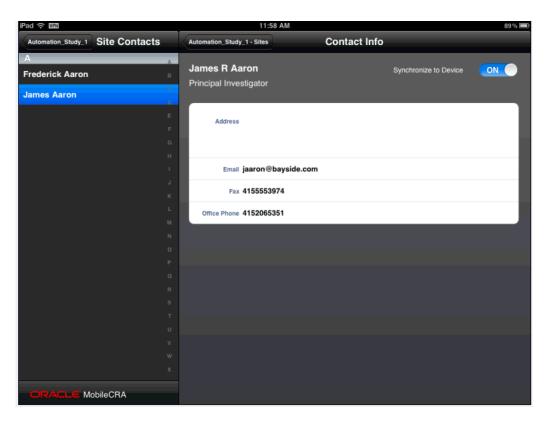


Figure 5–4 Synchronize Contacts

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

Q Search			
A		James R A	Aaron
Ray Aamos			_Study_1 / Site Amsterdan
Frederick G Aaron		Memorial Hospital	
Frederick G Aaron	. work	4152-065351	
James R Aaron	work fax	4155-553974	
James R Aaron	work	jaaron@baysid	le.com
Meredith A Aaron			
Michael A Aaron	notes		
Joshua B Aarons			
Joshua B Aarons			
Lisa M Abbot			
Lisa M Abbot	, Se	nd Message	Share Contact
Janet Able			
Janet Able			

Figure 5–5 Contact Available on Device Contact List

GeoLocation Services

This section contains the following topics:

- Introduction on page 6-1
- Registering a Site Visit on page 6-1
- Map on page 6-4

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 iPad 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.

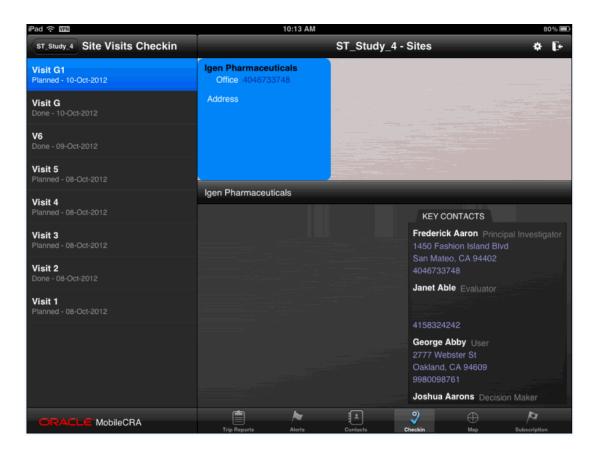


Figure 6–1 Checkin for a Study-Site

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

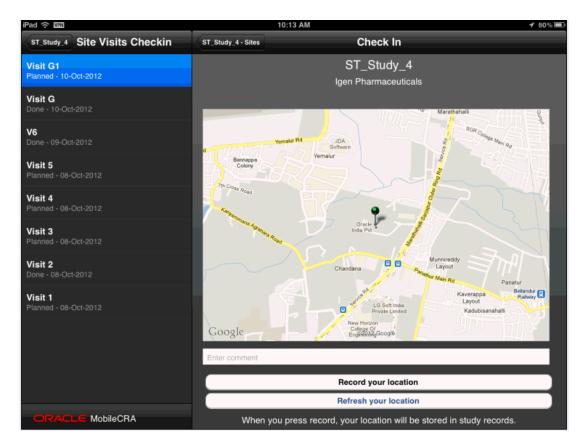


Figure 6–2 Location Capture Map

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, then the **Refresh your location** option will refresh the map and indicate your current location.

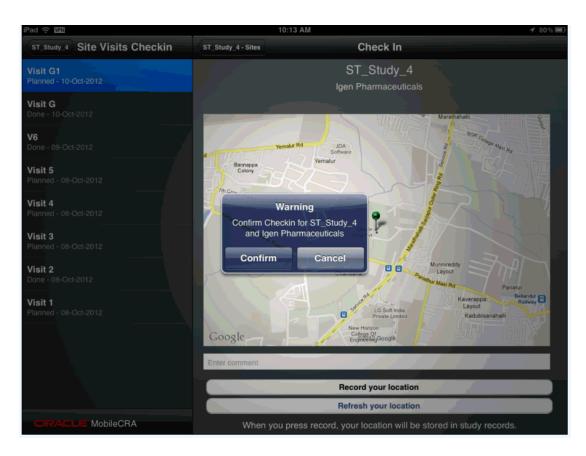


Figure 6–3 Checkin Prompt

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.

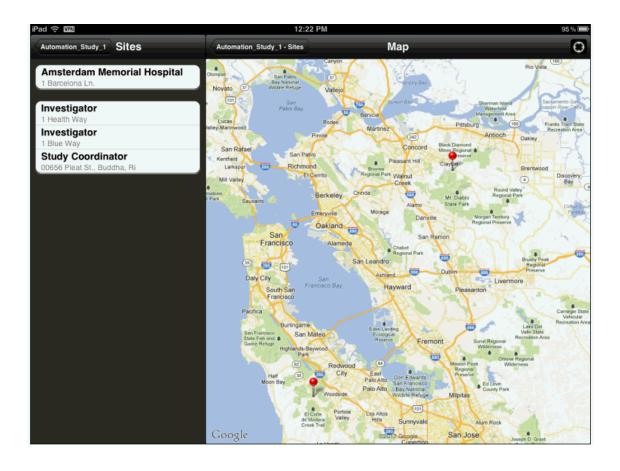


Figure 6–5 Map with Site Locations

7

Offline Services

When visiting a site, or any other location, you may 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:

Offline Functionality on page 7-1

7.1 Offline Functionality

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 Apple iPhone and iPod

This part of the Oracle Health Sciences Mobile Clinical Research Associate Server User Guide describes how to use Mobile CRA on the Apple iPhone and iPod.

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

Accessing the Application

This chapter contains the following topics:

- Logging into Oracle Health Sciences Mobile Clinical Research Associate on page 8-1
- Oracle Health Sciences Mobile Clinical Research Associate Server Menu on page 8-3
- Logging Out of Oracle Health Sciences Mobile Clinical Research Associate on page 8-8

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 Apple iPhone or iPod:

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



Figure 8–1 Mobile CRA Application Icon

2. The following login screen is displayed:

Figure 8–2 Mobile CRA Login Screen

iPod 奈 🚾 1:04 PM	S
Mobile CRA	
Username	
Password	
Log	In
QWERTYU	ΟΡ
ASDFGHJ	KL
	M
.?123 space	return

Enter the following details:

- User name Enter your user name
- Password Enter your password
- **3.** Tap **Log In**. The Mobile CRA menu is displayed.

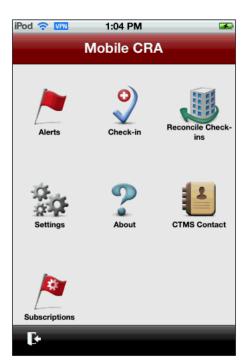


Figure 8–3 Mobile CRA Menu

8.2 Oracle Health Sciences Mobile Clinical Research Associate Server Menu

The menu screen provides access to all major functions within the application. Functions are displayed in a grid. The grid expands to support new functions as they become available. The menu grid paginates if more than nine launch icons are present.



Figure 8–4 Mobile CRA Menu

Following is a description of the available menu icons:

- Alerts navigates to the alert list. For more details, refer to Chapter 9, "Alerts"
- Check-In launches a check-in.
- Reconcile Check-Ins lets you connect unrelated check-ins to site visits.
- Settings launches the settings page. For more details, refer to Settings on page 8-4.
- About contains information about the Mobile CRA application. This includes the build number and licensed user agreement.
- **CTMS 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.
- Logout Icon present at the bottom left lets you log out from the application and navigates to the login screen. The logout option is only available in the main menu.

8.3 Settings

There are two ways to modify Mobile CRA settings.

Device Settings

1. Tap Settings on your iPhone or iPod menu.



Figure 8–5 Device Menu

2. Tap Mobile CRA.

Figure 8–6 Settings



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

iPod 🛜 🚾 2:07 PM	
Settings MobileCR	Ą
Mobile CRA Server	
Time out	10 Min 🔉
Server Address	
QWERTY	UIOP
ASDFGH	JKL
	N M 🗵
123 🌐 🔒 / .	com return

Figure 8–7 Mobile CRA Settings

This screen contains the following fields that you can modify:

• **Time out** - 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

iPod 奈 💵	2:07 PM	-
MobileCRA	Time out	
5 Min		
10 Min		~
15 Min		
30 Min		
60 Min		

• Server Address - This is the address of the Mobile CRA server.

Mobile CRA Settings

Perform the following steps to modify the settings from your Mobile CRA application.

1. Tap **Settings** in the Mobile CRA menu.

Figure 8–9 Mobile CRA Menu



2. The following screen is displayed. You can edit the CRA server settings here.

Figure 8–10 Server Settings

iPod 奈 🚾	1:04 PM	F
Mobile CRA	Settings	
Server Addr	ess	
	C	ĸ
QWE	RTYU	ΙΟΡ
ASI	D F G H J	KL
	K C V B N	M
123	space	return

8.4 Logging Out of Oracle Health Sciences Mobile Clinical Research Associate

The logout option, shown in Figure 8–11, is present on the bottom left side of the main menu. This option is only available in the main menu.

Figure 8–11 Logout Icon



Perform the following steps to log out of Mobile CRA:

1. Navigate to the main menu.

Figure 8–12 Mobile CRA Menu

iPod 🛜 💵	1:04 PM	~
	Mobile CR/	A
Alerts	Check-in	Reconcile Check- ins
Settings	About	CTMS Contact
Subscriptions		

2. Tap the log out icon. A confirmation message will appear.



_

Figure 8–13 Logout Confirmation

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.

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

- Viewing Alerts on page 9-3
- Alerts Subscription on page 9-5
- Predefined Alerts on page 9-21
- Resetting Alerts on page 9-22
- Marking an Alert as Important on page 9-23
- Alerts while Application is Closed on page 9-26

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*.

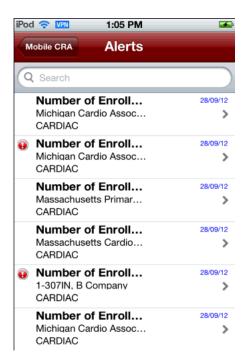
You can also flag an alert as 'Important'. This ensures that alerts carrying important information of your interest or those requiring your attention are flagged.

9.1.1 Alert Views

Alerts can be generated for a study or for a study-site. 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 iPhone or iPod.
- 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.

Pod 奈	VPN 11:35 AM	9
Alerts	Alerts	
	Procleve Pharmaceuticals >)
Number	of Enrolled Patients is Greater Than Threshold,	
Trigg	ered Monday at 5:11 AM.	
ST_A	lert Study	
	ber of enrolled patients at leve Pharmaceuticals is greater 3	
	Mark important)

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, "Marking an Alert as Important" on page 9-23.

9.2 Viewing Alerts

The Mobile CRA menu contains the Alerts icon with a badge to show the number of unread alerts in the list. 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.

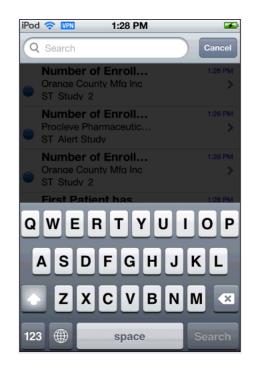
Figure 9–4 Alerts List

iPod 奈 🚾 1:05 PM	
Mobile CRA Alerts	
Q Search	
Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12
Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12
Number of Enroll Massachusetts Primar CARDIAC	28/09/12
Number of Enroll Massachusetts Cardio CARDIAC	28/09/12
Number of Enroll 1-307IN, B Company CARDIAC	28/09/12
Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12

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 Study Alerts

iPod 🗢 🚾 3:11 PM	F
Mobile CRA Sites And Studies	
Automation_Study_1	
Amsterdam Memorial Hospital	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Very Big National Health Plan	>
Protocol3 Test	
Hibbing Mfg	>

3. Tap Study Alerts.

Pod 奈 VPN	3:11 PM	-
Sites And Studies	Subscriptions	
Study Alerts		:
Site Alerts		:

Figure 9–8 Alerts for Studies or Sites

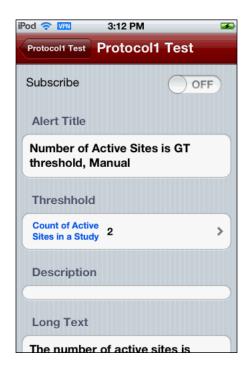
4. A list of alerts for the study is displayed.

Figure 9–9 List of Alerts for a Study

iPod 🗢 🔽 3:11 PM	S
Subscriptions Protocol1 Test	
Number of Active Sites is GT threshold, Manual	>
Number of Study Sites GT than Threshold, Manual	>
Number of Sites is GT than Planned, No Reset	>

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

Figure 9–10 Alert Details



6. If you wish, modify the threshold value by tapping Threshhold.

Figure 9–11 Modify the Threshold

iPod 奈 🔽	3:12 PM	Z
Cancel COL	unt of Active	Done
10		
1	2 АВС	3 Def
4 сні	5 JKL	6 MNO
7 PQRS	8 тих	9 wxyz
	0	€

- **7.** Tap **Done** on the top right. If you do not wish to save your changes, tap **Cancel** to go back to the alert details.
- 8. 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 9–12 A Subscribed Alert

iPod 🛜 🎹 5:27 PM	
Protocol1 Test Protocol1 Test	t in the second s
Subscribe	
Alert Title	
Number of Study Sites GT the Threshold, Manual	an
Threshhold	
Count of Sites in a Study 10	>
Description	
Long Text	

Subscribing to an Alert for a Study-Site

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



Figure 9–13 Mobile CRA Menu

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

Figure 9–14 List of Study Alerts

iPod 奈 🚾 3:11 PM	F
Mobile CRA Sites And Studies	
Automation_Study_1	
Amsterdam Memorial Hospital	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Very Big National Health Plan	>
Protocol3 Test	
Hibbing Mfg	>

3. Tap Site Alerts.

iPod 奈 💵	3:11 PM	4
Sites And Studies	Subscriptions	
Study Alerts		>
Site Alerts		>

Figure 9–15 Study and Site Alerts

4. A list of alerts is displayed.

Figure 9–16 List of Alerts for a Study-Site

iPod 🔶 VIII 3:11 PM	N
Subscriptions Protocol1 Test	
Number of Active Sites is GT threshold, Manual	>
Number of Study Sites GT than Threshold, Manual	>
Number of Sites is GT than Planned, No Reset	>

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

iPod 奈 💴 3:43 PN	I 至
Hibbing Mfg Hibbing	Mfg
Subscribe	OFF
Alert Title	
Percentage of Close Discrepancies, Auto	
Threshhold	
No of Enrolled Patient 10	>
Description	
Long Text)
Percentage of Close	h

Figure 9–17 Alert Details

6. If you wish, modify the threshold value by tapping on Threshhold.

Figure 9–18 Modify the Threshold



7. Tap **Done** on the top right. The alert details are displayed.

Note: However, if you do not wish to save your changes, tap **Cancel** to go back to the alert details.

8. 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**).

iPod 🛜 🚾 🔆 🛛 3:43 PM	*
Hibbing Mfg Hibbing	Vlfg
Subscribe	ON
Alert Title	
Percentage of Closed Discrepancies, Auto	t
Threshhold	
No of Enrolled Patient 10	>
Description	
Long Text	
Percentage of Closed	4

Figure 9–19 Tun 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 9–20 Mobile CRA Menu

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

Figure 9–21 List of Studies

iPod 奈 🚾 3:11 PM	F
Mobile CRA Sites And Studies	
Automation_Study_1	
Amsterdam Memorial Hospital	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Very Big National Health Plan	>
Protocol3 Test	
Hibbing Mfg	>

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

iPod 奈 🔽	3:11 PM	
Sites And Studies	Subscriptions	
Study Alerts		1
Site Alerts		1

Figure 9–22 Alerts for Studies or Sites

4. Tap the alert that you want to modify.

Figure 9–23 List of Alerts for a Study

iPod 奈 💵 3:11 PM	1
Subscriptions Protocol1 Test	
Number of Active Sites is GT threshold, Manual	>
Number of Study Sites GT than Threshold, Manual	>
Number of Sites is GT than Planned, No Reset	>

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

Figure 9–24 Turn an Alert OFF

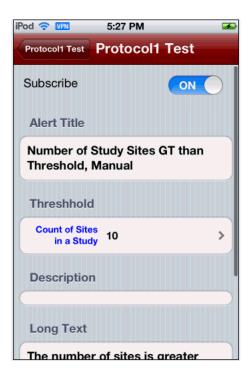


Figure 9–25 Alert Details

iPod 奈 💴	3:12 PM	5
Protocol1 Test	Protocol1 T	est
Subscribe	(OFF
Alert Title		
Number of A threshold, M	ctive Sites is lanual	GT
Threshhold		
Count of Active Sites in a Study		>
Description		
Long Text		
The number	of active sites	sis

Unsubscribe an Alert for a Study-Site

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



Figure 9–26 Mobile CRA Menu

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

Figure 9–27 List of Studies

iPod 奈 🚾 3:11 PM	
Mobile CRA Sites And Studies	s
Automation_Study_1	
Amsterdam Memorial Hospital	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Very Big National Health Plan	>
Protocol3 Test	
Hibbing Mfg	>

3. Tap Site Alerts.

iPod 奈 🔽	3:11 PM	4
Sites And Studies	Subscriptions	
Study Alerts		>
Site Alerts		>

Figure 9–28 Study and Site Alerts

4. A list of alerts is displayed.

Figure 9–29 List of Alerts for a Study-Site

iPod 奈 💵 3:11 PM	F
Subscriptions Protocol1 Test	
Number of Active Sites is GT threshold, Manual	>
Number of Study Sites GT than Threshold, Manual	>
Number of Sites is GT than Planned, No Reset	

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

iPod 🛜 🚾 🔆 🛛 3:43 PM	-			
Hibbing Mfg Hibbing Mfg				
Subscribe	ON			
Alert Title				
Percentage of Closed Discrepancies, Auto				
Threshhold				
No of Enrolled Patient 10	>			
Description				
Long Text				
Percentage of Close	d			

Figure 9–30 Alert Details

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

Figure 9–31 Alert Details

iPod 奈 💵 3:43 PM	
Hibbing Mfg Hibbing M	lfg
Subscribe	OFF
Alert Title	
Percentage of Closed Discrepancies, Auto	
Threshhold	
No of Enrolled Patient 10	>
Description	
Long Text	
Percentage of Closed	

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 9–32 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.

	Iobile CRA Alerts	
0	L Search	
	Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/1
•	Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/1
	Number of Enroll Massachusetts Primar CARDIAC	28/09/1
	Number of Enroll Massachusetts Cardio CARDIAC	28/09/1
•	Number of Enroll 1-307IN, B Company CARDIAC	28/09/1
	Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/1

Figure 9–33 Alerts List

- **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 wish 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:

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

Table 9–1 Predefined Alerts

Predefined Alert	Description
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

Table 9–1 (Cont.) Predefined Alerts

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:

1. Tap the alert to view its details.

iPod 穼 🛛	1:04 PM	F
Alerts	Alerts	
	Orange County Mfg Inc	*
Number of	Enrolled Patients since Last Site Visit, Ma	nual
Trigge	red Tuesday at 1:01 PM.	
ST_Sti	udy_2	
Count	of enrolled patients since I	ast
site visit > 3		
Mark important		
	Reset this alert	

Figure 9–34 Alert Details

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



Figure 9–35 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.

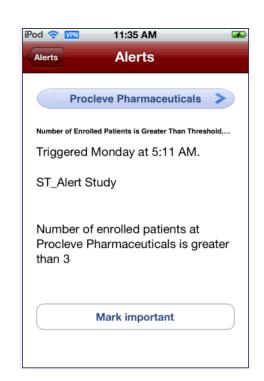


Figure 9–36 Alert Details

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

Figure 9–37 Alert Marked Important

iPod 穼	VPN 1:05 PM	F
Alerts	Alerts	
	Michigan Cardio Associates >	
Numbe	r of Enrolled Patients is Greater Than Threshold,	
Trigg	gered Friday at 10:21 PM.	
CAR	DIAC	
No o 3	f enrolled Patient is higher then	
	Mark unimportant)

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

Poo	1 🗢 💵 1:05 PM	*
Mobile CRA Alerts		
9	Search	
	Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12 >
U	Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12
	Number of Enroll Massachusetts Primar CARDIAC	28/09/12
	Number of Enroll Massachusetts Cardio CARDIAC	28/09/12
U	Number of Enroll 1-307IN, B Company CARDIAC	28/09/12
	Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12

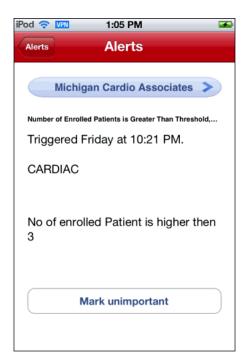
Figure 9–38 Important Alerts in the List

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 9–39 Mark Alert Unimportant



2. Tap Mark Unimportant.

3. The important flag will be cleared in the list of alerts.

iPod 🗢 💴 1:05 PM	
Mobile CRA Alerts	
Q Search	
Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12 >
Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12 >
Number of Enroll Massachusetts Primar CARDIAC	28/09/12 >
Number of Enroll Massachusetts Cardio CARDIAC	28/09/12 >
Number of Enroll 1-307IN, B Company CARDIAC	28/09/12 >
Number of Enroll Michigan Cardio Assoc CARDIAC	28/09/12

Figure 9–40 Important Icon Removed

9.8 Alerts while Application is Closed

When the application is closed or running in the background the iOS system will signal you when an alert has been triggered.



Figure 9–41 Alert Signal

View proceeds to open the application to the new alert. You will be required to log in if there is no active session. **Close** shuts the alert signal.

10 Contacts

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

- Introduction to Contacts on page 10-1
- Linking an Alert to a Contact on page 10-4
- Removing Contact from Site on page 10-9

10.1 Introduction to Contacts

Mobile CRA maintains a contact list separate from your iPhone or iPod 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 CTMS Contacts in the Mobile CRA menu. A list of studies is displayed.

iPod 🛜 VPN 5:26 PM 1 Mobile CRA Sites And Studies Automation_Study_1 Amsterdam Memorial Hospital > Protocol1 Test > Hibbing Mfg Protocol1 Test Hibbing Mfg > Protocol1 Test Very Big National Health Plan > Protocol3 Test Hibbing Mfg >

Figure 10–1 List of Studies

2. Tap a study to view the contacts for it.

Figure 10–2 Contact List for a Study

iPod 奈 🕅 5:26 PM		S
Sites And Studies Site Contacts		
Q Search	\supset	Q A
Α		BC
THOMAS ALEX	>	D E F
MOHAMMED ALI	>	G H
Christian Aubon	>	J K
		L M N
		O P Q
		R S
		T U V
		W X Y
		Z

3. Tap a contact to view the details.

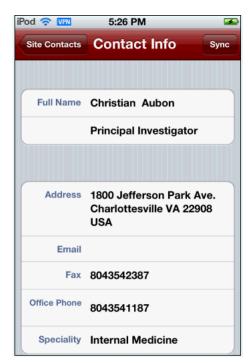


Figure 10–3 Contact Details

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

Figure 10–4 Synchronize CRA Contacts with Device Contacts

iPod 奈 🔽	5:26 PM	S
Site Contacts	Contact Info	Sync
Full Name	Christian Aubon	
	Principal Investigator	
Address	1800 Jefferson Park A Charlottesville VA 229 USA	
Email		
Fax	8043542387	
Office Phone	8043541187	
Speciality	Internal Medicine	

5. To synchronize Mobile CRA contacts with CTMS contacts, drag the contact list downward.

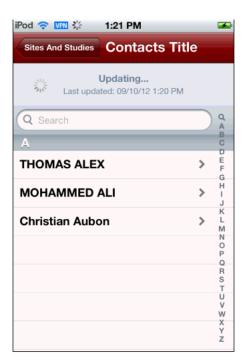


Figure 10–5 Synchronize CRA Contacts with CTMS

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 iPhone 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.

iPod 奈	VPN 11:35 AM	F
Alerts	Alerts	
	Procleve Pharmaceuticals >	
Number	r of Enrolled Patients is Greater Than Threshold,	
Trigg	ered Monday at 5:11 AM.	
ST_A	Alert Study	
1	ber of enrolled patients at leve Pharmaceuticals is greater 3	
	Mark important	

Figure 10–6 Alert Details

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

Figure 10–7 View Site Contact Details

iPo	d 奈 🕅	11:35 AM	S
0	Alerts	Contact Site	
	Procle	eve Pharmaceut	icals
	110010		iouio
	Dial nev	w number	
	Select f	rom Contact List	

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

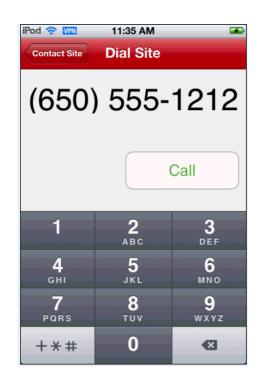


Figure 10–8 Dial a New Number

Figure 10–9 Contact Associated with Site

iPod 奈 🕎	11:35 AM	4
Alerts	Contact Site	
Procle	eve Pharmace	uticals
(650) 5	55-1212	69
Dial ne	w number	
Select	from Contact List	

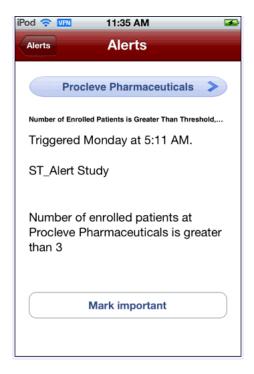
If you dial more than one number, they all will be linked to one site.

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:

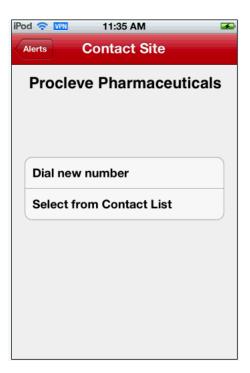
1. Tap the alert to view its details.

Figure 10–10 Alert Details



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

Figure 10–11 View Site Contact Details



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

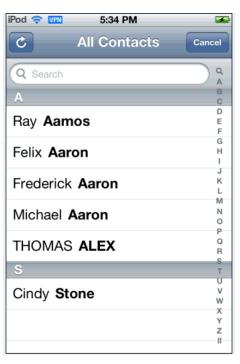


Figure 10–12 Select Number from Contact List

4. Tap the contact you want to associate with the site.

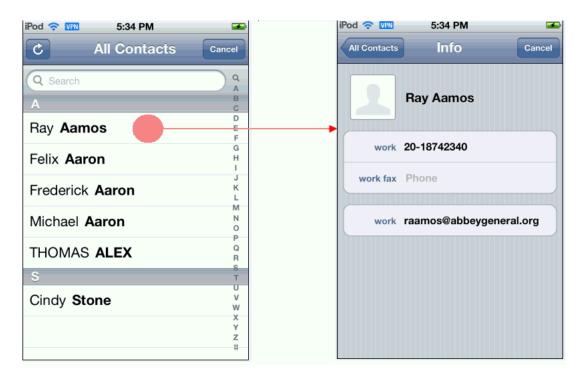


Figure 10–13 Select Contact to Associate with Site

5. Once the call is initiated the name and number are associated with the site.

Procleve Phar	Site
(650) 555-1212	Ø
Ray Aamos 2018742340	0
Dial new number	
Select from Conta	ict List

Figure 10–14 Contact Associated with a Site

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.

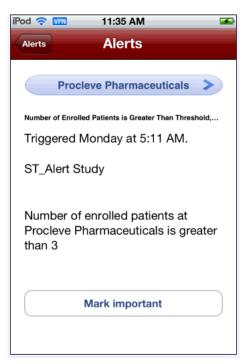
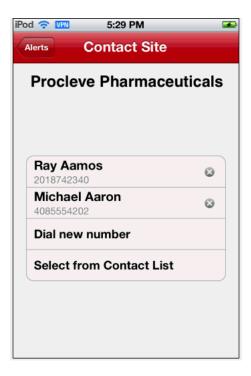


Figure 10–15 Alert Details

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

Figure 10–16 View Site Contact Details



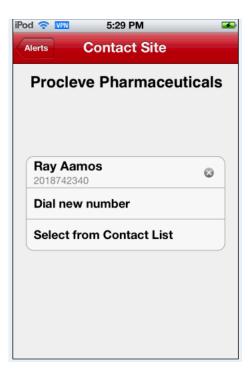
3. Tap the x icon in the contact to remove it from a site. You will be prompted whether you want to delete the contact.

iPod 🗢 🚾 5:29 PM 🗳
Procleve Pharmaceuticals
Delete contact? Do you really want to delete this Ray Aamos contact?
Cancel Delete
Select from Contact List

Figure 10–17 Prompt to Delete Contact

4. Tap **Delete**. The contact will be dissociated from the site.

Figure 10–18 Remove Contact



11

GeoLocation Services

This chapter contains the following topics:

- Introduction on page 11-1
- Registering a Site Visit on page 11-1
- Capturing Location without Selecting a Study-Site Pair on page 11-4
- Reconcile Check In on page 11-7

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 attempts to access the Geolocation services while it is turned off, an error message is displayed. To sue 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 iPhone 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:

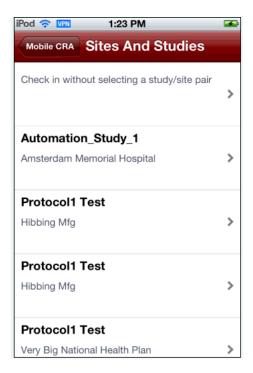
1. Tap Check-In on the Mobile CRA menu. A list of studies is displayed.



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**.

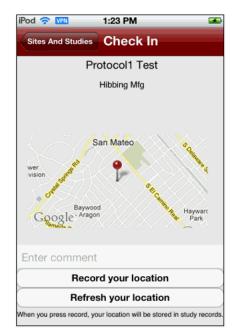
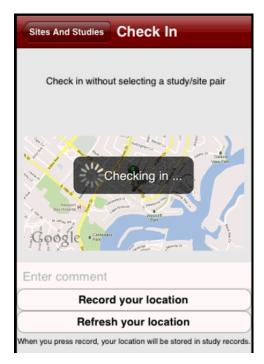


Figure 11–3 Record Your Location

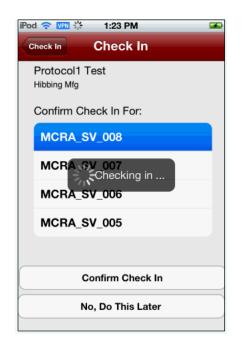
4. A list of study-sites is displayed. Select the site for which you want to check in.

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 wish to check in later, tap **No**, **Do This Later**. 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 Check-in on the Mobile CRA menu.



Figure 11–6 Mobile CRA menu

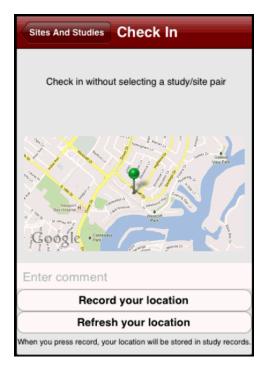
2. Tap Check in without selecting a study/site pair.

Figure 11–7 Select a Study Site Pair

iPod 奈 🚾 1:23 PM	N
Mobile CRA Sites And Studies	
Check in without selecting a study/site pair	>
Automation_Study_1	
Amsterdam Memorial Hospital	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Hibbing Mfg	>
Protocol1 Test	
Very Big National Health Plan	>

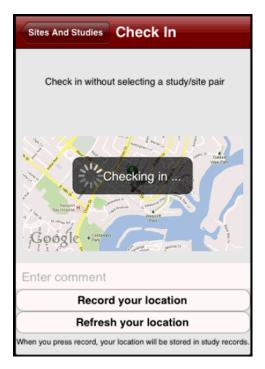
3. Tap **Record Your Location**.





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, "Reconcile Check In" on page 11-7.

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 Check-ins** on the Mobile CRA menu.

Figure 11–10 Mobile CRA Menu



2. A list of unlinked location captures is displayed.

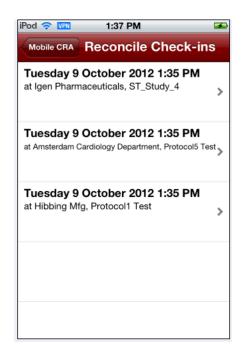


Figure 11–11 Unlinked Location Capture

3. Select a capture. The location map is displayed.

Figure 11–12 Check In

iPod 奈 🚾 1:37 PM 🛥
Reconcile Check-ins Check In
Protocol5 Test
Amsterdam Cardiology Department
Yemalur Yemalur Chandana B B Chandana B B Chandana B B Layout Layout Panatur Karluheacanaballi
Enter comment
Record your location
Refresh your location
When you press record, your location will be stored in study records.

- **4.** Tap **Record your location**. A list of sites is displayed.
- **5.** Select the site and tap **Confirm Check In**. You will be checked in for the selected site.

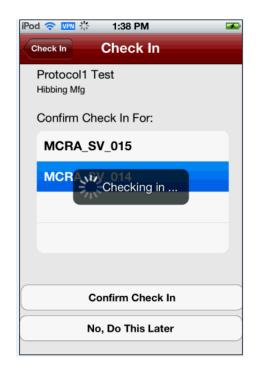


Figure 11–13 Check In in Progress

Offline Services

When visiting a site, or any other location, you may 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:

Offline Functionality on page 12-1

12.1 Offline Functionality

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.

Apple Note

The Apple 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.

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.

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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