

**Oracle Health Sciences Mobile Clinical Research
Associate Server**

Administrator's Guide

Release 2.0

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Preface

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

This preface contains the following topics:

- [Audience](#) on page v
- [Documentation Accessibility](#) on page v
- [Finding Information and Patches on My Oracle Support](#) on page v
- [Finding Documentation on Oracle Technology Network](#) on page vii
- [Related Documents](#) on page vii
- [Conventions](#) on page viii

Audience

This guide is intended for the following job classifications:

- Mobile CRA Configuration Utility Administrators

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 that have purchased support 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.

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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

For more information, see the following documents:

Oracle Business Intelligence Enterprise Edition (OBIEE) Documentation

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

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

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

Siebel Clinical Documentation

The Siebel Clinical documentation set includes:

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

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
<i>italic</i>	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.

This chapter contains the following sections:

- [Section 1.1, "Overview"](#)
- [Section 1.2, "Logging In"](#)

1.1 Overview

Oracle Health Sciences Mobile Clinical Research Associate Server (Mobile CRA) integrates with Oracle Clinical Development Analytics (CDA) and Oracle Siebel Clinical Trial Management System (CTMS) with the help of integration adapters.

The Mobile CRA Server Configuration Utility is a Web-based application that lets you manage the configuration of these integration adapters. The Configuration Utility supports the following integration adapters:

- CDA Alert Notifications
- CTMS Mobile Trip Reports

The application can support new adapters from different systems, if required.

1.2 Logging In

[Figure 1-1](#) displays the Configuration Utility Login screen.

Figure 1–1 The Configuration Utility Login Screen

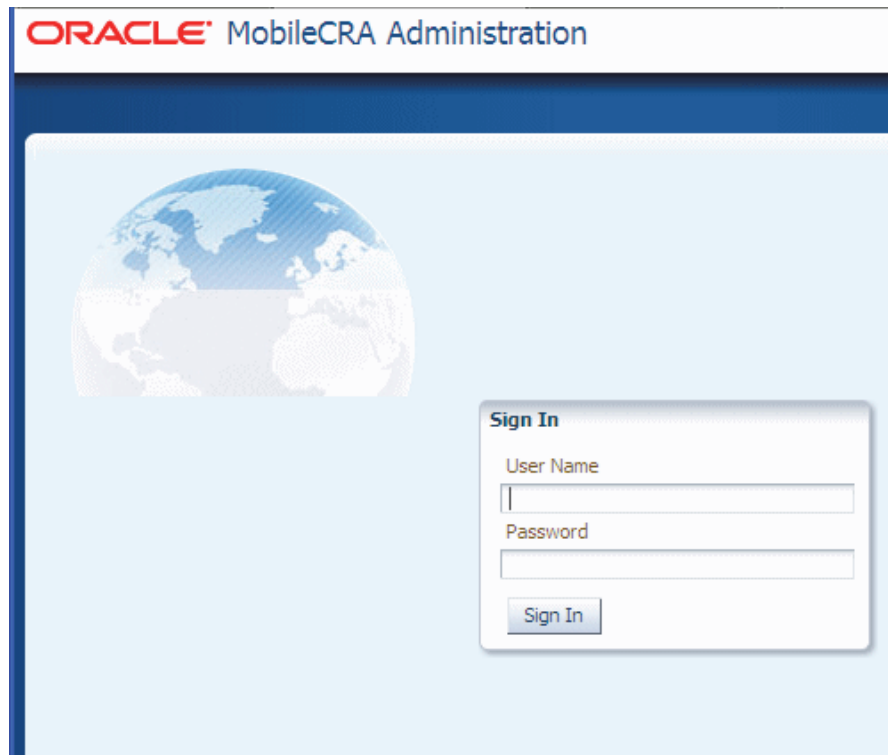
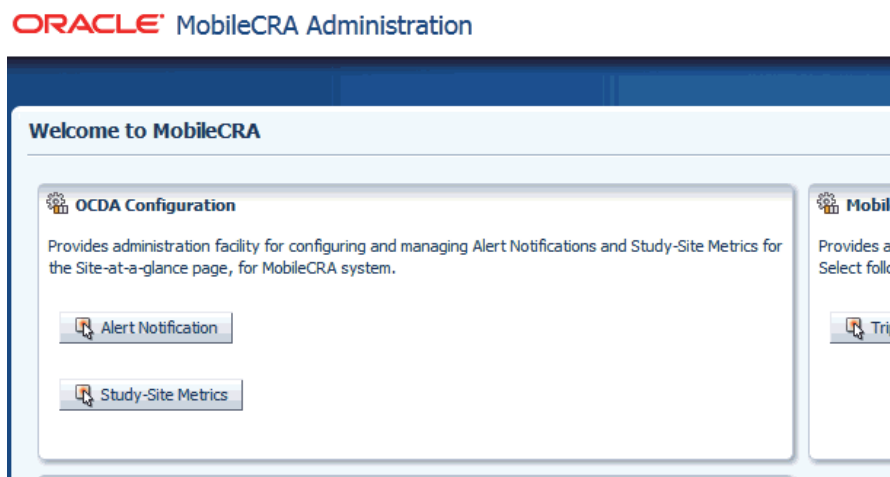


Figure 1–2 displays the Configuration Utility Home screen.

Figure 1–2 The Configuration Utility Home Screen



Alert Notification and Study-Site Metrics

This chapter contains the following sections:

- [Section 2.1, "Alerts"](#)
- [Section 2.2, "Managing Alerts in Oracle Business Intelligence Enterprise Edition"](#)
- [Section 2.3, "Mobile Alert Notification Configuration"](#)
- [Section 2.4, "Parameter List"](#)
- [Section 2.5, "Study-Site Metrics"](#)

2.1 Alerts

An Alert is a notification by which CRAs are notified about the various aspects of the studies that they are involved. These alerts may be a site's performance, number of patients enrolled in sites, visit dates, and so on.

Mobile CRA lets you create subscriptions for such notifications. It sends alerts to the CRAs who have subscribed to such Alerts as and when the thresholds (set against that particular alert) are met.

2.1.1 Types of Alerts

Mobile CRA has two types of alerts:

- [Section 2.1.1.1, "Standard or System Alerts"](#)
- [Section 2.1.1.2, "User Defined Alerts"](#)

2.1.1.1 Standard or System Alerts

Mobile CRA has 13 out-of-the-box alerts. If required, you can customize these alerts using OBIEE. The following is the list of all 13 alerts.

2.1.1.1.1 Out-of-the-Box Alerts

The following are the Standard Alerts:

Table 2–1 Out-of-the-Box Alerts

Alerts	Description
Count of Enrolled Patient is a Multiple of Five, No Reset	When the count of patients enrolled in a particular site reaches a number that is a multiple of 5. You do not need to reset the alert to be triggered.
First Patient has Enrolled at Site, No Reset	When the first patient has been enrolled in a site.
Number of Active Sites is GT threshold, Manual	When the number of active sites they are assigned to exceeds the threshold set by the administrator or user. ACTIVE_SITE_COUNT is the parameter associated with this alert.
Number of CRFs waiting for Verification, Auto	When the number of CRFs of a particular site, ready for source data verification, exceeds the threshold set by the administrator or user. CRF_UNVERIFIED is the parameter associated with this alert. This is an auto reset alert where the site is pre-defined.
Number of CRFs waiting for Verification, Manual	When the number of CRFs of a defined site, ready for source data verification, exceeds the threshold set by the administrator or user. CRF_UNVERIFIED is the parameter associated with this alert. This is a manual reset alert where the site has to be defined.
Number of Enrolled Patients is Greater Than Threshold, Auto	When the number of patients enrolled in a particular site exceeds the threshold set by the administrator or user. ENROLLED_PATIENT is the parameter associated with this alert.
Number of Enrolled Patients since Last Site Visit, Manual	When the number of patients enrolled since the last visit in a particular site exceeds the threshold set by the administrator or user. ENROLLED_SINCE_LAST_VISIT is the parameter associated with this alert.
Number of screen failures, Auto	When the number of failures in patient screening for enrollment exceeds the threshold set by the Administrator or User. SCREENING_DATE and SCREEN_FAILURE_COUNT are parameters associated with this alert.
Number of Study Sites GT than Threshold, Manual	When the number of studies assigned to the CRA exceeds the threshold set by the administrator or user. STUDY_SITE_COUNT is the parameter associated with this alert.
Percentage of Closed Discrepancies, Auto	When the percentage of discrepancies during source data verification exceeds the threshold set by the administrator or user. CLOSED_DISCREP_COUNT is the parameter associated with this alert. This is an auto reset alert.
Percentage of Closed Discrepancies, Manual	When the percentage of discrepancies during source data verification exceeds the threshold set by the administrator or user. CLOSED_DISCREP_COUNT is the parameter associated with this alert. This is a manual reset alert.
Number of screen failures, Auto	When the number of patients who failed to pass the enrollment screening exceeds the threshold set by the administrator or user. SCREENING_DATE and SCREEN_FAILURE_COUNT are the parameters associated with this alert.
Percentage of Open Queries, Manual	When the count of the open queries in a particular site exceeds the threshold set by the administrator or user. OPEN_QUERY_COUNT is the parameter associated with this alert.

2.1.1.2 User Defined Alerts

You can create new alerts as per your specific needs.

2.1.2 Alert Management

You can perform alert management activities as follows:

Table 2–2 Alert Management Activities

Application where activity is performed	Activity
Oracle Business Intelligence Enterprise Edition (OBIEE)	Create, modify, or delete an alert
Mobile CRA Server Configuration Utility	Register an alert created in OBIEE Create an alert rule Update status of an alert to either active or inactive
Mobile CRA Application (on either an iPhone or iPad)	Subscribe to alerts Set threshold for an alert View an alert

2.2 Managing Alerts in Oracle Business Intelligence Enterprise Edition

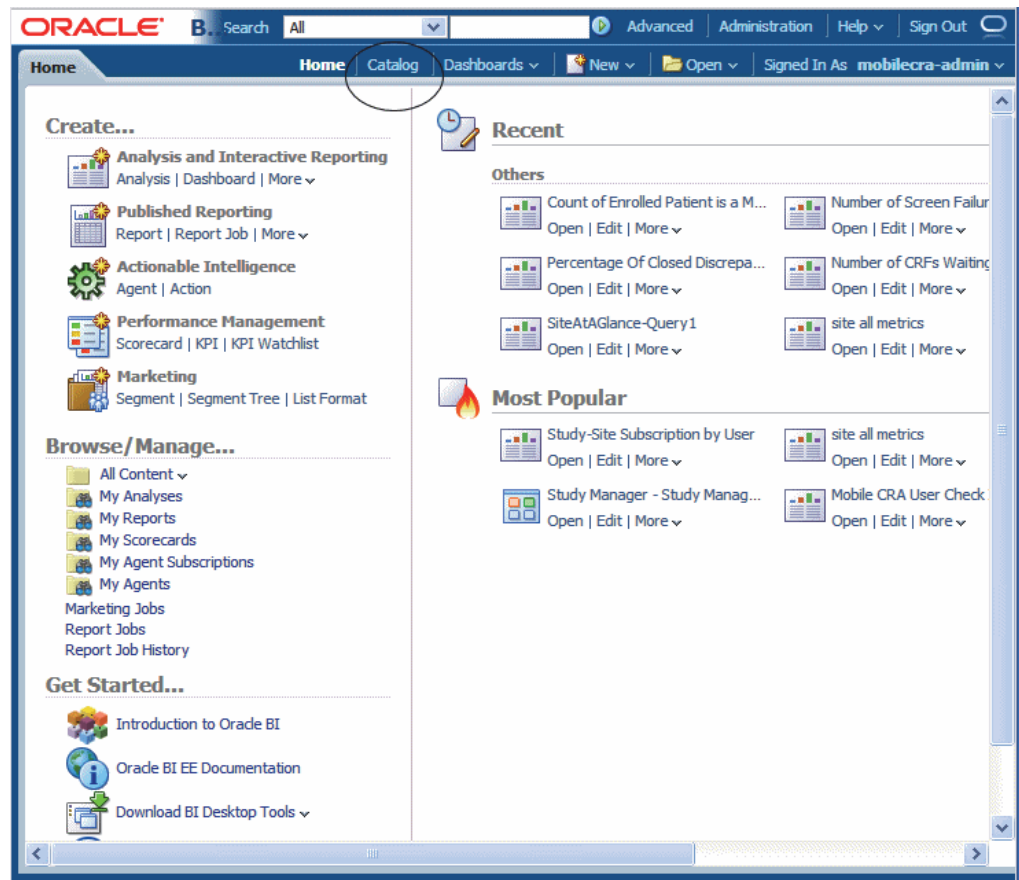
You can perform the following in Oracle Business Intelligence Enterprise Edition (OBIEE) for alerts:

2.2.1 Customizing a Standard Alert

To customize a standard Alert:

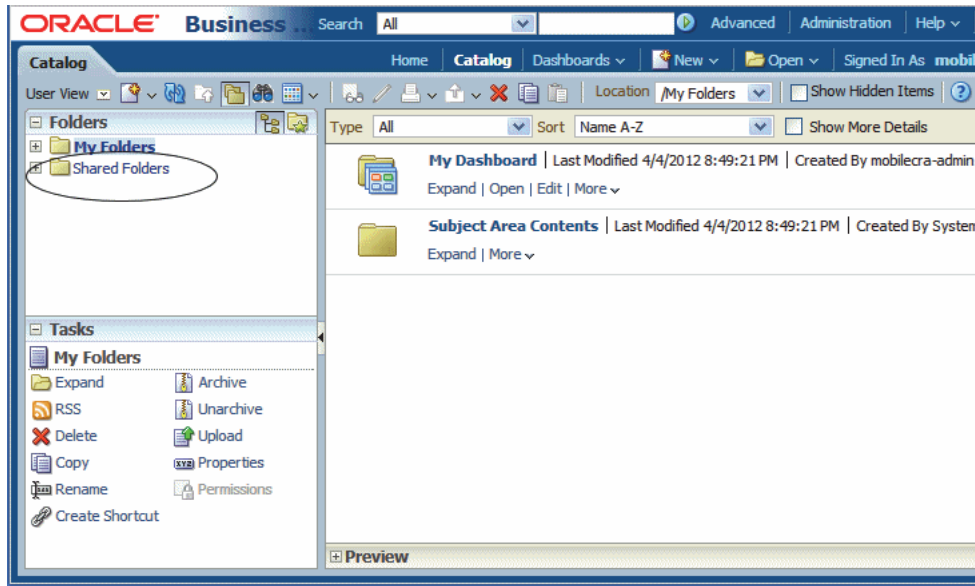
1. Sign in to Oracle Business Intelligence Enterprise Edition.
2. In the global header, click **Catalog** to display the Catalog page.

Figure 2–1 Catalog Link



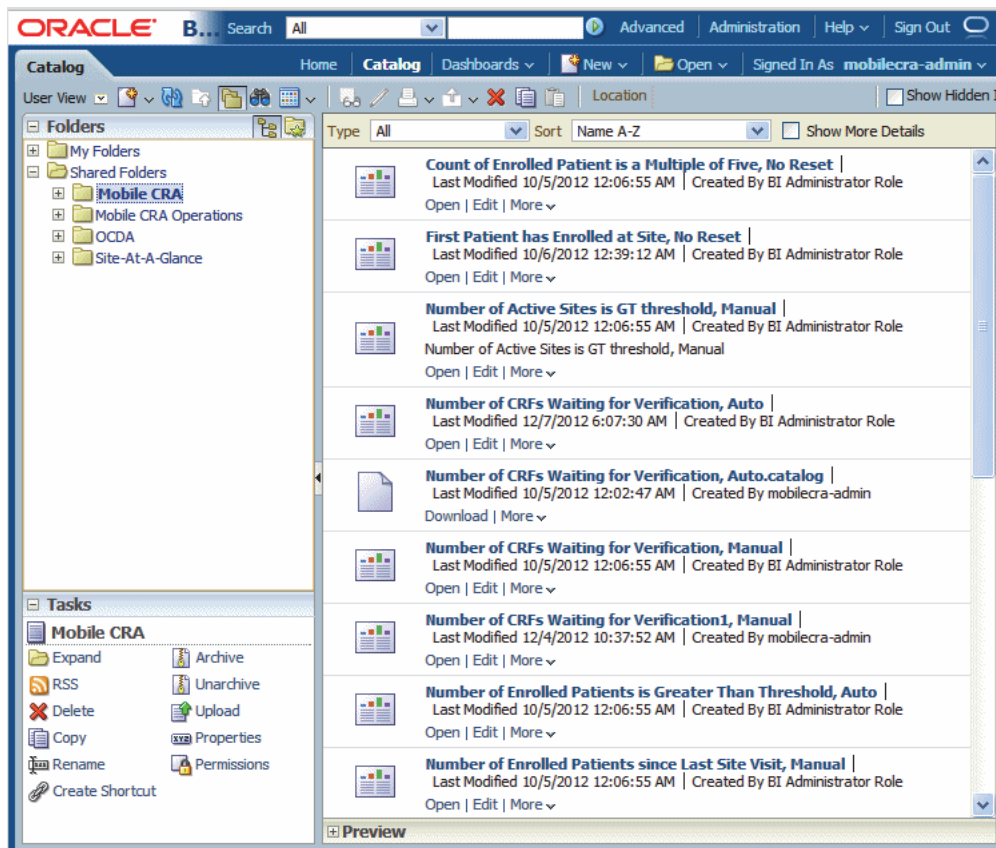
3. Click **Shared Folders**.

Figure 2–2 Shared Folders



4. Click the Mobile CRA folder.

Figure 2–3 Mobile CRA Folder



5. All the standard alerts are displayed in the right-hand pane. Navigate to the alert you want to edit and click the **Edit** link. The alert is displayed in the Analysis Editor.

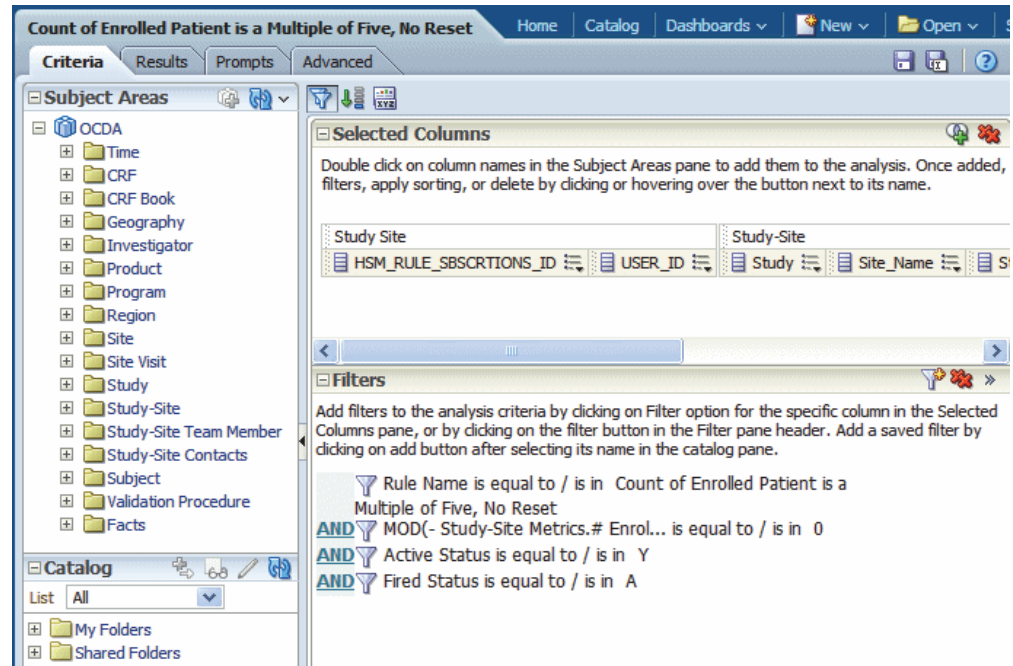
6. Navigate to the **Criteria** tab.

On the left-hand side, the Subject Area pane displays **OCDA** subject area and its hierarchical columns.

On the right-hand side upper section, the Selected Columns pane shows the name of the column's folder (for example, Site-Name) and name of the column (for example, Site_Name).

On the right-hand side lower section, the Filters pane shows filters to create or edit filters for the alert.

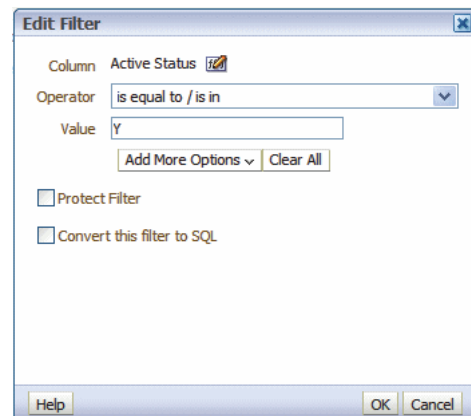
Figure 2-4 Criteria Tab



7. Drag and drop columns from the left-hand side Subject Area pane to the **Selected Columns** pane to modify the alert.

8. Click the **Filter** option to edit filters of the alert for the specific column or click **Filter** in the Filter pane header.

Figure 2-5 Edit Filter



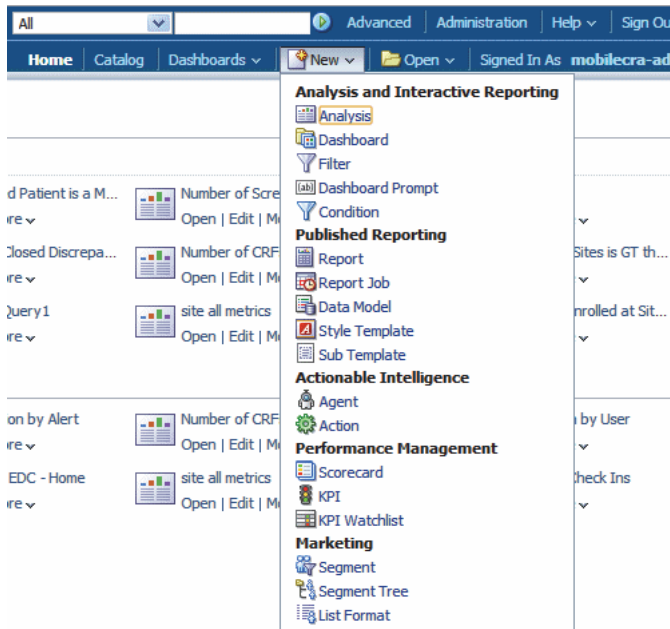
9. Click **OK** to save the filter.

2.2.2 Creating a New Alert

To create a new alert, perform the following steps:

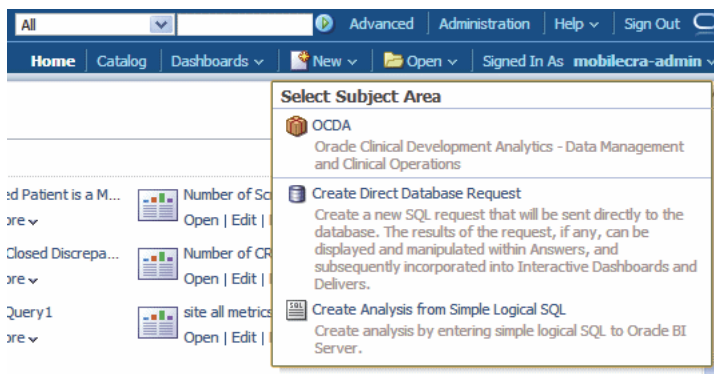
1. Sign in to Oracle Business Intelligence Enterprise Edition.
2. In the global header, click **New**, then **Analysis**.

Figure 2–6 The New Tab



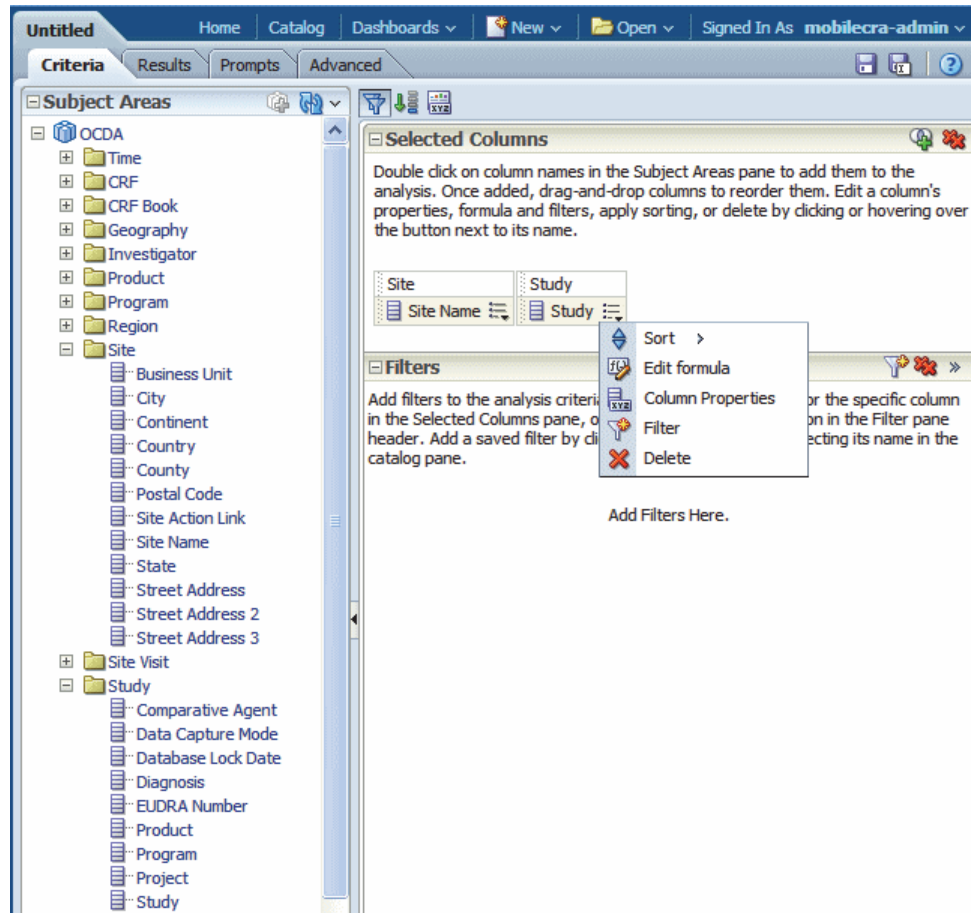
3. Click **OCDA** in Select Subject Area menu.

Figure 2–7 Subject Area



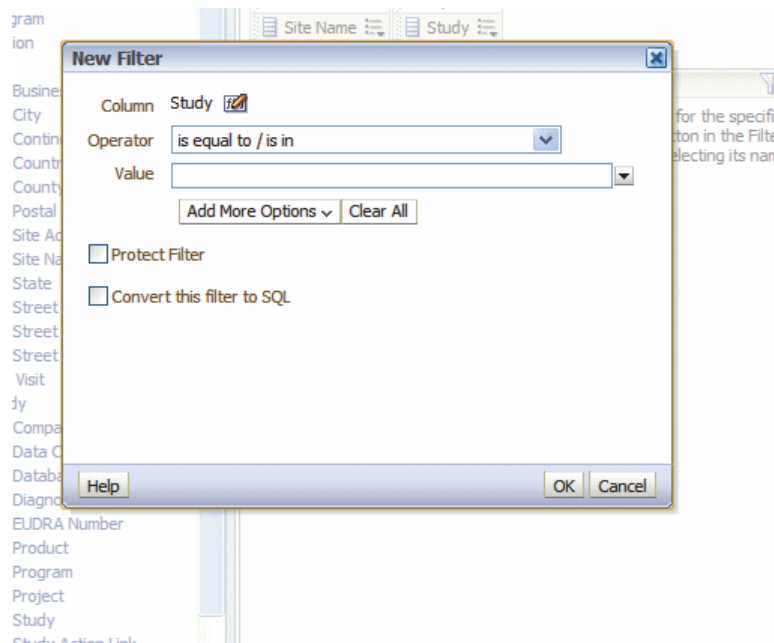
4. Navigate to the **Criteria** tab.
5. Drag and drop columns from the left-hand side Subject Area pane to the **Selected Columns** pane to specify criteria for the alert.
6. Click the **Filter** option to add filters to the alert for the specific column or click **Filter** in the Filter pane header.

Figure 2–8 Filter for a Column



7. Specify the filter condition in **New Filter** dialog box.

Figure 2–9 New Filter Condition



8. Click **OK** to save the filter.
9. Click the **Results** tab to see the results, if any.
10. In the Analysis editor, click **Save Analysis** to display the dialog to save the analysis.
11. If you want to save the analysis to a personal or shared folder:
 - a. In the **Save In** box, select the personal or shared folder to save the analysis.
 - b. In the **Name** field, enter a name for the analysis, such as Site Names by Study.
 - c. Click **OK**.
12. Click **OK**. The new alert is created.

For the CDA Adapter, the Configuration Utility server lets a system administrator maintain two key areas of the Mobile CRA system:

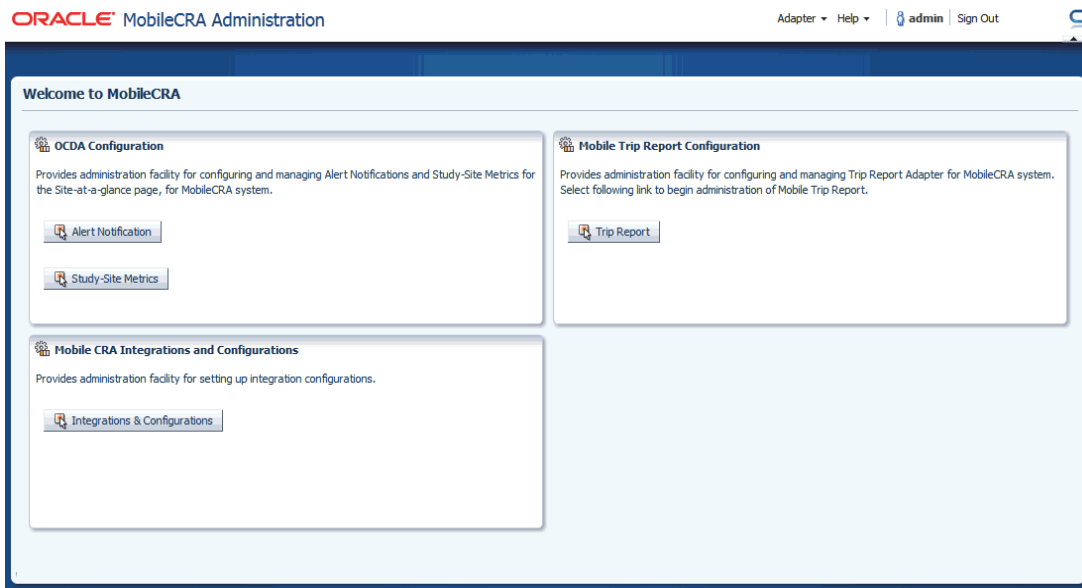
- [Section 2.3.1, "Rule Management in Administration User Interface"](#)
- [Section 2.4, "Parameter List"](#)

2.3 Mobile Alert Notification Configuration

Getting to the Mobile Alert Notification Screen:

Click **Alert Notification** in left pane of the Home page to reach the Mobile Alert Notification Configuration Screen.

Figure 2–10 Alert Notification



This section contains the following topics:

- [Section 2.3.1, "Rule Management in Administration User Interface"](#)

2.3.1 Rule Management in Administration User Interface

The Rule management module lets you manage Rule definitions and corresponding thresholds. To manage a rule, select the alert name from the navigation panel. When

you select a rule, the right pane displays the Rule definition form, which consists of the rule parameters and rule thresholds.

The Rule definition form lets an administrator create, update, or delete a rule based on the business rules defined for the Rule category.

This section contains the following topics:

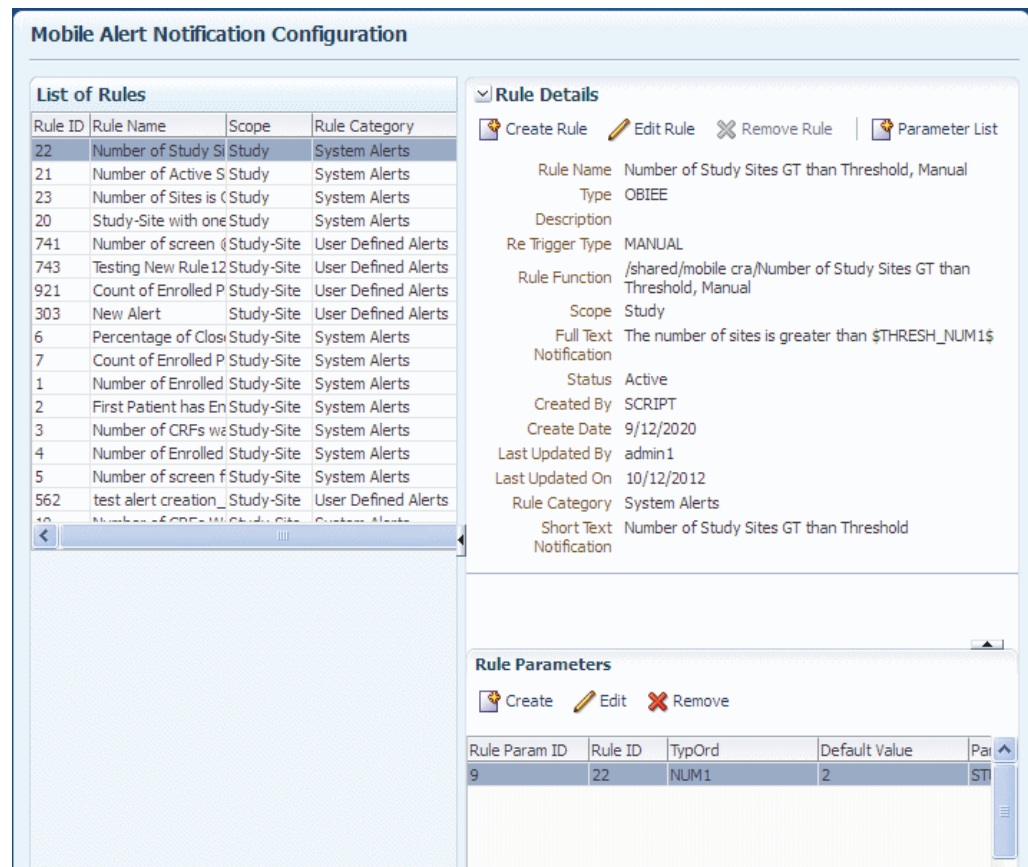
- Section 2.3.1.1, "Rule Management Interface"
- Section 2.3.1.2, "Rule Management Operations"

2.3.1.1 Rule Management Interface

Figure 2–11 represents the basic UI layout for rules and alerts. The left pane displays a list of all rules (which can be sorted). The right upper pane displays rule details and right lower pane displays Rule Parameters with default values.

When you select a rule in the left pane, the right pane displays the information for that particular rule. The toolbar icons are for specific **Create**, **Edit**, and **Remove** operations.

Figure 2–11 Rule Management Screen



The following fields of rules are displayed in the Rule Details pane:

Table 2–3 Field Descriptions - Rule

Field Name	Field Description
Alert Name	The alert name as defined in the CDA.
Description	The details or summary. This is displayed in the Description field of Subscriptions.

Table 2–3 (Cont.) Field Descriptions - Rule

Field Name	Field Description
Re Trigger Type	This lets you specify how the alert triggers after the first time. The re-trigger types available are Manual Alert, Auto Alert, and One time Alert.
Rule Function	This column includes the name of the function associated with the rule. For an OBIEE rule, it includes the name of the OBIEE rule. For an SQL based rule, it includes the SQL statement representing the rule.
Scope	The valid scope of the alert. The valid values are: STUDY_ID - when the scope is for a study. STUDY_SITE_ID when the scope is for a particular site within a study.
Full Text Notification	This is the notification template. It includes the text that is sent as a message to the mobile device. The text includes tags which are replaced by the actual values before being sent.
Status	Defines whether the rule is active or not. A rule is in the DRAFT status while it is being configured or tested. The available options are ACTIVE, INACTIVE, and DRAFT.
Created By	The login name of the user who creates the alert.
Create Date	The alert creation date.
Last Updated	The date on which the alert was last modified, updated, edited, and saved.

The following fields of rule parameters are displayed in Rule parameters pane:

Table 2–4 Rule Parameter Fields

Field Name	Field Description
Rule ID	Reference to primary key of the HSM_Rules table.
TypOrd	This column is created for de-normalized threshold table (HSM_OBI_THRESHS). It defines the position (that is, column) in the HSM_OBI_THRESHS table, and represents the data type and the position of the parameter. The valid values are: For string columns - STR1, STR2,STR3, STR4, and STR5 For date columns - DT1, DT2, DT3, DT4, and DT5 For numeric columns - NUM1,NUM2, NUM3, NUM4, and NUM5.
Default Value	The default value of the parameter at the rule level.
Parameter Name	The parameter name.
Re-Evaluation Type	Determines how the parameter is re-evaluated. It is used in combination with the RE_EVALUATE_FUNC column, which includes the name of the function. The valid values are SYSTEM (implementations are provided by Oracle) and USER (user provides the implementation).
Re-Evaluation Function	Includes the name of the function which is executed to calculate the new value of the parameter at the time of reset. These functions can be provided by Oracle or the client depending on the re-evaluate type column.

2.3.1.2 Rule Management Operations

The Rule Management module supports the following key operations:

- [Section 2.3.1.2.1, "Creating a Rule"](#)
- [Section 2.3.1.2.2, "Editing a Rule"](#)
- [Section 2.3.1.2.3, "Removing a Rule"](#)
- [Section 2.3.1.2.4, "Rule Statuses"](#)

2.3.1.2.1 Creating a Rule

To create a new rule and its thresholds, perform the following steps:

The default category for a new user-defined rule is User Alert.

1. Click **Create Rule** in Rule Details pane.
2. Enter requisite fields in the Rules Attributes screen.

Figure 2–12 Rule Attributes Screen

3. Click **OK** to create the rule.

2.3.1.2.2 Editing a Rule

You can edit an existing user-defined rule and subscription threshold values.

To edit a rule and its thresholds, perform the following steps:

1. Click a rule in the List of Rules pane.
2. Click **Edit Rule** in the Rule Details pane.
3. Modify requisite fields in the Rules Attributes screen.
4. Click **OK** to save the rule.

2.3.1.2.3 Removing a Rule

You can only remove user-defined rules, and a rule only if no Rule thresholds or user subscriptions exist.

Note: If any rule parameters exist for a rule, Remove Rule will be disabled. You must first delete all rule parameters, before you delete a rule.

To remove a rule, perform the following steps:

1. Click a rule in the List of Rules pane.

2. Click **Remove Rule** in the Rule Details pane.
3. Click **Yes** in the Remove Rule dialog box.

2.3.1.2.4 Rule Statuses

A rule can have three statuses, DRAFT, ACTIVE, and INACTIVE.

You can change the status of a rule through the Edit Rule operation. The Permitted status changes are:

Table 2–5 Permitted Status Changes

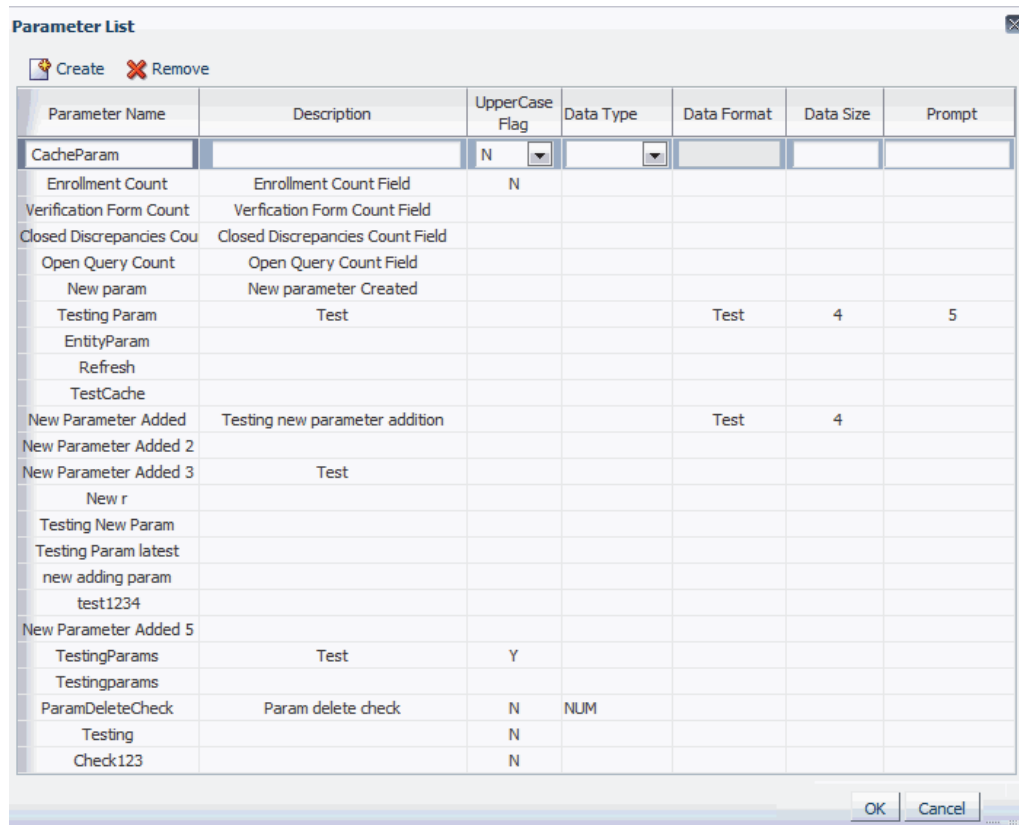
Current Status	Permitted Statuses
DRAFT	ACTIVE AND INACTIVE
ACTIVE	INACTIVE
INACTIVE	DRAFT

When a system administrator creates the rule, the default status is DRAFT.

2.4 Parameter List

Parameters list lets you manage the standardized list of parameters that are used in the Rule definitions. The interface lets you create and remove existing parameter definitions.

Figure 2–13 Parameter List



The Rule Parameters list supports the following key operations:

- **Create** - The Create icon lets you create a new Rule Parameter definition. When you click it, it displays the list of attributes required for creating a new Rule Parameter definition.
- **Delete** - The Delete icon lets you delete a parameter definition from the Rule Parameters table. When you select a parameter for removal, and click **Delete**, a confirmation dialog box is displayed to remove the Rule.

When you click **OK**, the parameter record is deleted and the Select Columns table is refreshed.

2.5 Study-Site Metrics

Earlier versions of Mobile CRA displayed only 6 KPIs in the application. Now, there are 27 KPIs which can be configured, the first three are used for the trending graphs. You can also change the display order of these KPIs.

Figure 2–14 The Study-Site Metrics Screen

Display Order	KPI Name	KPI Display Name
1	# Completed Site Visits	Site Visits Compl't'd
2	% of Total Screened in Study	% Total Screened
3	# Currently Enrolled plus # Normally Terminated	Enrolled + Term'd
4	# Days Since Last Enrollment for Study-Site	Days Since LastEnrol
5	# Days Since Latest Site Visit	Days Since LastVisit
6	# Discrepancies Irresolvable	Disc. Irresolvable
7	# Enrolled	Subjects EnrollCount
8	# Open Discrepancies	Open Discrepancies
9	# Site Visits	Site Visits
10	# Subjects	Subjects Count
11	# Subjects - Current Status Randomized	Subjs. Randomized
12	# Subjects - Current Status Re-Screened	Subjs. Re-Screened
13	# Subjects - Current Status Screen Failure	Subjs. Scr. Failure
14	# Subjects - Current Status Screened	Subjs. Screened
15	# Subjects Planned for Study-Site	Subjs. Planned/Site
16	# Subjects who have completed Study	Subjs. Compl't'd Test
17	# Visit Reports Awaiting Approval	Visit Rpts for Appri
18	# eCRFs Approved	eCRFs Approved
19	# eCRFs Awaiting Re-Approval	eCRFs ReApproval
20	# eCRFs Not Verified	eCRFs Unverified

2.5.1 Changing the Display Order

You can change the order of the KPIs displayed. Perform the following steps:

1. Select the KPI whose display order you want to change. Click **Edit**.
2. Enter the new display order number in **Display Order**. Click **OK**.

Figure 2–15 Existing KPI Order

Display Order	KPI Name	KPI Display Name
1	# Days Since Latest Site Visit	Days Since LastVisit
3	# Enrolled	Subjects EnrollCount
4	# eCRFs Not Verified	eCRFs Unverified
5	# Days Since Last Enrollment for Study-Site	Days Since LastEnrol
5	# eCRFs To be Verified	eCRFs to be Verified
6	# Open Discrepancies	Open Discrepancies
7	# eCRFs Awaiting Re-Approval	eCRFs ReApproval
8	# Completed Site Visits	Site Visits Compl't'd
9	# Subjects	Cnt of Subjects
10	# Subjects - Current Status Re-Screened	Subjs. Re-Screened
11	# Subjects - Current Status Screen Failure	Subjs. Scr. Failure
12	# Subjects Planned for Study-Site	Subjs. Planned/Site
13	# Visit Reports Awaiting Approval	Visit Rpts for Appr'l
14	# Discrepancies Irresolvable	Disc. Irresolvable
15	# eCRFs Approved	eCRFs Approved
16	# Subjects who have completed Study	Subjs. Compl't'd Test
17	% Subjects Early Terminated for Study-Site	% Subjs. Eryl Term'd
18	# Currently Enrolled plus # Normally Terminated	Enrolled + Term'd
19	# Subjects - Current Status Randomized	Subjs. Randomized
20	# Subjects - Current Status Screened	Subjs. Screened
21	# Current Active Subjects	Active Subjects
22	% Enrolled to Total Planned at Study-Site	% Enrolled/Planned
23	% of Total Enrolled in Study	% Total Enrolled
24	% of Total Randomized in Study	% Total Randomized

Figure 2–16 displays the corresponding display on the Ipad.

Figure 2–16 Corresponding Display Order on Ipad

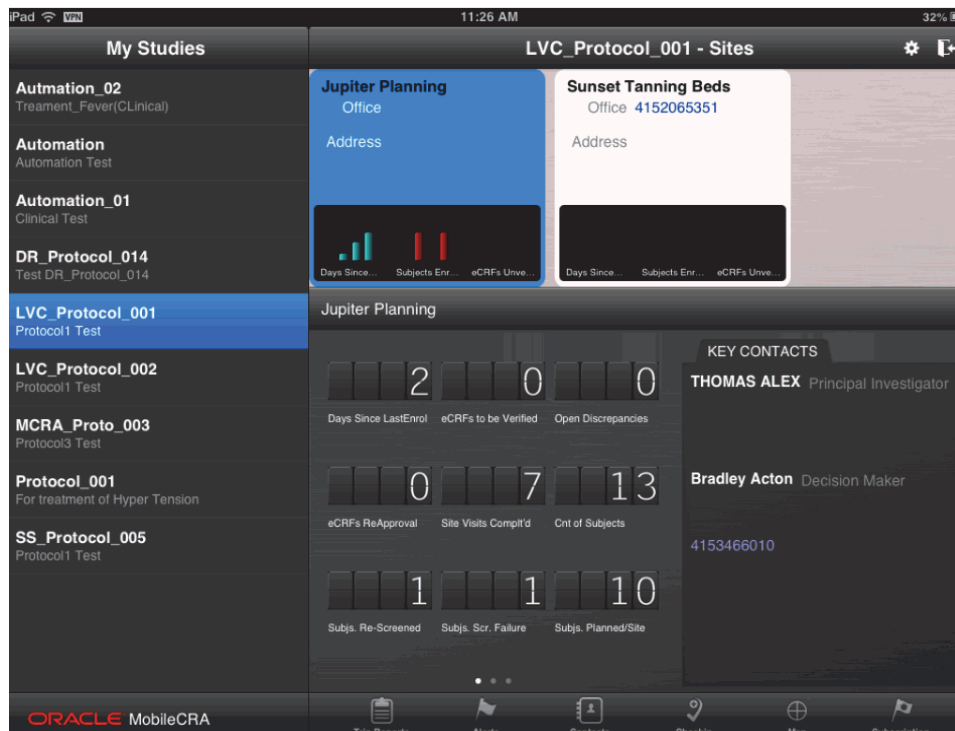


Figure 2–17 displays the changed order in the Configuration Utility.

Figure 2–17 Changed Display Order

ORACLE MobileCRA Administration

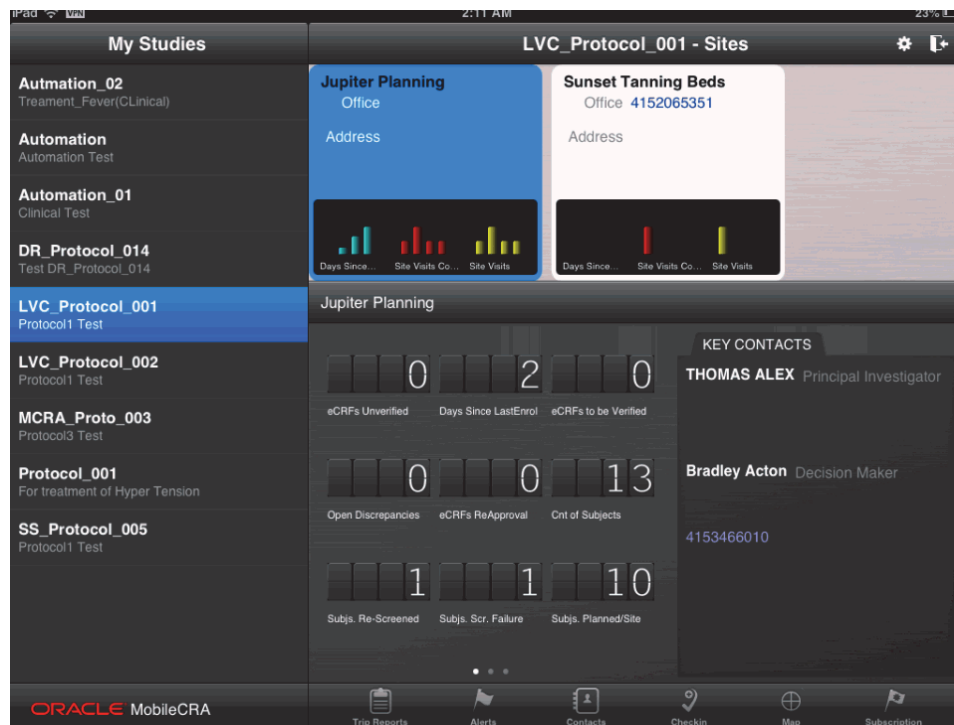
Study-Site Metrics

View Save Undo

Display Order	KPI Name	KPI Display Name
1	# Days Since Latest Site Visit	Days Since LastVisit
2	# Completed Site Visits	Site Visits Compl't'd
3	# Site Visits	Site Visits
4	# eCRFs Not Verified	eCRFs Unverified
5	# eCRFs To be Verified	eCRFs to be Verified
5	# Days Since Last Enrollment for Study-Site	Days Since LastEnrol
6	# Open Discrepancies	Open Discrepancies
7	# eCRFs Awaiting Re-Approval	eCRFs ReApproval
9	# Subjects	Cnt of Subjects
10	# Subjects - Current Status Re-Screened	Subjs. Re-Screened
11	# Subjects - Current Status Screen Failure	Subjs. Scr. Failure
12	# Subjects Planned for Study-Site	Subjs. Planned/Site
13	# Visit Reports Awaiting Approval	Visit Rpts for Appri
14	# Discrepancies Irresolvable	Disc. Irresolvable
15	# eCRFs Approved	eCRFs Approved
16	# Subjects who have completed Study	Subjs. Compl't'd Test
17	% Subjects Early Terminated for Study-Site	% Subjs. Eryl Term'd
18	# Currently Enrolled plus # Normally Terminated	Enrolled + Term'd
19	# Subjects - Current Status Randomized	Subjs. Randomized
20	# Subjects - Current Status Screened	Subjs. Screened
21	# Current Active Subjects	Active Subjects
22	% Enrolled to Total Planned at Study-Site	% Enrolled/Planned
23	% of Total Enrolled in Study	% Total Enrolled
24	% of Total Randomized in Study	% Total Randomized

Figure 2–18 displays the changed display in the Ipad.

Figure 2–18 Corresponding Changed Display Order in Ipad



Trip Reports

The trip report you see on mobile devices such as the iPhone or iPad is called a Canonical trip report. The Canonical trip reports' generic trip report structure can accommodate different kinds of configurations for Trip Reports in the CTMS.

Different implementations configure CTMS differently, either by extending the default trip report shipped out-of-the-box in CTMS or by completely replacing the default trip report with one of their own.

You must transform the out-of-the-box CTMS trip report to the Canonical trip report by extending the default transformation. You can make this transformation through Extensible Stylesheet Language Transformations (XSLT), a unique but flexible XML transformation language.

A Canonical trip report is simple in its structure. It is composed of two basic components:

- Attributes
- Items

Each item can have attributes and (or) items nested inside. It supports multi-level nesting. This generic structure lets you create any kind of trip report. For example, a trip report can have a checklist item, follow-up item, and attendee apart from its attributes. The checklist item may have a nested follow-up item underneath it. Thus, you may have a 3 level nested Trip Report structure.

To extend the configurations of the default CTMS trip report to your mobile device:

1. Understand the CTMS trip report structure by inspecting the XML coming out of the CTMS trip report web service.
2. Come up with a Canonical trip report structure that may or may not be same as the CTMS trip report depending on their needs. For example, a user may default certain values in the web service so that they can come up with a minimal trip report structure to make it easy for the Mobile CRA to quickly fill in or they can design it to accommodate all the fields in CTMS.
3. Transform the CTMS trip report to Canonical trip report using XSLT.
4. Define the display characteristics for those transformed attributes in the Configuration Utility. The Configuration Utility is where the user defines the attributes, the item types, and their relationship along with the display characteristics. The items, attributes, and relationship must mirror the transformation structure in the XSLT. For example, if a trip report is defined to have two items types such as checklist.

3.1 Configuring a Trip Report

Getting to the Mobile Trip Report Configuration Screen:

Click **Trip Reports** in right pane of the Home page to reach the Configuration Screen.

This section contains the following topics:

- [Section 3.1.1, "Defining Trip Report Types"](#)
- [Section 3.1.2, "Defining Attributes"](#)
- [Section 3.1.3, "Defining Subitems"](#)
- [Section 3.1.4, "Defining the Category Order"](#)
- [Section 3.1.5, "Using EXTensible Stylesheet Language Transformations to Create a Trip Report"](#)
- [Section 3.1.6, "Source Data Verification"](#)
- [Section 3.1.7, "Sample Trip Report in the CTMS"](#)

3.1.1 Defining Trip Report Types

This module lets you define how a trip report is displayed on the device. You can define the various sections, attributes, and associated checks of the trip report type. You can also define the order of display.

[Figure 3–1](#) represents the Mobile Trip Report Configuration screen. The left pane displays a list of all tasks. The right pane displays the corresponding default types in the top pane and the details of the type selected in the bottom pane.

Figure 3–1 The Mobile Trip Report Configuration Screen

Mobile Trip Report Configuration

Tasks

- Define Trip Report Types
- Define Picklist Sources
- Define Trip Report Styles

Trip Report Types

Actions View Create Edit Remove Audit

Default	Type Name	Caption	Category	Description
★	Trip Report	Trip Report	Trip Report	Trip Report - Top Level
★	Attendee		Attendees	Trip Report Attendees
★	Checklist Item		Checklist Items	Checklist Items used in trip report
★	FollowUp Item		Follow Up Items	Follow Up Items used in trip report
★	Assignee	Assignee	Assignees	Check List and Follow Up item Assignee
☆	abc			
☆	subtest2			

Columns Hidden 6 Type Co

Selected Type: Trip Report

Attributes Subitems

Actions View Add Edit Remove

Attribute Name	Caption	Category	Order	Data Type	Default Value	Max Length	Hidden	Require
AccountId	AccountId	About	1	Text		30	true	
AccountLocation	AccountLocation	About	1	Text		30	true	
Approver	Approver	About	1	Text		20	false	no
Approver Comments	Approver Comm	About	1	Text		100	false	no
AssignedTo	Assigned To	About	3	Text		20	false	yes
Comments	Comments	Summary	1	Text		100	false	no
Completed	Completed	About	1	Date			false	no
Description	Description	About	2	Text		20	false	no
InvestigatorFirstName	PI First Name	About	1	Text		20	false	no
InvestigatorLastName	PI Last Name	About	2	Text		20	false	no
PrimaryInvestigatorId	Primary Investigator	About	1	Text			true	
ProtocolId	ProtocolId	About	1	Text		30	true	
ProtocolNumber	Protocol	About	1	Text		20	false	yes
ProtocolTitle	Protocol Title	About	1	Text		20	false	no
Reviewer	Reviewer	About	1	Text		20	false	no
Reviewer Comments	Reviewer Comm	About	1	Text		100	false	no
SiteId	SiteId	About	1	Text		30	true	
SiteName	Account	About	1	Text			false	no
SiteNumber	Site	About	1	Text		20	false	no
Started	Start Caption	About	1	Date			true	no

Columns Hidden 1 Attribute Coun

When you select a task from the left pane, the right pane displays the screens related to that particular task. The toolbar buttons are **Action**, **View**, **Create**, **Edit**, **Remove**, and **Audit**.

You can define the various sections, sub-sections, the fields among these sections and sub sections, the date type, and rules around each of these fields.

Mobile CRA has the following report types:

- Trip Report
- Attendees
- Checklist Items
- Follow-up Items
- Assignees

The star icon denotes that this is a standard trip report type. You cannot delete the standard trip report types.

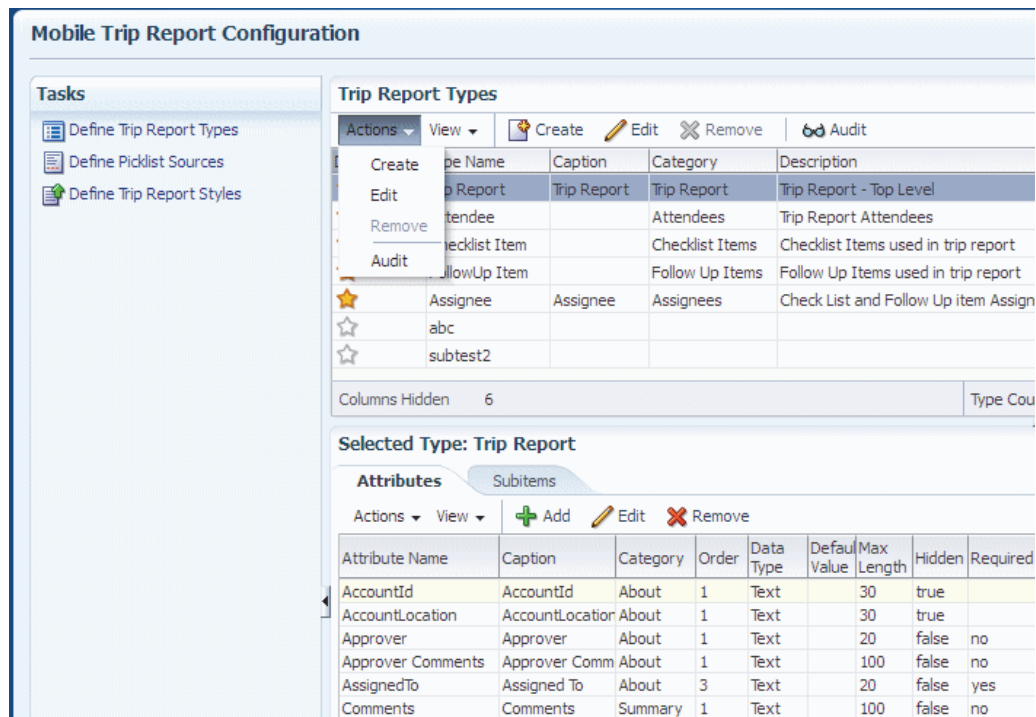
This section contains the following sub sections:

- Section 3.1.1.1, "The Action Drop-down List"
- Section 3.1.1.2, "The View Drop-down List"
- Section 3.1.1.3, "Creating a Trip Report Type"
- Section 3.1.1.4, "Editing a Trip Report"
- Section 3.1.1.5, "Audit Details"

3.1.1.1 The Action Drop-down List

Figure 3–2 represents the **Action** drop-down list:

Figure 3–2 The Action Drop-down List

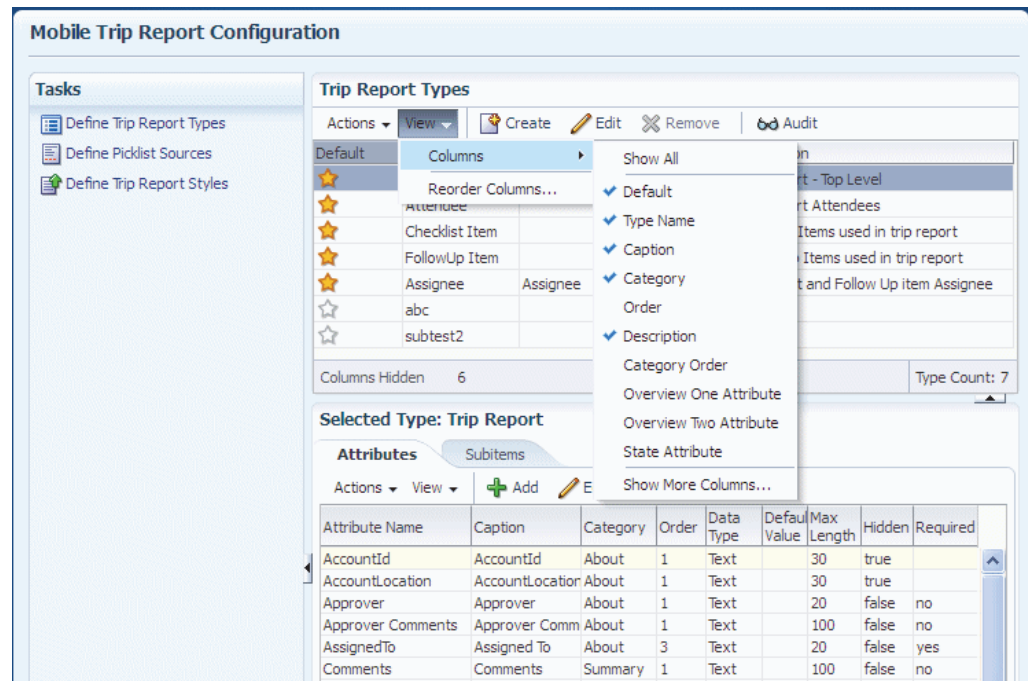


When you select **Action**, it displays the options, **Create**, **Edit**, **Remove**, and **Audit**.

3.1.1.2 The View Drop-down List

Figure 3–2 represents the **View** drop-down list:

Figure 3-3 View Drop-Down List



When you click **View**, it lets you control the display, and the order in which the columns are displayed.

When you click **Columns**, it lets you define what columns are to be displayed, and what columns are to be hidden. To do this:

1. Click **View**.
2. Select **Columns**.
3. Select the columns that you want to display.

Reorder lets you rearrange the order of the columns. To do this:

1. Click **View**.
2. Select **Reorder Columns**.
3. You can view the list of **Visible columns**. Use the arrow keys on the right to rearrange the order of the columns displayed.

3.1.1.3 Creating a Trip Report Type

To create a trip report type:

1. Click **Create** to create a Trip Report Type.

Figure 3–4 Create Trip Report Type Screen

The screen displays the list of attributes required for creating a new trip report type.

2. Enter requisite fields in the Create Trip Report Type screen.

Table 3–1 Field Descriptions

Serial Number	Field Name	Description
1	Type Name	Provide a name for the trip report type.
2	Caption	Enter the name for an attribute within a section.
3	Category	Enter the heading title.
4	Order	Enter a number between 1 to 5.
5	Description	Add comments, details, or description around the trip report type.
6	Category Order	Specify the order in which the various sections appear within a trip report type. Each section has to be separated by a comma.
7	Caption Attribute	Defines the field from which the value is picked up by the system as a header for the Trip Report Type.
8	Overview Attribute 1	Define the option that comes up for a particular attribute. You can choose the value from the list of options.
9	Overview Attribute 2	Defines the pick list applicable for a particular trip report type. For example, for checklist items, status is defined as an Overview Attribute, and this brings in the values as a pick list for the user to choose a value.
11	Order Attribute	Defines the sequence ordering for the trip report type

3. Click **OK** to create a trip report type.

3.1.1.4 Editing a Trip Report

To edit a trip report type:

1. Click **Edit** to edit a trip report.

Figure 3–5 Edit Trip Report Type Screen

2. The Edit Trip Report Type screen displays the list of attributes that can be edited in a Trip Report type. Click **Show More** on the screen to display additional attributes.
3. Click **OK** to save the changes.

3.1.1.5 Audit Details

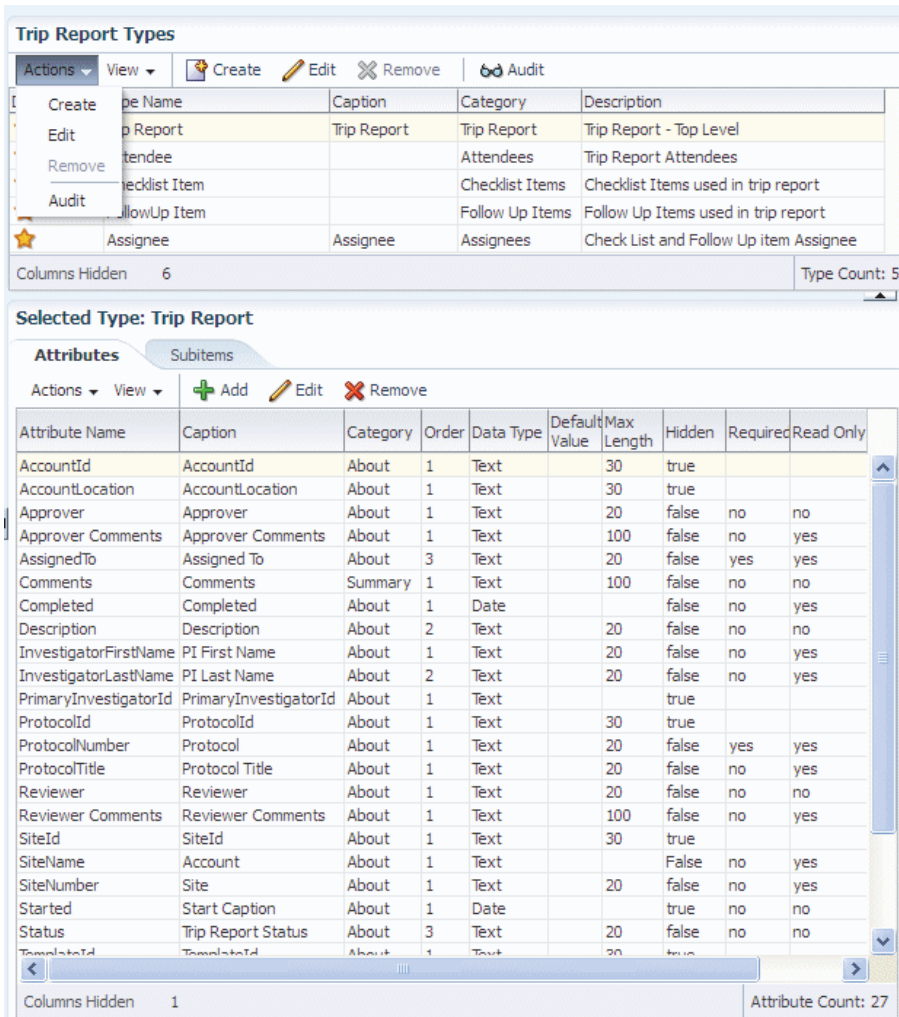
Click **Audit** to view the timestamp of when the trip report component was last created and (or) modified along with the user details.

Figure 3–6 Audit Details Screen

3.1.2 Defining Attributes

When you select a trip report in the top Trip Report Types pane, it displays the **Selected Type Trip Report** screen in the bottom pane.

Figure 3-7 Selected Trip Report Type Screen



The screen has two tabs: **Attributes** and **Subitems**. By default, the **Attributes** tab is displayed.

The toolbar displays the **Actions**, **View**, **Add**, **Edit**, and **Remove** icons.

The Action Drop-down List

When you click **Action**, it lets you view the options, **Add**, **Edit**, and **Remove**.

The View Drop-down List

When you click **View**, it lets you control the display and the order in which the columns are displayed.

When you click **Columns** it lets you define what columns are to be displayed and what columns are to be hidden. To do this:

1. Click **View**.
2. Select **Columns**.
3. Select the columns that you want to display.

Reorder lets you rearrange the order of the columns. To do this:

1. Click **View**.
2. Select **Reorder Columns**.
3. You can view the list of **Visible columns**. Use the arrow keys on the right to rearrange the order of the columns displayed.

Adding Attributes

When you click **Add**, it lets you add an attribute type. The Add attributes screen displays the list of attributes required for creating a new attribute type. Fields marked with a star (*) are mandatory fields.

Figure 3–8 Add Type Attributes Screen

Table 3–2 describes the Add Type Attribute field descriptions.

Table 3–2 Add Type Attribute Field Descriptions.

Serial Number	Field Name	Descriptions
1	Attribute Name	Enter the name of the attribute.
4	Order	Enter the number that is used by the system to order the attribute.
5	Data Type	Select the data type from the available options, Text, Number, Date, and Boolean.
6	Max Length	Enter the number that is used by the system to determine the maximum length of the text input on the mobile application.
7	Default Value	Enter any default value that needs to be displayed.
8	Picklist Field	Select the source of values, in case the attribute is a Picklist.
9	Hidden	Specify if the attribute has to be hidden or displayed. The values are True and False.
10	Required	Specify if the attribute has to be mandated or optional. The values are Yes and No.
11	Read Only	Specify if the attribute has to be display only or the user can type in an input. The values are Yes and No.

Table 3–2 (Cont.) Add Type Attribute Field Descriptions.

Serial Number	Field Name	Descriptions
2	Caption	Enter the caption for the attribute.
3	Category	Specify the sub-section under which the particular attribute shall be displayed.
4	Order	Enter the number that is used by the system to order the attribute.
5	Data Type	Select the data type from the available options, Text, Number, Date, and Boolean.
6	Max Length	Enter the number that is used by the system to determine the maximum length of the text input on the mobile application.
7	Default Value	Enter any default value that needs to be displayed.
8	Picklist Field	Select the source of values, in case the attribute is a Picklist.
9	Hidden	Specify if the attribute has to be hidden or displayed. The values are True and False.
10	Required	Specify if the attribute has to be mandated or optional. The values are Yes and No.
11	Read Only	Specify if the attribute has to be display only or the user can type in an input. The values are Yes and No.

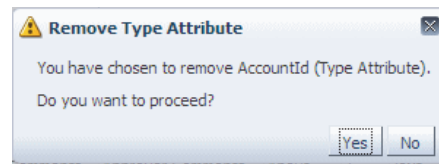
Editing a Type Attribute

When you click **Edit**, it lets you edit an attribute type. The Edit Attribute Type screen displays the list of attributes that can be edited in an attribute type.

Figure 3–9 Editing an Attribute Type

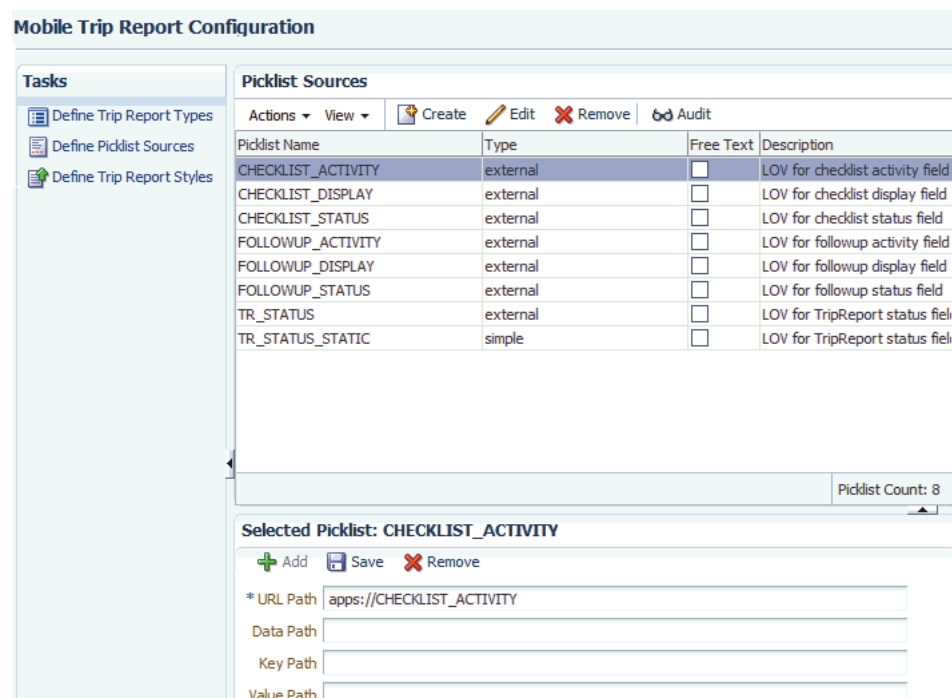
Removing an Attribute Type

When you click **Remove**, it deletes the selected attribute type.

Figure 3–10 Removing an Attribute Type

3.1.2.1 Defining Picklist Sources

Some of the fields in the trip reports need to display a list of values. The **Define Picklists Sources** section lets you define the picklists and the source of values for such fields. Once defined, these can be attached to the required and relevant attributes in the trip report types.

Figure 3–11 Defining Picklist Sources

Click **Define Picklist Sources** to view the Picklists screen.

When you select a picklist from the top pane, the bottom pane displays the selected Picklist details. The toolbar icons are **Action**, **View**, **Create**, **Edit**, **Remove**, and **Audit**.

The primary function of the picklist source table is to define the picklist items used for the Choice field in the Group Attribute field definition. Each picklist item is created with an associated type that corresponds to the available Web service based options, which are key-value pairs.

Define Picklist Source Operation:

To create a picklist for a Metadata field, define a Picklist Source Item:

1. Enter the name, description, and picklist type in the Picklist Item table.
2. The Picklist Type item is either a key-value pair value or a URL-based web service.

3. After creating the picklist item, select the corresponding Type tab for entering values.
4. Use constraints to prevent items from being created with different types for same item

Picklist Types:

- Key-Value - Defines a list of key-value pairs.
- External - Defines a web service for retrieving Picklist items.

Entity Objects:

- HSM_CTMS_PICKLIST

View Object Fields:

- PICKLIST_NAME is the name of Picklist source.
- PICKLIST_TYPE is the type of Picklist (Key-Value or External).
- PICKLIST_DESCR is the description of the Picklist item.

Defining Picklist Source Values:

The Picklist item values tabs primary function is to define the values associated with each Picklist source name. The values for a Picklist Item can be different based on the Picklist type.

Defining the Picklist Source Value Operation:

1. Select a picklist name and type row from the Picklist Source table.
2. Select the corresponding picklist type from either the Key-Value or Web Service tab.
3. A new record is created with required attributes pertaining to type within designated tab.
4. The Key-value type may contain multiple records per picklist source item.
5. The external web service type contains one record per Picklist source item.

Entity Objects:

- HSM_CTMS_PICKLIST_KEYVAL
- HSM_CTMS_PICKLIST_EXT

View Object Fields—Key-Value Type

- PICKLIST_TYPE is the name of type (key-value).
- PICKLIST_KEY is the name of the picklist value to display.
- PICKLIST_VALUE is the data value of the picklist name.
- PICKLIST_DESCR is the description of the Picklist name.
- DISPLAY_ORDER is the sequence of items to display.

View Object Fields—External Type

- PICKLIST_TYPE is the name of type (external).
- URL_PATH – external REST URL to fetch data from an external source.
- DATA_PATH is the path within the received data structure that points to array of options to display.
- KEY_PATH is the path within the received data structure that points to a unique option key.
- VALUE_PATH is the path within the received data structure that points to unique option displayable value.

3.1.3 Defining Subitems

The tool bar displays the **Actions**, **View**, **Add**, **Save**, and **Remove** icons.

The Action Drop-down List

When you click **Action**, it lets you view the three options: **Add**, **Delete**, and **Save**.

The View Drop-down List

When you click **View**, it lets you control the display and the order in which the columns are displayed.

When you click **Columns** it lets you define what columns are to be displayed and what columns are to be hidden. To do this:

- Click **View**.
- Select **Columns**.
- Select the columns that you want to display.

Reorder lets you rearrange the order of the columns. To do this:

- Click **View**.
- Select **Reorder Columns**.
- You can view the list of **Visible columns**. Use the arrow keys on the right to rearrange the order of the columns displayed.

Adding a Subitem

When you click **Add**, it lets you add a Subitem type. The Add Subitem screen displays the list of attributes required for creating a new Subitem type. Fields marked with a star (*) are mandatory fields.

Figure 3–12 Adding a Subitem

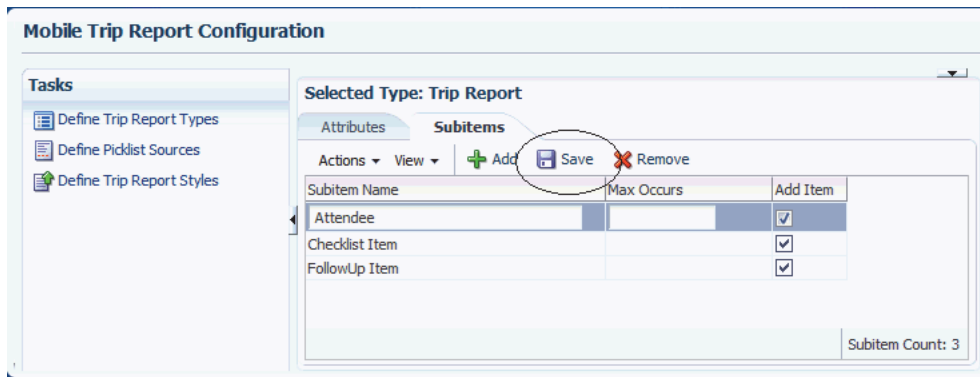
The screenshot shows a dialog box titled "Adding a Subitem". It has a close button (X) in the top right corner. The dialog contains three input fields:

- A text field labeled "* Subitem Name" with a red asterisk indicating it is mandatory.
- A text field labeled "Max Occurs".
- A checkbox labeled "Add Item".

 At the bottom right of the dialog, there are two buttons: "OK" and "Cancel".

Saving a Subitem Type

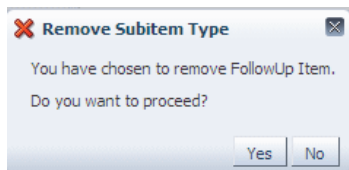
Figure 3–13 Saving a Subitem



When you click **Save** it saves the Subitem type.

Removing a Subitem

Figure 3–14 Removing a Subitem



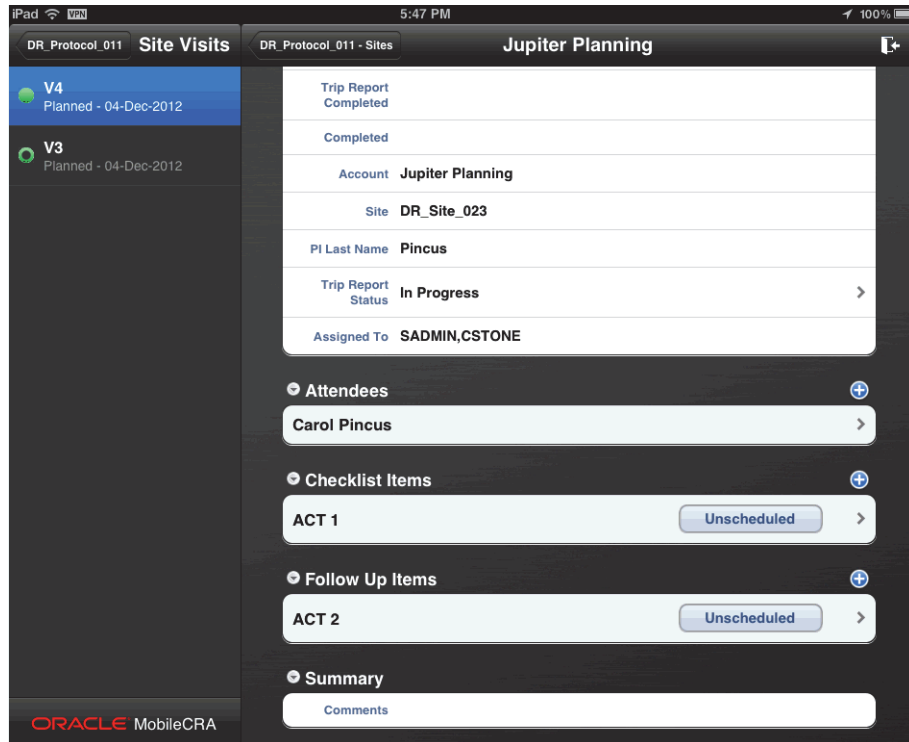
1. When you click **Remove**, the Remove Subitem Type dialog box is displayed.
2. Click **Yes** to delete the selected Subitem type.

3.1.4 Defining the Category Order

Order is a text field to key in the number that is used by the system to order the **Category** attribute.

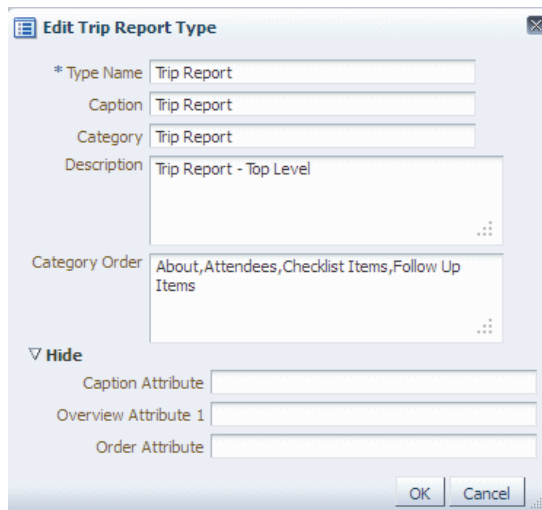
The standard application on the iDevice comes with a default category order.

Figure 3–15 Existing Order in the iPad.



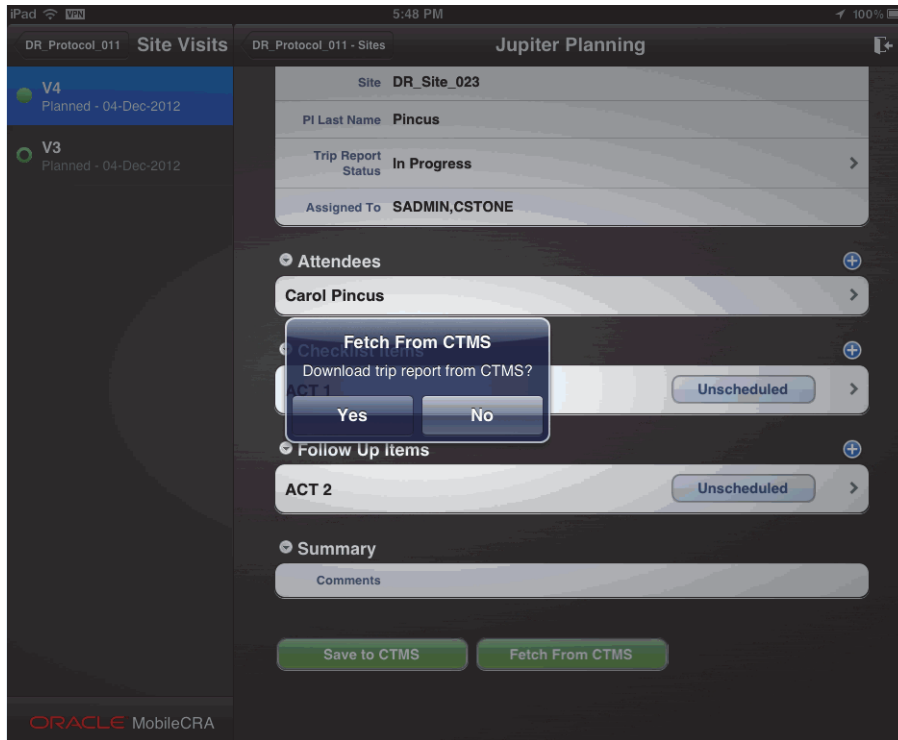
You can re-arrange the order categories per your requirements.

Figure 3–16 Re-arranged Order



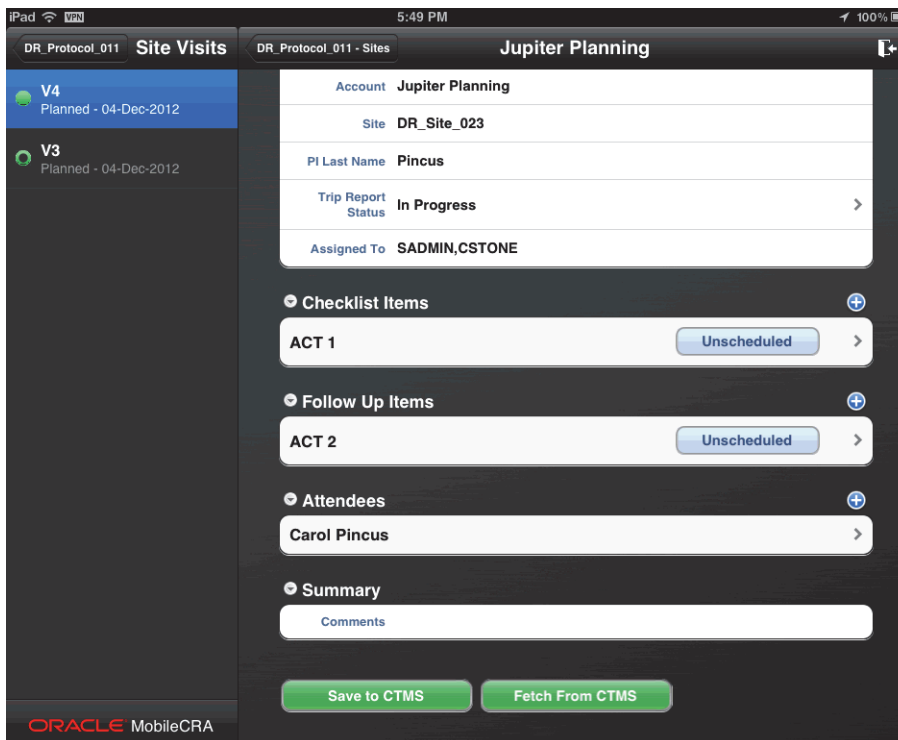
Click **Fetch from CTMS** to view the re-arranged order.

Figure 3–17 Fetch from CTMS



You can now view the new order on the iPad.

Figure 3–18 New Order



3.1.5 Using Extensible Stylesheet Language Transformations to Create a Trip Report

The four XSLTs that are needed for the creation of the trip report are:

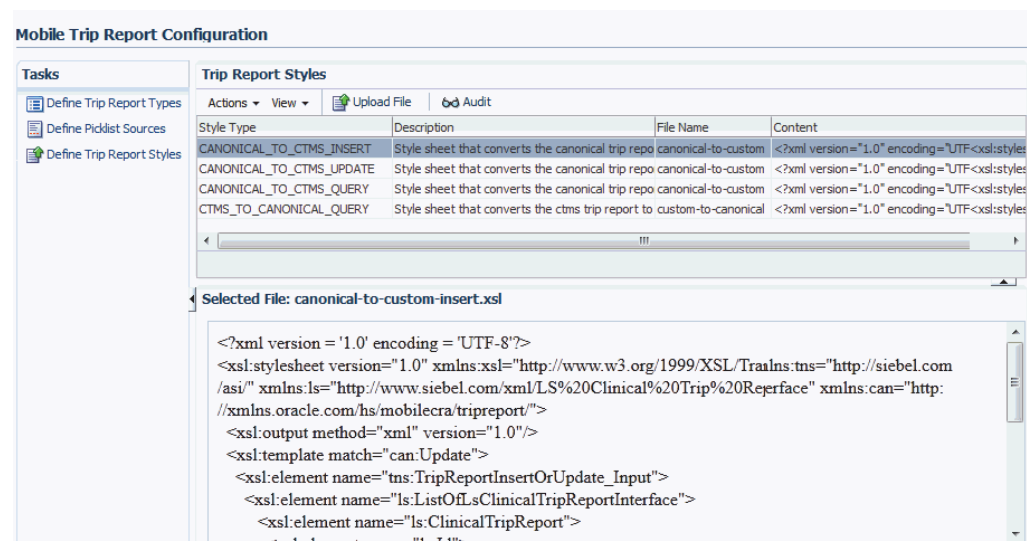
- **Canonical to Custom Insert** - Converts the canonical trip report from the client to the custom trip report creation XML for invoking web service on the CTMS. Since the result from the CTMS is a true or false response depending on whether the insert operation is successful or not, you do not need an XSLT for Custom to Canonical Insert.
- **Canonical to Custom Query** - Converts the canonical trip report query request to a custom CTMS request. Since the result is the CTMS XML, another XSLT is needed to convert it back to canonical.
- **Custom to Canonical Query** - Converts the XML that was recovered as a result from the CTMS into the canonical trip report.
- **Canonical to Custom Update** - Converts the canonical trip report from the client to custom trip report update XML for invoking web service on the CTMS. Since the result from the CTMS is a true or false response depending on whether the update operation is successful or not, you do not need an XSLT for Custom to Canonical Update.

3.1.5.1 Defining Trip Report Styles

Click **Define Trip Report Style** to view the Define Trip Report Style screen.

When you select a trip report style from the top pane, the bottom pane displays the selected trip report style details mode. You can visually inspect the contents of the uploaded file. You must modify and validate the style sheet structure and data outside the Configuration Utility server. If you want to make changes in the selected style type, use the **File Upload** icon to re-upload a new style sheet file. See data model specifications for additional information on entity attributes.

Figure 3–19 Define Trip Report Styles Screen



View Contents Operation

- Use the Inline Frame component to display the Style Sheet file contents.
- Use the Servlet applet to read the contents from the CLOB database field.

- Servlet transforms XML content into HTML markup representation for display.
- The contents are displayed in Inline Frame component in the read-only mode.

Entity Objects

- HSM_CTMS_STYLE

View Object Fields

- CONTENT (read-only) – contents of field that contains XSLT data

3.1.6 Source Data Verification

Mobile CRA now supports Source Data Verification (SDV) for InForm enabled studies. You must ensure the following:

- InForm must be 6.0 or above
- InForm must have the data adapter and data discrepancy services installed
- The CTMS site must be mapped to the InForm sites from the Mobile CRA Administration Console.

CRA's will not conduct SDV at every type of site visit. The Mobile CRA Administration Console permits the selection of which CTMS site visit template can access InForm. For example, CRA's may conduct a site visit initiation visits. A specific trip report template is created to support this type of visit. However, it is not required to conduct SDV activities during this type of visit. Mobile CRA permits the administrator to select which templates permit SDV.

3.1.6.1 Linking a CTMS Study to an InForm Study

All CTMS studies are pre-populated into the Study Mapping table as shown in [Figure 3–20](#).

Figure 3–20 Study Mapping

CTMS Study ID	CTMS Study Name	InForm URL	InForm Adapter URL	InForm Discrepancy URL
88-3H8XP				
88-3EBG2	Automation Test			
88-2WCHH				
88-2WCHL				
88-3AY19				
88-3AY19				

Additionally, the list of CTMS sites are automatically populated.

Enabling InForm Source Data Verification for a Study

To enable InForm SDV for a study in Mobile CRA, perform the following steps:

1. Enter the InForm URLs for the study enabled against the CTMS Study Name or ID.

Figure 3–21 CTMS Study Mapping Attributes

- a. Enter the main InForm URL, the InForm Adapter URL, and the InForm Discrepancies adapter.
- b. Select the type of SDV reporting that will be returned from SDV sessions to the trip report.

Figure 3–22 Selecting the SDV Reporting Type
Table 3–3 SDV Reporting Options

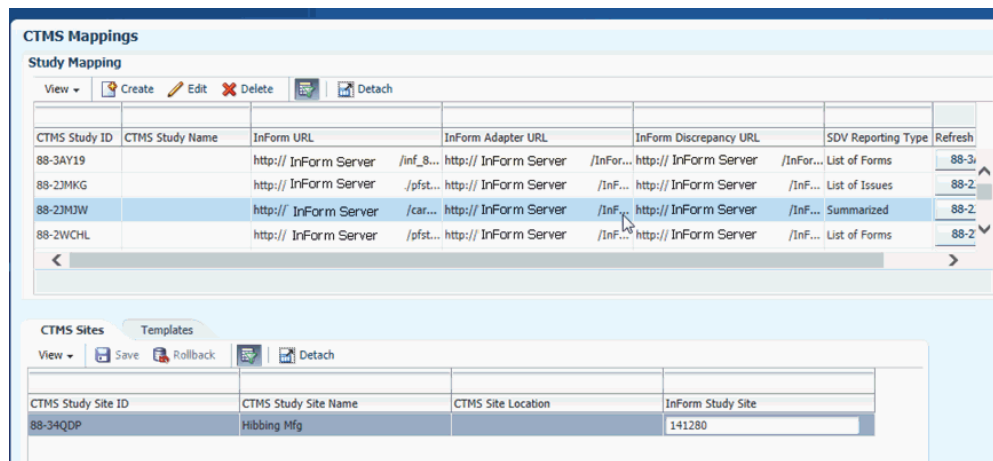
Reporting Type	Behavior
List of Issues	One checklist item is created for each form where query is created. Text for Checklist - '<Patient ID> had form for Visit <#>, <Form Name> with an issue' Text for Comment - '<Query Text>'
Summarized	One checklist item is created for each SDV session. Text for Checklist - 'SDV Completed for <x> number of forms'. Text for Comment - 'Forms SDV Complete:< # forms> : Forms Partial Verify: <# Forms> : Forms with Issues: <# Forms>
List of Forms	One checklist item is created for each form that are fully verified or partially verified. Text for Checklist - 'SDV ["Completed" or "Partial"] for Visit <#>, <Form Name>' Text for Comment - 'Record Status <Verified/Partial Verified/Issue> : <If Issue, record query text in comment>'
Summarized/Finding Detail	One checklist item is created. Text for Checklist - 'SDV completed for # forms: <#> issues found' Text for Comment - 'Forms with Issues: <# Forms>
By Patient	One checklist item is created for each patient that are verified for each SDV Session. Text for Checklist - 'SDV on Patient <Patient ID>: <#> of forms verified. <#> issues found' Text for Comment - 'Forms SDV Complete:< # forms> : Forms Partial Verify: <# Forms> : Forms with Issues: <# Forms>

The system differentiates between CRF pages that are fully verified (all fields verified) and pages that are partially verified, (some fields are verified).

Since various studies operate under different SDV reporting rules, the system lets the administrator select a reporting type on a study by study basis. For example, Study 1 may be operating under strict controls, requiring individual report for each form verified, while Study 2 is operating under less strict business rules (that is, a post marketing study), which only requires a summary report.

2. Map the CTMS site to the InForm sites.

Figure 3–23 Mapping CTMS Sites to InForm Sites



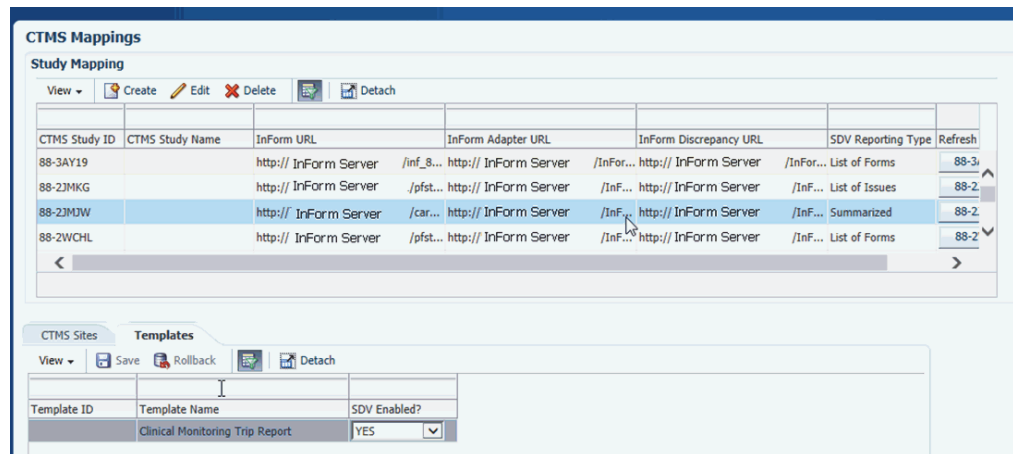
Once the InForm URLs are in place, the system selects all CTMS sites and names for the study, and displays them in the CTMS Studies tab.

The InForm Study site names that maps to the CTMS study site must be entered into the appropriate field.

3. Select templates where SDV will be performed.

SDV may not be performed for every template. For example, a template designed to support a Site Initiation visit may not require SDV, because patients have not yet enrolled at the site.

In the second tab, **Templates**, the administrator can select the templates where SDV will be accessible.

Figure 3–24 Selecting Templates to Perform Source Data Verification

Click **Yes** or **No** for each template.

When the trip report is saved, the SDV results are automatically mapped to the default checklist section in the out-of-the-box CTMS trip report, with a Sub Activity of **SDV Activity**.

Note: In CTMS, if the Sub Activity field does not permit the value of SDV Activity, add this to the picklist.

If required, the XSLT mappings can be modified to direct the SDV records to CTMS applet other than checklist. For details on altering the mappings, see [Section 3.1.5](#).

3.1.7 Sample Trip Report in the CTMS

Figure 3–25 describes a sample out-of-the-box trip report in CTMS:

Figure 3–25 Sample Out-of-the-Box Trip Report in the CTMS

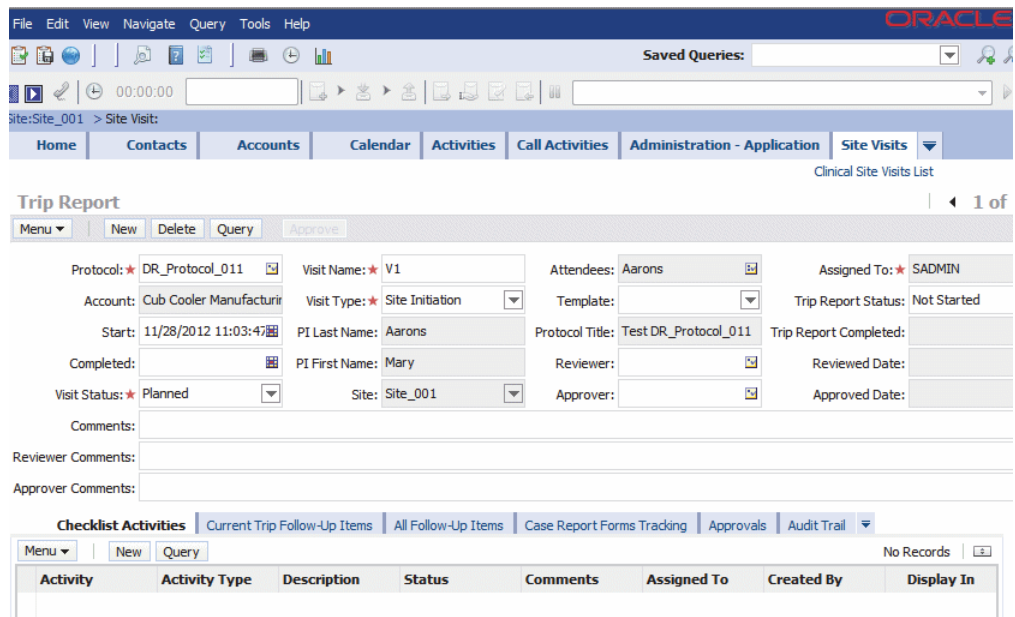


Figure 3–26 shows a trip report in the out-of-the-box CTMS with the trip report header section and its various subitems highlighted. This trip report has the following items:

- Attendees
- Check list items
- Follow-up items
- Comments summary
- The checklist and the follow up items have the assignee items within.

These items have various attributes:

Figure 3–26 Sections within a Trip Report

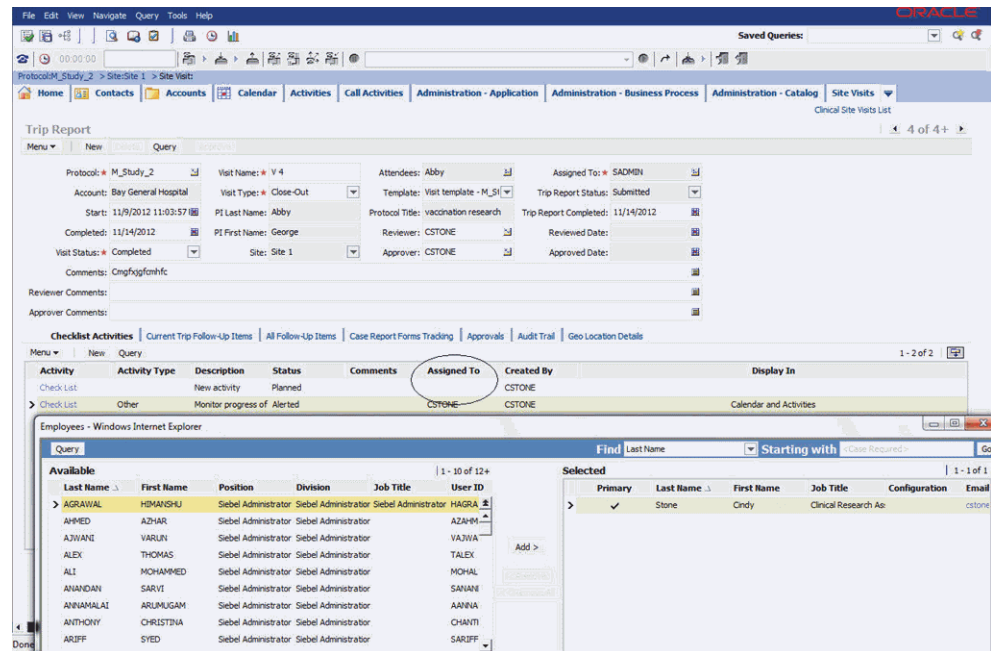
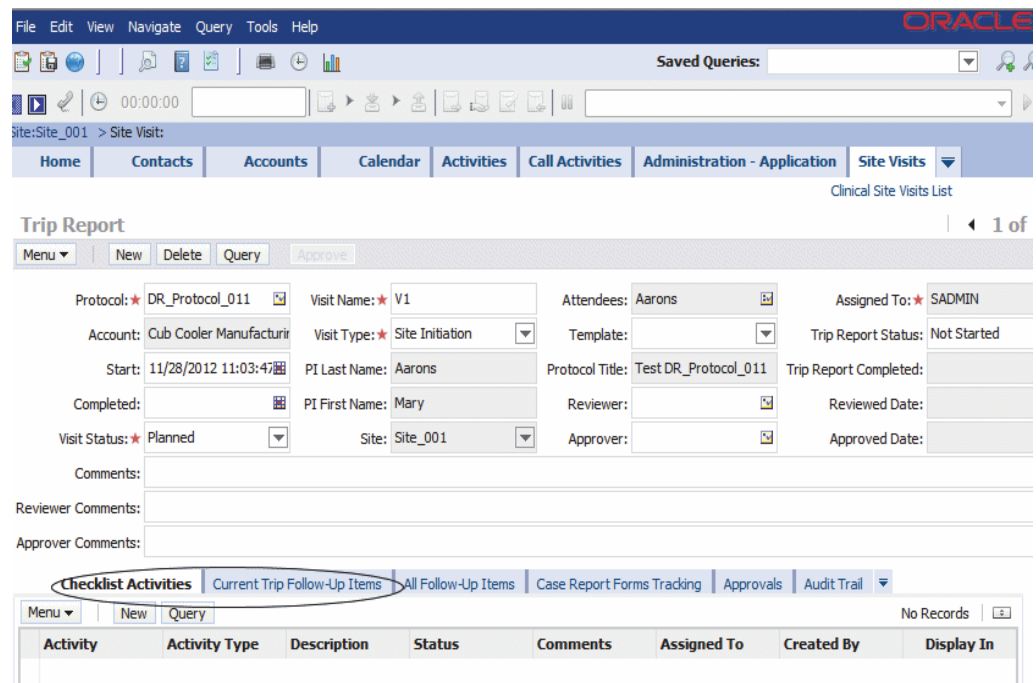


Figure 3–27 displays the sections within a trip report.

Figure 3–27 CTMS Items Represented as Item Types on Mobile CRA Configuration Utility



The above items in the CTMS can be represented as various item types on the Mobile CRA Configuration Utility screen.

These items are represented as five different items in the Configuration Utility, including the trip report container element, and the assignee item, which are present

under both checklist item and follow up item. All hierarchical items are represented as flat items in the Configuration Utility.

The attributes under each of these elements are defined in the hierarchical order. All the attributes under the trip report element go under trip report, all the attributes under checklist items go under checklist items, and so on.

The attributes contain various properties which control the behavior of those attributes on the mobile screen. These attributes include editable, hidden, and so on.

Figure 3–28 displays the attributes for a trip report type in the Configuration Utility.

Figure 3–28 Attributes for a Trip Report Type in MobileCRA Configuration Utility

Selected Type: Trip Report									
Attributes									
Subitems									
Actions View Add Edit Remove									
Attribute Name	Caption	Category	Order	Data Type	Default Value	Max Length	Hidden	Required	Read Only
SiteName	Account	About	1	Text			False	no	yes
AccountId	AccountId	About	1	Text		30	true		
AccountLocation	AccountLocation	About	1	Text		30	true		
Approver	Approver	About	1	Text		20	false	no	no
Approver Comments	Approver Comments	About	1	Text		100	false	no	yes
AssignedTo	Assigned To	About	3	Text		20	false	yes	yes
Comments	Comments	Summary	1	Text		100	false	no	no
Completed	Completed	About	1	Date			false	no	yes
Description	Description	About	2	Text		20	false	no	no
InvestigatorFirstName	PI First Name	About	1	Text		20	false	no	yes
InvestigatorLastName	PI Last Name	About	2	Text		20	false	no	yes
PrimaryInvestigatorId	PrimaryInvestigator	About	1	Text			true		
ProtocolNumber	Protocol	About	1	Text		20	false	yes	yes
ProtocolTitle	Protocol Title	About	1	Text		20	false	no	yes
ProtocolId	ProtocolId	About	1	Text		30	true		
Reviewer	Reviewer	About	1	Text		20	false	no	no
Reviewer Comments	Reviewer Comments	About	1	Text		100	false	no	yes
SiteNumber	Site	About	1	Text		20	false	no	yes
SiteId	SiteId	About	1	Text		30	true		
Started	Start Caption	About	1	Date			true	no	no
TemplateName	Template	About	1	Text			false	no	yes
TemplateId	TemplateId	About	1	Text		30	true		
TripReportCompleted	Trip Report Complet	About	1	Date		20	false	no	yes
Status	Trip Report Status	About	3	Text		20	false	no	no
Visit Name	Visit Name	About	2	Text		20	false	yes	no
Visit Status	Visit Status	About	1	Text		20	false	yes	no
Visit Type	Visit Type	about	2	Text		20	false	yes	no

You can display each of the attributes and items in a separate display category. You can use this functionality for representing the elements in the UI using certain logical grouping. For example, all attributes in the header section are displayed under a single display section called **About**. However, if you want, you can place them in different groupings. For example, **Assigned To**, **Approver**, and **Reviewer** in a workflow section, and all the other fields in the **About** section.

Figure 3–29 represents the sample canonical form. The canonical form has two basic elements, that is, items and attributes. An item can have attributes and (or) items in a hierarchical structure at any number of levels. The figure represents the out-of-the-box trip report with three levels, the trip report at the top level, the checklist, follow up, attendees at the second level with assigned to at the third level inside the checklist and follow up item.

Figure 3–29 Trip Report XSLT

```

<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<can:TripReport xmlns:can="http://xmlns.oracle.com/hs/mobilecra/tripreport/" id="8SIA-8PD1I" type="Trip Report">
  <can:Attribute name="ProtocolNumber">
    <can:Value>MCRA Pro 1</can:Value>
  </can:Attribute>
  .....
  <can:Item id="8SIA-8Q1UG" type="Checklist Item">
    <can:Attribute name="ActivityType">
      <can:Value>Other</can:Value>
    </can:Attribute>
    .....
    <can:Item id="8SIA-8Q1UK" type="Assignee">
      <can:Attribute name="FirstName">
        <can:Value>Edison</can:Value>
      </can:Attribute>
      .....
    </can:Item>
  </can:Item>
  <can:Item id="8SIA-8Q596" type="Followup Item">
    <can:Attribute name="ActivityType">
      <can:Value>OtherChanged</can:Value>
    </can:Attribute>
    .....
  </can:Item>
  <can:Item id="8SIA-8Q1UM" type="Attendee">
    <can:Attribute name="FirstName">
      <can:Value>Thomas</can:Value>
    </can:Attribute>
  </can:Item>
  .....
</can:TripReport>

```

Figure 3–30 represents the sample CTMS XML that is dispatched as part of the trip report web service XML. It mirrors the hierarchy of the trip report in the CTMS. The mobile trip report can follow the same hierarchy or a completely different hierarchy.

Figure 3–30 Sample CTMS XML

```

<SOAP-ENV:Envelope xmlns:SOAP-ENV="http://schemas.xmlsoap.org/soap/envelope/" xmlns:xsi="http://www.w3.org/2001/
  <SOAP-ENV:Body>
    <ns:TripReportQueryById_Output xmlns:ns="http://siebel.com/asi/"
      <ListOfLsClinicalTripReportInterface xmlns="http://www.siebel.com/xml/LS%20Clinical%20Trip%20Report%20I
        <ClinicalTripReport>
          <Id>8SIA-8NUH6</Id>
          <ActivityUID>8SIA-8NUH6</ActivityUID>
          <ApproverLogin>SRADMIN</ApproverLogin>
          <Comment>Super comments</Comment>
          <Completed>N</Completed>
          <Description>Venkat Site Visit</Description>
          <DisplayInvestigatorFirstName>Cindy</DisplayInvestigatorFirstName>
          <DisplayInvestigatorLastName>Stone</DisplayInvestigatorLastName>
          <Done>07/13/2012 00:00:00</Done>
          <Planned>06/26/2012 13:12:51</Planned>
          <ProtocolNumber>CARDIAC</ProtocolNumber>
          <ProtocolSiteId>8SIA-8KXIH</ProtocolSiteId>
          <ProtocolTitle>Treatment of cardiac diseases</ProtocolTitle>
          <ReviewerComments>Super reviewer comments</ReviewerComments>
          <ReviewerLogin>SRADMIN</ReviewerLogin>
          <ApproverComments>Super approver comments</ApproverComments>
          <SiteName>Massachusetts Cardio Associates</SiteName>
          <SiteNumber>Site 1</SiteNumber>
          <Status>Done</Status>
          <TemplateName>Clinical Initiation Trip Report</TemplateName>
          <TripReportCompleted>07/13/2012</TripReportCompleted>
          <TripReportStatus>In Progress</TripReportStatus>
          <Type>Site Initiation</Type>
          <ListOfLsClinicalSit ... alSiteVisitAssignee>
            <ListOfClinicalAttendee>
              <ClinicalAttendee>
                <Id>1-4TTR</Id>

```

Figure 3–31 shows how the XSLT coding is done to transform the XML from one form to another.

In the example below, the CTMS XML that was returned is converted. As a result the CTMS web service XML is converted back to canonical XML.

For example, for every occurrence of a trip report element in the CTMS trip report, a Trip Report element is created in the canonical trip report. Also, the example below shows how to create a canonical element attribute from a CTMS attribute. In this case, whenever there is a protocol number attribute in the trip report header, an attribute is created in the canonical form, whose name is Protocol Number, and whose value is the same as the value in the CTMS.

Figure 3–31 Custom to Canonical XSL

```

<?xml version="1.0" encoding="UTF-8"?>
<xsl:stylesheet version="1.0"
  xmlns:xsl="http://www.w3.org/1999/XSL/Transform"
  xmlns:xi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns:tms="http://www.siebel.com/xml/LS420Clinical420Trip420Report420Interface"
  xmlns:can="http://xmlns.oracle.com/hs/mobilecra/tripreport/">
  <xsl:output method="xml" version="1.0" />
  <!--
  Maps CTMS <ClinicalTripReport> element to Mobile CRA <TripReport> trip report element
  -->
  <xsl:template match="tms:ClinicalTripReport">
    <xsl:element name="can:TripReport">
      <!--
      Select elements under <ClinicalTripReport> to be mapped to mobile CRA elements
      Currently selected elements are <Id>, <Comment> and <Status>.
      This document should define respective XSL template for each of the elements below,
      otherwise it the element will not be mapped.
      -->
      <!-- attribute id -->
      <xsl:attribute name="id">
        <xsl:value-of select="tms:ActivityUID" />
      </xsl:attribute>
      <!-- attribute type -->
      <xsl:attribute name="type">Trip Report</xsl:attribute>
      <!-- protocol number -->
      <xsl:element name="can:Attribute">
        <xsl:attribute name="name">ProtocolNumber</xsl:attribute>
        <xsl:element name="can:Value">
          <xsl:value-of select="tms:ProtocolNumber" />
        </xsl:element>
      </xsl:element>
    </xsl:element>
  </xsl:template>
  </xsl:stylesheet>
  
```

The example below shows a special handling for trip report status attribute, which is, again, an attribute inside the trip report. Here, whenever you query the trip report from CTMS in *Submitted* or *Submitted for Approval*, it is put in the *In Review* status in the Mobile CRA. This is one of the normalized Trip Report statuses in the mobile client. To accommodate all kinds of workflow, the mobile client has the following recognized statuses:

- Editable status - The CTMS status can be retained as is except for the below status values, which have a special meaning. In this case, the trip report is editable in the mobile client.
- In Review status - The status in the CTMS for which the Mobile CRA will not update the update the trip report in the client.
- Submitted status - CTMS must have a Submitted status if it wants to submit the Trip Report for approval or review workflow. Also, during the submission, the client asks for the electronic signature.
- Approved status - CTMS must have an approved status. The status must be passed as is to the client. When the client sees any trip report in the approved status, it does not let the mobile client update any further. This is assumed as the final state in the mobile client.

Figure 3–32 represents the Managing Status in XSL.

Figure 3–32 Managing Status in XSL

```

Note that
- Status is a special attribute for Trip Report
- There is a predefined list of status values accepted by the mobile CRA app
  so CTMS status should be mapped to predefined mobile CRA status value.
  TODO: finalize mobile CRA predefined status values
- Admin UI should define "Status" attribute under "TripReport" group.

-->
<xsl:element name="can:Attribute">
  <xsl:attribute name="name">Status</xsl:attribute>
  <xsl:element name="can:Value">
    <!--xsl:value-of select="tns:Status" /-->
    <xsl:choose>
      <xsl:when test="tns:Status='Planned'">In Progress</xsl:when>
      <xsl:when test="tns:Status='Revised'">In Progress</xsl:when>
      <xsl:when test="tns:Status='Reviewed'">Submitted</xsl:when>
      <xsl:otherwise>
        <xsl:value-of select="tns:TripReportStatus"/>
      </xsl:otherwise>
    </xsl:choose>
  </xsl:element>
</xsl:element>
<!-- Status -->
<!--xsl:element name="can:Attribute">
  <xsl:attribute name="name">Status</xsl:attribute>
  <xsl:element name="can:Value">
    <xsl:value-of select="tns:Status" />
  </xsl:element>
</xsl:element-->
<!-- Started -->
<xsl:element name="can:Attribute">
  <xsl:attribute name="name">Started</xsl:attribute>
  <xsl:element name="can:Value">
    <xsl:value-of select="tns:Started" />
  </xsl:element>
</xsl:element-->

```

Figure 3–33 shows an example similar to the trip report item and its attribute conversion, where the checklist items can be converted from the CTMS to the canonical form. The example also includes the attributes under the checklist items.

Figure 3–33 Trip Report Item and its Attribute Conversion

```

<!-- Completed date missing -->
<!-- Manager Comments missing -->
<xsl:apply-templates
  select="tns:ListOfClinicalAttendee/tns:ClinicalAttendee" />
<xsl:apply-templates
  select="tns:ListOfClinicalChecklist/tns:ClinicalChecklist" />
<xsl:apply-templates
  select="tns:ListOfClinicalFollowUp/tns:ClinicalFollowUp" />
</xsl:element>
</xsl:template>

<xsl:template match="tns:ClinicalAttendee">
  <xsl:element name="can:Item">
    <xsl:attribute name="type">Attendee</xsl:attribute>
    <xsl:attribute name="id">
      <xsl:value-of select="tns:Id"/>
    </xsl:attribute>
    <!-- ContactId -->
    <xsl:element name="can:Attribute">
      <xsl:attribute name="name">ContactId</xsl:attribute>
      <xsl:element name="can:Value">
        <xsl:value-of select="tns:ContactId" />
      </xsl:element>
    </xsl:element>
    <!-- FirstName -->
    <xsl:element name="can:Attribute">
      <xsl:attribute name="name">FirstName</xsl:attribute>
      <xsl:element name="can:Value">
        <xsl:value-of select="tns:FirstName" />
      </xsl:element>
    </xsl:element>
    <!-- LastName -->
    <xsl:element name="can:Attribute">
      <xsl:attribute name="name">LastName</xsl:attribute>
    </xsl:element>
  </xsl:element>
</xsl:template>

```


Figure 3–34 displays a trip report item and its attribute conversion.

Figure 3–34 Trip Report Item and its Attribute Conversion

```

</xsl:template>
<xsl:template match="... ent"> </xsl:template>
<xsl:template match="tns:ClinicalChecklist">
  <xsl:element name="can:Item">
    <xsl:attribute name="type">Checklist Item</xsl:attribute>
    <xsl:attribute name="id">
      <xsl:value-of select="tns:ActivityUID"/>
    </xsl:attribute>
    <!-- ActivityType -->
    <xsl:element name="can:Attribute">
      <xsl:attribute name="name">ActivityType</xsl:attribute>
      <xsl:element name="can:Value">
        <xsl:value-of select="tns:Type" />
      </xsl:element>
    </xsl:element>
    <!-- Description -->
    <xsl:element name="can:Attribute">
      <xsl:attribute name="name">Description</xsl:attribute>
      <xsl:element name="can:Value">
        <xsl:value-of select="tns:Description" />
      </xsl:element>
    </xsl:element>
    <!-- Status -->
    <xsl:element name="can:Attribute">
      <xsl:attribute name="name">Status</xsl:attribute>
      <xsl:element name="can:Value">
        <xsl:value-of select="tns:Status" />
      </xsl:element>
    </xsl:element>
    <!-- Comment -->
    <xsl:element name="can:Attribute">
  
```

Figure 3–35 displays assigning a picklist to the status attribute in the CRA Configuration Utility.

Figure 3–35 Assigning a Picklist to an Attribute

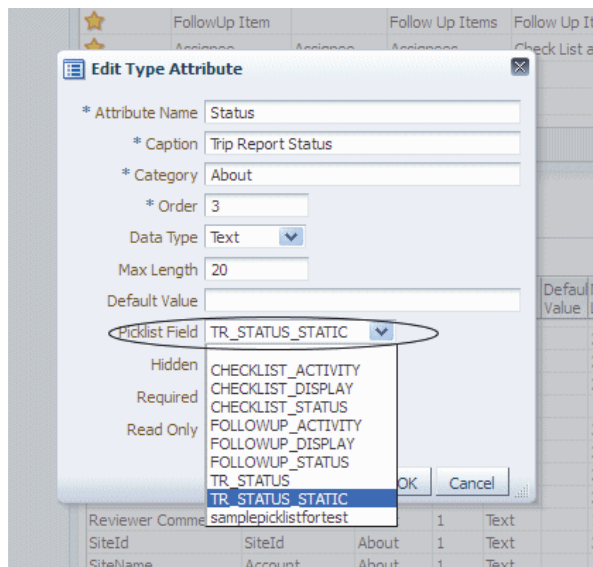


Figure 3–36 displays the Trip Reports About Section screen in the Ipad.

Figure 3-36 The Trip Reports About Section

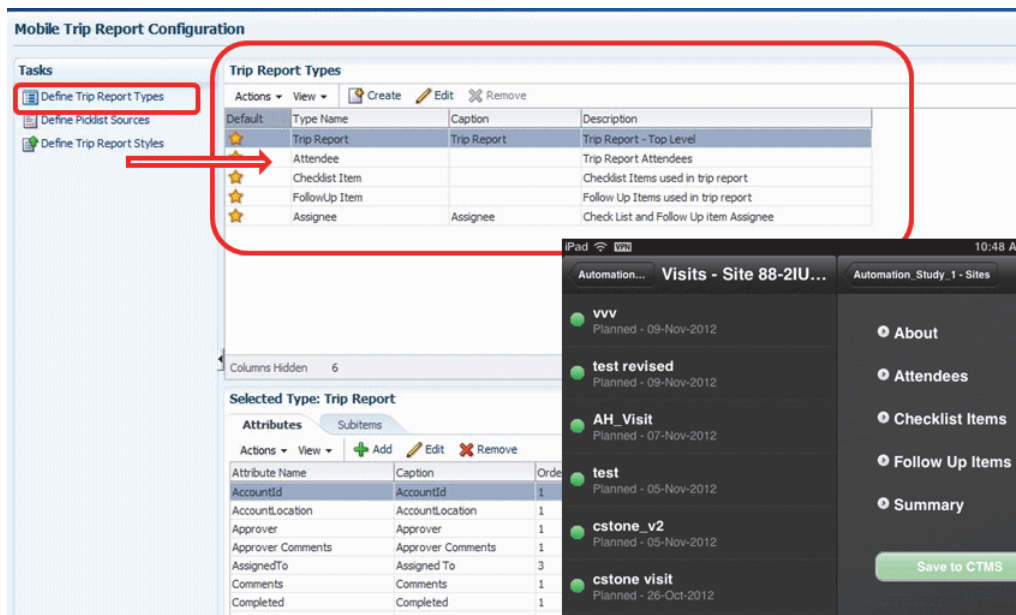
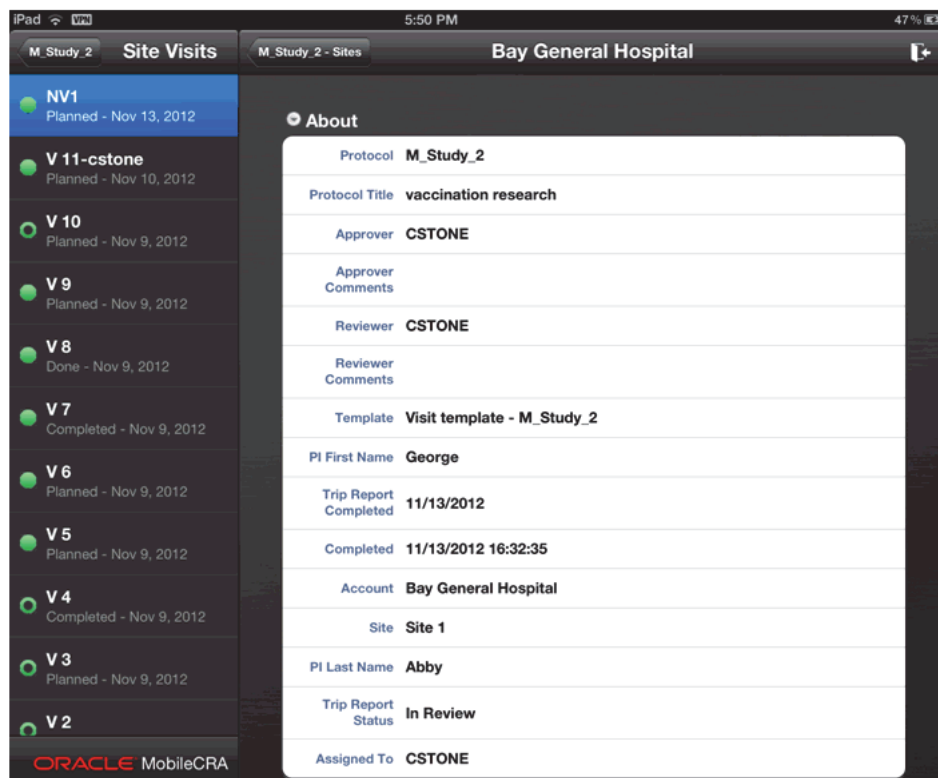


Figure 3-37 shows a Trip Report on the iPad.

Figure 3-37 Trip Report on the iPad



Integrations and Configurations

Mobile CRA lets you register, define, and manage key performance indicators (KPIs) either from OCDA or from other external sources. You can use the site-at-a-glance (SaaG) feature of Mobile CRA to view analytical data and metrics even if you do not use OCDA.

This chapter contains the following topics:

- [Section 4.1, "Registering the Client"](#)
- [Section 4.2, "Registering Sources"](#)
- [Section 4.3, "Adaptive Site-at-a-Glance"](#)
- [Section 4.4, "Alerts Registration"](#)

4.1 Registering the Client

You must provision the client in the Adaptive SaaG through WebLogic Server configuration. Use the *Client Name* and your credentials to receive the *Client ID* and *Client Key*.

You must procure (offline activity) and submit the Client ID and the Client Key through the Mobile CRA Configuration Utility application.

Figure 4–1 The Client Registration Screen

The screenshot displays the Oracle MobileCRA Administration web interface. At the top, the text "ORACLE MobileCRA Administration" is visible. Below this, there is a navigation menu on the left under the heading "Configurations". The menu items are: "Client Registration", "Source Registration", "Site At A Glance (Non OCDA)", and "Alerts Registration". The main content area is titled "Register Client" and contains two input fields: "Client Id" and "Client Key". Below these fields is a "Register" button.

Note: The Client ID and Client Key are sent to the Mobile CRA Configuration Utility user through offline communication such as an e-mail.

4.2 Registering Sources

You must register the various external sources (such as labs, imagery services, and so on) within the system before they can start sending information.

The Configuration Utility has the following enhancements for registering KPIs:

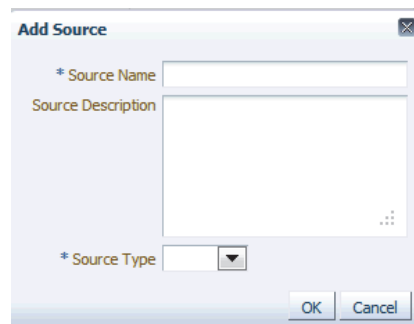
The **Source Registration** on the Configurations page. Send the *Source Name* and *Source Type* to the SaaG server. The returned information, **Source ID** and **Source Key**, is displayed.

4.2.1 Adding a Source

To add a source, perform the following:

1. Click **Add**. The **Add Source** window is displayed.
2. From the Source Type drop-down list, select **KPI** for a source that sends KPIs. Select **ALERT** for a source that sends alerts.
3. Enter the details and click **OK**.

Figure 4–2 Adding a Source



4.3 Adaptive Site-at-a-Glance

Mobile CRA's SaaG is a key feature as it assists CRAs in monitoring sites.

Earlier, Mobile CRA pulled in data only from the OCDA system. To let you use non-OCDA systems with this feature, Mobile CRA is re-designed to make SaaG an open feature by exposing APIs using which any system can push in KPI information, once registered into the system. This feature is now called the Adaptive SaaG.

The Mobile CRA Configuration Utility Web application now includes multiple enhancements for setting up KPIs from external systems.

4.3.1 Registering Key Performance Indicators

After the sources for KPIs are defined, you must define and manage the KPIs to be displayed on the mobile application.

Clicking **Site-at-a-glance** opens up the **Register KPIs** table on the right side of the page.

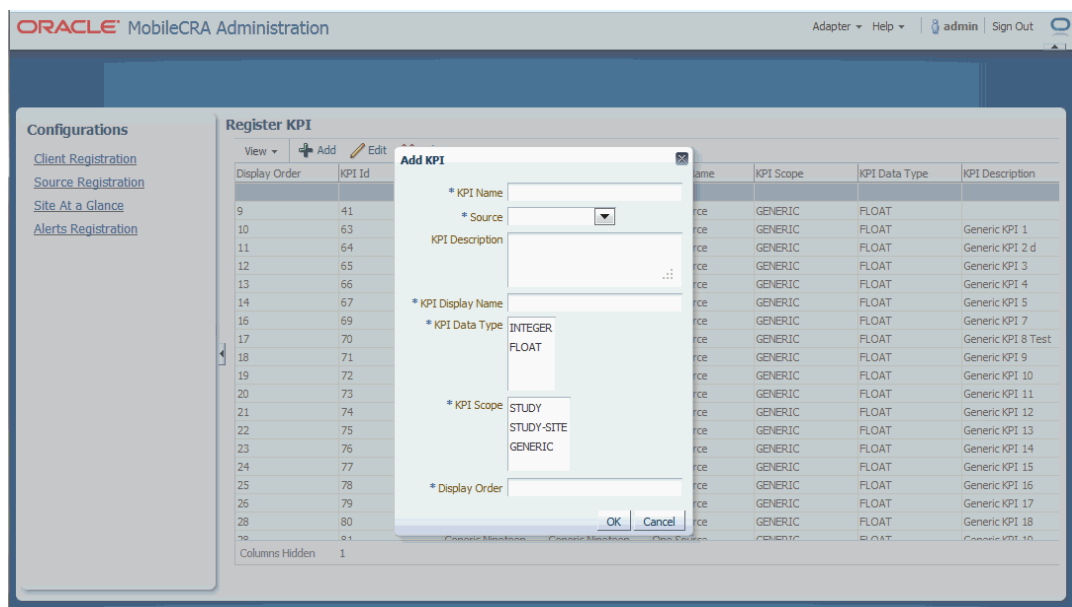
The system assigns the display order for the KPIs. However, you can add, edit, or delete a KPI as needed. There is no restriction on the number of KPIs that you can register.

4.3.1.1 Adding a KPI

To add a KPI, perform the following steps:

1. Click **Add**. The **Add KPI** window is displayed.
2. Enter the details and click **OK**.

Figure 4–3 Adding a KPI

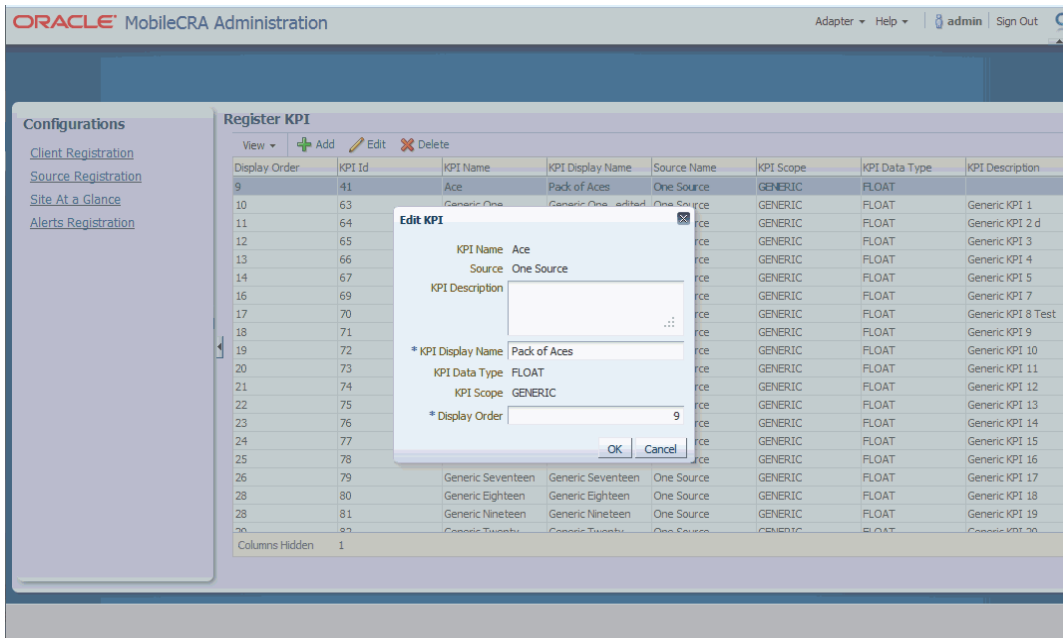


4.3.1.2 Editing a KPI

To edit a KPI, perform the following steps:

1. Click **Edit**. The **Edit KPI** window is displayed.
2. Edit the required details and click **OK**.

Figure 4–4 Editing a KPI

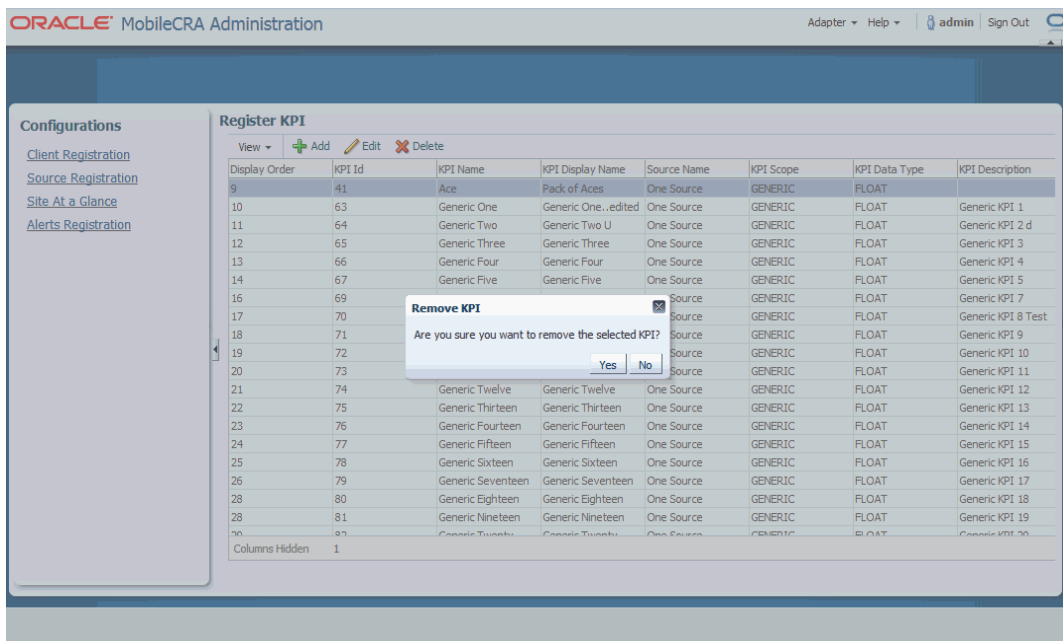


4.3.1.3 Deleting a KPI

To delete a KPI, perform the following steps:

1. Click **Delete**. The **Remove KPI** confirmation message is displayed.
2. Click **Yes**.

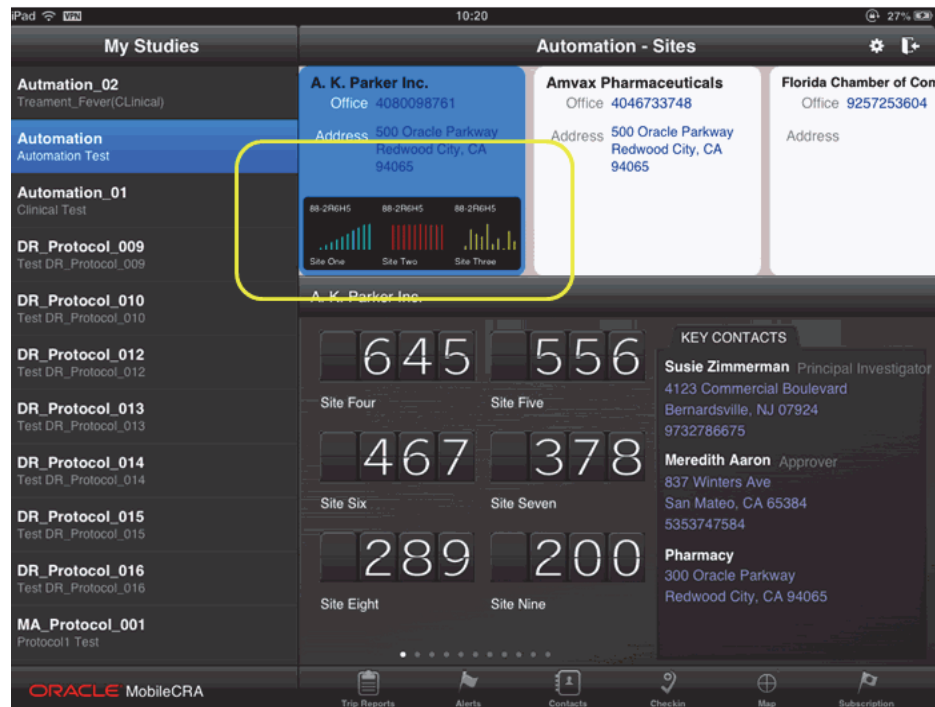
Figure 4–5 Deleting a KPI



4.3.2 Trending Graphs and KPIs Displayed

Any number of KPIs can be registered and defined here. The first three KPIs are used for the trending graphs in the mobile application. You can define the order in which these KPIs are displayed here. The order can be changed and the mobile application reflects the change accordingly, including the KPIs for the trending graphs.

Figure 4–6 The Trending Graphs



You can choose the number of KPIs you want to view on a page: 6, 9, or 12.

Figure 4-7 The 6 KPI Display



Figure 4-8 illustrates selecting the 9 KPI display setting.

Figure 4-8 Selecting the 9 KPI Display Setting

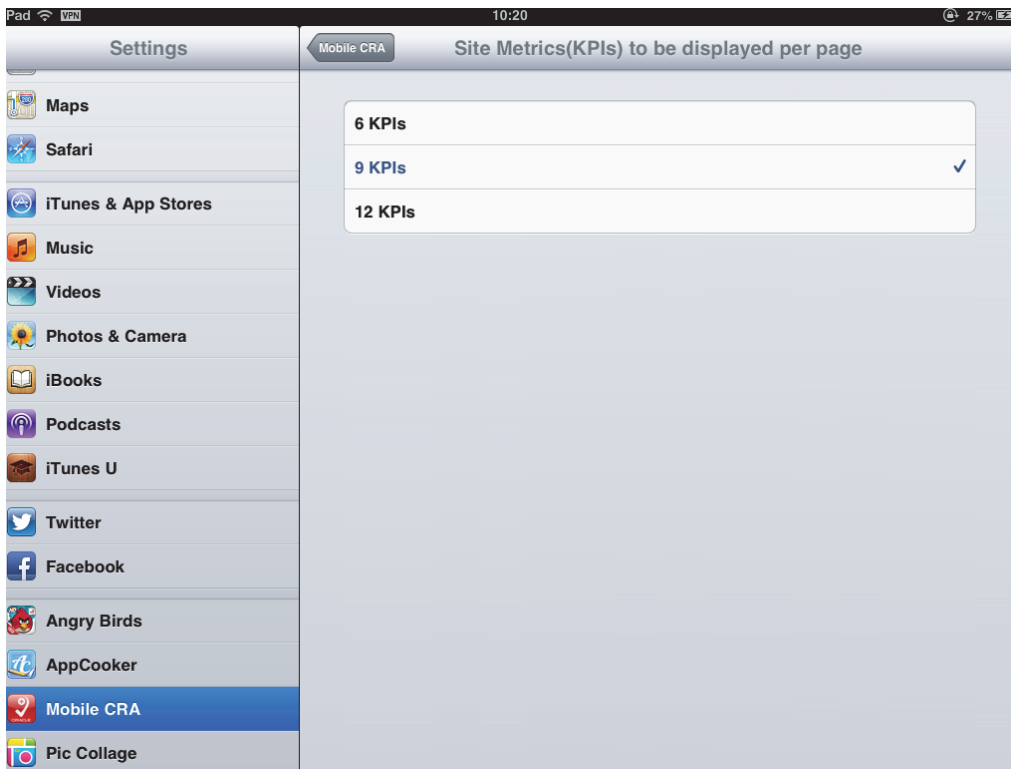


Figure 4–9 illustrates the 9 KPI display.

Figure 4–9 The 9 KPI Display

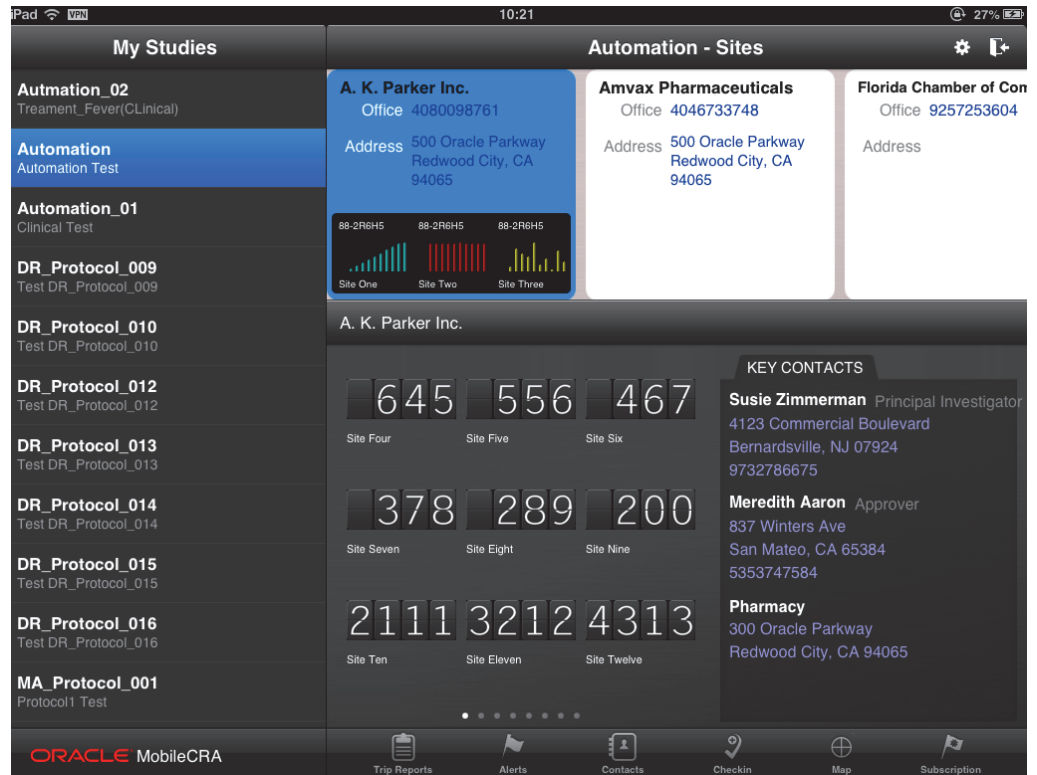


Figure 4–10 illustrates selecting the 12 KPI display setting.

Figure 4–10 Selecting the 12 KPI Display Setting

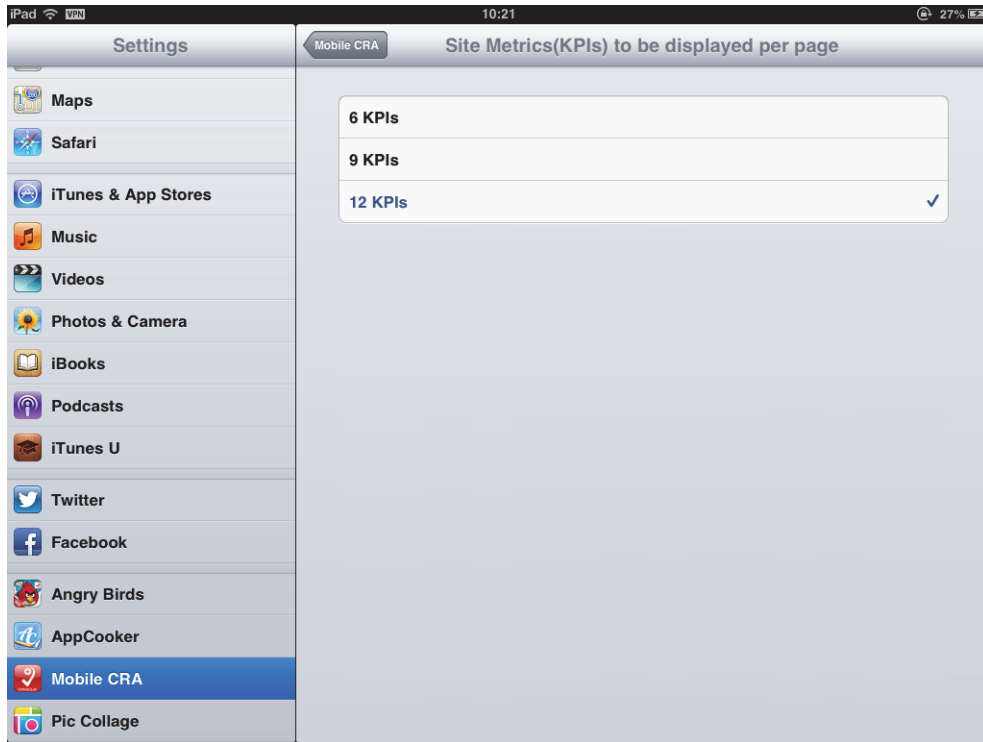
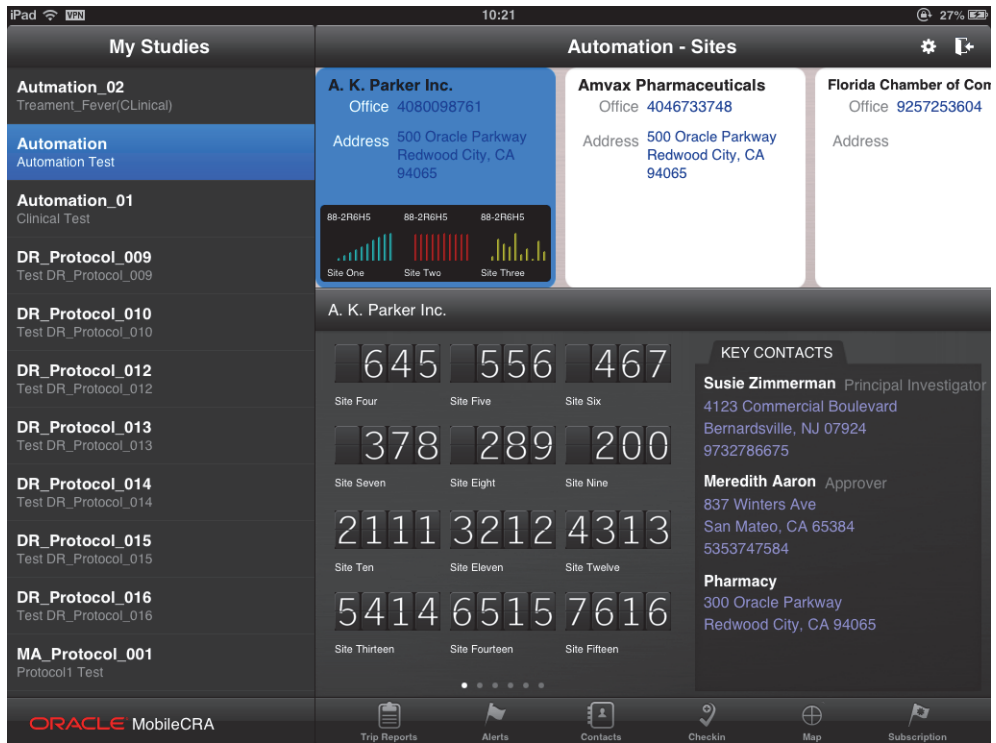


Figure 4–11 illustrates the 12 KPI Display

Figure 4–11 The 12 KPI Display



4.3.3 Changing the Display Order

You can change the order of the KPIs displayed. Perform the following steps:

1. Select the KPI whose display order you want to change. Click **Edit**.
2. Enter the new display order number in **Display Order**. Click **OK**.

Figure 4–12 Existing Order in the Configuration Utility

Display Order	KPI Id	KPI Name	KPI Display Name	Source Name	KPI Scope	KPI Data Type	KPI Description
51	104	Site Two	Site Two	One Source	STUDY-SITE	FLOAT	Site KPI 2
52	105	Site Three	Site Three	One Source	STUDY-SITE	FLOAT	Site KPI 3
53	42	King	Pack of Kings	One Source	STUDY-SITE	FLOAT	Site KPI 4
53	106	Site Four	Site Four	One Source	STUDY-SITE	FLOAT	Site KPI 4
54	107	Site Five	Site Five	One Source	STUDY-SITE	FLOAT	Site KPI 5
55	108	Site Six	Site Six	One Source	STUDY-SITE	FLOAT	Site KPI 6
56	109	Site Seven	Site Seven	One Source	STUDY-SITE	FLOAT	Site KPI 7
57	110	Site Eight	Site Eight	One Source	STUDY-SITE	FLOAT	Site KPI 8
58	111	Site Nine	Site Nine	One Source	STUDY-SITE	FLOAT	Site KPI 9
59	112	Site Ten	Site Ten	One Source	STUDY-SITE	FLOAT	Site KPI 10
60	113	Site Eleven	Site Eleven	One Source	STUDY-SITE	FLOAT	Site KPI 11
61	114	Site Twelve	Site Twelve	One Source	STUDY-SITE	FLOAT	Site KPI 12
62	115	Site Thirteen	Site Thirteen	One Source	STUDY-SITE	FLOAT	Site KPI 13
63	116	Site Fourteen	Site Fourteen	One Source	STUDY-SITE	FLOAT	Site KPI 14
64	117	Site Fifteen	Site Fifteen	One Source	STUDY-SITE	FLOAT	Site KPI 15
65	118	Site Sixteen	Site Sixteen	One Source	STUDY-SITE	FLOAT	Site KPI 16
66	119	Site Seventeen	Site Seventeen	One Source	STUDY-SITE	FLOAT	Site KPI 17
67	120	Site Eighteen	Site Eighteen	One Source	STUDY-SITE	FLOAT	Site KPI 18
68	121	Site Nineteen	Site Nineteen	One Source	STUDY-SITE	FLOAT	Site KPI 19
69	122	Site Twenty	Site Twenty	One Source	STUDY-SITE	FLOAT	Site KPI 20
70	123	Site Twentyone	Site Twentyone	One Source	STUDY-SITE	FLOAT	Site KPI 21
70	232	Test@test	test.123	One Source	STUDY-SITE	FLOAT	

Figure 4–13 displays the corresponding display on the iPad.

Figure 4–13 Corresponding Display in the iPad.

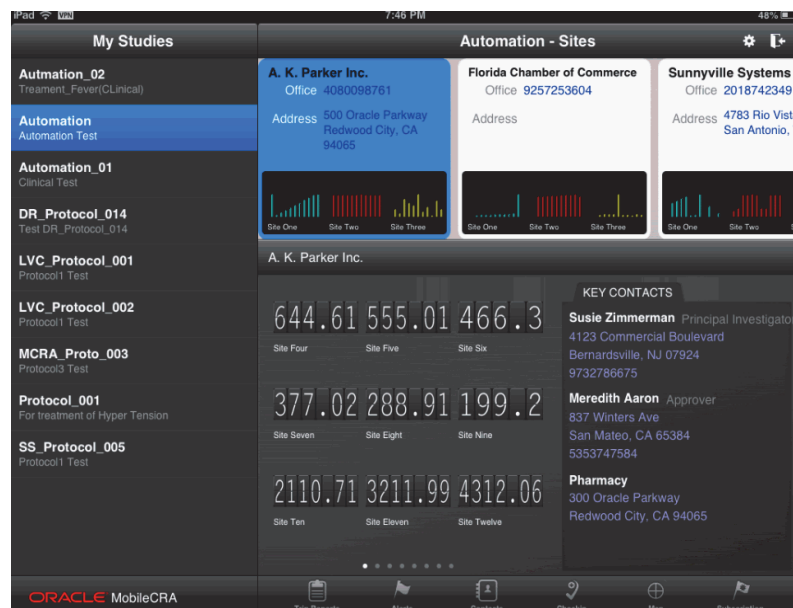


Figure 4–14 displays the changed order in the Configuration Utility.

Figure 4–14 Changed Display Order in the Configuration Utility

ORACLE MobileCRA Administration

Configurations

- Client Registration
- Source Registration
- Site At A Glance (Non-OCDA)
- Alerts Registration

Register KPIS

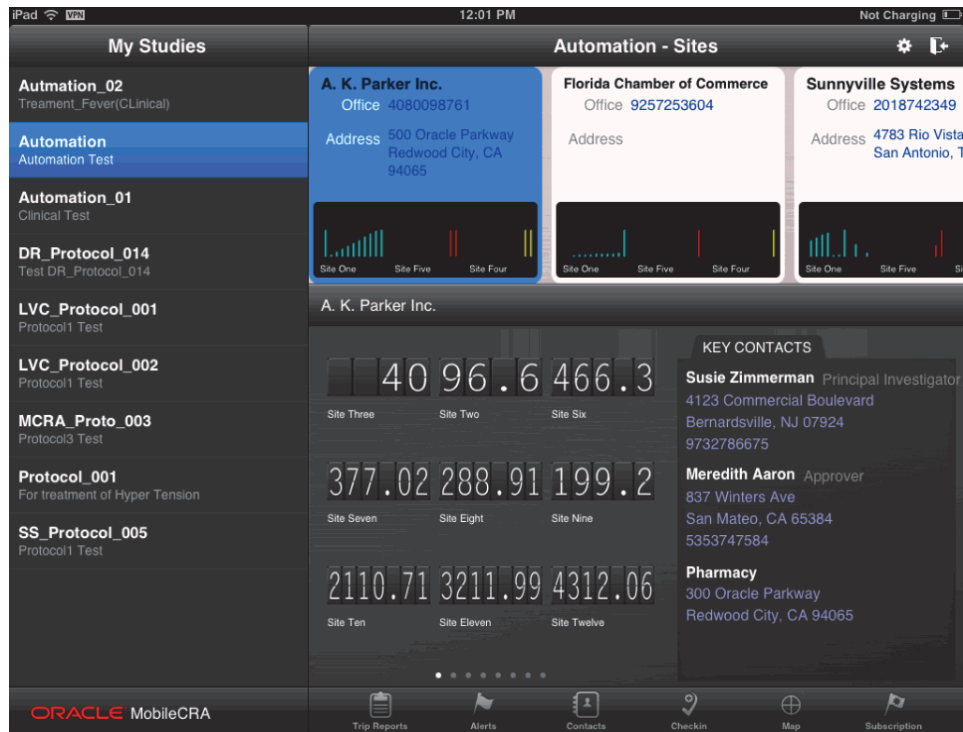
View Add Edit Delete

Display Order	KPI Id	KPI Name	KPI Display Name	Source Name	KPI Scope	KPI Data Type	KPI Description
37	90	Study Eight	Study Eight	One Source	STUDY	FLOAT	Study KPI 8
38	91	Study Nine	Study Nine	One Source	STUDY	FLOAT	Study KPI 9
39	92	Study Ten	Study Ten	One Source	STUDY	FLOAT	Study KPI 10
40	93	Study Eleven	Study Eleven	One Source	STUDY	FLOAT	Study KPI 11
41	94	Study Twelve	Study Twelve	One Source	STUDY	FLOAT	Study KPI 12
42	95	Study Thirteen	Study Thirteen	One Source	STUDY	FLOAT	Study KPI 13
43	96	Study Fourteen	Study Fourteen	One Source	STUDY	FLOAT	Study KPI 14
44	97	Study Fifteen	Study Fifteen	One Source	STUDY	FLOAT	Study KPI 15
45	98	Study Sixteen	Study Sixteen	One Source	STUDY	FLOAT	Study KPI 16
46	99	Study Seventeen	Study Seventeen	One Source	STUDY	FLOAT	Study KPI 17
47	100	Study Eighteen	Study Eighteen	One Source	STUDY	FLOAT	Study KPI 18
48	101	Study Nineteen	Study Nineteen	One Source	STUDY	FLOAT	Study KPI 19
49	102	Study Twenty	Study Twenty	One Source	STUDY	FLOAT	Study KPI 20
50	103	Site One	Site One	One Source	STUDY-SITE	FLOAT	Site KPI 1
51	104	Site Two	Site Two	One Source	STUDY-SITE	FLOAT	Site KPI 2
52	105	Site Three	Site Three	One Source	STUDY-SITE	FLOAT	Site KPI 3
53	106	Site Four	Site Four	One Source	STUDY-SITE	FLOAT	Site KPI 4
54	107	Site Five	Site Five	One Source	STUDY-SITE	FLOAT	Site KPI 5
55	108	Site Six	Site Six	One Source	STUDY-SITE	FLOAT	Site KPI 6
56	109	Site Seven	Site Seven	One Source	STUDY-SITE	FLOAT	Site KPI 7
57	110	Site Eight	Site Eight	One Source	STUDY-SITE	FLOAT	Site KPI 8
58	111	Site Nine	Site Nine	One Source	STUDY-SITE	FLOAT	Site KPI 9

Columns Hidden 1

Figure 4–15 displays the changed display in the iPad.

Figure 4–15 Corresponding Changed Display Order in the iPad



4.3.4 Pushing KPI Information to Mobile CRA

External sources (such as labs, drug companies, and imagery services) must use the Source ID and Source Key to push information such as KPI ID, KPI Name, Study Site ID or Study ID or General, and KPI Value.

The external source can send information in bulk or for a KPI at a time. In case of errors, appropriate error messages are sent back to the external source.

4.4 Alerts Registration

An alert is a notification by which CRAs are notified about the various aspects of the studies that they are involved in. These alerts may be about a site's performance, number of patients being enrolled in sites, visit dates, and so on.

Mobile CRA lets the users from non-OCDA sources create subscriptions for such notifications here. CRAs who have subscribed to such alerts receive these as and when the thresholds (set against that particular Alert) are met.

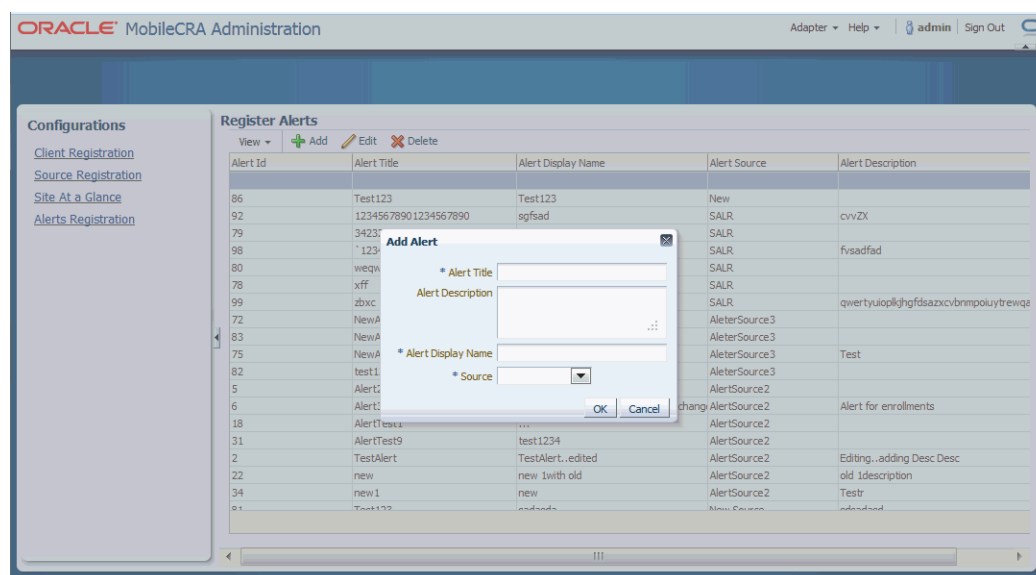
4.4.1 Adding an Alert

To add an alert, perform the following steps:

1. Click **Add**. The **Add Alert** window is displayed.
2. Enter the details and click **OK**.

Note: Only those sources registered as alerts (as type) are displayed.

Figure 4–16 Adding an Alert



4.4.2 Editing an Alert

To edit an Alert, perform the following steps:

1. Click **Edit**. The **Edit Alert** window is displayed.
2. Edit the required details and click **OK**.

