Oracle Health Sciences Mobile Clinical Research Associate Server

Administrator's Guide

Release 1.3

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

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Preface

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

This preface contains the following topics:

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

Audience

This guide is intended for the following job classifications:

Mobile CRA Admin UI 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 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.
- 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)
- Oracle® Fusion Middleware Security Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)
- Oracle® Fusion Middleware Developer's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)
- Oracle® Fusion Middleware Integrator's Guide for Oracle Business Intelligence Enterprise Edition 11g Release 1 (11.1.1.7.0)

Siebel Clinical Documentation

The Siebel Clinical documentation set includes:

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

Conventions

The following text conventions are used in this document:

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

Introduction

This chapter contains the following sections:

- Overview on page 1
- Logging In on page 1

1.1 Overview

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

The Mobile CRA Server Administration User Interface (Admin UI) is a Web based application that lets you manage the configuration of these integration adapters. The Admin UI supports the following integration adapters:

- CDA Alert Notifications, and
- CTMS Mobile Trip Reports.

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

1.2 Logging In

Figure 1-1 displays the Admin UI Login screen.

Figure 1–1 The Admin UI Login Screen

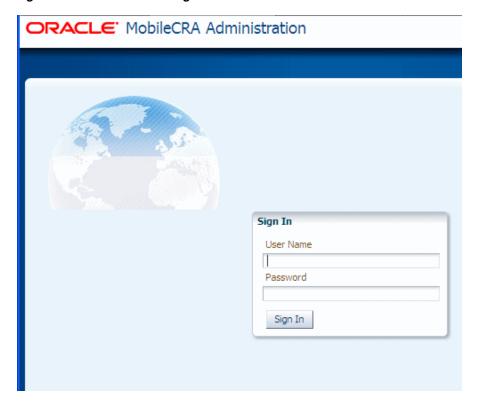
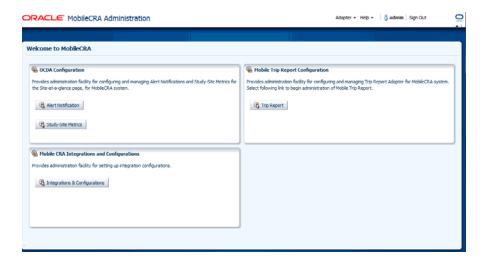


Figure 1-2 displays the new Admin UI Home screen.

Figure 1-2 The Admin UI Home Screen



Alert Notification and Study-Site Metrics

This chapter contains the following sections:

- Alerts on page 1
- Managing Alerts in OBIEE on page 3
- Mobile Alert Notification Configuration on page 8
- Parameter List on page 13
- Study-Site Metrics on page 14

2.1 Alerts

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 create subscriptions for such notifications. Mobile CRA 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:

- Standard or System Alerts
- **User Defined Alerts**

2.1.1.1 Standard or System Alerts

Mobile CRA has 13 out-of-the-box Alerts. If need be, you can customize these Alerts using OBIEE. Following is the list of all 13 Alerts.

2.1.1.1.1 Out-of-the-Box Alerts

Following are the Standard Alerts:

- Count of Enrolled Patient is a Multiple of Five, No Reset—whenever 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 the parameters associated with this Alert.
- Number of Study Sites GT than Threshold, Manual—when the number 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 2-1 Alert Management Activities

Application Where Activity is performed	Activity
Oracle Business Intelligence Enterprise Edition (OBIEE)	Create, modify, or delete an Alert.
Mobile CRA Server Admin UI	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 OBIEE

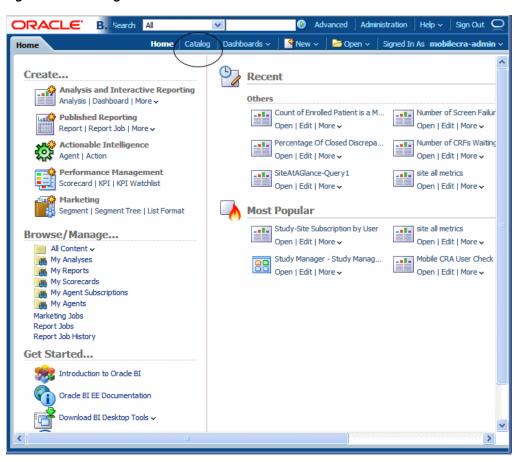
You can perform the following in OBIEE for Alerts:

2.2.1 Customizing a Standard Alert

To customize a standard Alert:

- Sign in to Oracle BI Enterprise Edition.
- In the global header, click **Catalog** to display the Catalog page. Figure 2-1 displays the **Catalog** link.

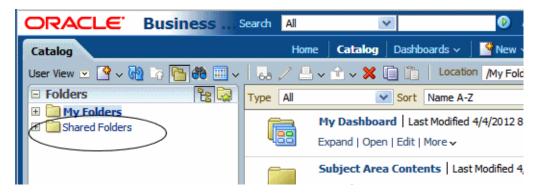
Figure 2-1 Catalog Link



3. Click Shared Folders.

Figure 2-2 displays the **Shared Folders** folder.

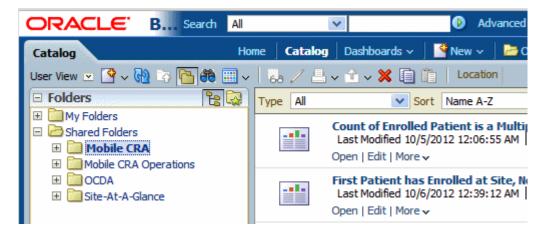
Figure 2-2 Shared Folders



Click the **Mobile CRA** Folder.

Figure 2-3 displays the **Mobile CRA** folder.

Figure 2-3 Mobile CRA Folder



- You see all the standard Alerts in the right-hand pane. Navigate to an Alert you want to edit and click the Edit link. The Alert is displayed in the Analysis Editor.
- Navigate to the **Criteria** tab.

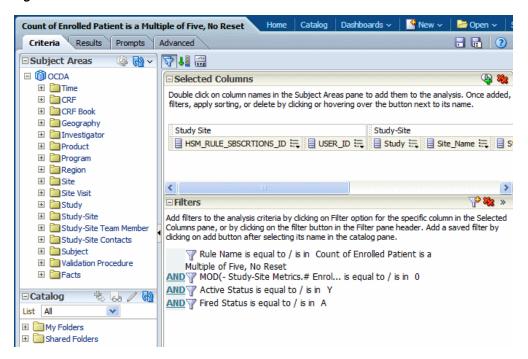
On the left hand side Subject Area pane displays **OCDA** subject area and its hierarchical columns.

On the right hand side upper section 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 Filters pane shows filters to create or edit filters for the Alert.

Figure 2-4 displays the Criteria tab.

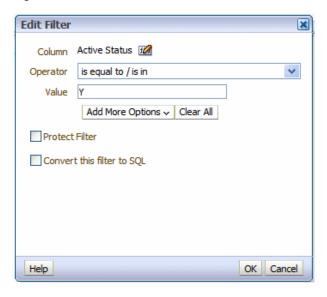
Figure 2-4 Criteria Tab



- Drag and Drop columns from the left hand side Subject Area pane to the **Selected Columns** pane to set modify the Alert.
- Edit filters of the Alert by clicking the Filter option for the specific column or by clicking the filter button in the Filter pane header.

Figure 2-5 displays the **Edit Filter**.

Figure 2-5 Edit Filter



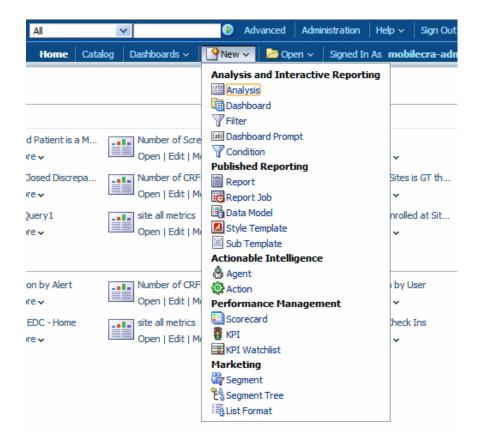
Click **OK** to save the filter.

2.2.2 Creating a New Alert:

Creating a new Alert:

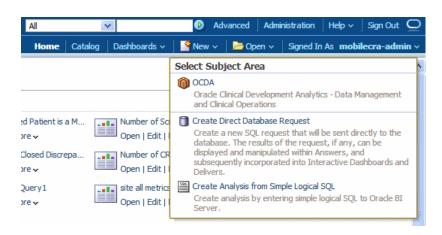
- Sign in to Oracle BI Enterprise Edition.
- In the global header, click New, then Analysis. Figure 2-6 displays the **New** tab.

Figure 2-6 The New Tab



Click **OCDA** in Select Subject Area menu. Figure 2-7 displays the **Select Subject Area** menu.

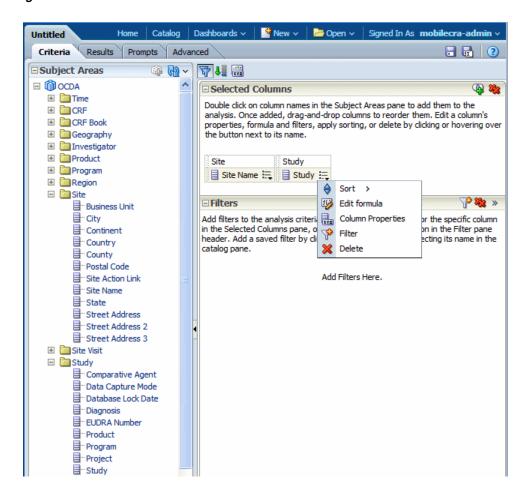
Figure 2-7 Subject Area



- Navigate to the **Criteria** tab.
- Drag and drop columns from the left hand side Subject Area pane to the **Selected Columns** pane to specify criteria for the Alert.
- Add filters to the Alert by clicking the **Filter** option for the specific column or by clicking on the filter button in the Filter pane header.

Figure 2-8 displays the **Filter** option for a column.

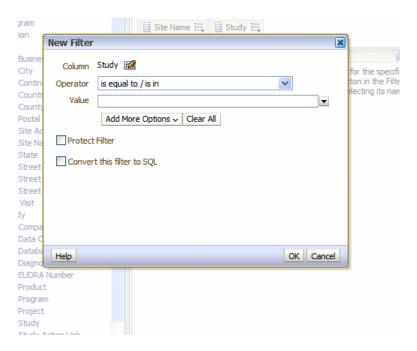
Figure 2-8 Filter for a Column



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

Figure 2-9 displays the **New Filter** dialog box.

Figure 2-9 New Filter Condition



- Click **OK** to save the filter.
- To see the results, if any, click the Results tab.
- 10. In the Analysis editor, click the Save Analysis toolbar button 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 in which 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 Admin UI server lets a System Administrator maintain two key areas of the Mobile CRA system:

- Rule Management in Admin UI on page 9
- Parameter List on page 13

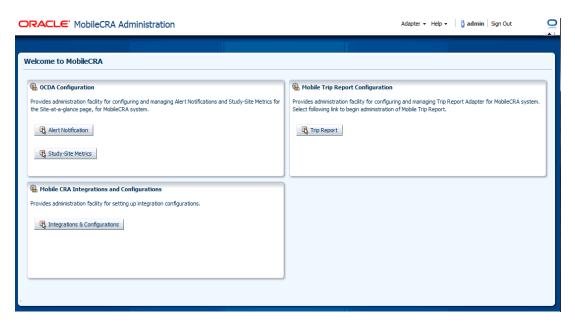
2.3 Mobile Alert Notification Configuration

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 displays the Mobile Alert Notification Configuration screen.

Figure 2–10 Alert Notification



This section contains the following topics:

Rule Management in Admin UI on page 9

2.3.1 Rule Management in Admin Ul

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:

- Rule Management Interface on page 9
- Rule Management Operations on page 11

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 tool bar icons are for specific Create, Edit, and Remove operations.

Figure 2-11 displays the user interface design for the Rule Management screen.

Mobile Alert Notification Configuration List of Rules ✓ Rule Details Rule ID Rule Name Scope Rule Category
22 Number of Study Si Study System Alerts Rule Name Number of Study Sites GT than Threshold, Manual 21 Number of Active S Study System Alerts
 23
 Number of Sites is (Study
 System Alerts
 Type

 20
 Study-Site with one Study
 System Alerts
 Description
 Type OBIEE 20 Study-Site with one Study System Alerts
741 Number of screen (Study-Site User Defined Alerts
743 Testing New Rule 12 Study-Site User Defined Alerts
921 Count of Enrolled P Study-Site User Defined Alerts
303 New Alert Study-Site User Defined Alerts
Scope Study

Study-Site Study-Site User Defined Alerts
Scope Study

Study-Site Study-Site Study-Site User Defined Alerts
Scope Study

Study-Site Study-Site Study-Site User Defined Alerts
Scope Study

Study-Site 503 New Alert Study-Site System Alerts
Count of Enrolled Study-Site System Alerts
Number of Enrolled Study-Site System Alerts
System Alerts Full Text The number of sites is greater than \$THRESH_NUM1\$ Notification
Status Active
Created By SCRIPT
Create Date 9/12/2020 Notification Short Text Number of Study Sites GT than Threshold Notification **Rule Parameters** Create // Edit X Remove Rule Param ID Rule ID TypOrd Par ^ Default Value 22 NUM1 STI

Figure 2-11 Rule Management Screen

Following fields of rules are displayed in Rule Details pane:

Table 2-2 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.	
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 for the current release are: STUDY_ID when the scope is for a Study, and 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 has created the Alert.	

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

Field Name	Field Description
Create Date	The Alert creation date.
Last Updated	The date on which the Alert was last modified, updated, edited, and saved.

Following fields of Rule Parameters are displayed in Rule parameters pane:

Table 2-3 Rule Parameter Fields

Field Name	Field Description
Rule ID	Reference to primary key of HSM_RuleS table.
TypOrd	This column is created for the purpose of de-normalized threshold table (HSM_OBI_THRESHS). It defines the position (i.e. column) in HSM_OBI_THRESHS table and represents the data type and the position of the parameter. The valid values for String columns are STR1, STR2,STR3, STR4, STR5, for Date columns DT1, DT2, DT3, DT4, DT5, and for Numeric columns NUM1,NUM2, NUM3, NUM4, 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 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:

- Creating a Rule on page 11
- Editing a Rule on page 12
- Removing a Rule on page 12
- Rule Statuses on page 12

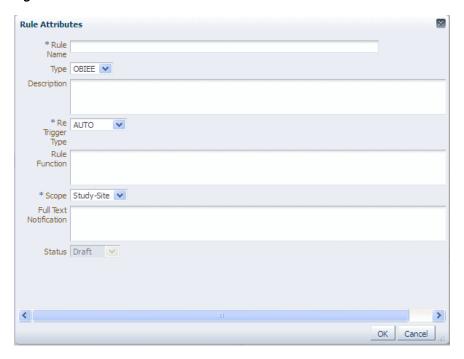
2.3.1.2.1 Creating a Rule To create a new Rule and its thresholds, perform the following:

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 Rules Attributes screen.

Figure 2-12 displays 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.

You can edit subscription threshold values.

To edit a Rule and its thresholds, perform the following:

- Click a rule in List of Rules pane.
- Click **Edit Rule** in Rule Details pane.
- Modify requisite fields in Rules Attributes screen.
- Click **OK** to save the rule.
- 2.3.1.2.3 Removing a Rule You can only remove user-defined rules. You can remove 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:

- Click a rule in List of Rules pane.
- Click **Remove Rule** in Rule Details pane.
- Click **Yes** in Remove Rule dialog.

2.3.1.2.4 Rule Statuses

A Rule can have three statuses: DRAFT, ACTIVE, and INACTIVE.

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

Table 2–4 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 Rule definitions. The interface lets you create and remove existing parameter definitions.

Figure 2-13 displays the **Parameter List** screen.

Parameter List UpperCase Data Type Parameter Name Data Format Data Size Flag CacheParam N 🔻 • Enrollment Count Enrollment Count Field

Verification Form Count Verfication Form Count Field Closed Discrepancies Cou Closed Discrepancies Count Field Open Query Count Field New param New parameter Created Test Testing Param 5 Test EntityParam Refresh TestCache New Parameter Added Testing new parameter addition New Parameter Added 2 New Parameter Added 3 Test New r Testing New Param Testing Param latest new adding param test1234 New Parameter Added 5 TestingParams Test Testingparams ParamDeleteCheck Param delete check Ν NUM Testing Check123 Ν OK Cancel

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**, it presents you with a confirmation dialog box 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 3 of which are used for the trending graphs. You can also change the display order of these KPIs.

Figure 2-14 displays the Study-Site Metrics screen.

Figure 2-14 The Study-Site Metrics Screen



2.5.1 Changing the Display Order

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

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

Figure 2-15 displays the existing KPI order in the Admin UI.

Figure 2–15 Existing KPI Order

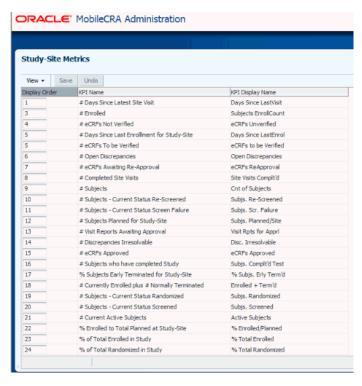


Figure 2-16 displays the corresponding display on the Ipad.



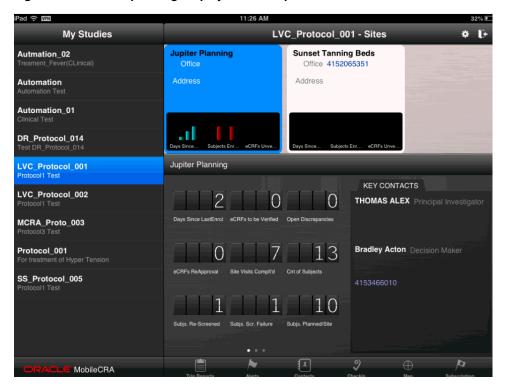


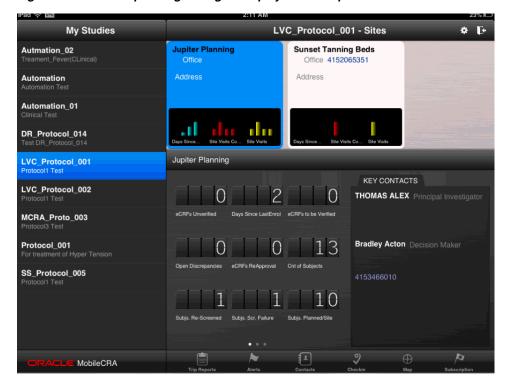
Figure 2-17 displays the changed order in the Admin UI.

Figure 2-17 Changed Display Order



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

Figure 2-18 Corresponding Changed Display Order in Ipad



Trip Reports

This chapter contains the following sections:

- Configuring a Trip Report on page 2
- Defining Trip Report Types on page 2
- Defining Attributes on page 8
- Using EXtensible Stylesheet Language Transformations to create a Trip Report on page 17
- Defining the Category Order on page 14
- Sample Trip Report in the CTMS: on page 18

The Trip Report you see on mobile devices such as the i-Phone or i-Pad 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 (this is rare).

You must transform the CTMS Trip Report to the Canonical Trip Report yourself— by extending the default transformation which transforms the Out-of-the-Box CTMS Trip Report to the Canonical Trip Report. You can make this transformation through 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 customer 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 the CTMS.

- Transform the CTMS Trip Report to Canonical Trip Report using XSLT.
- 4. Define the display characteristics for those transformed attributes in the Admin UI. The Admin UI is where the user defines the attributes, the item types and their relationship along with the display characteristics. The items, attributes and relationship should 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:

- Defining Trip Report Types on page 2
- Defining Attributes on page 8
- Defining Subitems on page 13
- Using EXtensible Stylesheet Language Transformations to create a Trip Report on page 17
- Sample Trip Report in the CTMS: on page 18

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.

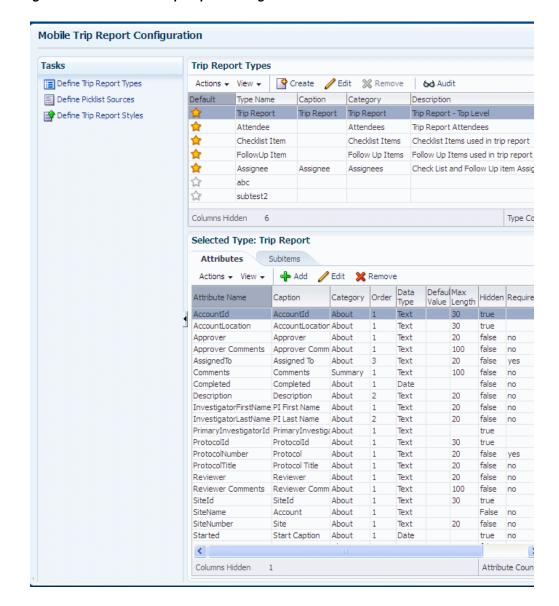


Figure 3-1 The Mobile Trip Report Configuration Screen

When you select a task from the left pane, the right pane displays the screens related to that particular task. The tool bar 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 Standard Trip Report types.

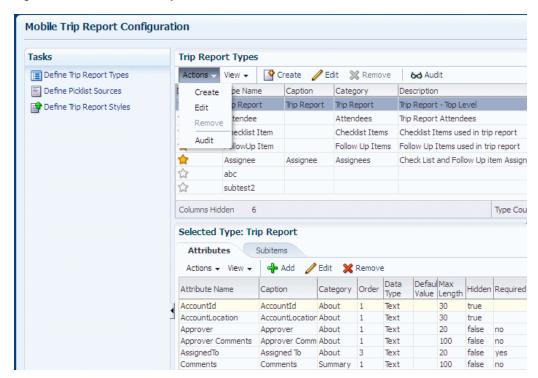
This section contains the following sub sections:

- The Action Drop-down List on page 4
- The View Drop-down List on page 4
- Creating a Trip Report Type on page 5
- Editing a Trip Report on page 7
- Audit Details on page 7
- Defining Picklist Sources on page 11

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 four options: Create, Edit, Remove, and Audit.

3.1.1.2 The View Drop-down List

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

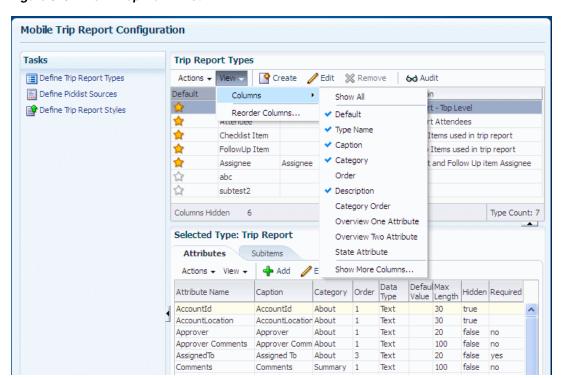


Figure 3–3 View Drop-Down List

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:

- 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.
- 2. 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.

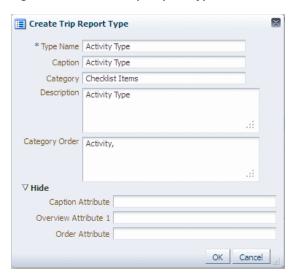
3.1.1.3 Creating a Trip Report Type

To create a trip report type:

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

Figure 3-4 displays the **Create Trip Report Type** screen.

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 Create Trip Report Type screen. Table 3-1 describes the Create Trip Report Type field descriptions.

Table 3-1 Field Descriptions

Serial Number	Field Name	Field Description
1	Type Name	This is a free text alphanumeric field to provide a name for the Trip Report Type.
2	Caption	This is a free text field to key in the name for an attribute within a section.
3	Category	This is a free text field to key in the heading title.
4	Order	Enter a number between 1 to 5.
5	Description	This is a free text field to add comments/details/description around the trip REPORT type.
6	Category Order	This is a free text field to 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	This 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	This is a free text field to define the option that would come up for a particular attribute. Users shall be able to pick a value from a list of options.
9	Overview Attribute 2	This 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	This defines the sequence ordering for the Trip Report Type

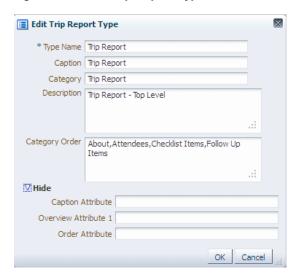
Click **OK** to create a Trip Report Type.

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 displays the **Edit Trip Report Type** screen.

Figure 3-5 Edit Trip Report Type Screen



- 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.
- 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 displays the **Audit Details** screen.

Figure 3-6 Audit Details Screen

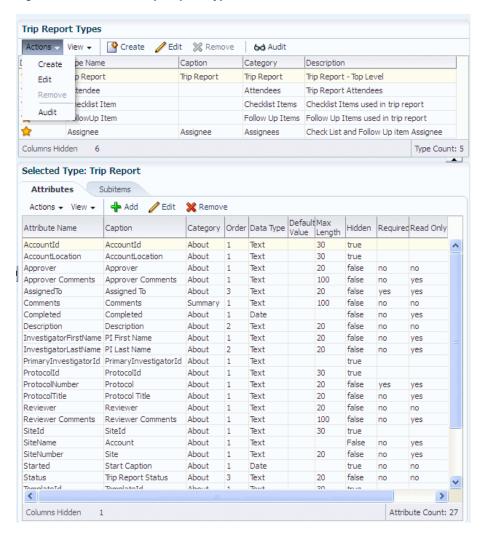


3.1.2 Defining Attributes

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 displays the Selected Type Trip Report screen.

Figure 3-7 Selected Trip Report Type Screen



The screen has two tabs: Attributes and Subitems. The Attributes tab is the displayed by default.

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

The Action Drop-down List

When you click **Action**, it lets you view the three 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.
- Select Columns. 2.
- 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 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 represents the **Add Type Attributes** screen:

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	Field Descriptions
1	Attribute Name	This is a free text field to key in the name of the attribute.
2	Caption	This is a free text field to key in the caption for the attribute.
3	Category	This is a free text field to specify the sub-section under which the particular attribute shall be displayed.
4	Order	This is a free text field to key in the number that is used by the system to order the attribute.
5	Data Type	This is a LOV field with the following options: Text, Number, Date, Boolean.
6	Max Length	This is a free text field to key in the number that is used by the system to determine the maximum length of the text input on the mobile application.
7	Default Value	This is a free text field to key in any default value that needs to be displayed.
8	Picklist Field	This is a LOV field to select the source of values, in case the attribute is a Picklist.
9	Hidden	This is a LOV field to specify if the attribute has to be hidden or displayed. Values are 'True' and 'False'.
10	Required	This is a LOV field to specify if the attribute has to be mandated or optional. Values are 'Yes' and 'No'.
11	Read Only	This is a LOV field to specify if the attribute has to be display only or the user can type in an input. 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 displays the **Edit Type Attribute** screen.

Figure 3–9 Editing an Attribute Type

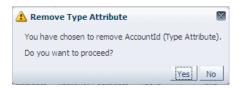


Removing an Attribute Type

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

Figure 3-10 displays the **Removing Attribute Type** screen.

Figure 3-10 Removing an Attribute Type

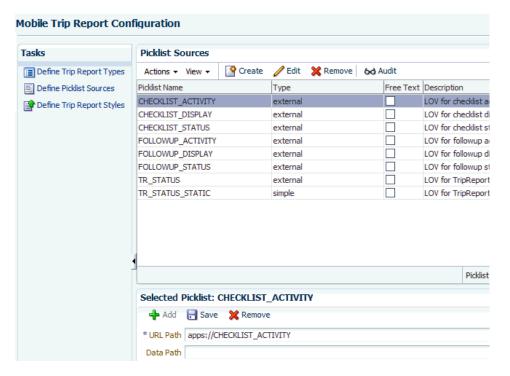


3.1.2.1 Defining Picklist Sources

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 represents the **Defining Picklist Sources** screen.

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, the first step is to define a Picklist Source Item:

- Enter the Name, Description, and Picklist Type in the Picklist Item table.
- 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
- **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:

- Select a Picklist name and type row from the Picklist Source table.
- 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.
- The Key-Value type may contain multiple records per Picklist source item.
- 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

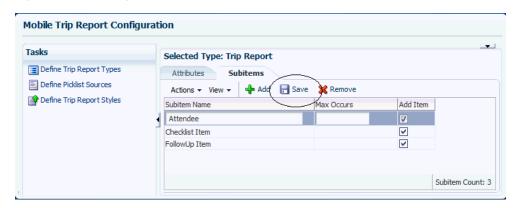
When you click **Add**, it lets you add a Subitem type. The Add Subitem screen displays the list of attributes required for creating a new Subitem type. Fields marked with a star (*) are mandatory fields.

Figure 3–12 Adding a Subitem



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



- When you click **Remove**, Remove Subitem Type dialog appears.
- 2. Click **Yes** to delete the selected Subitem type.

3.1.4 Defining the Category Order

Order is a free 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 displays the order in the Ipad.

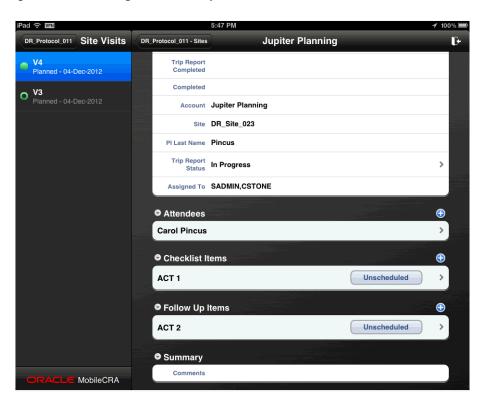


Figure 3-15 Existing Order in the Ipad.

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

Figure 3-16 displays the re-arranged order.

Figure 3–16 Re-arranged Order



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

Figure 3-17 displays the Fetch from CTMS screen.

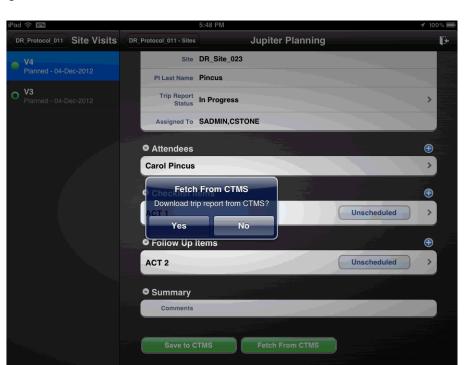


Figure 3-17 Fetch from CTMS

You can now view the new order on the Ipad.

Figure 3-18 displays the new order on the Ipad.

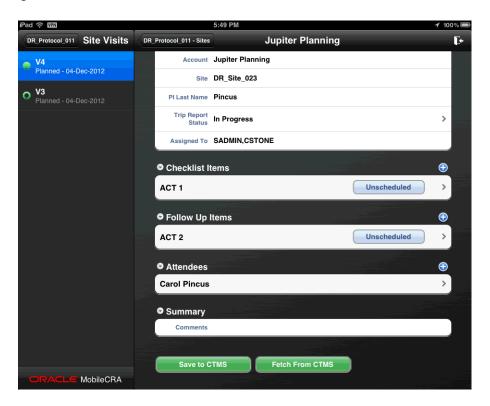


Figure 3–18 New Order

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 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 for 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 gotten back 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.

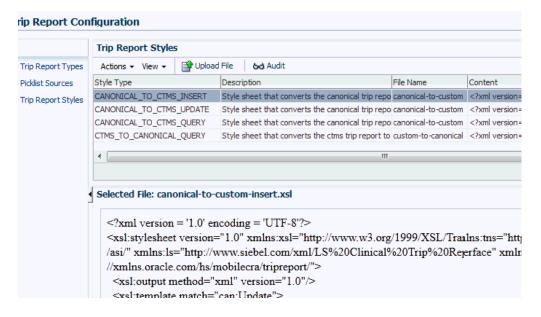
3.1.5.1 Defining Trip Report Styles

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 Admin UI 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 read-only mode.

Entity Objects

HSM_CTMS_STYLE

View Object Fields

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

3.1.6 Sample Trip Report in the CTMS:

Figure 3-20 describes a sample Out-of-the-Box Trip Report in the CTMS:

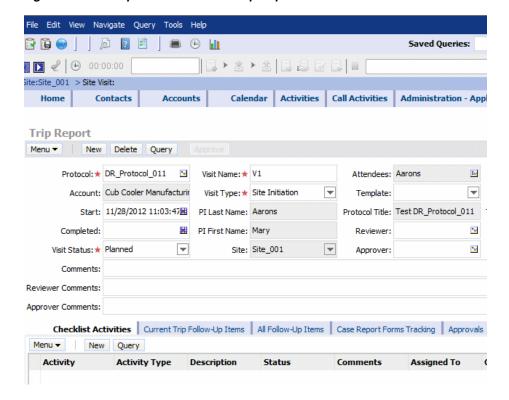


Figure 3-20 Sample Out-of-the-Box Trip Report in the CTMS

Figure 3-21 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
- Checklist Items
- Follow-up Items 3.
- Comments Summary 4.
- The checklist and the follow up items have the Assignee Items within. 5.

These items in turn have various attributes:

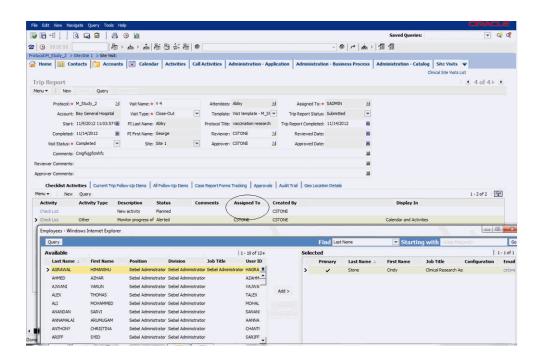
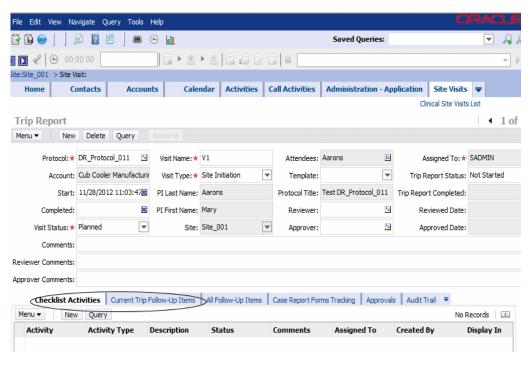


Figure 3-21 Sections within a Trip Report

Figure 3-22 displays the sections within a Trip Report.

Figure 3-22 CTMS Items represented as Item types on Mobile CRA Admin UI



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

These items are represented as 5 different items in the Admin UI, including the Trip Report container element and the assignee item which are present under both checklist item and followup item. All hierarchical items are represented as flat items in the Admin UI.

The attributes underneath each of these elements are defined in the hierarchical order. All the attributes under Trip Report element go under trip, 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 3-23 displays the Attributes for a Trip Report Type in the Admin UI.

Selected Type: Trip Report Attributes Subitems Actions ▼ View ▼ 4 Add / Edit X Remove Attribute Name Caption AC Category Order Data Type Default Value Required Read Only SiteName Account About 1 Text False no AccountId 30 AccountId About 1 Text true AccountLocation About 30 true About 1 false no Text 20 Approver Approver no 100 false no Approver Comments Approver Comment About 1 Text Text AssignedTo Assigned To About false yes 20 yes Comments Comments Summary 1 100 false no no Completed About 1 false no ves false no Description
InvestigatorFirstName PI First Name About 1

Of Lact Name About 2 About 2 Text 20 no 20 Taise 20 false no true Text Text ves true PrimaryInvestigatorId PrimaryInvestigator About 1 Text ProtocolNumber Protocol About Text false yes yes About 1 20 false no ProtocolTitle Protocol Title Text yes ProtocolId ProtocolId About 1 30 true Text Reviewer Reviewer About 1 20 false no no 100 Reviewer Comments Reviewer Comments About Text false no 20 Text false no SiteNumber Site About yes SiteId SiteId About 1 Text 30 true Start Caption Text About true no About 1 false no TemplateName yes Template TemplateId TemplateId About 1 Text 30 true 20 TripReportCompleted Trip Report Complet About 1
Status Trip Report Status About 3 Date Text false no yes false no no Text false yes Visit Name About 2 false yes Visit Status 20 Visit Status About 1 Text no Visit Type false yes Visit Type about Text 20

Figure 3-23 Attributes for a Trip Report Type in MobileCRA Admin UI

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 to add more meaning to it. For example, all the attributes in the header section are displayed under a single display section called **About**. However, if you want to, you could place them in different groupings. For example, **Assigned To**, **Approver**, **Reviewer** in a workflow section and all the other fields in say an **About** section.

Figure 3-24 represents the sample canonical form. The canonical form has two basic elements—items and attributes. An item can have attributes and (or) items in a hierarchical structure at any number of levels. The figure represents the OOTB trip REPORT with three levels—the Trip Report at the top level, the checklist, followup, attendees at the second level with assigned to at the third level inside the checklist and followup item.

Figure 3-24 Trip Report XSLT

```
<?xml version="1.0" encoding="UTF-8" standalone="no"?>
<can:Attribute name="ProtocolNumber">
     <can:Value>MCRA Pro 1</can:Value>
   </can:Attribute>
<can:Item id="8SIA-801UG" 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-80596" type="Followup Item">
    <can:Attribute name="ActivityType";</pre>
       <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 3-25 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 can come up with a completely different hierarchy.

Figure 3-25 Sample CTMS XML

```
■ <SQAP-ENV:Envelope xmlns:SQAP-ENV="http://schemas.xmlsoap.org/soap/envelope/" xmlns:xsi="http://www.w3.org/2001/]
          <SOAP-ENV: Body>
ΒĮ
                <ns:TripReportQueryById Output xmlns:ns="http://siebel.com/asi/">
                       <ListOfLsClinicalTripReportInterface xmlns="http://www.siebel.com/xml/LS$20Clinical$20Trip$20Report$20I</p>
 <ClinicalTripReport>
                                     <Id>8SIA-8NUH6</Id>
                                        <ActivityUID>8SIA-8NUH6</ActivityUID>
                                        <ApproverLogin>SADMIN</ApproverLogin>
                                        <Comment>Super comments</Comment>
                                        <Completed>N</Completed>
                                        <Description>Venkat Site Visit</Description>
                                        \verb|<DisplayInvestigatorFirstName>| Cindy<| DisplayInvestigatorFirstName>| Cindy<| DisplayInvestigatorFirstName>| Cindy<| Continued to the continued of the con
                                        <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>SADMIN</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>
                                                      <Td>1-4TTB</Td>
```

Figure 3-26 shows how the XSLT coding is done to transform the XML from one form to another.

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

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

Figure 3-26 Custom to Canonical XSL

```
TMSSite.java × | 🖒 Lowalue.java × | 🖒 CTMSLov.java × | 🖄 sample-canonical-trip-report.xml × | 🚾 custom-to-canonical-query.xe

<
            xmlns:tns="http://www.siebel.com/xml/LS#20Clinical#20Trip#20Report#20Interface"
xmlns:can="http://xmlns.oracle.com/hs/mobilecra/tripreport/">
B
            <xsl:output method="xml" version="1.0" />
               Maps CIMS (ClimicalTripReport) element to Mobile CRA (TripReport) trip report element
             <xsl:template match="tns:ClinicalTripReport">
              <xsl:element name="can:TripReport">
               Select classing under CriticestTExpReporty to be mapped to mobile CRA elements Currently selected elements are Cldy, (Comment) and (Status).

This document should define respective XSL template for each of the elements below, otherwise it the element will not be mapped.
                 <xsl:attribute name="id">
                 <xsl:value-of select="tns:ActivityUID" />
</xsl:attribute>
                  <!-- attribute type -->
<xsl:attribute name="type">Trip Report</xsl:attribute>
                    xel'element name="can:Attribute">
                    </r></re></re>
```

The example below shows a special handling for Trip Report status attribute, which is, again, an attribute inside the Trip Report. Here, whenever we query the Trip Report from CTMS in Submitted or Submitted for Approval, we put them in 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—Any CTMS status can be retained as it 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—Any status in the CTMS for which we do not want the MCRA to update the Trip Report in the client, we put in this status.
- Submitted status—CTMS should 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 should have an approved status. The status should be passed as it to the client. When the client sees any Trip Report in approved status, it does not let the mobile client update any further. This is assumed as the final state in the mobile client.

Figure 3-27 represents Managing Status in XSL.

Figure 3-27 Managing Status in XSL

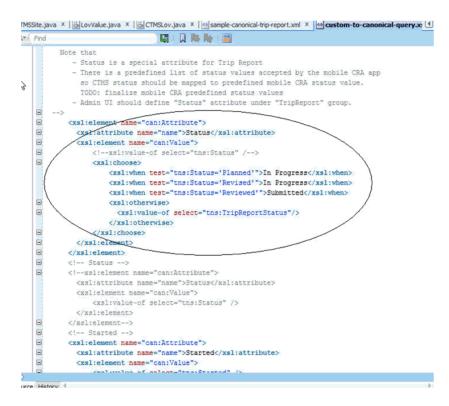


Figure 3-28 shows an example similar to the Trip Report item and its attribute conversion, where the checklist items can be converted from the CTMS to the canonical form. The example also includes the attributes underneath the checklist items.

Figure 3–28 Trip Report Item and its Attribute Conversion

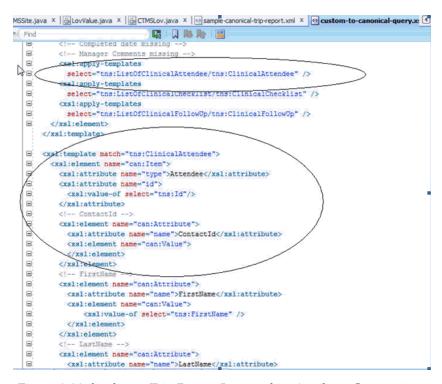


Figure 3-29 displays a Trip Report Item and its Attribute Conversion.

Figure 3–29 Trip Report Item and its Attribute Conversion

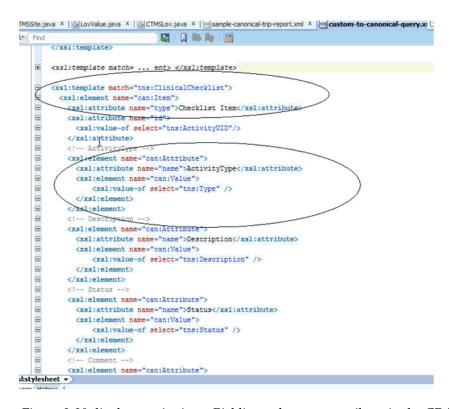


Figure 3-30 displays assigning a Picklist to the status attribute in the CRA Admin UI.

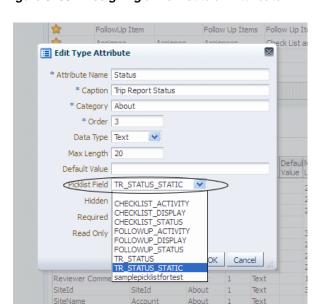


Figure 3-30 Assigning a Picklist to an Attribute

Figure 3-31 displays the Trip Reports About Section screen in the Ipad.

Figure 3–31 The Trip Reports About Section

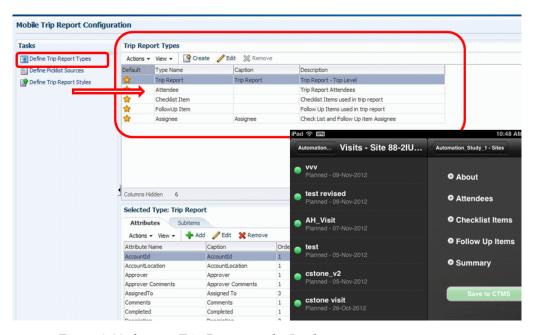


Figure 3-32 shows a Trip Report on the Ipad.

M_Study_2 Site Visits M_Study_2 - Sites **Bay General Hospital** NV1 Planned - Nov 13, 2012 About V 11-cstone
Planned - Nov 10, 2012 Protocol M_Study_2 Protocol Title vaccination research V 10
Planned - Nov 9, 2012 Approver CSTONE Approver Comments **V 9**Planned - Nov 9, 2012 Reviewer CSTONE **V 8**Done - Nov 9, 2012 Reviewer Comments V 7 Completed - Nov 9, 2012 Template Visit template - M_Study_2 PI First Name George V 6 Planned - Nov 9, 2012 Trip Report Completed 11/13/2012 V 5 Planned - Nov 9, 2012 Completed 11/13/2012 16:32:35 Account Bay General Hospital O V 4 Completed - Nov 9, 2012 Site Site 1 O V3 Planned - Nov 9, 2012 PI Last Name Abby Trip Report Status In Review O V 2 MobileCRA Assigned To CSTONE

Figure 3-32 Trip Report on the IPad

Integrations and Configurations

Version 1.2 of the Oracle Health Sciences Mobile Clinical Research Associate Server (Mobile CRA) lets you register, define, and manage key performance indicators (KPIs) either from the Oracle Health Sciences Development Analytics (OCDA) or from other external sources. You can now 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:

- Registering the Client on page 1
- Registering Sources on page 2
- Adaptive Site-at-a-Glance on page 2
- Alerts Registration on page 11

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 Admin UI application.

Figure 4-1 displays the **Client Registration** screen.

Figure 4-1 The Client Registration Screen



Note: The Client ID and Client Key are sent to the Mobile CRA Admin UI 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 Admin UI 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 displays the Add Source screen.

Figure 4–2 Adding a Source



4.3 Adaptive Site-at-a-Glance

Mobile CRA's site-at-a-glance is a key feature as it assists CRAs in monitoring sites.

Earlier, Mobile CRA pulled in data only from the Oracle CDA system. To let you use non-OCDA systems with this feature, Mobile CRA has been 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 Admin UI 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

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.

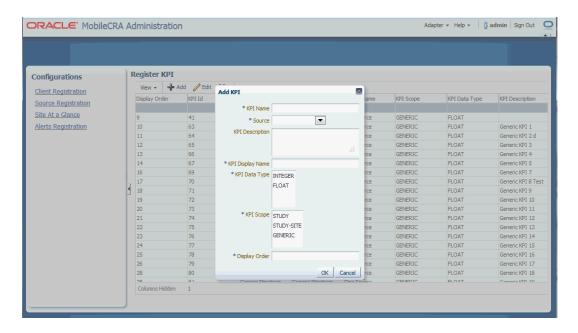
4.3.1.1 Adding a KPI

To add a KPI, perform the following:

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

Figure 4-3 displays the Add KPI screen.

Figure 4-3 Adding a KPI



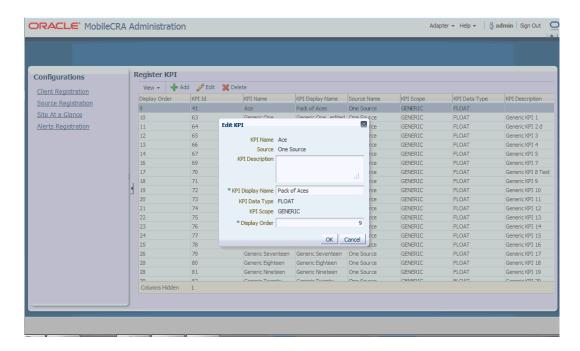
4.3.1.2 Editing a KPI

To edit a KPI, perform the following:

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

Figure 4-4 displays the **Edit KPI** screen.

Figure 4-4 Editing a KPI



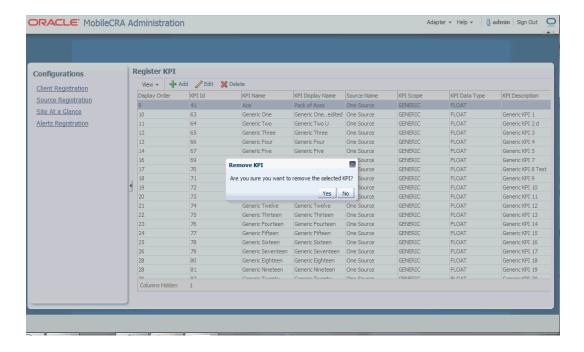
4.3.1.3 Deleting a KPI

To delete a KPI, perform the following:

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

Figure 4-5 displays the **Remove KPI** screen.

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 3 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 displays 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 illustrates the standard 6 KPI display screen.

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

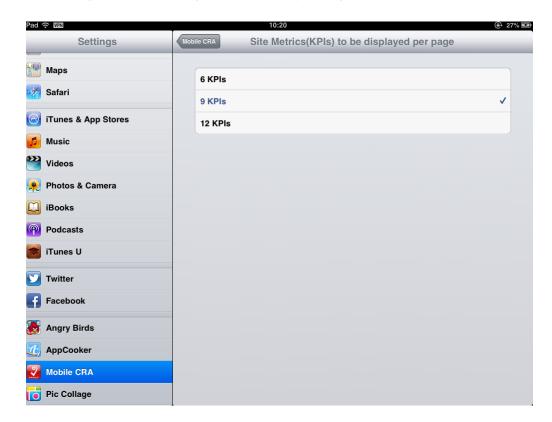


Figure 4-9 illustrates the 9 KPI display.

Figure 4–9 The 9 KPI Display

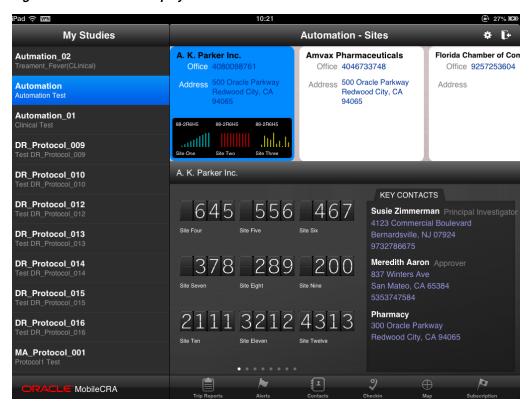


Figure 4-10 illustrates selecting the 12 KPI display setting.

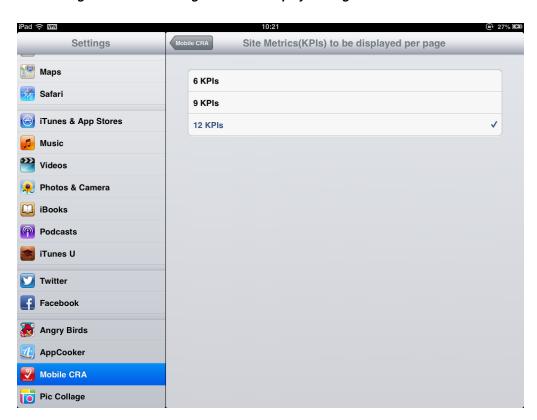


Figure 4-10 Selecting the 12 KPI Display Setting

Figure 4-11 illustrates the 12 KPI Display

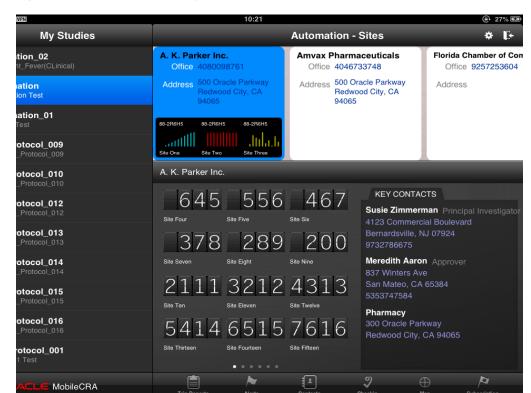


Figure 4-11 The 12 KPI Display

4.3.3 Changing the Display Order

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

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

Figure 4-12 displays the existing KPI order in Admin UI.

Figure 4-12 Existing Order in the Admin UI

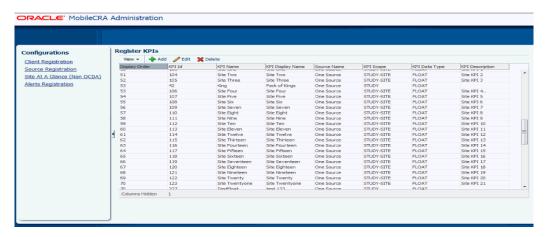


Figure 4-13 displays the corresponding display on the Ipad.

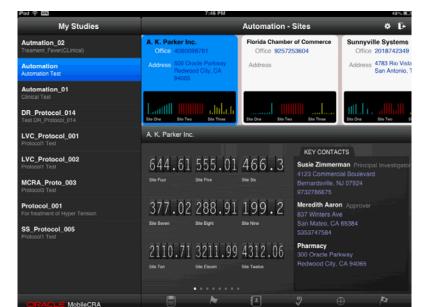


Figure 4–13 Corresponding Display in the Ipad.

Figure 4-14 displays the changed order in the ADmin UI.

Configurations
Client Registration
Source Registration
Source Registration
Size At A Clanace (Non OCDA)
Alerts Registration

Size At A Clanace (Non OCDA)
Alerts Registration

Alerts Registration

Re

Figure 4–14 Changed Display Order in the Admin UI

Figure 4-15 displays the changed display in the Ipad.

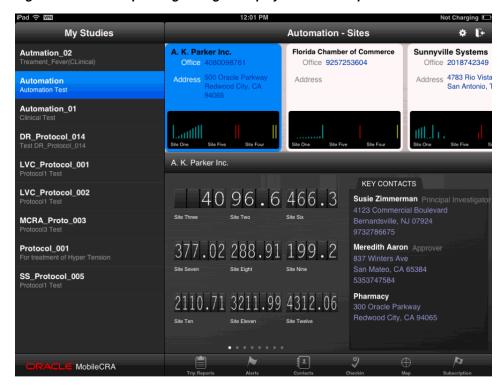


Figure 4-15 Corresponding Changed Display Order in the Ipad

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.

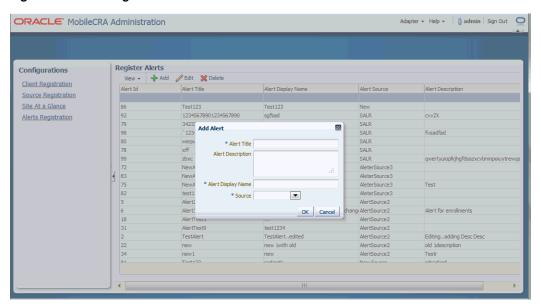
4.4.1 Adding an Alert

To add an Alert, perform the following:

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

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

Figure 4–16 Adding an Alert



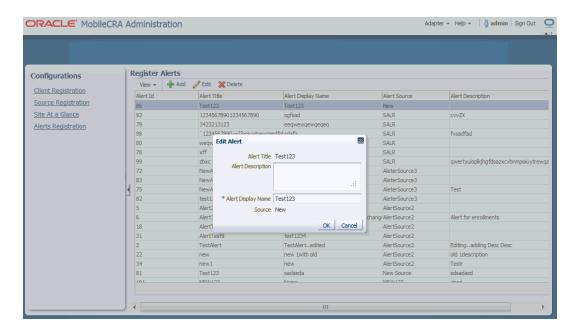
4.4.2 Editing an Alert

To edit an Alert, perform the following:

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

Figure 4-17 displays the **Edit Alert** screen.

Figure 4-17 Editing an Alert



4.4.3 Deleting an Alert

To delete an Alert, perform the following:

- **1.** Click **Delete**. The **Delete Alert** window is displayed.
- 2. Delete the required alert and click **OK**.

Figure 4-18 displays the **Remove Alert** screen.

Figure 4–18 Deleting an Alert

