

Oracle Argus Safety

Multi-tenancy Administration Guide



Release 8.4
F51742-01
September 2022

The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
- [Access to Oracle Support](#)

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>.

Related resources

For information about Oracle Argus patches, see [My Oracle Support](#).

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

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1

Overview

The multi-tenancy feature in Oracle Argus Safety enables multiple pharmaceutical clients of a CRO to reside as separate and unique tenants in a single database, with their data completely segregated and available to authorized users only.

It enables a CRO to achieve standard configuration across clients, and at the same time provides the ability to have different configurations for specific clients, as required.

It also provides the ability to a CRO to quickly set up a new client based on an existing configuration, and authorize users to the new client. It also enables CRO users who have access across multiple clients to view and understand their work across clients, and to make priority-based decisions.

2

Global Homepage

Global Homepage allows Argus users to perform specific actions across multiple active enterprises and supports multi-tenant installation.

For more information, see:

- [Global Homepage](#)
- [Global Worklist](#)
- [Global Enterprise Management](#)
- [Global User Management](#)
- [Application access](#)

Global Homepage

The following out-of-the-box Portlets are accessible to all multi-tenant users who need to access data across multiple enterprises, except the ones specifically recommended for administrators:

- Global Worklist
- Global Enterprise Management: Recommended for Administrators
- Global User Management: Recommended for Administrators
- Application Access

Global Homepage can be accessed using the SSO and the portal users who access Global Homepage need to be configured as LDAP user in all the enterprises in which the user is not a disabled user.

In multi-tenant installations, Global Homepage and Oracle Argus Safety are two different applications that are available for end-users and CRO/Hosting administrators.

Both these web applications have separate web URLs which can be accessed independently.

When you enter the URL of any of these web applications, the SSO module authenticates the user credentials and allows access to these applications without asking for any user credentials.

For Global Homepage, if the SSO authentication fails, the application displays an error message returned by SSO module.

For Oracle Argus Safety, if the SSO authentication fails, the application displays an error message returned by the SSO module.

Global Worklist

The Global Worklist portlets allow you to access work items across authorized enterprises or clients. You can filter the Worklist for specific enterprises or clients that you can access.

When you use a filter for a specific enterprise or client, any further operations on the retrieved Worklist items are restricted to that specific enterprise or client.

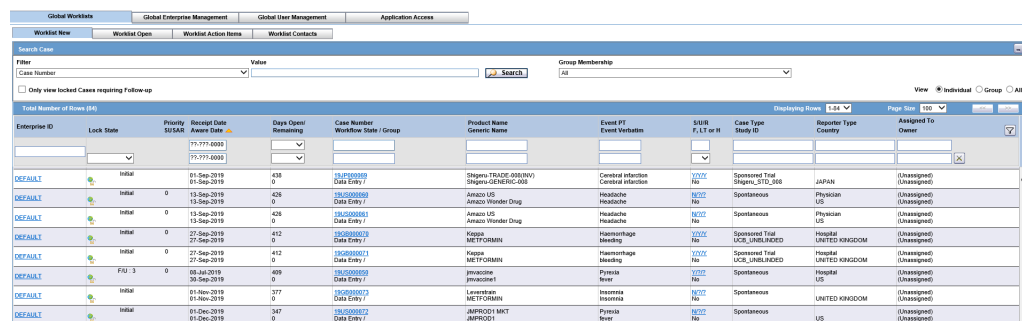
1. The context menu that is invoked on Global Worklist displays the action menu items based on your access rights and roles in the enterprise to which the selected records belong.
2. The user preferences of each Global Worklist are remembered for the user every time the Worklist is loaded. User preferences for Global Worklists are maintained in addition to the enterprise-specific user preferences which are applicable for the user in Argus Safety Worklists.
3. Each of these Global Worklists only displays data from the enterprises within which the user has access to that specific Worklist Menu item.

The following Global Worklist Portlets are provided in the Global Homepage:

- **Global Worklist - New:** This Worklist displays a list of cases across all enterprises and clients, or specific to one enterprise or client, according to your selection. You can only see cases that you have access to, or which have been assigned to you, but are not yet accepted.
- **Global Worklist - Open:** This Worklist displays a list of cases across all enterprises and clients, or specific to one enterprise or client, according to your selection. You can only see cases that you have access to, and were accepted by you or your user group.
- **Global Worklist - Action Items:** This Worklist displays a list of pending action items across all enterprises and clients, or specific to one enterprise or client, according to your selection. You can only see cases that you have access to.
- **Global Worklist - Contacts and Letters:** This Worklist displays a list of pending letters across all enterprises and clients, or specific to one enterprise or client, according to your selection. You can only see cases that you have access to.

 **Note:**

The application offers the flexibility to hide some of the fields or columns in the Global Worklist portlets through the Global Worklist grid or menu XMLs, which reside on the Web Server(s). We recommend that you only hide the fields or columns which are not updated, nor referred by any Worklist context menu actions.



Enterprise ID	Lock State	Priority	Report Date	Data Open	Case Number	Product Name	Event PT	Event Verbatim	SDR	Case Type	Report Type	Assigned To
DEFAULT	Initial	0	01-Sep-2019	438	182000000	Shigen TRADE_000000	Control Interac	Control Interac	Y000	Sponsored Trial	SHIGEN_070_000	JAPAN
DEFAULT	Initial	0	13-Sep-2019	428	182000000	Amoxic US	Headache	Headache	N000	Spontaneous	Physician	(Unassigned)
DEFAULT	Initial	0	13-Sep-2019	428	182000001	Amoxic US	Headache	Headache	N000	Spontaneous	Physician	(Unassigned)
DEFAULT	Initial	0	27-Sep-2019	412	182000000	Kappa METFORMIN	Haemorrhage	bleeding	Y000	Sponsored Trial	USC_UNBLINDED	UNITED KINGDOM
DEFAULT	Initial	0	27-Sep-2019	412	182000001	Kappa METFORMIN	Haemorrhage	bleeding	Y000	Sponsored Trial	USC_UNBLINDED	UNITED KINGDOM
DEFAULT	FAU 3	0	08-Jul-2019	409	182000000	Invacore prolocon1	Pyloric	tear	Y000	Spontaneous	Hospital	(Unassigned)
DEFAULT	Initial	0	01-Nov-2019	377	182000000	Lanxaph METFORMIN	Incessa	incessa	N000	Spontaneous	Physician	UNITED KINGDOM
DEFAULT	Initial	0	01-Dec-2019	347	182000000	JMPROD1 MCT JMPROD1	Pyrexia	fever	N000	Spontaneous	Physician	US

Global Enterprise Management

Global Enterprise Management enables you to quickly create new enterprises or clients, and to authorize users. It also helps you quickly define enterprises based on existing configurations.

From the **Global Enterprise Management** tab, you can:

- [Add a new enterprise](#)
- [New enterprise setup](#)
- [Inactivate an enterprise](#)

Add a new enterprise

1. Click **Add New Enterprise**.
2. Enter information about your enterprise in the required fields.
3. Click **Next**.
4. From **Copy Configuration Data Source**, select an enterprise to use as a template for your new Enterprise.

 **Tip:**

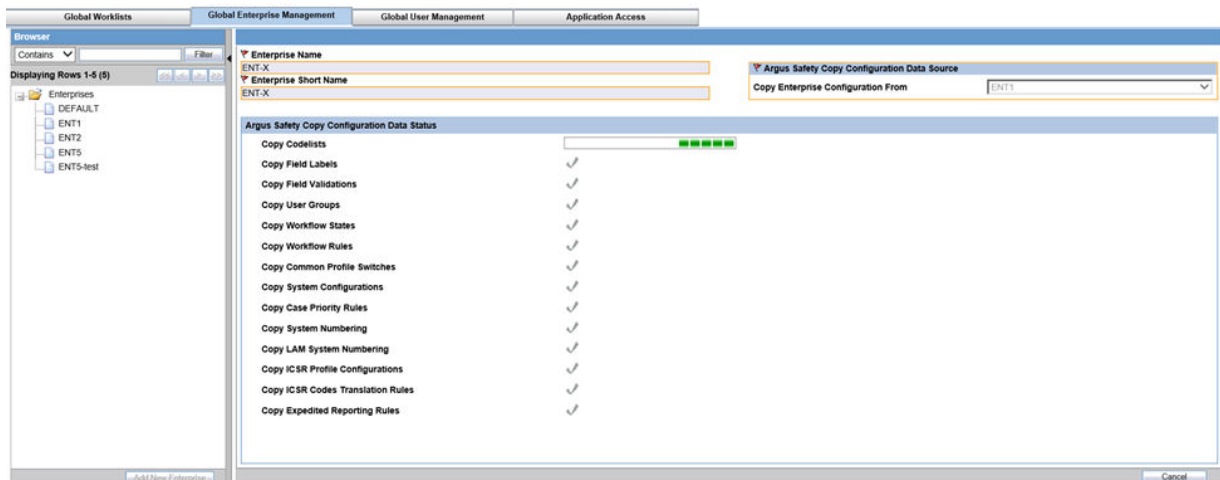
You can make changes to the configuration once the enterprise has been set up.

5. Click **Setup**.
6. Click **Finish**.

During Copy Configuration, the system copies the configuration to the new enterprise created:

- Codelists
- Field Labels
- Field Validations
- User Groups
- Workflow States
- Workflow Rules
- Common Profile switches
- System Configuration
- Case Priority Rules
- System Numbering
- LAM System Numbering
- ICSR Profile Configurations
- ICSR Codes Translation Rules

- Expedited Report Rules



New enterprise setup

You should create and choose enterprises with generic configuration data which can be used as a source to create new enterprises. We recommend you include the following items to ensure that the values being copied from the source enterprise are appropriate for the newly created enterprise:

- Advanced Conditions used within any configuration item Reporting
- Reporting Destination Code List > Company identifier field values System
- Numbering and LAM System Numbering Formats
- Reporting Destination codelist > EDI Tab > Incoming / Outgoing / Attachment folders for each agency.

Common Profile Switches

- MedWatch Configuration
- Documentum configuration
- Lot Number Web Service Configuration

Inactivate an enterprise

An enterprise can be made inactive by unchecking the Active check box on the Global Enterprise Management screen.

Note:

We recommend that you first archive all the cases belonging to the enterprise before inactivating the enterprise.

Global User Management

Global User Management allows you to associate the users to multiple enterprises, but also to keep their user attributes in sync across all enterprises.

 **Note:**

This portlet is displayed to the user having access to the **Global Admin** role for one or more enterprises.

The browser displays a left hand pane that lists the existing users (distinct users based on Login User ID) in the system, in a tree view. The tree displays users from the enterprise partitions for which the user has access. Service users are not listed in the tree view of the Global User Management screen.

 **Note:**

Oracle Argus Safety Console allows the same UserID to be used to create different users across multiple enterprises. It is recommended that this feature is only be used if users are not expected to be shared across enterprises. Otherwise, if the users are expected to be shared across multiple enterprises, then same UserID will not be used to create different users across different enterprises. Instead of that, a user created in one enterprise is associated to other enterprises through Global User Management.

For more information, see:

- [Synchronizable user attributes](#)
- [User-enterprise association](#)

Synchronizable user attributes

The purpose of the **Synchronizable User Attributes** section is to allow you to apply updates to user attributes displayed in this section, and keep them in sync across all enterprises.

The users that are listed to be administered in this screen are restricted by the following rules:

1. Admin users, System users and users for which the Service User is checked in Oracle Argus Safety Console are not listed.
2. Only the users from the enterprises for which you have access to the **Console User Management** screen, i.e. you should have access to all of the following in those enterprises:
 - Console User Management screen > Application Access field > Console checkbox.
 - Console Group Management screen > Menus section > Console, Access Management and User radio options are set to enabled at least for one user group in the respective enterprise partition.

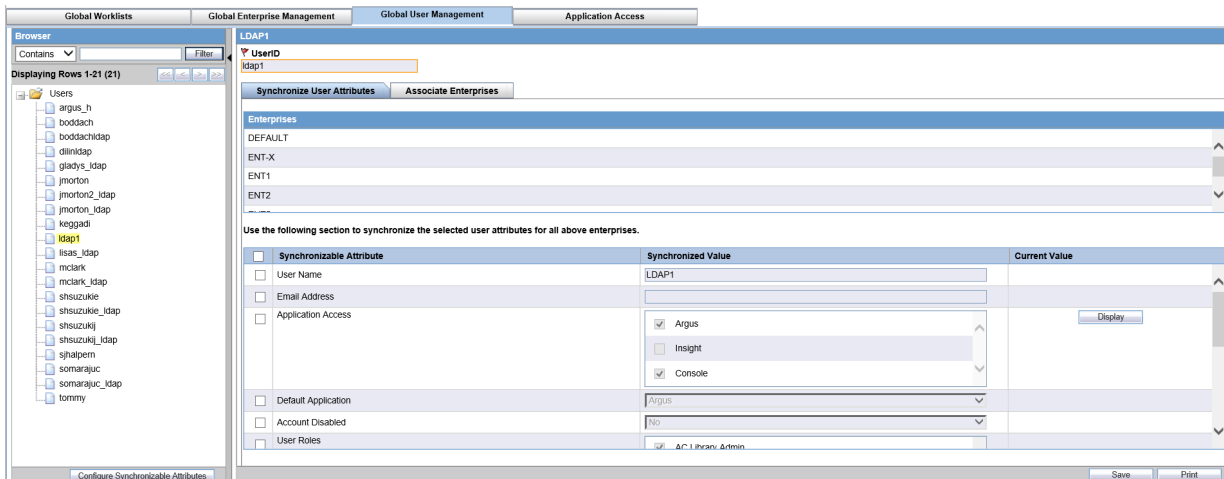
- Is not marked as **Account Disabled**.

When you select the **Synchronize User Attributes** tab, the left hand pane displays a list of enterprises to which the user being administered belongs to. The right hand pane displays a list of synchronizable user attributes in a grid.

The value of the synchronizable fields can be modified for a specific enterprise so that these attributes can be different for that enterprise as compared other enterprises.

The following the list of attributes on which synchronization can be done:

1. User Name
2. Email Address
3. Enable LDAP Login
4. LDAP Server Alias
5. Application Access
6. Default Application
7. Account Disabled
8. Worklist to display at Login
9. User Roles
10. Allow unblinding of cases
11. Protect from unblinded information
12. Protect from printing unblinded information
13. Allow closing of cases
14. Route on close case
15. Enable Checklist on Route



 **Note:**

If **User Name** and **Email Address** fields are updated in Oracle Argus Safety Console for a user which belongs to multiple enterprises, an error displays. If you make changes to the data on one of these tabs and attempts to move away from this current tab without saving the changes, then the warning message `You have made changes to the existing item, if you press OK, changes will be lost.` displays. Click **OK** to ignore changes. Click **Cancel** to stay on the current tab.

 **Note:**

The selected enterprise is used to set the attribute values for the user in the new enterprise to which the user is being associated. The attribute values for the already associated enterprises remain the same.

 **Note:**

In order to apply updates to the “Synchronizable” fields to all the enterprises in the system, the customer is required to maintain some administrative users with the `Console > Access Management > Groups > Menus > Console: Access Management: User menu access enabled for all enterprises in the system.`

User-enterprise association

To associate existing users from one enterprise to other enterprises:

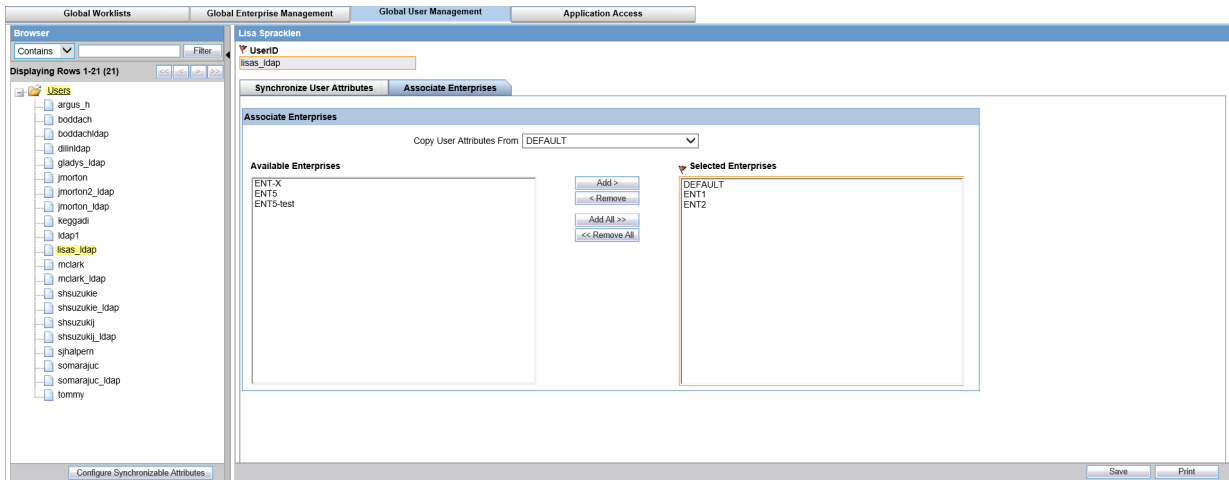
1. Select an enterprise from **Copy User Attributes From**.
2. Add an **Available Enterprise** or **Add All** available enterprises.
3. Select **Save**.

 **Note:**

During **Save**, all the user attributes are copied from the Enterprise selected in the **Copy User Attributes From** to all the newly associated Enterprises.

4. To print the user details of the current user or all the users, select **Current User** or **All Users** and click **Print**.

When a user is copied from one enterprise to another, it is expected that you have set up the appropriate site and the user groups in the target enterprise. Otherwise the user-association will fail with the appropriate error message.



Application access

The Applications Access Portlet allows the users to launch the Argus applications for an enterprise that they have access to.

The following options are provided in Application access:

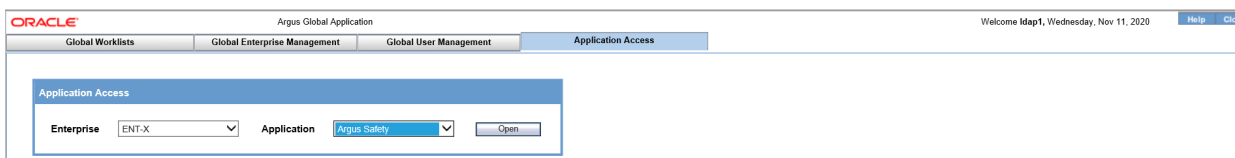
- Argus Safety
- Argus Safety Bookin
- Argus Affiliate
- Argus Affiliate Event Entry
- Argus Insight

Note:

During **Save**, all the user attributes are copied from the enterprise selected in the **Copy User Attributes From** to all the newly associated enterprises.

The Argus Safety Bookin option opens the Case Bookin screen within the Oracle Argus Safety for the selected enterprise.

The Argus Affiliate Event Entry option opens up the Local Event Entry screen within Oracle Argus Insight for the selected enterprise.



3

Data segregation

Multitenancy allows an organization to use a single database for many clients, which reduces the amount of hardware needed for an implementation. Fewer patches and dictionary upgrades are required, which decreases the resources necessary to support an implementation. This also allows administrators to use standard configurations, such as codelists, workflow steps and user/new client setup.

The entire Oracle Argus Safety application and all of its components and data are partitioned by Enterprise ID. The Enterprise ID is a unique identifier for a customer's client and contract. The appropriate context of the Enterprise ID selected by the user that the user has access to, is set by the system and operates within the partition of this context.

For more information, see:

- [Data segregation by module](#)
- [Data segregation by enterprise](#)
- [Data segregation impact on system-level configuration items](#)
- [Data shared across enterprises](#)

Data segregation by module

The following table describes how each module in the Oracle Health Sciences Safety suite provides data segregation in a multi-tenant environment.



Note:

It is not recommended that you open the Oracle Argus Safety application for multiple enterprises at the same time. Close the Oracle Argus Safety application for the previous enterprise before opening it for the next enterprise to avoid data issues.

It is recommended that you use the Application Access portlet to open the Oracle Argus Safety application for different enterprises, as it takes care of closing the previous enterprise before opening the new one.

Module	Cross Enterprise	Accessed Via Portal	Notes
Global Worklists	Yes	Yes	Displays data from across multiple enterprises.
Global User Management	Yes	Yes	Displays data from across multiple enterprises.
Global Enterprise Management.	Yes	Yes	Displays data from across multiple enterprises.

Module	Cross Enterprise	Accessed Via Portal	Notes
Applications Access	Yes	Yes	Displays Application Access options from across multiple enterprises.
Argus Safety	No	No	Displays data for one enterprise at a time to the logged-in user based on the selected enterprise.
Argus Console	No	No	Displays data only for the enterprise for which Argus Safety was opened by the user.
Argus Affiliate	No	No	Displays data for one enterprise at a time to the logged-in user, based on the selected enterprise.
Argus Unblinding	No	No	Displays data for one enterprise at a time to the logged-in user, based on the selected enterprise.
ESM Mapping Utility	No	No	Displays data for one enterprise at a time to the logged-in user, based on the selected enterprise. However, the screens related to ESM Service Configuration display data related to all the active enterprises, irrespective of the user access rights to those enterprises.
Argus Interchange Service	Yes	No	ESM Service process data from all the enterprises, as it is a background service.
ESM Service Configuration	Yes	No	As ESM Service is common across all the enterprises, hence its configuration tool is also common.
Argus Safety Service	Yes	No	Argus Safety Service processes data from all the enterprises as it is a background service.
AG Service Configuration Tool	Yes	No	As AG Service is common across all the enterprises, hence its configuration tool is also common.

Module	Cross Enterprise	Accessed Via Portal	Notes
MedDRA Re-code Tool	Yes	No	Allows the option to perform recoding of MedDRA terms across the enterprises.
MedDRA Dictionary Load	Yes	No	Single instance/version of the loaded MedDRA dictionary is available for all the enterprises.
MedDRA/WHO Web Services	Yes	No	These web services remain common to be used across all the enterprises. Their configuration is maintained in a common XML file on the web server(s).
J Drug Dictionary	Yes	No	Single instance/version of the loaded J Drug dictionary are available for all enterprises.
Case Intake	No	No	Case Intake messages for separate enterprises are segregated and loaded into appropriate enterprise partitions.
Literature Intake	No	No	Literature Case Intake data for separate enterprises are segregated and loaded into appropriate enterprise partitions.
PSL	No	No	The PSL interface segregates the incoming requests for each enterprise partition.
DLP	No	No	Partitions the case revisions by enterprises.
TMS Integration	No	No	TMS integration for single-pharma installations only.
Argus Dossier	No	No	As this module is linked to Periodic Reports, hence it partitions the periodic reports data by enterprise.

Data segregation by enterprise

Following is the list of items that are segregated by enterprises. It is recommended that you configure distinct values across enterprises to ensure proper data segregation across enterprises.

- **Literature Intake folder:** Console > Common Profile Switches > Safety Japan > Shared Path for the Literature Intake
- **Case Intake folder:** Console > Code List > User Sites > Intake
- **Site Printers:** Console > Code List > User Sites > Site Printers

Maintaining Consistency Across Enterprises

The following is the list of items that are segregated by enterprises but the CRO is recommended to maintain consistent across all enterprises:

- Common Profile Switches > Insight URL
- Common Profile Switches > Safety Load Balancer Server
- System Configuration > Enabled Modules

In order to apply updates to the **Synchronizable** fields to all the enterprises in the system, you should maintain some administrative users with the Console > Access Management > Groups > Menus > Console: Access Management: User menu access enabled for all enterprises in the system.

Data segregation impact on system-level configuration items

The following table specifies some specific system-level configuration items which are configured through Oracle Argus Safety Console. It specifies the impact on these configuration items due to data segregation design for multi-tenant installations and also specifies the recommendations for customers on these items.

Configuration Item	Application Design	Recommendation for Customers
Enable/Disable MedDRA/WHO Web Service Encoding	System keeps it segregated for each enterprise. However, the underlying web service used for MedDRA/WHO is common for all the enterprises as their configurations are maintained in common XML file on the web server(s).	None
Lot Number Web Service configuration	System keeps it segregated for each enterprise.	As this is related to the product, Oracle recommends you keep it specific for each enterprise.
Documentum Configuration	System keeps it segregated for each enterprise.	All parameters except for Cabinet Name are expected to be maintained as same for different enterprises.
Enable/disable LDAP & LDAP Server configuration	This will be maintained by application as common for all enterprises.	None
Enabled Modules	The system keeps it segregated for each enterprise.	None

Configuration Item	Application Design	Recommendation for Customers
Enable/disable SSO & SSO Header Configuration	This will be maintained by application as common for all enterprises.	None
Argus Insight URL	System keeps it segregated for each enterprise.	It is expected to be maintained same for across all enterprises by the customer.
Argus Safety Load Balancer Server	System keeps it segregated for each enterprise.	It is expected to be maintained same for across all enterprises by the customer.
User Information	System keeps it segregated for each enterprise.	For multitenant installations, user attributes can be synchronized for all the enterprises through Global User Management. However, user attributes can also be updated for a specific enterprise through Oracle Argus Safety Console as well.
Default Enterprise	System keeps it segregated for each enterprise.	This is a new internal common profile switch that marks an enterprise as the Default enterprise. This is set during the time of install. Default enterprise once created during database creation is fixed. This is required to avoid the data synchronization issues that may occur for AG Service users in different enterprises.
SMTP Configuration	System keeps it segregated for each enterprise.	None

Data shared across enterprises

Following is the list of items that are common for all enterprises.

- MedDRA and WHO Web Services
- Common Profile Switches > Security > LDAP > Enable/disable LDAP
- Common Profile Switches > Security > LDAP > LDAP Server Configuration
- Common Profile Switches > Security > Enable/disable SSO
- Common Profile Switches > Security > SSO Header Configuration
- Common Profile Switches > Case Processing > Auto Archiving > Execution Period (in Days)
- Default Enterprise

The common profile switches (related to SSO, LDAP, Auto Archiving job & frequency and Temporary Case Data Storage) which are common for all enterprises will only be displayed, updated and audit logged in DEFAULT enterprise. This is because any update to global level

profile switches impacts all enterprises and is controlled. Also, such an update will also require propagation of the audit log to all other enterprises where the current user may not even exist or may not have proper access.

4

Documentum migration

Existing single-tenant as well as multitenant Documentum users upgrading to AS 7.0 release, and are migrating/keeping all the documents in the Documentum server, is also add additional attributes - `enterprise_id` and `enterprise_short_name` and populate these appropriately for all their documents that are to be accessed by Oracle Argus Safety in Documentum server.

Existing single-tenant as well as multitenant users which are upgrading to AS 7.0 release, and have configured Use Logged in User's Username/Password for Console > System Configuration > Common Profile Switches > Document Management for Case Attachments will switch to Common Username/Password for Documentum login if not already configured for E2B, Expedited and Periodic Reports.

MedDRA and WHO Webservices: As MedDRA and WHO webservice is common for each enterprise, it will use only single version for encoding events and drugs. However, as these web services use the dictionaries configured in Console > System Configuration > Common Profile Switches > Case Form Configuration > Auto Encoding, Dictionary and Central Encoding section for the respective enterprises for populating dictionary id and dictionary version information for the encoded items, configure these dictionaries as same across all enterprises.

5

Pre-upgrade considerations for existing databases

Make sure that all the AG Service users (login user id) in all the databases that are to be merged into single database are in sync with the DEFAULT ENTERPRISE. If there are AG Service users in other enterprises which do not exist in the DEFAULT ENTERPRISE, then you can either rename their login user IDs to map them to existing AG Service users in the DEFAULT ENTERPRISE or delete them. If extra users are found in other enterprises during multi-tenant database migration, then they will be marked disabled and you will not be able to enable them later.

Make sure that all the event & indication and who-drug encoding dictionaries used in Console > System Configuration > Common Profile Switches > Case Form Configuration > Auto Encoding, Dictionary and Central Encoding section and Console > Business Configuration > Studies > Enable Study Specific Encoding > Auto Encoding dialog, in all databases that are to be merged into single database are already loaded in the target database with the same name. This is required to enable the automatic linking of dictionaries configured in the separate databases to the already existing dictionaries present in the target database during the database merge script/process.

6

Post-upgrade considerations for existing databases

Make sure that all the event & indication and who-drug encoding dictionaries used in Console > System Configuration > Common Profile Switches > Case Form Configuration > Auto Encoding, Dictionary and Central Encoding **section** and Console > Business Configuration > Studies > Enable Study Specific Encoding > Auto Encoding **dialog**, in the newly migrated enterprises are linked properly to the global dictionaries already present in the target database. This is required to correct any dictionary configuration linking that could not be done automatically by the database merge script due to mismatch in dictionary names in the source and target databases.