Oracle® Insight

Release Content Document (RCD)

Release 7.0

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Disclaimer

This Release Content Document (RCD) describes product features that are proposed for the specified release of the Oracle Argus Insight. This document describes new or changed functionality only. Existing functionality from prior point releases is not described. It is intended solely to help you assess the business benefits of upgrading to Release 7.0.

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Introduction

Purpose of Document

The Release Content Document (RCD), produced as part of Oracle's Applications Product Lifecycle (APL), communicates information about new or changed

functionality in the specified release of Oracle Argus Insight. Existing functionality from prior point releases is not described. However, content introduced by Family Packs, Mini-Packs or Standalone patches since the prior point release has been included in this document and denoted accordingly.

- Oracle Argus Insight 7.0

Release Overview

Contract Research Organizations (CROs) may offer a range of global safety and pharmacovigilance services which span from limited case management activities to full clinical trial and post-marketing services and anything in between.

Multi-tenancy support increases a CRO's ability to increase its profit margin. Multi-tenancy users are able to reduce from many databases to a single database. This enables them to reduce the amount of hardware needed for an implementation, reduce the number of patches and dictionary upgrades periodically performed, and subsequently reduce the resource requirements to support the implementation. They can leverage standard configurations such as code lists, workflow steps, and centralized user and enterprise setup.

Reference Documents

Name	Location	Completion Date
Argus Insight 7.0 BRD	Caliber RM	
Argus Insight 7.0 FDD	ClearCase	

Product Overview

Features

Following are the features that are new with the release of Oracle Argus Insight 7.0.

Segregate Data by Enterprise

Partitioned Data The option of segregating data by enterprise profiles allows the user to maintain the data set in one database but protected between different enterprises based on the security permissions defined for each user.

Display Enterprise Identifier The identifier for the partitioned data set is displayed when a user is viewing or processing queries, case series and reports.

Change Enterprises within the Same Session Users are able to create or access queries, case series and reports for one enterprise at a time. However some users may have been configured with permission to access multiple enterprises. Such users are able to switch from one enterprise to another without the need to log off from the application.

Set Up and Maintain Multi-Tenant Enterprises

Enable Multi-Tenant Usage When processing data for an enterprise, a CRO user requires that the enterprise's data and configuration be partitioned from other enterprises. Partitioning of data and the additional interfaces that support accessing separate enterprises are only available in the multi-tenancy deployment and not impact single-tenant implementations.

Establish Enterprises An "enterprise" is the highest level for which data is isolated. An enterprise can include one or more studies/programs, one or more products, one configuration, and one set of user permissions such as access to unblinded data. Each enterprise may have one or more dictionaries (i.e. dictionary by study).

Enterprise Configuration Setup Wizard To correctly set up a new enterprise, several sequential steps must be completed. The system administrator is able to quickly establish a new enterprise in the database, based upon selecting from standard libraries or by copying from an existing setup. Enterprise-specific adjustments can be to be made during the initial setup, or alternatively at some later time when enterprise-specific configurations are clearly identified.

- Enable the administrator to copy an existing enterprise configuration. Some enterprise-specific data is not included in a copy, including products, actual study information and license information.
- The wizard is launched from Argus Safety rather than Argus Insight, so that enterprise configuration is centralized in one place within the Argus suite.

Modify Enterprises The setup of an enterprise may need to be change. New studies or post-marketing services may be added or completed in an existing enterprise; therefore the configuration may need to be modified.

When an administrator modifies an enterprise setup, that enterprise's existing options must be clearly presented to the administrator. The ability to modify enterprise configurations is controlled by user permissions.

Control User Access to Enterprises and Enterprise Data Access to each enterprise's studies and projects is controlled on a user-by-user basis.

Migrate to Multi-Tenancy Existing CRO enterprises must be migrated from a single-tenant implementation to a multi-tenant implementation.

Security Requirements

A large CRO houses data for hundreds of clinical trials at a given time and can be the constant target of computer attacks. Since part of the safety application is exposed outside of the CRO, the application must be able to defend itself from hacking. Types of potential attacks include but are not limited to cross-site scripting, SQL injection, cross-site request forgery, and parameter tampering.

Limitations

Following are limitations that are new with the release of Oracle Argus Insight 7.0.

Support of Cognos Only

Oracle Argus Insight 7.0 supports Cognos but not BusinessObjects. Support of Business Objects is currently planned for a future release.

Retirement of Dashboards

The dashboard function is retired in both multi- and single-tenant mode.

Centralized User Maintenance

Users are created and maintained exclusively in Argus Console and no longer separately in Argus Insight.

Terminology

Term	Definition
CRO	Contract Research Organization
Enterprise	A tenant; the highest level at which data is partitioned in a multi-tenant environment
Study	Studies (or protocols) to evaluate the effectiveness and safety of medications or medical devices by monitoring their effects on large groups of people

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