ORACLE

Oracle Life Sciences

Central Coding Cloud Service

Service Descriptions and Metrics

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METRIC DEFINITIONS

Instance

Instance is defined as a single deployment of the Oracle Program. For details of deployment specific to the Oracle program please refer to service descriptions/entitlements.

GLOSSARY

Trial

Trial is defined as each research project, study or procedure created, modified, tracked and/or conducted by a Sponsor using the Oracle program(s) or Service(s).

SERVICE DESCRIPTIONS

Oracle Life Sciences Central Coding Cloud Service – Instance

Part #s:

- B91580
- B91663 *(Retired)*

Modules and Features

Users of the Cloud Service are authorized to access the following modules:

- Oracle Life Sciences Central Coding

Users and Access by Users

The Services may be accessed only by personnel involved in coding activity for Your Trial(s).

Oracle will grant User Manager and User Administrator roles for Central Coding to You. You are responsible for creating individual end user accounts for Your personnel in the Central Coding program.

Identity and Access Management Service (IAMS): Oracle Life Sciences Identity and Access Management Service (IAMS) provides Oracle single sign-on (SSO) functionality for IAMS-enabled versions of Central Coding. IAMS manages identity and access requests by users and roles. IAMS uses coarse-grained authentication to evaluate if users have been assigned privileges to open a Central Coding page that they are trying to access. When accessing Central Coding using a single sign-on account, users will automatically be signed into other IAMS-enabled Oracle Life Sciences Cloud Services, e.g. the InForm Cloud Service page for future access. IAMS is supported for UAT and Production environments in newly deployed Instances of Central Coding 3.1.0.1 or later. IAMS will not be supported for Training environments. Fine-grained privilege access control features may be accessed through the Central Coding program as described in the Central Coding program documentation.

Environments

The Cloud Service includes one (1) Production Environment that supports up to 200 Trials and one (1) Non-Production Environment for user acceptance testing that supports up to 200 Trials.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Instances defined in Your order
- You will need to purchase another Instance of Central Coding should you deploy more than 200 Trials.
- Database Storage: 250 GB per Instance

Disaster Recovery and Service Availability

As described in the Oracle Cloud Policies, this Oracle Cloud Service has the following Recovery Time and Recovery Point Objectives and Target Service Availability Level for the Production Environment:

RECOVERY TIME OBJECTIVE (RTO)	RECOVERY POINT OBJECTIVE (RPO)	TARGET SERVICE AVAILABILITY LEVEL
90 days	48 hours	99%

The RTO, RPO, and Target Service Availability Level do not apply to the Non Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. The Recovery Time and Recovery Point Objectives do not apply to customizations or third party software. For the purposes of this Cloud Service, the RTO, RPO, and Target Service Availability Level above take precedence over anything to the contrary in the Oracle Cloud Policies.

Oracle Cloud Policies

Your order for this Oracle Cloud Service is subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Deliverables and Customer Dependencies

Oracle Responsibilities – For a new Central Coding deployment, Oracle will provide the following common deliverables that apply to projects:

- Validation Package – If You build Your own Trials and Central Coding integration, You may request from Oracle a Validation Package document for Your Central Coding integration. The Validation Package may be used by You to perform Installation Qualification (IQ), Operational Qualification (OQ) and/or Performance Qualification (PQ) for the Central Coding integration.

- Online training for Central Coding for the named Trials for Central Coding users. The list of available online course(s) for Central Coding is provided in the Oracle Life Sciences Online Training for Oracle Life Sciences InForm Cloud Service Data Sheet

Your Responsibilities – Your responsibilities related to the above services are dependent upon the components included in the project, including but not limited to:

- Central Coding must be configured by You, or Oracle may assist with Your configuration of Central Coding for an additional fee.

- It is Your responsibility to include Central Coding items (such as dictionary version, coder/approver name, etc.) in the InForm eCRF design requirements for those eCRF's that are to be integrated with Central Coding in order to ensure that the InForm Cloud Service decommissioning package includes all relevant Central Coding information. A Central Coding database extract is specifically excluded.

Third Party Licensing Requirements

Dictionaries must be licensed separately. You are solely responsible for licensing any dictionaries used (e.g., MedDRA or WHODD) and must maintain a valid license to such dictionaries for the

duration of the Services Period. Such dictionaries are considered "materials" provided by You for purposes of the infringement indemnification obligations of the applicable agreement governing use of the Cloud Service.

Oracle will use reasonable efforts to attempt to verify with the appropriate licensing authority (e.g., MSSO or WHO) that You have a valid license prior to loading the dictionary in the Central Coding Instance and on an annual basis. However, this does not alleviate Your obligations to maintain a valid license to such dictionaries.

Oracle may suspend access to the Cloud Service immediately if Your dictionary licenses have expired. In such an event, You remain responsible for payment obligations under Your order.

Retrieval of Your Content and Information

Oracle will make Your Content from the Cloud Service available for the purpose of data retrieval by You as provided below, in accordance with Your Agreement and the Oracle Cloud Policies.

- Your Content for this Cloud Service is included with the Oracle Life Sciences InForm Cloud Service and is subject to Your Responsibilities above.