Oracle Life Sciences

Design Environment 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).

Oracle Life Sciences Design Environment Cloud Service – Instance

Part #s:

- B91579
- *B91664 (Retired)*

Modules and Features

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

- Central Designer

- InForm

- InForm Adapter (ODM (Operational Data Model), CIS (Clintrial Integration Solution), and Discrepancy interfaces only)

Note: Use of Cognos reporting with InForm is excluded.

Users and Access by Users

Your use of this Cloud Service is limited to personnel related to Your Trial(s) as authorized by You. Normally this consists of personnel from Your Company and may also include other sub-contracted personnel such as Contract Research Organization personnel. It is Your responsibility to ensure that anyone who is authorized by You to access this Cloud Service has a unique and individual account provisioned in order to enable appropriate audit trails.

Identity and Access Management Service (IAMS): Oracle Life Sciences Identity and Access Management Service (IAMS) provides Oracle single sign-on (SSO) functionality for Design Environment Cloud Service for IAMS-enabled versions. IAMS manages identity and access requests by Users and roles. IAMS uses coarse-grained authentication to evaluate if Users have been assigned privileges to the area of the Cloud Service that they are trying to access. When accessing this Cloud Service 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 instances. IAMS will is not supported for Training instances. Fine-grained privilege access control features may be accessed through this Cloud Service as described in the Central Designer program documentation.

Environments

For each Instance ordered, Oracle will provision one (1) Production Environment for Central Designer and one (1) Non-Production Environment for InForm.

Usage Limits

This Cloud Service is subject to usage limits based on:

- Number of Instances defined in Your order

- **The following usage limits apply per Instance:** An Instance has a maximum limit of up to 10 development Trials at a time. Each Instance of this Cloud Service and all Trials on that Instance are tied to a specific Central Designer version and to a specific InForm version required to support a

maximum of up to 10 development Trials at a time. Should You exceed this limit, You will need to purchase an additional Instance.

- The purpose of this Cloud Service is to build and test Your InForm Trial(s) prior to deployment to a Production instance. This Cloud Service is not intended to perform in a manner consistent with an Oracle Production instance that is designed for hosting live clinical Trials or live Data. You may not load into this Cloud Service any protected health information (PHI) or similarly sensitive personal information that imposes specific Data security obligations for the processing of such Data.

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	99.5%

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

The Services are 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 – Oracle responsibilities and deliverables include:

- Backups – Oracle will make daily backups of hosted application system and database files for this Cloud Service. Backups are not intended for and cannot be used for purposes of archiving a Trial.

- Performing patches and major and minor upgrades of Central Designer (including Data migration where applicable) and InForm.

- Provisioning of additional Central Designer and InForm servers within the environment that are required to accommodate upgrades for Central Designer and Oracle hosted InForm Trials. The additional servers are intended for major and minor upgrades for interim periods as follows: for Central Designer, up to 3 months; for InForm, up to 12 months. Upon completion of upgrades to Central Designer or to Oracle hosted InForm Trial(s), the server(s) required during the upgrade period will be decommissioned.

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

- Any Data migrations between InForm versions within this Cloud Service are excluded.

Your Responsibilities – You are responsible for the following activities:

- Building and testing the InForm Trial design (including but not limited to form design, visit structure design, and edit check programming) in accordance with Your standard operating procedures and/or work instructions, as well as creating and testing Your own test cases.

- Ensuring that InForm Trial designs (including design changes) are deployed to the InForm UAT instance and/or Production instance.

- Ensuring that all Users are trained prior to accessing this Cloud Service. This includes maintaining all training records.

- Provisioning and maintenance of all application administrator and User accounts for Your Users within the Oracle programs, including:
    - o provisioning of accounts for Oracle as required for support
    - o management of password policies and complexity

- Requesting software upgrades

- You agree that this Cloud Service is not certified under the Health Insurance Portability and Accountability Act (HIPAA) security standard and Oracle shall not be responsible for compliance under this standard. You shall comply with all laws to the extent that such laws are applicable to Your use and receipt of this service.

- Performance of the InForm program and prerequisite Oracle database will vary based on Your configuration and use. You should use the InForm program and Oracle database in accordance with Oracle documentation and recommended practices.

- Notwithstanding anything to the contrary in the agreement or the Service Specifications, You are responsible for extracting any configuration data, files, and custom functions that You require prior to decommissioning of Your InForm Trial(s). These will not be available for retrieval after the InForm Trial has been decommissioned. Oracle will not provide data or files from this Cloud Service.

- Managing InForm Trials, including start/stop/delete/configure, system configuration, and maintaining Trial server data

- Deploying Trials and copying Trial metadata design files (e.g. Central Designer deployment package, XML files) to the InForm server as needed

- You are solely responsible for necessary security for Your infrastructure and systems on which the InForm program and prerequisite Oracle database are installed. You are also responsible for addressing any issues or user requests that involve Your infrastructure, hardware, device, and software.

Retrieval of Your Content from the Cloud Service

For each InForm Trial: You are responsible for extracting any configuration data, files, and custom functions (**"Your DECS Content"**) that You require prior to submitting Your Request for Decommission for each of Your InForm Trials. Your DECS Content will not be available for retrieval after the applicable InForm Trial has been decommissioned.

At the End of the Services Period: Notwithstanding anything to the contrary in the Oracle Cloud Policies, Your Content residing in this Cloud Service will not be available for retrieval after expiration of the Services Period.