ORACLE

Oracle Life Sciences

InForm Trial Capacity Cloud Service

Service Descriptions and Metrics

13-July-2023

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METRIC DEFINITIONS

Customer

Customer is defined as the customer entity specified on Your order. The programs may not be used or accessed for the business operations of any third party, including but not limited to Your customers, partners, or Your affiliates. There is no limitation on the number of computers on which such programs may be copied, installed and used.

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

Data

For the purposes of this Service Description document, "Data" is clinical data. Data may be referred to as Your Content in Your respective agreement with Oracle for the Cloud Services.

InForm Trial Capacity Services Environment

"InForm Trial Capacity Services Environment" refers to the hosted environment for the InForm Trial Capacity Cloud Service, consisting of infrastructure and supporting software, which contains capacity for deploying Trial Packs for multiple Trials

Production instance

A **"Production instance"** is an instance for production use. Where applicable, a Production instance is used to capture Data.

Training instance

A **"Training instance"** is a non-production instance for training. The Training instance may be used by You to conduct training in addition to the online training provided.

Trial

A 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).

Trial Pack

A Trial Pack is the set of instances that are deployed for an individual Trial. Each Trial Pack includes a Production instance, a UAT instance, and if requested by You, a Training instance.

UAT instance

A **"UAT instance"** is a non-production instance for user acceptance testing. The UAT instance is used to perform user acceptance testing prior to production go-live and to test changes and fixes after

production go-live.

REGULATORY COMPLIANCE

Information on Oracle's practices for certain regulatory standards applicable to the Oracle Life Sciences InForm Trial Capacity Cloud Services as described in this Service Description may be viewed at support.oracle.com (Doc ID 2158526.1). References therein to Oracle's design, development, testing, or validation as they relate to Trial Build and Configuration Services apply only where You have ordered Trial Build or other Configuration services from Oracle.

SERVICE DESCRIPTIONS

Oracle Life Sciences InForm Trial Capacity Cloud Service – Customer

Part #s:

B91578 – Oracle Life Sciences InForm Trial Capacity Cloud Service

Cloud Service Set Up

Your Oracle Life Sciences InForm Trial Capacity Services Environment will be deployed in a hosting facility and will be maintained and managed by Oracle. Within the InForm Trial Capacity Services Environment Oracle will set up a Trial Pack for each Trial upon Your request, which will allow deployment of a Trial configuration for each Trial.

In addition to the online training provided, You may also contact Oracle for additional training options for which there may be additional cost. More information is available here.

Modules and Features

Oracle Life Sciences InForm Trial Capacity Cloud Service includes access to the following modules:

- InForm program
- InForm Adapter
- InForm CRF Submit
- InForm Portal
- InForm Publisher
- InForm Report Extractor (RE)
- Lab Normals Management Tool (LNMT)
- User Management Tool (UMT)
- User Management Interface
- Identity and Access Management Service (IAMS)

Measurement for Trial Capacity

The Trial Capacity is the maximum number of Concurrent Trials that may be deployed within Your InForm Trial Capacity Services Environment at any time during the applicable Services Period Year in accordance with Your Ordering Document ("Trial Capacity").

Each Concurrent Trial is measured starting from the first deployment of any Trial design for such Trial within any instance on Your InForm Trial Capacity Services Environment and ending when the Request for Decommission for such Trial has been submitted by You to Oracle (each a "Concurrent Trial").

The total aggregate number of Concurrent Trials shall not exceed the Trial Capacity for the applicable Services Period Year as set forth in Your Ordering Document.

Users and Access by Users

Your use of the Cloud Service is limited to personnel related to Your Trial(s) as authorized by You. Normally this consists of two main groupings of personnel: sponsor and site. The sponsor group typically consists of personnel from Your company and may also include other sub-contracted personnel such as Contract Research Organization personnel, monitors, and data managers. The site

personnel typically consist of the site coordinators (clinical research coordinators) and study investigators (principal investigators and sub-investigators).

Identity and Access Management Service (IAMS): Oracle Life Sciences Identity and Access Management Services (IAMS) provides Oracle single sign-on (SSO) functionality for InForm Trial Capacity Cloud Service for IAMS-enabled versions of InForm. 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 an InForm page that they are trying to access. For IAMS-enabled versions of InForm, Users may access an InForm page to which they are provided privileges using a single sign-on account. Once an InForm page is accessed by a User using a single sign-on account, the User will automatically be signed into such InForm page for future access. IAMS is supported for UAT and Production instances. IAMS will not be supported for Training instances. Fine-grained privilege access control features may be accessed through the InForm program as described in the InForm program documentation.

Environments

This Cloud Service includes one (1) Trial Pack per Trial (one (1) Production instance, one (1) UAT instance, and one (1) Training instance.)*

* A Training instance will be provided if requested by You.

Usage Limits

This Cloud Service is subject to usage limits based on:

- Maximum number of Concurrent Trials per Your Ordering Document

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 uses commercially reasonable efforts to complete Cognos reporting installations within 5 business days from the date the request is submitted.

Third Party License Requirements:

Oracle Life Sciences InForm Trial Capacity Cloud Service includes Cognos reporting in the Production and UAT instances. Cognos reporting is not available for Training instances.

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.

The *Oracle Life Sciences Cloud Services – GA and EOL Dates* document, which is available on the Oracle Life Sciences Support Cloud system (at https://hsgbu.custhelp.com/), lists current generally available (GA) and end of life (EOL) Oracle Life Sciences Cloud Service versions.

Deliverables and Customer Dependencies

Oracle Responsibilities – The deliverables for a given project are dependent upon the components included in that project. Not all projects will produce all of the deliverables and entitlements listed below. Some common deliverables and entitlements that apply to projects include:

- InForm Application Release for Go-Live – This is the release by Oracle for each Trial of the configured InForm program in the Production instance of the Trial Pack on Your InForm Trial Capacity Services Environment that Your approved Users may access.
- Database Extracts for Each Trial – These database extracts may be used by You to analyze and report on Your Data captured by the configured InForm program.
- Archives – Archives and reports for Your Trials are available for You and Your Sites to generate and download via the InForm CRF Submit self-service functionality within the InForm Trial Capacity Cloud Service, subject to Your obligations below. There is no limit on the number of CRF Submit Self-Service Files which may be generated by You and Your Sites through CRF Submit during a Trial up to Your Request for Decommission for such Trial.
- Online Training for Each Named Trial for InForm Users and for User Management Tool (UMT) Users – The list of available online courses is provided in the Oracle Life Sciences Online Training for Oracle Life Sciences InForm Cloud Service Data Sheet
- User Management Tool (UMT) Non-Production Environment – Except for critical patch updates, the latest generally available release of UMT will be released in the UMT non-production environment prior to release in the UMT production environment. Your UMT Users are entitled to access the latest generally available release of UMT in the UMT non-production environment to try new features, to update Sponsor internal standard operating procedures, and to train Sponsor end users to perform common trial administration tasks (including import of Users, Sites, and roles) prior to accessing the latest generally available release of UMT in the UMT production environment. The UMT non-production environment has no connectivity to InForm or Identity and Access Management Service (IAMS). Except for critical patch updates, the latest generally available release of UMT will be deployed in the UMT non-production environment, at Oracle's discretion, approximately three calendar weeks to 60 calendar days prior to release in the UMT production environment. The release preview timeframe will vary depending on the content of the release and the significance of new features.
- Clinical Development Analytics (CDA) – If requested by You for a Trial, Oracle will deploy the Oracle Life Sciences Clinical Development Analytics (CDA) integration package into the InForm Trial database(s) to help support integration of the Trial with compatible versions of CDA that You have licensed and deployed outside of the Oracle Cloud Services environment.
- Lab Normals Management Tool – The Oracle Life Sciences InForm Trial Capacity Cloud Service includes Lab Normals Management Tool (LNMT), which is designed to allow association of lab

results in a Trial with lab normal ranges. LNMT must be configured by You for each Trial. Oracle may assist with Your configuration of LNMT for an additional fee.

- InForm Integration – The Oracle Life Sciences InForm Trial Capacity Cloud Service includes deployment of Standard File-Based Integrations with Your InForm Trials if requested by You. A Standard File-Based Integration integrates InForm Trials with certain external systems via a flat file transfer. Each integration must be configured by You. Oracle may assist with Your configuration of the integrations for an additional fee.
- Report Extractor – If requested by You, Oracle will deploy Report Extractor for You to use with Your InForm Trial(s). Oracle will initially configure Report Extractor to connect to up to 200 of Your InForm Trials. Initial configuration may include configuration of Report Extractor for up to 20 Cognos Reports or SQL objects, which must be developed by You, or Oracle may assist with Your development of Cognos Reports or SQL objects for an additional fee. Design of the Cognos Reports or SQL objects must conform to Report Extractor requirements and specifications. After initial configuration of Report Extractor by Oracle, You will be responsible for any further configuration changes.
- Clinical One Digital Gateway – If Your Trial includes integrations that require Oracle Life Sciences Clinical One Digital Gateway, Your use of Oracle Life Sciences Clinical One Digital Gateway is included with Your purchase of Oracle Life Sciences InForm Cloud Service. Any such integration(s) must be configured by You, or Oracle may assist with Your configuration(s) of the integration(s) for an additional fee.
- Maintenance of the Cloud Services **–** Oracle will maintain the Cloud Services for each Trial, including upgrades, in accordance with the *Oracle Cloud Hosting and Delivery Policies* and the *Oracle Global Business Unit Cloud Service Pillar Document*. Upgrades are applied per InForm server and all Trials on the same server are upgraded at the same time.
    - Maintenance of the Production instance(s) **–** Upgrades and migrations are scheduled with You and are performed during the maintenance window.
    - Maintenance of the UAT instance(s)
        - Upon request, Oracle will update the UAT instance for a Trial with a fresh extract of the Production instance each time a change or fix to the InForm program in the Production instance requires testing.
        - Upgrades and migrations are scheduled with You and are performed during business hours.
        - For Trials using InForm versions prior to version 6.1.1, maintenance of the UAT instance may require a maintenance window for Your Production instance.
    - Maintenance of the Training instance(s)
        - If applicable, You may request that the Training instance for a Trial be updated to reflect subsequent changes or fixes within the corresponding Production instance. Copying Data from the Production instance to the Training instance is not allowed.
        - Upgrades and migrations are scheduled with You and are performed during business hours.
- Production instance backups **–** The terms of the O*racle Cloud Hosting and Delivery Policies* and the *Oracle Global Business Unit Cloud Services Pillar Document* apply for the purpose of

Production instance backups. Backups are not intended for and cannot be used for purposes of archiving a Trial. Oracle will make the following backups of Your Data hosted by Oracle in the Production instance for each Trial.

  - Daily backups of hosted application system and database files.
  - On four-hour intervals, backups are made of the Oracle Database Archive files where applicable.
  - Daily replication of backups to an offsite facility.

- For each Trial, a decommissioning package (i.e. archival Trial database and associated files related to hosting the Production instance including integrations, if any) will be provided to You for download after decommissioning. Notwithstanding anything to the contrary in the agreement or the Service Specifications, Oracle provides Your Data from the Production instance of the Cloud Services as part of the decommissioning package for a Trial. You will have 60 days to review and accept the decommissioning package for a Trial as described under Your Responsibilities below.
- For each Trial, archival documentation related to Oracle services will be provided to You for download periodically during the Services Period.

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

- If You require a Training instance for Your Trial, You are responsible for requesting that Oracle deploy a Training instance.
- If You build Your own Trials, (i) the initial Trial build related to project initiation and program set-up tasks to prepare the InForm program for user acceptance testing; and (ii) any post go-live fixes and changes.
- In accordance with Your standard operating procedures and/or work instructions, testing the InForm Trial configuration (e.g. conducting user acceptance testing) as well as creating and testing Your own test cases.
- In accordance with Your standard operating procedures and/or work instructions, ensuring packages and scripts are adequately tested before sending them to Oracle for deployment on Your UAT and Production instances. For any packages or scripts submitted by You, it is Your responsibility to examine the implementation logs for potential error messages and take appropriate action. Note that a 'successful' ticket completion means the script completed with or without errors.
- For integration of Your InForm Trials to Clinical Development Analytics (CDA), You are responsible for submitting a request for the deployment of the CDA integration package to each InForm Trial. For CDA deployed on Your premise, You will also need to provide necessary network connectivity to support this integration (e.g. VPN, MPLS, other such network connectivity) which may need to be ordered separately.
- User Management – You are responsible for managing access to Your Trial using the Identity and Access Management Service (IAMS), as well as adding Site and User information into User Management Tool (UMT) and/or for the initial creation of the Sites and Users by providing a completed Oracle template listing the Site and User information to be loaded into UMT.
- Performing testing and training in the UMT non-production environment in accordance with Your standard operating procedures and/or work instructions as well as creating and testing Your own test cases.

- Ensuring that all users are trained prior to accessing the system. This includes maintaining all training records.
- All Data management activities for the Trial, including but not limited to dictionary coding, query resolution, Serious Adverse Event ("SAE") reconciliation, and Trial lock.
- Managing and overseeing third party vendors (e.g., lab vendors, external partners, Your subcontractors, etc.). If Oracle will not supply End User Helpdesk support then You must ensure Your End User Helpdesk vendor is aware they need to administer Oracle users where appropriate.
- While InForm may be used to assist in adverse event notification, InForm is not designed to be a comprehensive safety case handling system. Should You decide to use the Cloud Service for collection and reporting of serious adverse events, You remain responsible for ensuring that all applicable regulatory obligations are met.
- Database Extracts – For each Trial, it is Your responsibility to request an export online and to download the export. Authorized Users may obtain a database extract in one of two ways:
    - Proactively log into InForm and generate an extract as needed
    - Request Oracle to schedule the extract generation – You may request up to once per day for each Trial in this manner
- Archives for Your Trial
    - You and Your Sites are responsible for generating, downloading, and maintaining archive and/or study submission PDFs, as well as any reports (**"CRF Submit Self-Service Files"**) that You or Your Sites may require for Your Trial through CRF Submit. Archive files are intended to document the Data as it existed in Your Production instance of the configured InForm program.
        - There is no limit on the number of CRF Submit Self-Service Files which may be generated by You and Your Sites through CRF Submit during a Trial up to Your Request for Decommission of the applicable Trial.
        - You may choose to generate CRF Submit Self-Service Files on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their CRF Submit Self-Service Files directly using CRF Submit.
        - CRF Submit Self-Service Files will be deleted or otherwise rendered inaccessible by Oracle upon the earlier of 120 calendar days after they were generated or decommissioning of the applicable Trial, and the CRF Submit Self-Service Files will not be available for download after such time. CRF Submit, and the CRF Submit Self-Service Files, will not be available after decommission of the Cloud Service.
        - You are responsible for making Your Sites aware of the services and their obligations hereunder.
        - If at any time there is a failure in the storage drive that stores CRF Submit Self-Service Files and storage cannot be restored after commercially reasonable effort, then You are responsible for regenerating the files using CRF Submit.
        - Your Request for Decommission confirms both Your and Your Sites' acceptance of the CRF Submit Self-Service Files. You are responsible for ensuring that You do not submit Your Request for Decommission until You and Your Sites have requested, downloaded, and reviewed the CRF Submit Self-Service Files that You and Your Sites require. It is

recommended that You request Database Lock and that the final CRF Submit Self-Service Files be generated and downloaded by You and Your Sites in a manner that permits sufficient time for review prior to the end of the Services Period. You are responsible for executing any extensions to Your order that You and Your Sites may require due to Your failure to submit Your Request for Decommission by the end of the Services Period.

- Reviewing and accepting the following deliverables within sixty (60) calendar days of Oracle's notice that the deliverables are available to you (the "acceptance period")by signing the designated Oracle forms within the acceptance period. If You fail to provide written notice of non-acceptance to Oracle within the acceptance period, as provided above, the deliverables shall be deemed accepted as of the end of the acceptance period and Oracle may permanently delete or otherwise render inaccessible the deliverables and Your Trial Data in Your instance(s):
    - the decommissioning package
    - relevant archival documentation related to Oracle services
- Distributing the decommissioning package and archival documentation, as appropriate
- Submitting a Request for Decommission for each Trial.
- Submitting the Request for Decommission for the last Trial in Your InForm Trial Capacity Services Environment prior to the end of the Services Period.
    - All Trials must be decommissioned by the end of Your Services Period unless the Services are extended or renewed in accordance with Your Ordering Document; otherwise Your InForm Trial Capacity Cloud Service, including any remaining Trials, will terminate upon the end of the Services Period.

Retrieval of Your Content and Information

Oracle will make Your Content from the Cloud Service available for retrieval by You in accordance with Your Agreement and the Oracle Cloud Policies as provided below, and You are responsible for retrieving Your Content within the applicable timeframe.

- Prior to submitting Your Request for Decommission for each Trial, You may generate and retrieve archives and/or study submission files in PDF format, as well as other reports, by using the CRF Submit self-service feature in the Cloud Service.
- After You have submitted Your Request to Decommission for each Trial, Oracle will also place on Oracle's sFTP site a copy of the Cloud Service database for such Trial, which may be used to recommission the Cloud Services if required.

Oracle will make the information below for the Cloud Service available for retrieval by You as provided below, in accordance with Your Agreement and the Oracle Cloud Policies.

- Support service request information is available via the Oracle Life Sciences Support Cloud. You are responsible for requesting and retrieving such information as needed to address your record retention purposes.
- Where required You may request a listing of user logon activity to the Cloud Service via a Service Request through the Oracle Life Sciences Support Cloud.

Central Coding

Central Coding is included with your InForm Trial Capacity Cloud Service if listed in the included Services in Your Ordering Document.

Modules and Features

Users of Central Coding 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.

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 Central Coding 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 instances, but is not be supported for Training instances. Fine-grained privilege access control features may be accessed through the Central Coding program as described in the Central Coding program documentation.

Environments

Each Instance of the Cloud Service includes one (1) Production Environment for production use and one (1) Non-Production Environment for user acceptance testing.

Usage Limits

In addition to any usage limits in Your order, this Cloud Service is subject to usage limits based on:

- The quantity of Instances defined in Your order
- The following usage limits apply per Instance:
  - The Production Environment and the Non-Production Environment each have a maximum limit of 50 Trials at a time. Should You exceed this limit, You will need to purchase an additional Instance.
  - An Instance is limited to a maximum of 250 GB of Database Storage.

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

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 – For a new Central Coding deployment, Oracle will provide the following common deliverables that apply to most 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 documentation 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 Trial 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 Services.

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

environment 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 Services immediately if Your dictionary licenses have expired. In such an event, You remain responsible for payment obligations hereunder.

Retrieval of Your Content from the Cloud Service

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

Design Environment Cloud Service (DECS)

Design Environment Cloud Service is included with your InForm Trial Capacity Cloud Service if listed in the included Services in Your Ordering Document.

Modules and Features

Users of Design Environment Cloud Service ("DECS") 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, but 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

The Cloud Service includes one (1) virtual application server for Central Designer and one (1) virtual application test server for InForm per Trial.

Usage Limits

In addition to any usage limits in Your order, this Cloud Service is subject to usage limits based on:

- The quantity 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 for DECS include:

- Backups – Oracle will make daily backups of hosted application system and database files. 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 (this includes and is not limited to form design, visit structure design, and programming of edit checks) 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:
    - provisioning of accounts for Oracle as required for support
    - 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 (**"Your DECS Content"**) that You require prior to submitting Your Request for Decommission for each of Your InForm Trial(s). Your DECS Content will not be available for retrieval after an 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

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

End User Helpdesk

End User Helpdesk is included with your InForm Trial Capacity Cloud Service if listed in the included Services in Your Ordering Document.

Users of the Oracle Life Sciences InForm Trial Capacity Cloud Service End User Helpdesk ("End User Helpdesk") may use the Services to perform the following activities:

- Routine User Management
    - InForm User activation/inactivation requests
    - InForm User termination/un-termination
    - InForm Site or User addition or change
    - InForm User password change
- Management of User Management Tool (UMT) accounts
- Change of InForm Trial configuration settings
- Creation/change of rights, roles, and groups
- Change of Trial version

End User Helpdesk is available in the following languages during normal Oracle business hours in the GMT time zone only, except if otherwise noted:

- English (available 24x7)
- Spanish
- French
- German
- Italian
- Japanese (available normal Oracle business hours in the JST time zone only)

Service Level Targets

End User Helpdesk has the following service level targets:

- Severity Level 1 issues will be responded to within one hour of the User logging a ticket.

  For the purpose of InForm Trial Capacity Cloud Service End User Helpdesk, Severity Level 1 is a catastrophic issue impacting multiple system Users of an active Production system. The issue may be perceived as presenting potential Data integrity risks**.**

Oracle Cloud Policies and Pillar Documentation

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.

Oracle Life Sciences InForm Trial Capacity Cloud Service Enhanced Disaster Recovery

Oracle Life Sciences InForm Trial Capacity Cloud Service Enhanced Disaster Recovery is included with your InForm Trial Capacity Cloud Service if listed in the included Services in Your Ordering Document.

Usage Limits

The Oracle Life Sciences InForm Trial Capacity Cloud Service Enhanced Disaster Recovery is subject to usage limits based on the following.

- Limited to Trials using InForm version 6.2 or later
- For Production instances only
- Supported for the following modules only:
  - InForm program
  - User Management Interface
  - InForm Adapter
  - InForm Publisher
  - Lab Normals Management Tool (LNMT)
  - Standard File-based Integrations (formerly known as IVRS)

Disaster Recovery and Service Availability

The InForm Trial Capacity Cloud Service Enhanced Disaster Recovery 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
24 hours	24 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.

Retrieval of Your Content from the Cloud Service

Your Content for this Cloud Service is the same as Your Content for the Oracle Life Sciences InForm Trial Capacity Cloud Service.