Oracle Health Sciences
Design Environment Cloud Service (DECS)
Service Descriptions and Metrics
November 14, 2016

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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.
Oracle Health Sciences Design Environment Cloud Service (DECS) – Instance

Your Oracle Health Sciences Design Environment Cloud Service (DECS) environment will be deployed in a hosting facility and will be maintained and managed by Oracle. The deployment of the DECS environment will consist of Central Designer and InForm. The purpose of this environment is to build and test InForm Trials prior to the deployment of a production environment. Each Instance of DECS 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. This DECS environment is not intended to perform in a manner consistent with an Oracle production hosting deployment that is designed for hosting live clinical trials or live data. You may not load any protected health information (PHI) or similarly sensitive personal information that imposes specific data security obligations for the processing of such data into the DECS environment.

Oracle Health Sciences Design Environment Cloud Service - Users and Access by Users

Your use of the DECS is limited to personnel related to Your Study 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 the environment has a unique and individual account provisioned in order to enable appropriate audit trails.

Oracle Health Sciences Design Environment Cloud Service - Deliverables and Customer Dependencies

Oracle responsibilities and deliverables under DECS include:

Responsibilities

- Configure Your dedicated virtual network (VLAN).
- Configure firewall and F5 content switch rules to secure Hypertext Transfer Protocol Secure (HTTPS) access to Oracle Programs.
- Manage Domain Name Service (DNS) inside of the DECS environment
- Install and configure virtual servers and physical Oracle database servers (where applicable) and the associated Storage Area Network (SAN) and tape storage devices.
- Install and configure the Oracle Programs and related Oracle database instance.
- Patch operating system and databases, where applicable.
- Create table spaces to be used with required applications
- Create operating system and database accounts required to install required applications
- Install and manage Anti-virus software on Windows servers
- Maintain database instance availability
- Manage database system table spaces
- Monitor system availability, file system usage, operating systems, CPU usage, and memory usage
• Backups - Oracle will make the following backups for the purposes of DECS: (Backup media is not intended for use as archive of study for any purposes other than as a means of data protection at a secure off-site location and to provide the ability for recovery activities to occur in the event of a disaster)
  o Daily backups of hosted application system and database files.
• Prior to handover to You, perform environment functional verification check after initial provisioning and after upgrades.
• Provide You with environment documentation
• Perform patches and major and minor upgrades of Central Designer instances (including data migration where applicable).
• Conduct regular maintenance of the environment, including upgrades to new releases of the Oracle Programs as described in the Ordering Document, including the Service Specifications, upon request or as determined by Oracle.
• Provision additional instances and upgrades of InForm servers within DECS that are required to accommodate upgrades for Oracle hosted InForm trials are included; this provisioning is intended for major and minor upgrades for interim periods of up to 12 months; upon completion of upgrades to Oracle hosted InForm trials, the servers required during the upgrade period will be decommissioned.
• Provision additional instances and upgrades of Central Designer servers within DECS that are required to accommodate upgrades for Central Designer are included; this provisioning is intended for major and minor upgrades for interim periods of up to 3 months; upon completion of upgrades to Central Designer, the servers required during the upgrade period will be decommissioned.
• Provide technical support for the Oracle Program as set forth in the Ordering Document.
• Online training for Central Designer for Central Designer users. The list of available online course(s) for Central Designer is provided in the Oracle Health Sciences Online Training for Oracle Health Sciences InForm Cloud Service Data Sheet.

In addition to the activities above, the following activities to provision, set-up and maintain InForm within the DECS apply:
• Work with You to provision the VPN from the DECS environment to Your premise
• Configure firewall and F5 content switch rules to secure remote access ¹ to Your virtual servers and the Oracle database server from Your facilities.
• Provision Your administrator accounts in operating system

¹ Note: Secure remote access currently defined as Hypertext Transfer Protocol Secure (https) and either secure shell (ssh) or terminal service access to the applications and servers in the VLAN.
• Provision Your administrator accounts in database
• Provide You with access to URI Manager tool
• Any data migrations between InForm versions within DECS are excluded.

Deliverables

Oracle deliverables for a single instance of DECS include:
• Central Designer software usage that comprises of the required virtual application server setup and hosting and prerequisite Oracle database.
• InForm application software usage that comprises of the required virtual application server test environment setup and hosting and prerequisite Oracle database.

You are responsible for the following activities related to DECS:
• 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 own 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 this environment for DECS activities. This includes maintaining all training records.
• Provisioning and maintenance of all application administrator and user accounts for Your users within the Oracle Programs
• Includes provisioning of application accounts for Oracle as required for support
• Includes management of password policies and complexity
• Requesting software upgrades
• You agree that the DECS environment 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 application and prerequisite Oracle database will vary based on Your configuration and use. You should use the InForm application and Oracle database consistent with Oracle documentation and recommended practices.

In addition to the activities above, You will be responsible for the following activities for InForm within the DECS:
• Work with Oracle to provision the IPSEC site to site VPN from Your premise to the DECS environment
• Provisioning required operating system accounts for Your users using the Oracle provided customer administrator account
• Provisioning required database accounts (e.g. to deploy trials or load data) using the Oracle provided customer administrator account
- Deploying InForm Trial servers and enable Trial servers to the Internet via URI Manager Tool
- Managing InForm Trial servers (start/stop/delete/configure)
- Managing InForm Trial server system configuration
- Copying trial metadata design files (e.g. Central Designer deployment package, XML files) to InForm server as needed
- Maintaining Trial Server data
- Loading InForm data extracts when desired including transferring extract files, creating trial specific table spaces (as required) and loading data
- Dropping InForm data in database as required
- Managing file system space as necessary
- Ensuring that required data is not deleted
- Ensuring that database or operating systems are not restarted
- Ensuring that operating system, database, or application security hardening is not relaxed
- You shall also have the right to download and self-host and use the InForm application and prerequisite Oracle database solely in connection with your order for DECS. You may not use the InForm application and prerequisite database for any other purpose including deployment of studies into production. Your right to use the InForm application and Oracle database shall co-terminate with Your order for DECS and at termination you shall no longer use the InForm application and Oracle database and shall uninstall the InForm application and Oracle database from Your system.

- You may download the InForm application and prerequisite Oracle database at the following URL: [http://edelivery.oracle.com](http://edelivery.oracle.com). You acknowledge that Oracle is under no further delivery obligation under this Service Description or Your order. You are solely responsible to ensure proper installation and configuration of the InForm application and prerequisite Oracle database and You are responsible for all related costs for configuration and installation.

- You are solely responsible for necessary security for Your infrastructure and systems on which the InForm application 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.

**Users of the Oracle Health Sciences Design Environment Cloud Service are authorized to access the following modules:**

- Central Designer
- InForm and the following InForm integration product –
  - InForm Adapter

  Note: Use of Cognos reporting with InForm is excluded.
**Usage Limits**: Oracle Health Sciences Design Environment Cloud Service is subject to usage limits based on:

- Number of Instances contracted
- The following usage limits apply per licensed metric:

<table>
<thead>
<tr>
<th>Metric</th>
<th>Database Storage (Records)</th>
<th>File Storage (GB)</th>
<th>Bandwidth</th>
<th>Included with Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instance</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>An Instance has a maximum limit of up to 10 Development Trials at a time. Should You exceed this limit, You will need to purchase an additional Instance.</td>
</tr>
</tbody>
</table>

**Service Level Targets**: The Oracle Health Sciences Design Environment Cloud Service has the following service level targets:

<table>
<thead>
<tr>
<th>Cloud Service</th>
<th>Recovery Time Objective (RTO)</th>
<th>Recovery Point Objective (RPO)</th>
<th>Target System Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>DECS (Central Designer component)</td>
<td>90 Days</td>
<td>48 hours</td>
<td>99%</td>
</tr>
<tr>
<td>DECS (InForm component)</td>
<td>N/A</td>
<td>N/A (data is not stored offsite)</td>
<td>99% (infrastructure only)</td>
</tr>
</tbody>
</table>

**Oracle Cloud Policies**

The Oracle Cloud Hosting and Delivery Policies describe and govern the Central Designer components. The Oracle Health Sciences Design Environment Cloud Service, Service Level Guide describes and governs the InForm components. Both policies are part of the Service Specifications of Your order and may be viewed at www.oracle.com/contracts.