ORACLE

Oracle Life Sciences
Clinical One Cloud Services
Service Descriptions and Metrics

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TABLE OF CONTENTS

METRIC DEFINITIONS

Integration

Integration is defined as one unique configured connection integrating data between two separate end point systems.

Integration Per Trial

Integration Per Trial is defined as one unique configured connection integrating data between two separate end point systems for the purpose of one clinical trial. Integrations connecting the same two systems for two different clinical trials will constitute two integrations.

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).

GLOSSARY

Clinical One Data Collection Capabilities and Entitlements

- Clinical One Release Assessment Environment *
- Configurable CRA and DM Dashboards
- Data Extract
- Data Review
- Central Coding *
- Electronic Signature
- Embedded Computer Based Training (CBT)
- Local Lab Entry
- Lab Range Management
- Oracle Clinical Connector (OCC)*
- Remote Data Entry
- Rule and Data Cleaning/Query Management
- SAS Exports
- Site Audit Archive (including submission-ready PDFs)
- Site Contact Management
- Source Data Verification (SDV)
- Standard Reports and Ad Hoc Analytics
- Study Archival
- Study Design
- Study/Site Closeout
- Targeted SDV
- Tabular Repeating Form Entry
- User Management

Clinical One Digital Gateway Capabilities and Entitlements

- Integration scheduling
- Integration Status Monitoring

Clinical One Randomization Capabilities and Entitlements

- Clinical One Release Assessment Environment *
- Embedded Computer Based Training (CBT)
- Randomization
- Randomization Design
- RTSM Study Specific Support *
- Site Contact Management
- Standard Reports and Ad Hoc Analytics
- Study Archival
- Study Design
- Study/Site Closeout
- User Management

Clinical One Supply Management Capabilities and Entitlements

- Clinical One Release Assessment Environment *
- Supply/Device Management
- Drug Reconciliation

** See Clinical One Entitlements section below*

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.

Patient

A "Patient" is a person who is enrolled (i.e. receiving treatment) in a Trial for which the Cloud Services are used. For the purposes of counting the quantity of Patients, the maximum number of Patients enrolled in the Trial must be counted.

Phase

For the purposes of Oracle Life Sciences Clinical One Cloud Services, "Phase" refers to the clinical research phase identified in the clinical trial protocol.

Oracle Life Sciences Clinical One Cloud Services may be used for Trials of any Phase or with no specified Phase, except as provided below.

The following Cloud Services are limited to Trials with protocols which specify Phase "I", "1", or "one":

- *B96201 - Oracle Life Sciences Clinical One Cloud Service – Basic, Data Collection, Phase 1, Single Trial* and
- *B96203 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Single Trial*.

Trials with combination phases (such as Phase I/II) or Trials with no phase (such as Trials for medical devices or other non-drug interventions) are not eligible for the Cloud Services listed in the bullets above.

Site

Site is defined as a single location from which the Service will be accessed (e.g., an investigator site or a customer location).

For the purposes of counting the number of Sites using the Oracle Life Sciences Clinical One Randomization Single Trial Cloud Service or the Oracle Life Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service, the total is the number of Sites marked Active in the Cloud Service concurrently at any time.

REGULATORY COMPLIANCE

Information on Oracle's practices for regulatory standards applicable to the handling or processing of data for the Cloud Services or delivery of Trial Build Services as described in this Service Description may be viewed at support.oracle.com. References therein to Oracle's design, development, testing, or validation as they relate to Trial Build Services apply only where You have ordered Trial Build Services from Oracle. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

SERVICE DESCRIPTIONS

Oracle Life Sciences Clinical One Cloud Service – Basic, Data Collection, Single Trial – Trial

Part #s:

- B96201 – Oracle Life Sciences Clinical One Cloud Service – Basic, Data Collection, Phase 1, Single Trial
- B96202 – Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Single Trial

Modules and Features

Users of the Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Data Collection Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Notwithstanding anything to the contrary in Your order, Your Content in the following components of Oracle Life Sciences Clinical One Cloud Services will be stored in Oracle's North America Data Center Region: Identity and Access Management Service (IAMS) and the Clinical One Release Assessment Environment.

Usage Limits

This Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.
- The following Cloud Service is limited to use for Phase 1 Trials, not inclusive of combination Trials (Phase I/II):
    - B96201 – Oracle Life Sciences Clinical One Cloud Service – Basic, Data Collection, Phase 1, Single Trial

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- Central Coding – See the Clinical One Entitlements section below.
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Archival and submission-ready PDFs may be generated and downloaded by You and Your Sites via the Archives feature. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service. All PDFs, reports, and extracts must be downloaded prior to the end of the Services Period.
    - You may choose to generate PDFs on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their PDFs directly from the Cloud Service. You are also responsible for making Your Sites aware of the services and their obligations with regard to record retention hereunder.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the "Your Responsibilities" section above.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Life Sciences Clinical One Cloud Service – Basic, Data Collection, Multi-Trial – Trial

Part #: B93067

Modules and Features

Users of the Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Data Collection Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Notwithstanding anything to the contrary in Your order, Your Content in the following components of Oracle Life Sciences Clinical One Cloud Services will be stored in Oracle's North America Data Center Region: Identity and Access Management Service (IAMS) and the Clinical One Release Assessment Environment.

Usage Limits

This Cloud Service is subject to usage limits based on:

- The quantity of Trials specified in your order
- For the purposes of counting the number of Trials using this Cloud Service, the total is the number of Trials using the Cloud Service concurrently at any time. A Trial begins when the first version of the Trial is provisioned in the Cloud Service and ends when the request to remove the Trial from the Cloud Service has been submitted to Oracle.
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- Central Coding – See the Clinical One Entitlements section below.
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Archival and submission-ready PDFs may be generated and downloaded by You and Your Sites via the Archives feature. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service. All PDFs, reports, and extracts must be downloaded prior to the end of the Services Period.
    - You may choose to generate PDFs on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their PDFs directly from the Cloud Service. You are also responsible for making Your Sites aware of the services and their obligations with regard to record retention hereunder.
- Locking and Decommissioning Your Trial(s) – You are responsible for removing access by Your Users to each completed Trial and submitting to Oracle a request to decommission each Trial.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

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.

- Prior to decommission of each Trial, You may retrieve Your Content for such Trial as described under Archival Trial Data in the "Your Responsibilities" section above.
- After decommission of each Trial, Oracle will also place on Oracle's sFTP site a copy of the production Cloud Service database for such Trial, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database may be used to recommission the Cloud Services for the Trial 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.

Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Single Trial – Trial

Part #s:

- B96203 – Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Single Trial
- B96204 – Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Single Trial

Modules and Features

Users of the Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Data Collection Capabilities and Entitlements
- All Clinical One Randomization Capabilities and Entitlements
- All Clinical One Supplies Management Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Notwithstanding anything to the contrary in Your order, Your Content in the following components of Oracle Life Sciences Clinical One Cloud Services will be stored in Oracle's North America Data Center Region: Identity and Access Management Service (IAMS) and the Clinical One Release Assessment Environment.

Usage Limits

This Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.
- The following Cloud Service is limited to use for Phase 1 Trials, not inclusive of combination Trials (Phase I/II):

- B96203 – Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Single Trial.

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- Central Coding – See the Clinical One Entitlements section below.
- RTSM Study Specific Support – See the Clinical One Entitlements section below
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Archival and submission-ready PDFs may be generated and downloaded by You and Your Sites via the Archives feature. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service. All PDFs, reports, and extracts must be downloaded prior to the end of the Services Period.
    - You may choose to generate PDFs on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their PDFs directly from the Cloud Service. You are also responsible for making Your Sites aware of the services and their obligations with regard to record retention hereunder.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the “Your Responsibilities” section above.

- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Life Sciences Clinical One Cloud Service – Plus, Data Collection and Randomization, Multi-Trial – Trial

Part #: B93068

Modules and Features

Users of the Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Data Collection Capabilities and Entitlements
- All Clinical One Randomization Capabilities and Entitlements
- All Clinical One Supplies Management Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Notwithstanding anything to the contrary in Your order, Your Content in the following components of Oracle Life Sciences Clinical One Cloud Services will be stored in Oracle's North America Data Center Region: Identity and Access Management Service (IAMS) and the Clinical One Release Assessment Environment.

Usage Limits

This Cloud Service is subject to usage limits based on:

- The quantity of Trials specified in your order
- For the purposes of counting the number of Trials using this Cloud Service, the total is the number of Trials using the Cloud Service concurrently at any time. A Trial begins when the first version of the Trial is provisioned in the Cloud Service and ends when the request to remove the Trial from the Cloud Service has been submitted to Oracle.

- No more than 25 Users may simultaneously access the Test and Training modes at any one time.

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- Central Coding – See the Clinical One Entitlements section below.
- RTSM Study Specific Support – See the Clinical One Entitlements section below
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Archival and submission-ready PDFs may be generated and downloaded by You and Your Sites via the Archives feature. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service. All PDFs, reports, and extracts must be downloaded prior to the end of the Services Period.
    - You may choose to generate PDFs on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their PDFs directly from the Cloud Service. You are also responsible for making Your Sites aware of the services and their obligations with regard to record retention hereunder.
- Locking and Decommissioning Your Trial(s) – You are responsible for removing access by Your Users to each completed Trial and submitting to Oracle a request to decommission each Trial.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

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.

- Prior to decommission of each Trial, You may retrieve Your Content for such Trial as described under Archival Trial Data in the "Your Responsibilities" section above.
- After decommission of each Trial, Oracle will also place on Oracle's sFTP site a copy of the production Cloud Service database for such Trial, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database may be used to recommission the Cloud Services for the Trial 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.

Oracle Life Sciences Clinical One Cloud Service - Randomization, Up to 75 Sites, Single Trial – Trial

Part #: B93059

Modules and Features

Users of this Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Randomization Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Notwithstanding anything to the contrary in Your order, Your Content in the following components of Oracle Life Sciences Clinical One Cloud Services will be stored in Oracle's North America Data Center Region: Identity and Access Management Service (IAMS) and the Clinical One Release Assessment Environment.

Usage Limits

The Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- A maximum of 75 Sites may be concurrently marked Active in the Cloud Service at any one time. If You require more than 75 Sites, You may purchase the optional service for Additional Sites.
- No more than 25 Users may simultaneously access the Test and Training modes at any one

time.

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
12 hours	1 hour	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.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- RTSM Study Specific Support – See the Clinical One Entitlements section below
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service and must be downloaded prior to submitting to Oracle a request to decommission the Trial.
- Locking Your Trial – You are responsible for removing access by Your Users to the completed Trial and submitting to Oracle a request to decommission the Trial.
- If You have not completed Locking Your Trial and submitting Your request to decommission by the end of the Services Period defined in Your order, You must extend or renew Your order for the Cloud Service. Except as expressly provided in Your order, You must pay Oracle through the end of the Services Period.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

Oracle Cloud Policies:

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the “Your Responsibilities” section above.

- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Life Sciences Clinical One Cloud Service – Randomization, Additional Sites, Single Trial – Trial *(Optional Service)*

Part #: B93060

Pre-Requisities

Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Randomization, Up to 75 Sites, Single Trial (Part #: B93059)

The Base Cloud Service identified above is a prerequisite for the Additional Sites option, which increases the number of Sites that may be concurrently marked Active in the Cloud Service at any one time.

Environments

This Cloud Service utilizes the environment(s) of the Base Cloud Service.

Usage Limits

The Additional Sites option is subject to usage limits based on:

- No more than 500 Sites may be simultaneously marked Active in the Cloud Service at any one time.
- The Additional Sites option is subject to the Usage Limits for the Base Cloud Service, except as otherwise specified in this section.

Your Responsibilities

- Your responsibilities for this Cloud Service are the same as Your responsibilities for the Base Cloud Service.
- You must purchase the Base Cloud Service, which is a prerequisite for use of the Additional Sites.

Oracle Cloud Policies:

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Retrieval of Your Content from the Cloud Service

Your Content for this Cloud Service is included with the Base Cloud Service.

Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Up to 75 Sites, Single Trial – Trial

Part #: B93061

Modules and Features

Users of this Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Randomization Capabilities and Entitlements
- All Clinical One Supplies Management Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Notwithstanding anything to the contrary in Your order, Your Content in the following components of Oracle Life Sciences Clinical One Cloud Services will be stored in Oracle's North America Data Center Region: Identity and Access Management Service (IAMS) and the Clinical One Release Assessment Environment.

Usage Limits

The Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- A maximum of 75 Sites may be concurrently marked Active in the Cloud Service at any one time. If You require more than 75 Sites, You may purchase the optional service for Additional Sites.
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.

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
12 hours	1 hour	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.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- RTSM Study Specific Support – See the Clinical One Entitlements section below
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service and must be downloaded prior to submitting to Oracle a request to decommission the Trial.
- Locking Your Trial – You are responsible for removing access by Your Users to the completed Trial and submitting to Oracle a request to decommission the Trial.
- If You have not completed Locking Your Trial and submitting Your request to decommission by the end of the Services Period defined in Your order, You must extend or renew Your order for the Cloud Service. Except as expressly provided in Your order, You must pay Oracle through the end of the Services Period.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

Oracle Cloud Policies:

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the "Your Responsibilities" section above.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Additional Sites, Single Trial – Trial *(Optional Service)*

Part #: B93062

Pre-Requisities

Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Up to 75 Sites, Single Trial (Part #: B93061)

The Base Cloud Service identified above is a prerequisite for this Additional Sites option, which increases the number of Sites that may be concurrently marked Active in the Cloud Service at any one time.

Environments

This Cloud Service utilizes the environment(s) of the Base Cloud Service.

Usage Limits

The Additional Sites option is subject to usage limits based on:

- No more than 500 Sites may be simultaneously marked Active in the Cloud Service at any one time.
- The Additional Sites option is subject to the Usage Limits for the Base Cloud Service, except as otherwise specified in this section.

Your Responsibilities

- Your responsibilities for this Cloud Service are the same as Your responsibilities for the Base Cloud Service.
- You must purchase the Base Cloud Service, which is a prerequisite for use of the Additional Sites.

Oracle Cloud Policies:

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Retrieval of Your Content from the Cloud Service

Your Content for this Cloud Service is included with the Base Cloud Service.

Oracle Life Sciences Clinical One Cloud Service – Randomization, Multi-Trial – Trial

Part #: B93057

Modules and Features

Users of this Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Randomization Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Notwithstanding anything to the contrary in Your order, Your Content in the following components of Oracle Life Sciences Clinical One Cloud Services will be stored in Oracle's North America Data Center Region: Identity and Access Management Service (IAMS) and the Clinical One Release Assessment Environment.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Trials specified in Your order.
- For the purposes of counting the number of Trials using the Cloud Service, the total is the number of Trials using the Cloud Service concurrently at any time. A Trial begins when the first version of the Trial is provisioned in the Cloud Service and ends when the request to remove the Trial from the Cloud Service has been submitted to Oracle.
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and

Site Users using the Identity and Access Management Service (IAMS).

- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- RTSM Study Specific Support – See the Clinical One Entitlements section below
- Archival Trial Data – For each Trial, You are responsible for retrieving Your Trial Data from the Cloud Service. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service and must be downloaded prior to submitting to Oracle a request to decommission the Trial.
- Locking and Decommissioning Your Trial(s) – You are responsible for removing access by Your Users to each completed Trial and submitting to Oracle a request to decommission each Trial.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

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.

- Prior to decommission of each Trial, You may retrieve Your Content for such Trial as described under Archival Trial Data in the "Your Responsibilities" section above.
- After decommission of each Trial, Oracle will also place on Oracle's sFTP site a copy of the production Cloud Service database for such Trial, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database may be used to recommission the Cloud Services for the Trial 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.

Oracle Life Sciences Clinical One Cloud Service – Supplies Management, Multi-Trial – Trial *(Optional Service)*

Part #: B93058

Modules and Features

Users of this Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Supplies Management Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Pre-Requisities

Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service – Randomization, Multi-Trial (Part #: B93057)

The Base Cloud Service identified above is a prerequisite for this Cloud Service.

Environments

This Cloud Service utilizes the environment(s) of the Base Cloud Service.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Trials specified in Your order.
    - The number of Trials for this Cloud Service may not exceed the number of Trials for the Base Cloud Service.
    - For the purposes of counting the number of Trials using the Cloud Service, the total is the number of Trials using the Cloud Service concurrently at any time. A Trial begins when the first version of the Trial is provisioned in the Cloud Service and ends when the request to remove the Trial from the Cloud Service has been submitted to Oracle.
- The Cloud Service is subject to the Usage Limits for the Base Cloud Service.

Your Responsibilities

- Your responsibilities for this Cloud Service are the same as Your responsibilities for the Base Cloud Service.
- You must purchase the Base Cloud Service, which is a prerequisite for use of this Cloud Service.

Oracle Cloud Policies:

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Retrieval of Your Content from the Cloud Service

Your Content for this Cloud Service is included with the Base Cloud Service.

Oracle Life Science Clinical One Cloud Service - Access Management – Trial

Part #s:

- B96207 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Phase 1, Access Management, Single Trial
- B96208 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Access Management, Up to 75 Sites, Single Trial
- B96209 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Access Management, Over 75 Sites, Single Trial
- B96210 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Access Management, Multi-Trial

- B96211 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Access Management, Single Trial
- B96212 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Access Management, Up to 75 Sites, Single Trial
- B96213 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Access Management, Over 75 Sites, Single Trial
- B96214 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Access Management, Multi-Trial
- B96215 - Oracle Life Sciences Clinical One Cloud Service - Randomization, Access Management, Up to 75 Sites, Single Trial
- B96216 - Oracle Life Sciences Clinical One Cloud Service - Randomization, Access Management, Over 75 Sites, Single Trial
- B96217 - Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Access Management, Up to 75 Sites, Single Trial
- B96218 - Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Access Management, Over 75 Sites, Single Trial
- B96219 - Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Access Management, Multi-Trial

Modules and Features

Subject to the Usage Limits and Your Responsibilities below, Your users may use the Services for the following activities for the Base Cloud Service(s):

- Resetting passwords
- Unlocking accounts
- Assisting with login issues
- User Management for:
  - Adding or modifying:
    - site and sponsor users
    - site and sponsor user roles
    - sites and depots
    - rights and roles
  - Activating or deactivating site and sponsor users

Hours and Languages

For the purpose of these Services, the following takes precedence over anything to the contrary in the *Oracle Cloud Hosting and Delivery Policies*.

Requests for resetting passwords, unlocking accounts, or assistance with login issues may be made by submitting Support Requests online in the Oracle Life Sciences Support Cloud system (available at https://hsgbu.custhelp.com/) or by calling the Support phone numbers for Clinical One Cloud Service (available at https://www.oracle.com/life-sciences/support/).

Phone support is available in the following languages during standard Oracle business hours in the GMT time zone, except as noted below:

- English (available 24x7)
- Spanish
- French

- German
- Italian
- Japanese (available standard Oracle business hours in the JST time zone)

Requests for User Management may be made by Your Delegated Administrator(s) (as defined below) submitting Support Requests in the Oracle Life Sciences Support Cloud system (available at https://hsgbu.custhelp.com/).

Base Cloud Services

For each Service listed below, the Base Cloud Service identified is a prerequisite for such Service.

- For B96207 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Phase 1, Access Management, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Phase 1, Single Trial (Part #: B96201)
- For B96208 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Access Management, Up to 75 Sites, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Single Trial (Part #: B96202)
- For B96209 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Access Management, Over 75 Sites, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Single Trial (Part #: B96202)
- For B96210 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Access Management, Multi-Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service – Basic, Data Collection, Multi-Trial (Part #: B93067)
- For B96211 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Access Management, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Single Trial (Part #: B96203)
- For B96212 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Access Management, Up to 75 Sites, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Single Trial (Part #: B96204)
- For B96213 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Access Management, Over 75 Sites, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Single Trial (Part #: B96204)
- For B96214 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Access Management, Multi-Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service – Plus, Data Collection and Randomization, Multi-Trial (Part #: B93068)
- For B96215 - Oracle Life Sciences Clinical One Cloud Service - Randomization, Access Management, Up to 75 Sites, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Randomization, Up to 75 Sites, Single Trial (Part #: B93059)
- For B96216 - Oracle Life Sciences Clinical One Cloud Service - Randomization, Access Management, Over 75 Sites, Single Trial

    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Randomization, Up to 75 Sites, Single Trial (Part #: B93059)
- For B96217 - Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Access Management, Up to 75 Sites, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Up to 75 Sites, Single Trial (Part #: B93061)
- For B96218 - Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Access Management, Over 75 Sites, Single Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Up to 75 Sites, Single Trial (Part #: B93061)
- For B96219 - Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Access Management, Multi-Trial
    - Base Cloud Service: Oracle Life Sciences Clinical One Cloud Service – Randomization, Multi-Trial (Part #: B93057)

Usage Limits

The Service is subject to usage limits based on and limited to:

- The quantity of Trials specified in your order.
- Use for the applicable Base Cloud Service(s) identified above.
- The following Services are limited to use for Phase 1 Trials, not inclusive of combination Trials (Phase I/II):
    - B96207 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Phase 1, Access Management, Single Trial
    - B96211 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Access Management, Single Trial
- The following Services are limited to use for Trials with 75 Sites or less:
    - B96208 - Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Access Management, Up to 75 Sites, Single Trial
    - B96212 - Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Access Management, Up to 75 Sites, Single Trial
    - B96215 - Oracle Life Sciences Clinical One Cloud Service - Randomization, Access Management, Up to 75 Sites, Single Trial
    - B96217 - Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Access Management, Up to 75 Sites, Single Trial

Disaster Recovery and Service Availability

Disaster Recovery and Target Service Availability Levels are not applicable to the Services.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

The Severity Definitions section and the Change to Service Request Severity Level section of the *Oracle Cloud Hosting and Delivery Policies* do not apply to these Services.

Your Responsibilities

You are responsible for the following:

- Designating Your users who will have administrative privileges for the Service (Your **"Delegated Administrator(s)"**), providing to Oracle the contact information for Your Delegated Administrator(s) (such as names, phone numbers, e-mail addresses, and other appropriate contact information), and notifying Oracle of any changes to Your Delegated Administrator(s) during the Services Period of the Service.
- Ensuring that User Management requests are submitted by Your Delegated Administrator(s).
- Assigning to Oracle Customer Delegated Administrator privileges for the Base Cloud Service and limiting Oracle's access to any production or shared development environments to the extent necessary for Oracle to perform the Services.
- Restricting Oracle's access to any content or information that imposes privacy, security, or regulatory obligations greater than those specified in Your order.
- Promptly updating Oracle with respect to business and technology changes or events that may impact the Services (such as, but not limited to, configuration changes, implementation of new business functionality, modifications to Your change control policies, etc.).
- Ensuring that Your users of the Services follow your security policies.
- If You require an escalation, You are responsible for following the standard escalation process for Support Requests within the Oracle Life Sciences Support Cloud system.

Retrieval of Your Content from the Cloud Service

After termination of the Service, no data will be available for retrieval from the Services. Your Content may be retrieved from Your applicable Base Cloud Services as provided for in the applicable order for the Base Cloud Services.

Oracle Life Sciences Clinical One Cloud Service – Digital Gateway

Part #s:

- B94574 - Oracle Life Sciences Clinical One Cloud Service – Digital Gateway, Trial based Integration, Single Trial – Integration per Trial
- B94575 - Oracle Life Sciences Clinical One Cloud Service – Digital Gateway, Trial based Integration, Multi Trial – Integration per Trial
- B94576 - Oracle Life Sciences Clinical One Cloud Service – Digital Gateway, non-Trial based Integration – Integration

Modules and Features

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

- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations between systems other than Clinical One Cloud Service)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for setting up and configuring integrations and does not contain

data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Usage Limits

This Cloud Service is subject to usage limits based on:

- For B94574 - Oracle Life Sciences Clinical One Cloud Service – Digital Gateway, Trial based integration, Single Trial: the quantity of Integrations per Trial specified in Your order, which may be used for a maximum of one Trial
- For B94575 - Oracle Life Sciences Clinical One Cloud Service – Digital Gateway, Trial based integration, Multi Trial – Integration per Trial: the quantity of Integrations per Trial specified in Your order
    - The quantity of Integrations per Trial ordered is the total number of Integrations across any and all Trials. Integrations connecting the same two systems for two different clinical trials will constitute two separate Integrations per Trial.
    - For the purposes of counting the number of Integrations per Trial using this Cloud Service, the total is the number of Integrations per Trial using the Cloud Service concurrently at any time. An Integration per Trial begins when the first version of the Integration per Trial is provisioned in the Cloud Service and ends when the request to remove the Integration per Trial from the Cloud Service has been submitted to Oracle.
- For B94576 - Oracle Life Sciences Clinical One Cloud Service – Digital Gateway, non-Trial based Integration: the quantity of Integrations specified in Your order
    - For the purposes of counting the number of Integrations using this Cloud Service, the total is the number of Integrations using the Cloud Service concurrently at any time. An Integration begins when the first version of the Integration is put into Testing mode in the Cloud Service and ends when the request to remove the Integration from the Cloud Service has been submitted by You to Oracle.
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Integration(s) which use this Cloud Service must be configured. Oracle may assist with Your configuration(s) of the integration(s) for an additional fee.

Retrieval of Your Content from the Cloud Service

Data is stored in this Cloud Service on a temporary, pass-through basis only. The data processed by this Cloud Service will be available in the destination application or Cloud Service that receives data from this Cloud Service. After termination of the Cloud Service, no data will be available for retrieval from this Cloud Service.

Oracle Life Sciences Clinical One Cloud Service – Non-Production Trial – Trial

Part #: B94963

Modules and Features

This Non-Production Cloud Service is provided for the Oracle Life Sciences Clinical One platform. Oracle will automatically upgrade this Cloud Service to the latest Clinical One version approximately four weeks prior to the date it is released for general availability for production Cloud Services.

Environments

Oracle will provide one (1) environment for non-production use supporting multiple modes (Design, Test, and Training). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Trials specified in your order.
- For the purposes of counting the number of Trials using this Cloud Service, the total is the number of Trials using the Cloud Service concurrently at any time. A Trial begins when the first version of the Trial is provisioned in the Cloud Service and ends when the request to remove the Trial from the Cloud Service has been submitted to Oracle.
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.
- This Non-Production Cloud Service is not intended for, and should not be used for, production Data. Copying Data from a production Cloud Service to the Non-Production Cloud Service is not allowed.
- Certain programs and optional services may not be able to run in the Non-Production Cloud Service. Additionally, the Non-Production Cloud Service is separate from any production

Clinical One Cloud Services You have purchased, and settings and services controlled within production Clinical One Cloud Services are not available in the Non-Production Cloud Service (such as, but not limited to user/role management and tenant-controlled code lists).

Disaster Recovery and Service Availability

Disaster Recovery and Service Availability targets are not applicable to the Non-Production Cloud Service.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).

Retrieval of Your Content from the Cloud Service

After termination of the Cloud Service, no data from the Non-Production Cloud Service will be available for retrieval by You, and Oracle has no obligation to maintain, transfer, or otherwise provide data from the Non-Production Cloud Service to You.

CLINICAL ONE ENTITLEMENTS

The entitlements listed below are included with the Cloud Services if indicated in the corresponding Clinical One Capabilities and Entitlements section for such Cloud Services in the Glossary above.

Clinical One Release Assessment Environment

- Oracle automatically upgrades the production Oracle Life Sciences Clinical One Cloud Services to the latest version of Clinical One when it is released for general availability. Approximately four weeks prior to major/minor releases (e.g. 24.1), Oracle will release the latest version of Clinical One into a Release Assessment Environment.
- **Patch Sets:** Depending on scope and contents of release, Oracle may, at its discretion, release that latest patch set release into the Release Assessment Environment for up to two weeks prior to release for general availability.
- **Patches:** Patches will not be available in the Release Assessment Environment prior to the date they are released for general availability. Oracle will release the latest patch into production and the Release Assessment Environment at the same time.
- The Release Assessment Environment is a Non-Production Environment, which will be accessible by all Clinical One Cloud Service customers; no production or confidential information may be included.
- For each customer, the Release Assessment Environment includes one pre-configured Trial and one non-configured Trial solely for Your use, which You may access to try new features, to update internal standard operating procedures, and to train end users prior to accessing the latest generally available version of Clinical One Cloud Services in production. You may request up to three additional non-configured Trials via the Oracle Life Sciences Support website.
- Access to the Release Assessment Environment will be provided for Your Admin User(s). Additional user access may be requested via the Oracle Life Sciences Support website.
- Support severity levels and service level agreements or targets described in the Oracle Cloud Policies are not applicable to the Release Assessment Environment.
- Certain Clinical One components and features may not be available in the Release Assessment Environment, including but not limited to Central Coding, Digital Gateway, and any items controlled in Your Clinical One tenant (such as user roles/management and tenant-controlled code lists). To perform additional assessment and testing not available in the Release Assessment Environment, You may purchase the Clinical One Non-Production Cloud Service.

Your Responsibilities

With regard to Your use of the Clinical One Release Assessment Environment, You are responsible for the following:

- Submitting requests via the Oracle Life Sciences Support website (available at https://hsgbu.custhelp.com/) for granting or removing access for any of Your users to the Release Assessment Environment, or to request additional non-configured Trials.
- Ensuring that no production data or confidential information (such as Trial names, investigational drug details, actual subject data, or code lists) are entered into the Release

Assessment Environment. Any code list created in the Release Assessment Environment is visible to all Clinical One Cloud Service customers.

- Configuration of Your Trials, including the non-configured Trial(s) and any updates to the Oracle pre-configured Trial.
- Assessment and training in the Release Assessment Environment in accordance with Your standard operating procedures and/or work instructions, as well as creating and executing Your own assessment cases.

Oracle Life Sciences Central Coding

If requested by You, Oracle will deploy Oracle Life Sciences Central Coding for use with Clinical One.

Your Responsibilities

- If You require Central Coding for Your Trial(s), You are responsible for requesting that Oracle deploy Central Coding.
- For each Trial for which You use the Central Coding feature, You are responsible for its configuration, or Oracle may assist with Your configuration for an additional fee.

Third Party Licensing Requirements

If You use the Central Coding feature, the following Third Party Licensing Requirements apply:

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 Your use of Central Coding. 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 Central Coding. However, this does not alleviate Your obligations to maintain a valid license to such dictionaries.

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

Oracle Clinical Connector

Oracle Clinical Connector (OCC) is an entitlement for Clinical One Data Collection Trials. If requested by You, Oracle will enable OCC for the requested Trial and Site(s) in Clinical One.

Your Responsibilities

- For each Trial for which You require OCC, You must request OCC enablement from Oracle and specify the Sites that will use OCC.
- You are responsible for ensuring each Site is enabled on the Oracle Health Data Intelligence (HDI) platform.
- For each Trial for which You will use OCC, You are responsible for electronic health record (EHR) data mapping and Site EHR configuration within the Clinical One Trial, or Oracle may assist You for an additional fee.

RTSM Study Specific Support

RTSM Study Specific Support includes the following:

- For each Trial, Oracle will provide You with a Clinical One RTSM End User Support Guide containing pre-defined End User support scenarios and the available pre-defined options for Oracle courses of action for each scenario.
- Oracle will provide End User support in accordance with Your pre-selected choices as documented in Your Clinical One RTSM End User Support Guide for the applicable Trial.
- When new versions of Clinical One are released, Oracle may change the pre-defined support scenarios and/or the available pre-defined options to align with new or modified Clinical One capabilities and features, and Oracle will work with You to update the Support Guide for Your Trial, including Your Oracle response selections, if required.

Your Responsibilities

With regard to Your use of the RTSM Study Specific Support, You are responsible for the following:

- Prior to the date the first Patient is enrolled in Your Trial, finalize the Clinical One RTSM End User Support Guide for the Trial by selecting from the available pre-defined options for Oracle courses of action for each End User Support scenario, signing, and returning the finalized Support Guide to Oracle.
- You may request updates to Your Support Guide selections for a Trial by submitting a Change Request via the Oracle Life Sciences Support website (available at https://hsgbu.custhelp.com/) and signing and returning an updated Clinical One RTSM End User Support Guide to Oracle.
- For any updates to the Support Guide for Your Trial as a result of new Clinical One releases, You must finalize the updated Support Guide by updating or making new selections from the available pre-defined options, signing, and returning the updated Support Guide to Oracle.

RETIRED OFFERINGS

GLOSSARY FOR RETIRED OFFERINGS

For the purposes of the following retired offerings the Glossary above applies.

- B93065 – Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Up to 75 Patients, Single Trial
- B93066 – Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, >75 Patients, Single Trial

For all other retired offerings below, the glossary terms below apply.

Clinical One Randomization and Data Collection Basic Capabilities

- Data Extract
- Central Coding
- Electronic Signature
- Embedded Computer Based Training (CBT)
- Local Lab Entry
- Lab Range Management
- Oracle Clinical Connector
- Randomization
- Randomization Design
- Remote Data Entry
- Rule and Data Cleaning/Query Management
- SAS Exports
- Site Audit Archive (including submission-ready PDFs)
- Site Contact Management
- Source Data Verification (SDV)
- Standard Reports
- Study Archival
- Study Design
- Study/Site Closeout
- Tabular Repeating Form Entry
- User Management

Clinical One Randomization and Data Collection Plus Capabilities

All Clinical One Randomization and Data Collection Basic Capabilities listed above, and:

- Data Review
- Drug Reconciliation
- Supply/Device Management
- Targeted SDV

SERVICE DESCRIPTIONS FOR RETIRED OFFERINGS

Oracle Health Sciences Clinical One Cloud Service – Basic, Data Collection, Single Trial – Trial

Part #s:

- B93063 – Oracle Health Sciences Clinical One Cloud Service – Basic, Data Collection, Up to 75 Patients, Single Trial
- B93064 – Oracle Health Sciences Clinical One Cloud Service - Basic, Data Collection, > 75 Patients, Single Trial

Modules and Features

Users of the Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Data Collection Capabilities and Entitlements
- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Usage Limits

This Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.
- A maximum of 75 Patients applies for the following Cloud Service:
    - B93063 – Oracle Health Sciences Clinical One Cloud Service – Basic, Data Collection, Up to 75 Patients, Single Trial

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- Central Coding – See the Clinical One Entitlements section below.
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service.

Archival and submission-ready PDFs may be generated and downloaded by You and Your Sites via the Archives feature. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service. All PDFs, reports, and extracts must be downloaded prior to the end of the Services Period.

  - You may choose to generate PDFs on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their PDFs directly from the Cloud Service. You are also responsible for making Your Sites aware of the services and their obligations with regard to record retention hereunder.

- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the "Your Responsibilities" section above.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Single Trial – Trial

Part #s:

- B93065 – Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Up to 75 Patients, Single Trial
- B93066 – Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, >75 Patients, Single Trial

Modules and Features

Users of the Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Data Collection Capabilities and Entitlements
- All Clinical One Randomization Capabilities and Entitlements
- All Clinical One Supplies Management Capabilities and Entitlements

- All Clinical One Digital Gateway Capabilities and Entitlements (for integrations of this Clinical One Cloud Service with other systems)

Environments

Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production). The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.

Usage Limits

This Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- No more than 25 Users may simultaneously access the Test and Training modes at any one time.
- A maximum of 75 Patients applies for the following Cloud Service:
    - B93065 – Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Up to 75 Patients, Single Trial.

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Clinical One Release Assessment Environment – See the Clinical One Entitlements section below.
- Central Coding – See the Clinical One Entitlements section below.
- RTSM Study Specific Support – See the Clinical One Entitlements section below
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service.

Archival and submission-ready PDFs may be generated and downloaded by You and Your Sites via the Archives feature. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service. All PDFs, reports, and extracts must be downloaded prior to the end of the Services Period.

  - You may choose to generate PDFs on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their PDFs directly from the Cloud Service. You are also responsible for making Your Sites aware of the services and their obligations with regard to record retention hereunder.

- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the "Your Responsibilities" section above.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Plus Cloud Service, Up to 75 Patients – Trial

Part #: B92195

Modules and Features

Users of the Cloud Service are authorized to access the following features or capabilities:

- All Clinical One Randomization and Data Collection Basic Capabilities and Plus Capabilities

Usage Limits

This Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- A maximum of 75 Patients. If Your Trial requires more than 75 Patients, You may purchase the optional service for Additional Patients.

- A maximum of 4.0 GB of database storage
- Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production).
    - The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.
    - No more than 25 Users may simultaneously access the Test and Training modes at any one time. Exceeding these quantities may adversely affect service performance, and Oracle is not responsible for resulting performance issues including missed service levels.

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
12 hours	1 hour	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 Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Central Coding – If You use the Central Coding feature, You are responsible for its configuration, or Oracle may assist with Your configuration for an additional fee.
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Archival and submission-ready PDFs may be generated and downloaded by You and Your Sites via the Archives feature. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service. All PDFs, reports, and extracts must be downloaded prior to the end of the Services Period.
    - You may choose to generate PDFs on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their PDFs directly from the Cloud Service. You are also responsible for making Your Sites aware of the services and their obligations with regard to record retention hereunder.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under

this service description, the order, and the agreement.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the "Your Responsibilities" section above.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Plus Cloud Service, Additional Patients – 100 Patients

Part #: B92196

The Additional Patients option adds quantity of Patients for which the Cloud Service may be used, in addition to the 75 Patients included with the Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Plus Cloud Service.

Usage Limits

This Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- The quantity of "100 Patients" specified in your order
- The Additional Patients option utilizes the environment of, and is subject to the Usage Limits and Service Level Targets for, the Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Plus Cloud Service, except as otherwise specified in this section.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Your Responsibilities

- Your responsibilities for this Cloud Service are the same as Your responsibilities for the Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Basic Cloud Service.

- You must purchase Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Basic Cloud Service, which is a prerequisite for use of the Additional Patients.

Retrieval of Your Content from the Cloud Service

Your Content for this Cloud Service is included with the Base Cloud Service.

Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service – up to 75 Sites – Trial

Part #: B87792

The Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service is a business service for Trial randomization, supplies management, and dispensation within the Oracle Health Sciences Clinical One platform.

Modules and Features

Users of the Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service are authorized to access the following features or capabilities:

- Oracle Health Sciences Clinical One Randomization
- Oracle Health Sciences Clinical One Supplies Management

Usage Limits

The Cloud Service is subject to usage limits based on:

- A maximum of one Trial
- A maximum of 75 Sites may be concurrently marked Active in the Cloud Service at any one time. If You require more than 75 Sites, You may purchase the optional service for Additional Sites.
- A maximum of 4.0 GB of database storage
- Oracle will provide one (1) environment supporting multiple modes (Design, Test, Training, and Production).
    - The Design mode is for creating and configuring the design of a Trial and does not contain data. The Test and Training modes are designed for testing and training respectively and are intended for use with non-production test data only. The production mode is designed for production operations of live data.
    - No more than 25 Users may simultaneously access the Test and Training modes at any one time. Exceeding these quantities may adversely affect service performance, and Oracle is not responsible for resulting performance issues including missed service levels.

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
12 hours	1 hour	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.

Your Responsibilities

- User Management – You are responsible for performing user management for Your Users and Site Users using the Identity and Access Management Service (IAMS).
- Archival Trial Data – You are responsible for retrieving Your Trial Data from the Cloud Service. Final extracts/reports detailing Your Trial Data may be downloaded via the Reports feature in the Cloud Service and must be downloaded prior to submitting to Oracle a request to decommission the Trial.
- Locking Your Trial – You are responsible for removing access by Your Users to the completed Trial and submitting to Oracle a request to decommission the Trial.
- If You have not completed Locking Your Trial and submitting Your request to decommission by the end of the Services Period defined in Your order, You must extend or renew Your order for the Cloud Service. Except as expressly provided in Your order, You must pay Oracle through the end of the Services Period.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

Oracle Cloud Policies:

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

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.

- At any time prior to termination of the Cloud Service, You may retrieve Your Content as described under Archival Trial Data in the "Your Responsibilities" section above.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the production Cloud Service database, which will be available for the retrieval period stated in the Oracle Cloud Policies. The database 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.

Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service – Additional Sites – Trial

Part #: B87793

The Additional Sites option for Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service increases the number of Sites that may be concurrently marked Active in the Cloud Service at any one time.

Usage Limits

The Additional Sites option for Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service is subject to usage limits based on:

- No more than 500 Sites may be simultaneously marked Active in the Cloud Service at any one time. Exceeding these quantities may adversely affect service performance, and Oracle is not responsible for resulting performance issues including missed service levels.
- The Additional Sites option utilizes the environment of, and is subject to the Usage Limits and Service Level Targets for, the Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service, except as otherwise specified in this section.

Your Responsibilities

- Your responsibilities for this Cloud Service are the same as Your responsibilities for the Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service.
- You must purchase the Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service, which is a prerequisite for use of the Additional Sites.

Oracle Cloud Policies:

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Industries Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services/.

Retrieval of Your Content from the Cloud Service

Your Content for this Cloud Service is included with the Base Cloud Service.