



Oracle Life Sciences

Argus Cloud Service

Service Descriptions and Metrics

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METRIC DEFINITIONS

Case

“Case” is defined as a record in the Cloud Service, identified by a case ID number, which contains data elements related to the safety of a product. A Case does not include Oracle Life Sciences Argus features in Japanese language.

Case – Pooled Capacity

“Case – Pooled Capacity” means the quantity of Cases purchased will be made available as a pool of Cases which may be used during the term of the Services Period. Each Case used is deducted from the available pool of Cases. A Case is **“used”** when it is created in the Cloud Service, including but not limited to Cases identified as “E2B”, “Deleted”, and “Literature” Cases. Notwithstanding the preceding sentence, Migrated Cases are excluded from the quantity of Cases used. Any unused Cases expire at the end of the Services Period and do not carry over to subsequent Services Periods.

Japan Case

“Japan Case” is defined as a record in the Cloud Service, identified by a case ID number, which contains data elements related to the safety of a product and uses Oracle Life Sciences Argus pages and/or data items in Japanese language. A Japanese Case may originate from any region worldwide and is used in assessment and/or submission to PMDA (Pharmaceuticals and Medical Devices Agency).

Japan Case – Pooled Capacity

“Japan Case – Pooled Capacity” means the quantity of Japan Cases purchased will be made available as a pool of Japan Cases which may be used during the term of the Services Period. Each Japan Case used is deducted from the available pool of Japan Cases. A Japan Case is **“used”** when it is created in the Cloud Service, including but not limited to Cases identified as “E2B”, “Deleted”, and “Literature” Cases. Notwithstanding the preceding sentence, Migrated Cases are excluded from the quantity of Japan Cases used. Any unused Japan Cases expire at the end of the Services Period and do not carry over to subsequent Services Periods.

Instance

Instance is defined as single deployment of the application. For details of deployment specific to the application please refer to service descriptions/entitlements.

Safety Source Document – Pooled Capacity

Safety Source Document is defined as a document processed by the Oracle Life Sciences Safety One Intake Cloud Service including but not limited to an email, fax, E2B report, regulatory report, call center and/or customer complaint report, case series, literature review, signal analysis, clinical trial report, and/or social media post. **“Pooled Capacity”** means the quantity purchased is a pool of Safety Source Documents that may be processed over the duration of the Services Period.

GLOSSARY

Migrated Case

A Migrated Case is an archived historical case for which there is no additional follow up, where such case was originally created in an external system and is subsequently migrated into Oracle Life Sciences Argus. Migrated Cases must be included in a UTIL_MIGRATION_CASE table to be excluded from the quantity of Cases or Japan Cases used, as further described in the Oracle Life Sciences Argus Program Documentation. Migrated Cases exclude current active Cases or Japan Cases migrated into Oracle Life Sciences Argus.

Non-Production Environment

Non-Production Environment may be either a Test or Development Environment provided to You as part of the Cloud Services. The Non-Production Environment(s) are specifically sized and designed for development and training purposes and may not be used for production purposes or for performance or stress testing. Any service levels, performance targets and disaster recovery described for the applicable Oracle Cloud Service are not applicable to Non-Production Environments.

Production Environment

Production Environment is defined as the environment provided to You as part of the Oracle Cloud Service that is designed for daily commercial use and production operations of live data. Unless otherwise specified, a single Production Environment is provided for an Oracle Cloud Service.

SERVICE DESCRIPTIONS

Oracle Life Sciences Argus Advanced Cloud Service, Base - Instance

Part #: B93361

Modules and Features

Users of the Oracle Life Sciences Argus Advanced Cloud Service, Base are authorized to access the following modules:

- Argus Safety
- Argus Affiliate
- Argus Interchange
- Argus Dossier
- Argus Insight
- Argus Analytics
- Argus Mart
- B2B

Environments

The Cloud Service includes one (1) Production Environment and two (2) Non-Production Environments for each Instance you have ordered.

The Cloud Service also provides 2 node RAC database and web servers. These are load balanced to provide a high availability solution in the event of a failure on the primary servers.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Instances defined in your order.

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
24 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. 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.

Third Party License Requirements

Oracle Life Sciences Argus Interchange module, used with an electronic gateway, enables electronic submissions and exchanges. The Oracle B2B gateway is supported as an option for the electronic gateway. Oracle Life Sciences Argus Interchange module can also be used along with Axway B2Bi for electronic submission. Axway B2Bi is required as the electronic gateway for Partition Mode, as described below. The permitted exchange protocols are AS1 and AS2 with message encryption and/or HTTPS-enabled transmission. For AS1 communication, configuration of IMAP/POP3 is supported using SMTP over VPN.

For Oracle to provide the Oracle Life Sciences Argus Cloud Service, You are required to obtain the necessary licenses to any of the following third party software You will use:

- Axway B2Bi 2.6 SP1
- JDrug
- MedDRA/MedDRA J Dictionaries
- Microsoft Office
- RightFax 10.6 (32-bit) *(subject to the limitations below)*
- WHO Drug Dictionary

Third Party Software Limitations

- Documentum is not supported for Oracle Life Sciences Argus Cloud Service.
- Use of RightFax with Oracle Life Sciences Argus Cloud Service is partially enabled. For faxing from Oracle Life Sciences Argus Cloud Service, fax via email using Your fax as the end point. Fax status tracking and fax responses are not available in Oracle Life Sciences Argus Cloud Service.

For any required third party software You will use, You must purchase a license, as well as all consents, permits, and authorizations necessary for Oracle to access and use this software on Your behalf directly from such third parties as part of this offering. You must provide evidence of such licenses prior to Oracle's installation of such, as well as a copy of the licensed software if applicable, and You are responsible for supporting such software (including the purchase of support contracts from the third party vendors as applicable).

For Axway B2Bi, You must provide Oracle with Your Axway "Support Identifier". You will permit Oracle to use your Axway Support Identifier to file service requests with Axway. You will provide the assistance necessary for Oracle to pursue and escalate any issues and requests with Axway as needed to attempt to resolve issues impacting Your ability to use the Services; however, You are ultimately responsible for support of the Axway software.

Use of the Oracle Life Sciences Argus Cloud Service offering is subject to certain expectations and requirements regarding the following 3rd party software:

1. To use MedDRA within the Argus Cloud Service, You will work with Oracle to establish the necessary private circuit or VPN solution to facilitate secure web service communications between the Oracle servers and Your network. You will be required to have an authentication mechanism in place to secure the web service communication.
2. To use the SMTP capabilities from within the Argus Cloud Service, You must host within

Your network the required SMTP server necessary for these capabilities, and the SMTP service must be accessible to the Oracle servers over a private circuit or VPN line.

3. Oracle requires any digital certificates provided by You to Oracle for the purpose of system integrations be issued by a commercial certificate authority. It is Your responsibility to ensure digital certificates are issued by a commercial certificate authority. You bear all risk, and Oracle assumes no liability, if You provide Oracle with and/or You use self-signed digital certificates or self-signed certificates of any third party system for system integration purposes.

The services listed below require a separate service engagement with Oracle to define, configure/ implement, test, and deploy:

- Any data migration between versions
- Customer-specific migration services required for transformation of Your data to Oracle data models
- All services not listed in this services description

Use of Utilities

The Cloud Service may include access to certain Oracle Life Sciences Argus utilities, which is subject to Your Responsibilities set forth below.

Argus Cloud Extensibility and Integrations Utility

Oracle Responsibilities:

- Upon Your request, deploy Your customizations or extensions in Your Non-Production Environment(s) in accordance with Your Installation Documentation (as defined below).
- Upon Your confirmation that You have validated the customizations or extensions in Your Non-Production Environment(s), deploy the customizations or extensions in Your Production Environment in accordance with Your Installation Documentation.
- Provide You with 30 calendar days' notice prior to upgrading the base application code version in Your Environment(s).

Your Responsibilities:

- Develop Your own customizations or extensions using the Argus Cloud Extensibility and Integrations Utility in accordance with Oracle's extensibility guidelines, which are available at support.oracle.com (Doc ID 2399180.1). You are responsible for the quality of Your customization or extension code and ensuring that secure coding practices are followed.
- Submit to Oracle change management requests to add customizations or extensions to Your Non-Production and Production Environments, which must include:
 - Argus Cloud Extensibility checklist (available at support.oracle.com, Doc ID 2399180.1).
 - Clear, concise, and accurate documentation detailing installation steps for Your customizations or extensions in the Non-Production and Production Environments of the Cloud Service ("Your Installation Documentation")

- Installation script
- Review and validate customizations or extensions in Your Non-Production Environment(s) before the customizations or extensions may be deployed in Your Production Environment and, upon request by Oracle, confirm within 30 calendar days that You have validated Your customizations or extensions and that they may be deployed in Your Production Environment.
- You are solely responsible for Your customizations or extensions created using the Argus Cloud Extensibility and Integrations Utility, including without limitation:
 - Validating and resolving issues related to any impacts of maintenance or change management (including but not limited to patches, upgrades, or new releases) on Your customizations or extensions.
 - Changes to customizations and extensions to ensure compatibility with the Cloud Services.
- Oracle reserves the right to disable such customizations and extensions if you do not validate or resolve issues in an agreed to timeframe and/ or Oracle believes in its discretion that the customizations and extensions pose issues and/ or risks to its services.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content 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 by exporting Case data and/or by generating and downloading reports in the Cloud Service.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the Cloud Service database residing in Your Cloud Services Production Environment, which will be available for the retrieval period stated in the Oracle Cloud Policies.

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 Argus Advanced Cloud Service, Case – Case - Pooled Capacity

Part #: B93362

Modules and Features

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

- Oracle Life Sciences Argus Advanced Cloud Service, Base

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Advanced Cloud Service, Base (Part #: B93361)

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 Cases - Pooled Capacity defined in Your order

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability for this Oracle Cloud Service are provided with the Base Cloud Service.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Argus Advanced Cloud Service, Japan Case – Japan Case - Pooled Capacity

Part #: B93363

Modules and Features

Users of the Oracle Life Sciences Argus Advanced Cloud Service, Japan Case are authorized to access the following modules:

- Oracle Life Sciences Argus Advanced Cloud Service, Base
- Oracle Life Sciences Argus Safety Japan

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Advanced Cloud Service, Base (Part #: B93361)

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 Japan Cases - Pooled Capacity defined in your order.

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability for this Oracle Cloud Service are provided with the Base Cloud Service.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Argus Advanced Cloud Service, Additional Non-Production Environment – Instance

Part #: B93364

Modules and Features

Oracle Life Sciences Argus Advanced Cloud Service, Additional Non-Production Environment is provided for the following modules:

- Oracle Life Sciences Argus Advanced Cloud Service

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Advanced Cloud Service, Base (Part #: B93361)

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

Environments

The Cloud Service includes one (1) Non-Production Environment for each Instance You have ordered. The maintenance or upgrade schedule for the Additional Non-Production Environment is the same as the schedule for Your Base Cloud Service.

Usage Limits

The Additional Non-Production Environment is subject to usage limits based on:

- The quantity of Instances defined in your order.
- Limited to use for Your Oracle Life Sciences Argus Advanced Cloud Service.
- Certain programs and optional services may not be able to run in the Additional Non-Production Environment.

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability applicable to Your Production Environment(s), including Target Service Availability Level, are not applicable to the Additional Non-Production Environment.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Argus Advanced Cloud Service, Data Replication – Instance

Part #: B93365

Modules and Features

Oracle Life Sciences Argus Advanced Data Replication Cloud Service is provided for the following modules that You have purchased:

- Oracle Life Sciences Argus Advanced Cloud Service, Base
- Oracle Life Sciences Argus Advanced Cloud Service, Case
- Oracle Life Sciences Argus Advanced Cloud Service, Japan Case

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Advanced Cloud Service, Base (Part #: B93361)

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.

Setup

Setup includes configuration of the source database for this Cloud Service.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Instances defined in your order.

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
24 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. For the purposes of this Cloud Service, the RTO, RPO, and Target Service Availability Level above take precedence over anything to the contrary in the Oracle Cloud Policies.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Argus Advanced Cloud Service, Data Replication, Additional Non-Production Environment – Instance

Part #: B93366

Modules and Features

Oracle Life Sciences Argus Advanced Cloud Service, Data Replication, Additional Non-Production Environment is provided for the following modules that You have purchased:

- Oracle Life Sciences Argus Advanced Cloud Service, Base
- Oracle Life Sciences Argus Advanced Cloud Service, Case
- Oracle Life Sciences Argus Advanced Cloud Service, Japan Case

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Advanced Cloud Service, Data Replication (Part #: B93365)

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.

Setup

Setup includes configuration of the source database for this Cloud Service.

Usage Limits

The Additional Non-Production Environment is subject to usage limits based on:

- The quantity of Instances defined in your order.

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability applicable to Your Production Environment(s), including Target Service Availability Level, are not applicable to the Additional Non-Production Environment. Disaster Recovery is not available for the Additional Non-Production Environment.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Argus Advanced Cloud Service, Safety One Intake – Safety Source Document – Pooled Capacity

Part #: B108001

Modules and Features

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

- Oracle Life Sciences Safety One Intake

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Advanced Cloud Service, Base (Part #: B93361) on Oracle Life Sciences Argus version 8.4.1 or higher

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

Environments

One (1) Production Environment and (2) Non-Production Environments are included for this Cloud Service.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Safety Source Documents defined in Your order.
- If all Safety Source Documents purchased are used prior to the end of the Services Period, You may purchase additional quantity. Safety Source Documents which have not been used by the end of the Services Period will expire and may not be rolled over.
- A Safety Source Document has maximum size limit of 100 pages. Any pages in a Safety Source Document in excess of 100 pages count as additional Safety Source Document(s) in increments of 100 pages. For example, 300 pages will count as three Safety Source Documents. One page is equivalent to one side of a single sheet of paper.

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 Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content and Information

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

Oracle Life Sciences Argus Basic Cloud Service, Base – Instance

Part #: B93357

Modules and Features

Users of Oracle Life Sciences Argus Basic Cloud Service, Base are authorized to use the following modules:

- Argus Safety

- Argus Affiliate
- Argus Interchange
- Argus Dossier
- Oracle B2B

Environments

The Cloud Service includes one (1) Production Environment and two (2) Non-Production Environments for each Instance You have ordered.

The Cloud Service also provides 2 node RAC database and web servers. These are load balanced to provide a high availability solution in the event of a failure on the primary servers.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Instances defined in your order.

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
30 to 90 days	48 Hours	99.5%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. 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.

Third Party License Requirements

Oracle Life Sciences Argus Interchange module, used with an electronic gateway, enables electronic submissions and exchanges. The Oracle B2B gateway is supported as an option for the electronic gateway. Oracle Life Sciences Argus Interchange module can also be used along with Axway B2Bi for electronic submission. Axway B2Bi is required as the electronic gateway for Partition Mode, as described below. The permitted exchange protocols are AS1 and AS2 with message encryption and/or HTTPS-enabled transmission. For AS1 communication, configuration of IMAP/POP3 is supported using SMTP over VPN.

For Oracle to provide the Oracle Life Sciences Argus Cloud Service, You are required to obtain the necessary licenses to any of the following third party software You will use:

- Axway B2Bi 2.6 SP1
- JDrug
- MedDRA/MedDRA J Dictionaries

- Microsoft Office
- RightFax 10.6 (32-bit) *(subject to the limitations below)*
- WHO Drug Dictionary

Third Party Software Limitations

- Documentum is not supported for Oracle Life Sciences Argus Cloud Service.
- Use of RightFax with Oracle Life Sciences Argus Cloud Service is partially enabled. For faxing from Oracle Life Sciences Argus Cloud Service, fax via email using Your fax as the end point. Fax status tracking and fax responses are not available in Oracle Life Sciences Argus Cloud Service.

For any required third party software You will use, You must purchase a license, as well as all consents, permits, and authorizations necessary for Oracle to access and use this software on Your behalf directly from such third parties as part of this offering. You must provide evidence of such licenses prior to Oracle’s installation of such, as well as a copy of the licensed software if applicable, and You are responsible for supporting such software (including the purchase of support contracts from the third party vendors as applicable).

For Axway B2Bi, You must provide Oracle with Your Axway “Support Identifier”. You will permit Oracle to use your Axway Support Identifier to file service requests with Axway. You will provide the assistance necessary for Oracle to pursue and escalate any issues and requests with Axway as needed to attempt to resolve issues impacting Your ability to use the Services; however, You are ultimately responsible for support of the Axway software.

Use of the Oracle Life Sciences Argus Cloud Service offering is subject to certain expectations and requirements regarding the following 3rd party software:

1. To use MedDRA within the Argus Cloud Service, You will work with Oracle to establish the necessary private circuit or VPN solution to facilitate secure web service communications between the Oracle servers and Your network. You will be required to have an authentication mechanism in place to secure the web service communication.
2. To use the SMTP capabilities from within the Argus Cloud Service, You must host within Your network the required SMTP server necessary for these capabilities, and the SMTP service must be accessible to the Oracle servers over a private circuit or VPN line.
3. Oracle requires any digital certificates provided by You to Oracle for the purpose of system integrations be issued by a commercial certificate authority. It is Your responsibility to ensure digital certificates are issued by a commercial certificate authority. You bear all risk, and Oracle assumes no liability, if You provide Oracle with and/or You use self-signed digital certificates or self-signed certificates of any third party system for system integration purposes.

The services listed below require a separate service engagement with Oracle to define, configure/ implement, test, and deploy:

- Any data migration between versions
- Customer-specific migration services required for transformation of Your data to Oracle data models

- All services not listed in this services description

Use of Utilities

The Cloud Service may include access to certain Oracle Life Sciences Argus utilities, which is subject to Your Responsibilities set forth below.

Argus Cloud Extensibility and Integrations Utility

Oracle Responsibilities:

- Upon Your request, deploy Your customizations or extensions in Your Non-Production Environment(s) in accordance with Your Installation Documentation (as defined below).
- Upon Your confirmation that You have validated the customizations or extensions in Your Non-Production Environment(s), deploy the customizations or extensions in Your Production Environment in accordance with Your Installation Documentation.
- Provide You with 30 calendar days' notice prior to upgrading the base application code version in Your Environment(s).

Your Responsibilities:

- Develop Your own customizations or extensions using the Argus Cloud Extensibility and Integrations Utility in accordance with Oracle's extensibility guidelines, which are available at support.oracle.com (Doc ID 2399180.1). You are responsible for the quality of Your customization or extension code and ensuring that secure coding practices are followed.
- Submit to Oracle change management requests to add customizations or extensions to Your Non-Production and Production Environments, which must include:
 - Argus Cloud Extensibility checklist (available at support.oracle.com, Doc ID 2399180.1).
 - Clear, concise, and accurate documentation detailing installation steps for Your customizations or extensions in the Non-Production and Production Environments of the Cloud Service ("Your Installation Documentation")
 - Installation script
- Review and validate customizations or extensions in Your Non-Production Environment(s) before the customizations or extensions may be deployed in Your Production Environment and, upon request by Oracle, confirm within 30 calendar days that You have validated Your customizations or extensions and that they may be deployed in Your Production Environment.
- You are solely responsible for Your customizations or extensions created using the Argus Cloud Extensibility and Integrations Utility, including without limitation:
 - Validating and resolving issues related to any impacts of maintenance or change management (including but not limited to patches, upgrades, or new releases) on Your customizations or extensions.
 - Changes to customizations and extensions to ensure compatibility with the Cloud Services.
- Oracle reserves the right to disable such customizations and extensions if you do not validate or

resolve issues in an agreed to timeframe and/ or Oracle believes in its discretion that the customizations and extensions pose issues and/ or risks to its services.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content 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 by exporting Case data and/or by generating and downloading reports in the Cloud Service.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the Cloud Service database residing in Your Cloud Services Production Environment, which will be available for the retrieval period stated in the Oracle Cloud Policies.

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 Argus Basic Cloud Service, Case – Case - Pooled Capacity

Part #: B93358

Modules and Features

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

- Oracle Life Sciences Argus Basic Cloud Service, Base

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Basic Cloud Service, Base (Part #: B93357)

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 Cases - Pooled Capacity defined in Your order
- Case Maximum: A combined maximum of 20,000 Cases and Japan Cases may be used (as defined above) during the Services Period (including the quantity purchased on the initial order and any subsequent orders expanding the quantity). Exceeding this maximum may result in degradation of performance and service availability.

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability for this Oracle Cloud Service are provided with the Base Cloud Service.

The Case Maximum described in the Usage Limits section above is required to maintain operational stability, availability, and performance. The Target Service Availability Level does not apply if Your use of the Cloud Service exceeds the Case Maximum.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Argus Basic Cloud Service, Japan Case – Japan Case - Pooled Capacity

Part #: B93359

Modules and Features

Users of the Oracle Life Sciences Argus Basic Cloud Service, Japan Case are authorized to access the following modules:

- Oracle Life Sciences Argus Basic Cloud Service, Base
- Oracle Life Sciences Argus Safety Japan

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Basic Cloud Service, Base (Part #: B93357)

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 Cases - Pooled Capacity defined in your order.
- A combined maximum of 20,000 Cases and Japan Cases may be used (as defined above) during the Services Period (including the quantity purchased on the initial order and any subsequent orders expanding the quantity). If You require more than 20,000 then You may be required to upgrade to Oracle Life Sciences Argus Advanced Cloud Service.

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability for this Oracle Cloud Service are provided with the Base Cloud Service.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Argus Basic Cloud Service, Additional Non-Production Environment – Instance

Part #: B93360

Modules and Features

Oracle Life Sciences Argus Basic Cloud Service, Additional Non-Production Environment is provided for the following modules:

- Oracle Life Sciences Argus Basic Cloud Service

Pre-Requisites

Base Cloud Service: Oracle Life Sciences Argus Basic Cloud Service, Base (Part #: B93357)

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

Environments

This Cloud Service includes one (1) Non-Production Environment for each Instance You have ordered. The maintenance or upgrade schedule for the Additional Non-Production Environment is the same as the schedule for Your Oracle Life Sciences Argus Basic Cloud Service.

Usage Limits

The Additional Non-Production Environment is subject to usage limits based on:

- The quantity of Instances defined in your order.
- Limited to use for Your Oracle Life Sciences Argus Basic Cloud Service.

- Certain programs and optional services may not be able to run in the Additional Non-Production Environment.

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability applicable to Your Production Environment(s), including Target Service Availability Level, are not applicable to the Additional Non-Production Environment.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

DEFINITIONS FOR RETIRED OFFERINGS

Case

Case is defined as a safety concept identified by a case ID number and which contains data elements related to the safety of a product. If the total number of Cases created (including E2B, Deleted, and Literature cases) in any Oracle Life Sciences Argus Cloud Service in any 12-month period following the Cloud Services Start Date exceed the number purchased, then additional Cases must be purchased. Migrated cases are excluded.

SERVICE DESCRIPTIONS FOR RETIRED OFFERINGS

Oracle Argus Enterprise Edition Cloud Service – Case

Part #: B73043

Modules and Features

Users of the Oracle Argus Enterprise Edition Cloud Service are authorized to access the following modules:

- Oracle Argus Safety
- Oracle Argus Affiliate
- Oracle Argus Interchange
- Oracle Argus Dossier
- Oracle Argus Insight
- Oracle Argus Analytics
- Oracle Argus Mart
- Oracle B2B

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Cases defined in your order.
- A combined maximum of 500,000 Cases and Japan Cases. If You require more than 500,000 then You may need to place an additional order for Oracle Argus Enterprise Edition Cloud Service.
- Oracle will provision one Production Environment and two Non-Production Environments (Test and Development) for this Cloud Service.
- The Cloud Service provides 2 node RAC database and web servers. These are load balanced to provide a high availability solution in the event of a failure on the primary servers.
- Up to 5 terabytes of database storage per database instance.

Disaster Recovery and Service Availability *

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

RECOVERY TIME OBJECTIVE (RTO)	RECOVERY POINT OBJECTIVE (RPO)	TARGET SERVICE AVAILABILITY LEVEL
30 to 90 days	48 Hours	99.5%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. 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.

* If You have purchased Oracle Argus Enhanced Disaster Recovery Cloud Service then the Disaster Recovery and Service Availability for Oracle Argus Enhanced Disaster Recovery Cloud Service apply to this Cloud Service.

Third Party License Requirements

Oracle Argus Interchange module, used with an electronic gateway, enables electronic submissions and exchanges. The Oracle B2B gateway is supported as an option for the electronic gateway. Oracle Argus Interchange module can also be used along with Axway B2Bi for electronic submission. Axway B2Bi is required as the electronic gateway for Partition Mode, as described below. The permitted exchange protocols are AS1 and AS2 with message encryption and/or HTTPS-enabled transmission. For AS1 communication, configuration of IMAP/POP3 is supported using SMTP over VPN.

For Oracle to provide the Oracle Argus Cloud Service, You are required to obtain the necessary licenses to any of the following third party software You will use:

- Axway B2Bi 2.6 SP1
- JDrug
- MedDRA/MedDRA J Dictionaries
- Microsoft Office
- RightFax 10.6 (32-bit) (*subject to the limitations below*)
- WHO Drug Dictionary

Third Party Software Limitations

- Documentum is not supported for Oracle Argus Cloud Service.
- Use of RightFax with Oracle Argus Cloud Service is partially enabled. For faxing from Oracle Argus Cloud Service, fax via email using Your fax as the end point. Fax status tracking and fax responses are not available in Oracle Argus Cloud Service.

For any required third party software You will use, You must purchase a license, as well as all consents, permits, and authorizations necessary for Oracle to access and use this software on Your behalf directly from such third parties as part of this offering. You must provide evidence of such licenses prior to Oracle's installation of such, as well as a copy of the licensed software if applicable, and You are responsible for supporting such software (including the purchase of support contracts from the third party vendors as applicable).

For Axway B2Bi, You must provide Oracle with Your Axway "Support Identifier". You will permit Oracle to use your Axway Support Identifier to file service requests with Axway. You will provide the assistance

necessary for Oracle to pursue and escalate any issues and requests with Axway as needed to attempt to resolve issues impacting Your ability to use the Services; however, You are ultimately responsible for support of the Axway software.

Use of the Oracle Argus Cloud Service offering is subject to certain expectations and requirements regarding the following 3rd party software:

1. To use MedDRA within the Oracle Argus Cloud Service, You will work with Oracle to establish the necessary private circuit or VPN solution to facilitate secure web service communications between the Oracle servers and Your network. You will be required to have an authentication mechanism in place to secure the web service communication.
2. To use the SMTP capabilities from within the Argus Cloud Service, You must host within Your network the required SMTP server necessary for these capabilities, and the SMTP service must be accessible to the Oracle servers over a private circuit or VPN line.
3. Oracle requires any digital certificates provided by You to Oracle for the purpose of system integrations be issued by a commercial certificate authority. It is Your responsibility to ensure digital certificates are issued by a commercial certificate authority. You bear all risk, and Oracle assumes no liability, if You provide Oracle with and/or You use self-signed digital certificates or self-signed certificates of any third party system for system integration purposes.

The services listed below require a separate service engagement with Oracle to define, configure/ implement, test, and deploy:

- Any data migration between versions
- Customer-specific migration services required for transformation of Your data to Oracle data models
- All services not listed in this services description

Use of Utilities

The Cloud Service may include access to certain Oracle Argus utilities, which is subject to Your Responsibilities set forth below.

Argus Cloud Extensibility and Integrations Utility

Oracle Responsibilities:

- Upon Your request, deploy Your customizations or extensions in Your Non-Production Environment(s) in accordance with Your Installation Documentation (as defined below).
- Upon Your confirmation that You have validated the customizations or extensions in Your Non-Production Environment(s), deploy the customizations or extensions in Your Production Environment in accordance with Your Installation Documentation.
- Provide You with 30 calendar days' notice prior to upgrading the base application code version in Your Environment(s).

Your Responsibilities:

- Develop Your own customizations or extensions using the Argus Cloud Extensibility and Integrations Utility in accordance with Oracle's extensibility guidelines, which are available at support.oracle.com (Doc ID 2399180.1). You are responsible for the quality of Your customization or extension code and ensuring that secure coding practices are followed.

- Submit to Oracle change management requests to add customizations or extensions to Your Non-Production and Production Environments, which must include:
 - Argus Cloud Extensibility checklist (available at support.oracle.com, Doc ID 2399180.1).
 - Clear, concise, and accurate documentation detailing installation steps for Your customizations or extensions in the Non-Production and Production Environments of the Cloud Service (“Your Installation Documentation”)
 - Installation script
- Review and validate customizations or extensions in Your Non-Production Environment(s) before the customizations or extensions may be deployed in Your Production Environment and, upon request by Oracle, confirm within 30 calendar days that You have validated Your customizations or extensions and that they may be deployed in Your Production Environment.
- You are solely responsible for Your customizations or extensions created using the Argus Cloud Extensibility and Integrations Utility, including without limitation:
 - Validating and resolving issues related to any impacts of maintenance or change management (including but not limited to patches, upgrades, or new releases) on Your customizations or extensions.
 - Changes to customizations and extensions to ensure compatibility with the Cloud Services.
- Oracle reserves the right to disable such customizations and extensions if you do not validate or resolve issues in an agreed to timeframe and/ or Oracle believes in its discretion that the customizations and extensions pose issues and/ or risks to its services.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content 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 by exporting Case data and/or by generating and downloading reports in the Cloud Service.
- Upon termination of the Cloud Service, Oracle will place on Oracle’s sFTP site a copy of the Cloud Service database residing in Your Cloud Services Production Environment, which will be available for the retrieval period stated in the Oracle Cloud Policies.

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 Argus Safety Japan Enterprise Edition Cloud Service – Case

Part #: B89666

Modules and Features

Users of the Oracle Argus Safety Japan Enterprise Edition Cloud Service are authorized to access the following modules:

- Oracle Argus Safety Japan

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Cases defined in your order.
- A combined maximum of 500,000 Cases and Japan Cases. If You require more than 500,000 then You may need to place an additional order for Oracle Argus Safety Japan Enterprise Edition Cloud Service.
- One Argus Enterprise Edition Cloud Service Case is required for each Oracle Argus Safety Japan Enterprise Edition Cloud Service Case.
- For the purposes of Oracle Argus Safety Japan Enterprise Edition Cloud Service, a Case includes PMDA (Pharmaceuticals and Medical Devices Agency) information using Japanese data items. Cases that do not contain PMDA information or Japanese data items are not considered Cases for the purposes of this Cloud Service. Japanese data (also known as PMDA data) is supported on case forms, including data items such as reporter, products, and licenses.
- Oracle will provision one Production Environment and two Non-Production Environments (Test and Development) for this Cloud Service.
- This Cloud Service provides 2 node RAC database and web servers. These are load balanced to provide a high availability solution in the event of a failure on the primary servers.
- Up to 5 terabytes of database storage per database instance.

Disaster Recovery and Service Availability *

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

RECOVERY TIME OBJECTIVE (RTO)	RECOVERY POINT OBJECTIVE (RPO)	TARGET SERVICE AVAILABILITY LEVEL
30 to 90 days	48 Hours	99.5%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. 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.

* If You have purchased Oracle Argus Enhanced Disaster Recovery Cloud Service then the Disaster Recovery and Service Availability for Oracle Argus Enhanced Disaster Recovery Cloud Service apply to this Cloud Service.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content 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 by exporting Case data and/or by generating and downloading reports in the Cloud Service.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the Cloud Service database residing in Your Cloud Services Production Environment, which will be available for the retrieval period stated in the Oracle Cloud Policies.

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 Argus Enterprise Edition Enhanced Disaster Recovery Cloud Service – Case

Part #: B89667

Modules and Features

Oracle Argus Enterprise Edition Enhanced Disaster Recovery Cloud Service is provided for the following modules that You have purchased:

- Oracle Argus Enterprise Edition Cloud Service
- Oracle Argus Safety Japan Enterprise Edition Cloud Service

Usage Limits

The Oracle Argus Enterprise Edition Enhanced Disaster Recovery Cloud Service is subject to usage limits based on:

- The quantity of Cases defined in your order.
- Oracle will provision one (1) Production Environment for this Cloud Service.

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
24 Hours	1 Hour	99.5%

*Excluding periods of bulk load.

For the purposes of this Cloud Service, the Disaster Recovery and Service Availability above take precedence over anything to the contrary in the Oracle Cloud Policies.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Argus Enterprise Edition Cloud Service Additional Non-Production Environment – Instance

Part #: B89668

Modules and Features

Oracle Argus Enterprise Edition Cloud Service Additional Non-Production Environment is provided for the following modules:

- Oracle Argus Enterprise Edition Cloud Service

Usage Limits

The Additional Non-Production Environment is subject to usage limits based on:

- The quantity of Instances defined in your order.
- Limited to use for Your Oracle Argus Enterprise Edition Cloud Service.
- Oracle will provision one (1) Non-Production Environment for each Instance you have ordered.
- Certain programs and optional services may not be able to run in the Additional Non-Production Environment.
- The maintenance or upgrade schedule for the Additional Non-Production Environment is the same as the schedule for Your Production Environment.

Disaster Recovery and Service Availability

The Disaster Recovery and Service Availability applicable to Your Production Environment(s), including Target Service Availability Level, are not applicable to the Additional Non-Production Environment. Disaster Recovery is not available for the Additional Non-Production Environment.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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

Oracle Argus Standard Edition Cloud Service – Case

Part #: B73042

Modules and Features

Users of Oracle Argus Standard Edition Cloud Service are authorized to use the following modules:

- Oracle Argus Safety
- Oracle Argus Affiliate
- Oracle Argus Interchange
- Oracle Argus Dossier
- Oracle B2B

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Cases defined in your order.
- A combined maximum of 20,000 Cases and Japan Cases during the Services Period (including the quantity purchased on the initial order and any subsequent orders expanding the quantity). If You require more than 20,000 then You must place a separate order for Oracle Argus Enterprise Edition Cloud Service.
- Oracle will provision one Production Environment and two Non-Production Environments (Test and Development) for this Cloud Service.
- The Cloud Service provides 2 node RAC database and web servers. These are load balanced to provide a high availability solution in the event of a failure on the primary servers.
- Up to 5 terabytes of database storage per database instance.

Disaster Recovery and Service Availability *

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

RECOVERY TIME OBJECTIVE (RTO)	RECOVERY POINT OBJECTIVE (RPO)	TARGET SERVICE AVAILABILITY LEVEL
30 to 90 days	48 Hours	99.5%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. 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.

* If You have purchased Oracle Argus Enhanced Disaster Recovery Cloud Service then the Disaster Recovery and Service Availability for Oracle Argus Enhanced Disaster Recovery Cloud Service apply to this Cloud Service.

Third Party License Requirements

Oracle Argus Interchange module, used with an electronic gateway, enables electronic submissions and exchanges. The Oracle B2B gateway is supported as an option for the electronic gateway. Oracle Argus Interchange module can also be used along with Axway B2Bi for electronic submission. Axway B2Bi is required as the electronic gateway for Partition Mode, as described below. The permitted exchange protocols are AS1 and AS2 with message encryption and/or HTTPS-enabled transmission. For AS1 communication, configuration of IMAP/POP3 is supported using SMTP over VPN.

For Oracle to provide the Oracle Argus Cloud Service, You are required to obtain the necessary licenses to any of the following third party software You will use:

- Axway B2Bi 2.6 SP1
- JDrug
- MedDRA/MedDRA J Dictionaries
- Microsoft Office
- RightFax 10.6 (32-bit) (*subject to the limitations below*)
- WHO Drug Dictionary

Third Party Software Limitations

- Documentum is not supported for Oracle Argus Cloud Service.
- Use of RightFax with Oracle Argus Cloud Service is partially enabled. For faxing from Oracle Argus Cloud Service, fax via email using Your fax as the end point. Fax status tracking and fax responses are not available in Oracle Argus Cloud Service.

For any required third party software You will use, You must purchase a license, as well as all consents, permits, and authorizations necessary for Oracle to access and use this software on Your behalf directly from such third parties as part of this offering. You must provide evidence of such licenses prior to Oracle's installation of such, as well as a copy of the licensed software if applicable, and You are responsible for supporting such software (including the purchase of support contracts from the third party vendors as applicable).

For Axway B2Bi, You must provide Oracle with Your Axway "Support Identifier". You will permit Oracle to use your Axway Support Identifier to file service requests with Axway. You will provide the assistance necessary for Oracle to pursue and escalate any issues and requests with Axway as needed to attempt to resolve issues impacting Your ability to use the Services; however, You are ultimately responsible for support of the Axway software.

Use of the Oracle Argus Cloud Service offering is subject to certain expectations and requirements regarding the following 3rd party software:

1. To use MedDRA within the Oracle Argus Cloud Service, You will work with Oracle to establish the necessary private circuit or VPN solution to facilitate secure web service communications between the Oracle servers and Your network. You will be required to have an authentication mechanism in place to secure the web service communication.
2. To use the SMTP capabilities from within the Argus Cloud Service, You must host within Your network the required SMTP server necessary for these capabilities, and the SMTP service must be accessible to the Oracle servers over a private circuit or VPN line.
3. Oracle requires any digital certificates provided by You to Oracle for the purpose of system integrations be issued by a commercial certificate authority. It is Your responsibility to ensure

digital certificates are issued by a commercial certificate authority. You bear all risk, and Oracle assumes no liability, if You provide Oracle with and/or You use self-signed digital certificates or self-signed certificates of any third party system for system integration purposes.

The services listed below require a separate service engagement with Oracle to define, configure/ implement, test, and deploy:

- Any data migration between versions
- Customer-specific migration services required for transformation of Your data to Oracle data models
- All services not listed in this services description

Use of Utilities

The Cloud Service may include access to certain Oracle Argus utilities, which is subject to Your Responsibilities set forth below.

Argus Cloud Extensibility and Integrations Utility

Oracle Responsibilities:

- Upon Your request, deploy Your customizations or extensions in Your Non-Production Environment(s) in accordance with Your Installation Documentation (as defined below).
- Upon Your confirmation that You have validated the customizations or extensions in Your Non-Production Environment(s), deploy the customizations or extensions in Your Production Environment in accordance with Your Installation Documentation.
- Provide You with 30 calendar days' notice prior to upgrading the base application code version in Your Environment(s).

Your Responsibilities:

- Develop Your own customizations or extensions using the Argus Cloud Extensibility and Integrations Utility in accordance with Oracle's extensibility guidelines, which are available at support.oracle.com (Doc ID 2399180.1). You are responsible for the quality of Your customization or extension code and ensuring that secure coding practices are followed.
- Submit to Oracle change management requests to add customizations or extensions to Your Non-Production and Production Environments, which must include:
 - Argus Cloud Extensibility checklist (available at support.oracle.com, Doc ID 2399180.1).
 - Clear, concise, and accurate documentation detailing installation steps for Your customizations or extensions in the Non-Production and Production Environments of the Cloud Service ("Your Installation Documentation")
 - Installation script
- Review and validate customizations or extensions in Your Non-Production Environment(s) before the customizations or extensions may be deployed in Your Production Environment and, upon request by Oracle, confirm within 30 calendar days that You have validated Your customizations or extensions and that they may be deployed in Your Production Environment.
- You are solely responsible for Your customizations or extensions created using the Argus Cloud Extensibility and Integrations Utility, including without limitation:

- Validating and resolving issues related to any impacts of maintenance or change management (including but not limited to patches, upgrades, or new releases) on Your customizations or extensions.
- Changes to customizations and extensions to ensure compatibility with the Cloud Services.
- Oracle reserves the right to disable such customizations and extensions if you do not validate or resolve issues in an agreed to timeframe and/ or Oracle believes in its discretion that the customizations and extensions pose issues and/ or risks to its services.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content 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 by exporting Case data and/or by generating and downloading reports in the Cloud Service.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the Cloud Service database residing in Your Cloud Services Production Environment, which will be available for the retrieval period stated in the Oracle Cloud Policies.

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 Argus Safety Japan Standard Edition Cloud Service – Case

Part #: B89663

Modules and Features

Users of the Oracle Argus Safety Japan Standard Edition Cloud Service are authorized to access the following modules:

- Oracle Argus Safety Japan

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Cases defined in your order.

- A maximum of 20,000 Cases and Japan Cases during the Services Period (including the quantity purchased on the initial order and any subsequent orders expanding the quantity). If You require more than 20,000 then You may need to place a separate order for Oracle Argus Safety Japan Enterprise Edition Cloud Service.
- One Argus Standard Edition Cloud Service Case is required for each Oracle Argus Safety Japan Standard Edition Cloud Service Case.
- For the purposes of Oracle Argus Safety Japan Standard Edition Cloud Service, a Case includes PMDA (Pharmaceuticals and Medical Devices Agency) information using Japanese data items. Cases that do not contain PMDA information or Japanese data items are not considered Cases for the purposes of this Cloud Service. Japanese data (also known as PMDA data) is supported on case forms, including data items such as reporter, products, and licenses.
- Oracle will provision one Production Environment and two Non-Production Environments (Test and Development) for this Cloud Service.
- This Cloud Service provides 2 node RAC database and web servers. These are load balanced to provide a high availability solution in the event of a failure on the primary servers.
- Up to 5 terabytes of database storage per database instance.

Disaster Recovery and Service Availability *

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

RECOVERY TIME OBJECTIVE (RTO)	RECOVERY POINT OBJECTIVE (RPO)	TARGET SERVICE AVAILABILITY LEVEL
30 to 90 days	48 Hours	99.5%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. 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.

* If You have purchased Oracle Argus Enhanced Disaster Recovery Cloud Service then the Disaster Recovery and Service Availability for Oracle Argus Enhanced Disaster Recovery Cloud Service apply to this Cloud Service.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content 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 by exporting Case data and/or by generating and downloading reports in the Cloud Service.
- Upon termination of the Cloud Service, Oracle will place on Oracle's sFTP site a copy of the Cloud Service database residing in Your Cloud Services Production Environment, which will be available for the retrieval period stated in the Oracle Cloud Policies.

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 Argus Standard Edition Enhanced Disaster Recovery Cloud Service – Case

Part #: B89664

Modules and Features

Oracle Argus Standard Edition Enhanced Disaster Recovery Cloud Service is provided for the following modules that You have purchased:

- Oracle Argus Standard Edition Cloud Service
- Oracle Argus Safety Japan Standard Edition Cloud Service

Usage Limits

The Oracle Argus Standard Edition Enhanced Disaster Recovery Cloud Service is subject to usage limits based on:

- The quantity of Cases defined in your order.
- Oracle will provision one (1) Production Environment for this Cloud Service.

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
24 Hours	1 Hour	99.5%

*Excluding periods of bulk load.

For the purposes of this Cloud Service, the Disaster Recovery and Service Availability above take precedence over anything to the contrary in the Oracle Cloud Policies.

Oracle Cloud Policies

The Services are subject to the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts.

Retrieval of Your Content from the Cloud Service

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