ORACLE

Oracle Life Sciences

Empirica Signal and Empirica Topics Cloud Services

Service Descriptions and Metrics

13-July-2023

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METRIC DEFINITIONS

Customer

Customer is defined as the customer entity specified on Your order.

Hosted Named Life Sciences User

Hosted Named Life Sciences User is defined as an individual authorized by You to access the Cloud Service, regardless of whether the individual is actively accessing the Cloud Service at any given time.

For the purposes of the Cloud Services described herein, when using the login group feature for logical data separation in the Cloud Service, one Hosted Named Life Sciences User applies to one individual user for one login group only. For example, an individual accessing two separate login groups will be counted as two Hosted Named Life Sciences Users.

Instance

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

GLOSSARY

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.

EMPIRICA SIGNAL SERVICE DESCRIPTIONS

Oracle Life Sciences Empirica Signal Cloud Service – Hosted Named Life Science User

Part #: B75782

Oracle Life Sciences Empirica Signal is a web-based safety data mining and analysis system for use with adverse event case data from post-marketing surveillance; refer to the Program Documentation for details. Empirica Signal is offered along with optional data services (as described below). Empirica Signal can also be configured through a separately-purchased consulting services engagement to work with customer-provided adverse event data.

Modules and Features

Oracle Life Sciences Empirica Signal Cloud Service includes the following modules:

- Home page
- Drugs profile page (if configured)
- Data Mining Runs page
- Data Mining Results page
- Queries page
- Case Series page
- Reports page

Environments

The Cloud Service includes two (2) Environments: Production and Non-Production (User Acceptance Testing). The Non-Production Environment may be refreshed, at Your request, up to once per quarter.

Usage Limits

This Oracle Cloud Service is subject to usage limits based on:

- The quantity of Hosted Named Life Science Users defined in Your order.
- Oracle Life Sciences Empirica Signal Cloud Service has the following usage limits for the Production Environment:
    - Database Storage: 1,000 GB (Database storage space is used for table spaces, indices, audit and temp files etc.; effective space available for safety and user data is approximately 50% of this gross storage volume.)
    - Application File Storage: 200 GB

Disaster Recovery and Service Availability

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

RECOVERY TIME OBJECTIVE (RTO)	RECOVERY POINT OBJECTIVE (RPO)	TARGET SERVICE AVAILABILITY LEVEL
90 days	48 hours	99%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. The Recovery Time and Recovery Point Objectives do not apply to customizations or third party software. For the purposes of this Cloud Service, the RTO, RPO, and Target Service Availability Level above take precedence over anything to the contrary in the Oracle Cloud Policies.

* If You have purchased Oracle Life Sciences Empirica Signal Enhanced Disaster Recovery Cloud Service then its Service Level Targets apply to this Cloud Service.

System Access

For single sign-on (SSO) functionality, authentication service, and LDAP groups for OAS (Oracle Analytics Service, if used), the Cloud Services are deployed with Oracle Life Sciences Identity and Access Management Services (IAMS) or the Oracle Identity Cloud Service (IDCS).

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.

- 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 Empirica Topics for Signal Management Cloud Service – Hosted Named Life Science User

Part #: B75783

Modules and Features

Users of the Oracle Life Sciences Empirica Topics for Signal Management Cloud Service are authorized to access the following modules:

- Home page
- Drugs profile page (if configured)
- Queries page
- Case Series page
- Reports page (excluding report editor)

- Signal Review page (if configured)
- Topics Management page (if configured)

Prerequisites

Base Cloud Service: Oracle Life Sciences Empirica Signal Cloud Service (Part #: B75782)

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 Hosted Named Life Science Users defined in Your order.
- This Cloud Service is subject to the Usage Limits for the Base Cloud Service.
- If the Base Cloud Service lapses or otherwise ends, this Cloud Service will also automatically end.

Disaster Recovery and Service Availability

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

System Access

The Hosted Named Life Sciences Users of this Cloud Service may be the same individuals as licensed to access the Base Cloud Service (to enable access to the combined set of application modules), or may be different individuals (with the respective module access profile as defined for each licensed 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 Empirica Signal Enhanced Disaster Recovery Cloud Service – Hosted Named Life Science User

Part #: B91141

Modules and Features

The Oracle Life Sciences Empirica Signal Enhanced Disaster Recovery Cloud Service is provided for the following Cloud Services:

- Oracle Life Sciences Empirica Signal Cloud Service *
- Oracle Life Sciences Empirica Topics for Signal Management Cloud Service **

- Oracle Life Sciences Empirica Signal FDA AERS Database Cloud Service **
- Oracle Life Sciences Empirica Signal VAERS Database Cloud Service **
- Oracle Life Sciences Empirica Signal WHO UMC Vigibase Extract Cloud Service **
- Oracle Life Sciences Empirica Signal PMDA JADER Database Cloud Service **

* *base service*
** *optional service to the base service*

Prerequisites

Base Cloud Service: Oracle Life Sciences Empirica Signal Cloud Service (Part #: B75782)

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

In order to use this Oracle Cloud Service when using Oracle Life Sciences Empirica Signal Cloud Service with Oracle Argus Enterprise Edition Cloud Service, you must first purchase Oracle Argus Enterprise Edition Enhanced Disaster Recovery.

Environments

The Cloud Service includes one (1) Production Environment.

Usage Limits

The Cloud Service is subject to usage limits based on:

- Limited to use for Oracle Life Sciences Empirica Signal Cloud Service deployments using Empirica Signal version 8.1 or later
- The quantity of Hosted Named Life Science Users defined in Your order.
- The quantity of Hosted Named Life Science Users purchased for Oracle Life Sciences Empirica Signal Enhanced Disaster Recovery Cloud Service must match the quantity of Hosted Named Life Science Users purchased for the Base Cloud Service (excluding optional services).
- The Usage Limits of the Base Cloud Service, as well as the Usage Limits for any optional Oracle Life Sciences Empirica services, apply to 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%

The RTO, RPO, and Target Service Availability Level do not apply to the Non Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. The Recovery Time and Recovery Point Objectives do not apply to customizations or third party software. For the purposes of this Cloud Service, the RTO, RPO, and Target Service Availability Level above take precedence over anything to the contrary in the Oracle Cloud Policies.

Oracle Cloud Policies

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

Retrieval of Your Content from the Cloud Service

Your Content for this Cloud Service is the same as Your Content for the Base Cloud Service.

Oracle Life Sciences Empirica Signal Cloud Service Additional Non-Production Environment – Instance

Part #: B88976

The Oracle Life Sciences Empirica Signal Cloud Service Additional Non-Production Environment provides an additional Non-Production Environment for use with Your Oracle Life Sciences Empirica Signal Cloud Service.

Modules and Features

The Oracle Life Sciences Empirica Signal Cloud Service Additional Non-Production Environment is provided for the following Cloud Services:

- Oracle Life Sciences Empirica Signal Cloud Service *
- Oracle Life Sciences Empirica Topics for Signal Management Cloud Service **
- Oracle Life Sciences Empirica Signal FDA AERS Database Cloud Service **
- Oracle Life Sciences Empirica Signal VAERS Database Cloud Service **
- Oracle Life Sciences Empirica Signal WHO UMC Vigibase Extract Cloud Service **
- Oracle Life Sciences Empirica Signal PMDA JADER Database Cloud Service **

* *base service*
** *optional service to the base service*

Prerequisites

Base Cloud Service: Oracle Life Sciences Empirica Signal Cloud Service (Part #: B75782)

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

Environments

The Cloud Service includes one (1) additional Non-Production Environment for each Instance You have ordered. The Additional Non-Production Environment may be refreshed, at Your request, up to once per quarter. The maintenance or upgrade schedule for the Additional Non-Production Environment is the same as the schedule for the Base Cloud Service.

Usage Limits

This Cloud Service is subject to usage limits based on:

- The quantity of Instances defined in Your order.
- 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

After 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 Empirica Signal FDA AERS Database Cloud Service – Customer

Part #: B75784

Modules and Features

The Empirica Signal FDA AERS Database Cloud Service is accessible through the Empirica Signal Cloud Service. New data releases will be available approximately once each quarter of a year after the raw data release by the U.S. Food and Drug Administrationand data and Oracle's preparation of the data. You may import new data releases and the applicable dictionaries into the Empirica Signal Cloud Service.

This Cloud Service includes access to MedDRA dictionary information. You must provide written confirmation to Oracle that You are validly licensed for the MedDRA dictionary prior to being provided access to the dictionary. You may only purchase and use this Cloud Service if Your are a current member of the Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization Program (the "MedDRA Program"). If You are no longer a member of the MedDRA Program and/or if Your MedDRA Program membership lapses during the Services Period of Your order, You may not use any Oracle Cloud Service that includes MedDRA information. Oracle will suspend such Service without refund in such situations. Oracle reserves the right, but is under no obligation, to re-verify that You have a valid license if the Service Period of Your order exceeds the term of Your dictionary license.

Prerequisites

Base Cloud Service: Oracle Life Sciences Empirica Signal Cloud Service (Part #: B75782)

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.

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 Empirica Signal VAERS Database Cloud Service – Customer

Part #: B75785

Modules and Features

The Empirica Signal VAERS Database Cloud Service is accessible through the Empirica Signal Cloud Service. New data releases will be available approximately once each quarter of a year after the raw data release by the US FDA and CDC joint VAERS program and Oracle's preparation of the data. You may import new data releases and the applicable dictionaries into the Empirica Signal Cloud Service.

This Cloud Service includes access to MedDRA dictionary information. You must provide written confirmation to Oracle that You are validly licensed for the MedDRA dictionary prior to being provided access to the dictionary. You may only purchase and use this Cloud Service if You are a current member of the Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization Program (the "MedDRA Program"). If You are no longer a member of the MedDRA Program and/or if Your MedDRA Program membership lapses during the Services Period of Your order, You may not use any Oracle Cloud Service that includes MedDRA information. Oracle will suspend such Service without refund in such situations. Oracle reserves the right, but is under no obligation, to re-verify that You have a valid license if the Service Period of Your order exceeds the term of Your dictionary license.

Prerequisites

Base Cloud Service: Oracle Life Sciences Empirica Signal Cloud Service (Part #: B75782)

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.

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 Empirica Signal WHO UMC Vigibase Extract Cloud Service – Customer

Part #: B92488

Modules and Features

The Empirica Signal WHO UMC Vigibase Extract Cloud Service is accessible through the Empirica Signal Cloud Service. New data releases will be available approximately once each quarter of a year after the raw data release by WHO Uppsala Monitoring Center and Oracle's preparation of the data. You may import new data releases and the applicable dictionaries into the Empirica Signal Cloud Service.

This Cloud Service includes access to MedDRA dictionary information. You must provide written confirmation to Oracle that You are validly licensed for the MedDRA dictionary prior to being provided access to the dictionary. You may only purchase and use this Cloud Service if You are a current member of the Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization Program (the "MedDRA Program"). If You are no longer a member of the MedDRA Program and/or if Your MedDRA Program membership lapses during the Services Period of Your order, You may not use any Oracle Cloud Service that includes MedDRA information. Oracle will suspend such Service without refund in such situations. Oracle reserves the right, but is under no obligation, to re-verify that You have a valid license if the Service Period of Your order exceeds the term of Your dictionary license.

You must provide written confirmation to Oracle that you are validly licensed for the VigiBase Extract Case Level and WHO Drug Dictionary prior to being provided access to the dataset. You are responsible for obtaining these licenses directly from WHO Uppsala Monitoring Centre (UMC) and maintaining valid licenses for the full duration of the Services Period of Your order. If Your license to the VigiBase Extract Case Level and/or WHO Drug Dictionary lapses during the Services Period of Your order, You may not use the Oracle Cloud Services that include VigiBase data or the WHO Drug Dictionary. Oracle may at its sole discretion suspend the Cloud Services without refund in such situations. Oracle reserves the right, but is under no obligation, to re-verify that You have a valid license if the Services Period of Your order exceeds the term of the data or dictionary license.

Prerequisite

Base Cloud Service: Oracle Life Sciences Empirica Signal Cloud Service (Part #: B75782)

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.

Third Party License Requirements

In addition, your usage of the Oracle Empirica Signal WHO UMC Vigibase Extract Cloud Service is subject to the Terms of Use below.

WHO Vigibase – Terms of Use ('Caveat Document')

Statement of reservations, limitations and conditions relating to data released from VigiBase, the WHO global database of reported potential side effects of medicinal products. Understanding and accepting the content of this document are formal conditions for the use of VigiBase data.

Uppsala Monitoring Centre (UMC) in its role as the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring receives reports of suspected adverse reactions to medicinal products from National Centres in countries participating in the WHO Programme for International Drug Monitoring. The information is stored in VigiBase, the WHO global medicinal product safety database. It is important to understand the limitations and qualifications that apply to this information and its use.

Tentative and variable nature of the data

Uncertainty: The reports submitted to UMC generally describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. In most instances it cannot be proven that a specific medicinal product is the cause of an event, rather than, for example, underlying illness or other concomitant medication.

Variability of source: Reports submitted to national centres come from both regulated and voluntary sources. Practice varies: some national centres accept reports only from medical practitioners; others from a broader range of reporters, including patients, some include reports from pharmaceutical companies.

Contingent influences: The volume of reports for a particular medicinal product may be influenced by the extent of use of the product, publicity, the nature of the adverse effects and other factors.

No prevalence data: No information is provided on the number of patients exposed to the product, and only a small part of the reactions occurring are reported.

Time to VigiBase: Some national centres make an assessment of the likelihood that a medicinal product caused the suspected reaction, while others do not. Time from receipt of a report by a national centre until submission to UMC varies from country to country. Information obtained from UMC may therefore differ from that obtained directly from national centres.

For these reasons, interpretations of adverse effect data, and particularly those based on comparisons between medicinal products, may be misleading. The data comes from a variety of sources and the likelihood of a causal relationship varies across reports. Any use of VigiBase data must take these significant variables into account.

Prohibited use of VigiBase Data includes, but is not limited to:

- patient identification or patient targeting
- identification, profiling or targeting of general practitioners or practice

Any publication, in whole or in part, of information obtained from VigiBase must include:

(i) a statement recording 'VigiBase, the WHO global database of reported potential side effects of medicinal products, developed and maintained by Uppsala Monitoring Centre' as the source of the information and/or the VigiBase logotype, in a chart or figure. The logotype in appropriate resolution and instructions on how to use it will be provided in connection with access to products.

(ii) an explanation that the information comes from a variety of sources, and the probability that the suspected adverse effect is drug-related is not the same in all cases.

(iii) an affirmation that the information does not represent the opinion of the UMC or the World Health Organization.

Omission of the above may exclude the responsible person or organization from receiving further information from VigiBase.

UMC may, in its sole discretion, provide further instructions to the user, responsible person and/or organization in addition to those specified in this statement and the user, responsible person and/or organization undertakes to comply with all such instructions.

Uppsala Monitoring Centre (UMC), Box 1051, SE-751 40, Uppsala, Sweden
E-mail: info@who-umc.org, www.who-umc.org

(End WHO Vigibase Terms of Use, 2021-11-10)

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 Empirica Signal PMDA JADER Database Cloud Service – Customer

Part #: B86793

Modules and Features

The Empirica Signal PMDA JADER Database Cloud Service is accessible through the Empirica Signal Cloud Service. New data releases will be available approximately once each quarter of a year after the raw data release by the Japanese regulator Pharmaceuticals and Medical Devices Agency (PMDA) and Oracle's preparation of the data. You may import new data releases and the applicable dictionaries into the Empirica Signal Cloud Service.

This Cloud Service includes access to MedDRA dictionary information, including the Japanese language version. Prior to accessing the MedDRA dictionary, You must provide written confirmation to Oracle that You are validly licensed for the MedDRA dictionary and are a current member of the Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization (MSSO) Program, or if You are based in Japan, the Japanese Maintenance Organization (JMO) Program, (the "MedDRA Program"). You must maintain for the duration of this Cloud Service a valid license for the MedDRA dictionary and Your membership in the MedDRA Program. If Your license or membership ends during the Services Period of Your order, You may not use any Oracle Cloud Service that includes MedDRA information and Oracle can suspend such Service without refund. Oracle reserves the right, but is under no obligation, to request that You re-verify that You have a valid license for the MedDRA dictionary and that You are a member of the MedDRA program at any time during the Service Period of Your order.

This Cloud Service includes access to Iyakuhinmei Data File Japanese Drug Dictionary ("IDF Drug Dictionary") information. Prior to being provided access to the IDF Drug Dictionary, You must provide written confirmation to Oracle that You are validly licensed for the IDF Drug Dictionary. You are responsible for licensing any dictionaries used and must have a valid license from Iyaku-Joho-Kenkyujo, Inc. ("Ijoken") in place for the full duration of the Services Period of Your order. You must maintain for the duration of this Cloud Service a valid license for the IDF Drug Dictionary. If Your license ends during the Services Period of Your order, You may not use any Oracle Cloud Service that includes IDF Drug Dictionary access and Oracle can suspend such Service without refund. Oracle reserves the right, but is under no obligation, to request that You re-verify that You have a valid license for the IDF Drug Dictionary at any time during the Service Period of Your order.

Prerequisite

Base Cloud Service: Oracle Life Sciences Empirica Signal Cloud Service (Part #: B75782)

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.

Third Party License Requirements

In addition, your usage of the Oracle Life Sciences Empirica Signal PMDA JADER Cloud Service is subject to the PMDA Terms of Use for the JADER data set, as published in Japanese on the PMDA website (https://www.pmda.go.jp/safety/info-services/drugs/adr-info/suspected-adr/0003.html). For convenience, a non-authoritative English translation is provided below.

Pharmaceuticals and Medical Devices Agency: Japanese Adverse Drug Event Report Database (JADER) Terms of Use

Article 1: Purpose

1. These Terms apply to all actions related to use of the Japanese Adverse Drug Event Report Database (hereinafter referred to as "the Database") provided by the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "PMDA").

Article 2: Definitions

1. The line-list data and the corresponding CSV data published on the section of PMDA's official Website (hereinafter referred to as "the PMDA Website") titled "Information on Reports of Suspected Adverse Drug Reactions," are together referred to as the Japanese Adverse Drug Event Report Database.
2. The party who views and uses the Database is referred to as the User.
3. Parties who use services that were developed by the User, utilizing information from the Database, are referred to as Secondary Users.
4. The User and Secondary Users are together referred to as the User, etc.
5. The Database and services developed using information from the Database are together referred to as the Database, etc.

Article 3: Termination of Use

1. The User, etc. of the Database agrees to the entirety of these Terms of Use.
2. In the case that the User violates these Terms of Use, or repeatedly causes an excessive load on the server, PMDA may deny the User access to the Database.

Article 4: Liability of User

1. The User will use the Database with appropriate judgment and responsibility.
2. The User will use the Database based on a clear understanding of the ICH/E2B (M2) guidelines.
3. The User will obtain the devices necessary to use the Database (including software and communication devices) at its own expense. Any telecommunications fees necessary for use of the Database, as well as any other fees related to use of the Database, will also be borne by the User.
4. In the case the User, etc. causes damage to PMDA or a third party in connection with use of the Database, the User, etc. will compensate for such damages.
5. If the User, etc., develops services using information from the Database, the User, etc. will inform PMDA of the services, to the extent that it can disclose.
6. The User, etc. will ensure that users of the services in the previous clause will obey these Terms of Use.

7. If the User, etc. publishes a research paper using information from the Database, etc., it will notify PMDA in advance. Also, the User, etc. must state within the research paper that it utilized data from PMDA's Japanese Adverse Drug Event Report database (JADER).
8. If the User, etc., in the course of research utilizing the Database, learns of information that could have a significant impact on the lives or health of the public (hereinafter referred to as "information on health risks"), then the User, etc. will report the information to PMDA. PMDA will consider necessary actions based on an evaluation of the reported information on health risks, in addition to other information.

Article 5: Prohibitions

1. The User, etc. must not commit any of the violations described in the following items, or any actions that might lead to any of these violations, in connection with use of the Database, etc.
   (1) Violations of any legitimate rights, such as intellectual property rights, including proprietary rights or copyrights, of PMDA or a third party.
   (2) Detriment or damages to other users, PMDA, or a third party.
   (3) Violations of public order or standards of decency.
   (4) Violations of laws, regulations, or ordinances.
   (5) Interference with the management or operation of the Database.
   (6) Actions that harm or destroy the credibility of the Database.
   (7) Unauthorized access to the Database.
   (8) Secondary sale or distribution of the Database is also prohibited in principle, even if modifications have been made to it.
   (9) Permitting Secondary Users to use services developed using information from the Database, without first providing those Secondary Users with these Terms of Use.
2. In the case that PMDA sustains any damages as a result of the violations described in the previous clause, the User, etc. must compensate PMDA for such damages.

Article 6: Exemptions from Liability

1. PMDA will bear no liability for damage to computer databases used in connection with use of the Database, or any other damages stemming from use of the Database.
2. PMDA will bear no liability for damages to computers, networks, software, or other environmental components used by the User, etc.
3. PMDA will bear no liability for any damages resulting to the User, etc. in connection with use of the Database, etc., or any damages caused by the User, etc. to a third party.
4. PMDA will bear no liability for any damages to the User, etc. or a third party resulting from modifications, suspension, termination, or abolishment of the Database, or any other system-related events.
5. PMDA will not provide any tools or software to analyze data in the Database.

Article 7: Usage Fees

1. Use of the Database is free of charge.
2. The User will bear the cost of computers and any other devices and equipment, as well as an Internet connection, needed for use of the Database.

Article 8: Copyright

1. All rights related to the Database, including copyright and other intellectual property rights, belong to PMDA.

Article 9: Maintenance

1. PMDA reserves the right to alter as necessary the name, content, URL, etc. of the Database. PMDA will post such changes on the PMDA Website.
2. PMDA reserves the right to temporarily suspend operation of the system in order to perform upgrades on the Database or ensure proper operation. PMDA will post notification of system suspension on the PMDA Website.

3. PMDA, in order to develop upgrades to the Database, may ask users for input on ways to improve/enhance the system.

Article 10: Termination of Provision of the Database
1. PMDA reserves the right to terminate provision of the Database, after providing notification in advance on the PMDA Website.

Article 11: Changes to the Terms of Use
1. PMDA reserves the right to modify these Terms of Use as deemed necessary, at any time, with no advance notification to the User, etc.
2. In the case that PMDA modifies these Terms of Use, PMDA, with the least delay, will post a notification to that effect on the PMDA Website.

Article 12: Governing laws, Consultation, and Courts of Jurisdiction
1. These Terms of Use are governed by Japanese law.
2. In the case that any questions or issues arise between PMDA and the User, etc. or a third party regarding permissible use of the Database under these Terms of Use, the parties will resolve each issue through mutual consultation in good faith.
3. In the case that the question or issue is not resolved through consultation, as per the previous clause, the Tokyo Summary Court or Tokyo District Court will have exclusive primary jurisdiction.

Article 13: Effect Date of Terms of Use
These Terms of Use are effective from April 27, 2012.
Addendum: July 10, 2013: This revision is effective from July 10, 2013.
Addendum: May 29, 2015: This revision is effective from May 29, 2015.

(End PMDA JADER Terms of Use)

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.

EMPIRICA TOPICS SERVICE DESCRIPTIONS

Oracle Life Sciences Empirica Topics Cloud Service – Hosted Named Life Science User

Part #: B75787

Oracle Life Sciences Empirica Topics is a web-based application for tracking the identification, investigation, and resolution of safety signals and other safety-related topics.

Modules and Features

Users of the Oracle Life Sciences Empirica Topics Cloud Service are authorized to use the following modules:

- Home tab
- Topics tab

Environments

The Cloud Service includes two (2) Environments: Production and Non-Production (User Acceptance Testing). The Non-Production Environment may be refreshed, at Your request, no more than once per quarter.

Usage Limits

The Cloud Service is subject to usage limits based on:

- The quantity of Hosted Named Life Science Users defined in Your order
- The Oracle Life Sciences Empirica Topics Cloud Services has the following usage limits for the Production Environment:
    - Database Storage: 1,000 GB (Database storage space is used for table spaces, indices, audit, and temp files, etc.; effective space available for user data is approx. 50% of this gross storage volume.)
    - Application File Storage: 200 GB

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 SYSTEM AVAILABILITY
90 days	48 hours	99%

The RTO, RPO, and Target Service Availability Level do not apply to the Non-Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. The Recovery Time and Recovery Point Objectives do not apply to customizations or third party software. For the purposes of this Cloud Service, the RTO, RPO, and Target Service Availability Level above take precedence over anything to the contrary in the Oracle Cloud Policies.

* If You have purchased Oracle Life Sciences Empirica Topics Enhanced Disaster Recovery Cloud Service then its Service Level Targets apply to this Cloud Service.

System Access

For single sign-on (SSO) functionality, authentication service, and LDAP groups for OAS (Oracle Analytics Service, if used), the Cloud Services are deployed with Oracle Life Sciences Identity and Access Management Services (IAMS) or the Oracle Identity Cloud Service (IDCS).

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.

- 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 Empirica Topics Enhanced Disaster Recovery Cloud Service – Hosted Named Life Sciences User

Part #: B91142

Modules and Features

The Oracle Life Sciences Empirica Topics Enhanced Disaster Recovery Cloud Service is provided for the following Cloud Services:

- Oracle Life Sciences Empirica Topics Cloud Service

Prerequisites

Base Cloud Service: Oracle Life Sciences Empirica Topics Cloud Service (Part #: B75787)

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

Environments

The Cloud Service includes one (1) Production Environment.

Usage Limits

Oracle Life Sciences Empirica Topics Enhanced Disaster Recovery Cloud Service is subject to usage limits based on:

- Limited to use for Oracle Life Sciences Empirica Topics Cloud Service deployments using Empirica Topics version 8.1 or later
- The quantity of Hosted Named Life Science Users defined in Your order.
- The quantity of Hosted Named Life Science Users purchased for Oracle Life Sciences Empirica Topics Enhanced Disaster Recovery Cloud Service must match the quantity of Hosted Named

Life Science Users purchased for the associated Oracle Life Sciences Empirica Topics Cloud Service.

- This Cloud Service is subject to the Usage Limits for the Base 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%

The RTO, RPO, and Target Service Availability Level do not apply to the Non Production Environment(s). The Target Service Availability Level does not apply in the event of a declared disaster. The Recovery Time and Recovery Point Objectives do not apply to customizations or third party software. For the purposes of this Cloud Service, the RTO, RPO, and Target Service Availability Level above take precedence over anything to the contrary in the Oracle Cloud Policies.

Oracle Cloud Policies

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

Retrieval of Your Content from the Cloud Service

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

Oracle Life Sciences Empirica Topics Cloud Service Additional Non-Production Environment – Instance

Part #: B88977

The Oracle Life Sciences Empirica Topics Cloud Service Additional Non-Production Environment provides an additional Non-Production Environment for use with Your Oracle Life Sciences Empirica Topics Cloud Service.

Modules and Features

The Oracle Life Sciences Empirica Topics Cloud Service Additional Non-Production Environment is provided for the following Cloud Services:

- Oracle Life Sciences Empirica Topics Cloud Service

Prerequisites

Base Cloud Service: Oracle Life Sciences Empirica Topics Cloud Service (Part #: B75787)

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

Environments

The Cloud Service includes one (1) Additional Non-Production Environment per Instance. The Non-Production Environment may be refreshed, at Your request, up to once per quarter. The maintenance or upgrade schedule for the Additional Non-Production Environment is the same as the schedule for the Base Cloud Service.

Usage Limits

This Cloud Service is subject to usage limits based on:

- The quantity of Instances defined in Your order.
- 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

After 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.

RETIRED SERVICES

Oracle Health Sciences Empirica Signal WHO UMC Vigibase Cloud Service – Customer

Part #: B75786

Oracle will load the Empirica Signal WHO UMC Vigibase Cloud Service into the Your Services Environment for Empirica Signal Cloud Service and configure the Empirica Signal Cloud Service to access it. The Empirica Signal WHO UMC Vigibase Cloud Service will be loaded approximately once each quarter of a year after the WHO Uppsala Monitoring Center releases the data.

This Cloud Service includes access to MedDRA dictionary information. You must provide written confirmation to Oracle that You are validly licensed for the MedDRA dictionary prior to being provided access to the dictionary. You may only purchase and use this Cloud Service if Your are a current member of the Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization Program (the "MedDRA Program"). If You are no longer a member of the MedDRA Program and/or if Your MedDRA Program membership lapses during the Services Period of Your order, You may not use any Oracle Cloud Service that includes MedDRA information. Oracle will suspend such Service without refund in such situations. Oracle reserves the right, but is under no obligation, to re-verify that You have a valid license if the Service Period of Your order exceeds the term of Your dictionary license.

You must provide written confirmation to Oracle that you are validly licensed for the WHO Drug Dictionary prior to being provided access to the dictionary. You are responsible for licensing any dictionaries used and must have a valid license from WHO Uppsala Monitoring Centre (UMC) in place for the full duration of the Services Period of Your order. If Your license to WHO Drug Dictionary lapses during the Services Period of Your order, You may not use any Oracle Cloud Services that include WHO Drug Dictionary access. Oracle may at its sole discretion suspend the Cloud Services without refund in such situations. Oracle reserves the right, but is under no obligation, to re-verify that You have a valid license if the Services Period of Your order exceeds the term of the dictionary license.

Third Party License Requirements

In addition, your usage of the Oracle Empirica Signal WHO UMC Vigibase Cloud Service is subject to the Terms of Use below.

WHO Vigibase – Terms of Use

Uppsala Monitoring Centre (UMC) in its role as the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring receives reports of suspected adverse reactions to medicinal products from National Centres in countries participating in the WHO pharmacovigilance network, the WHO Programme for International Drug Monitoring (PIDM). The information is stored in VigiBase, the WHO international database of suspected adverse drug reactions (ADRs). It is important to understand the limitations and qualifications that apply to this information and its use.

The reports submitted to UMC generally describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. In most instances it cannot be proven that a specific medicinal product (rather than, for example, underlying illness or other concomitant medication) is the cause of an event.

Reports submitted to National Centres (NCs) come from both regulated and voluntary sources. Some National Centres accept reports only from medical practitioners; other National Centres accept reports from a broader range of reporters, including patients. Some National Centres include reports from pharmaceutical companies in the information submitted to UMC; other National Centres do not.

The volume of reports for a particular medicinal product may be influenced by the extent of use of the product, publicity, the nature of the reactions and other factors. No information is provided on the number of patients exposed to the product.

Some National Centres that contribute information to VigiBase make an assessment of the likelihood that a medicinal product caused the suspected reaction, while others do not. Time from receipt of a report by a National Centre until submission to UMC varies from country to country. Information obtained from UMC may therefore differ from those obtained directly from National Centres.

If in doubt or in need of help for interpretation of country specific data, UMC recommends to contact the concerned NC before using the data.

For the above reasons interpretations of adverse reaction data, and particularly those based on comparisons between medicinal products, may be misleading. The supplied data come from a variety of sources. The likelihood of a causal relationship is not the same in all reports. Any use of this information must take these factors into account.

Confidential data

According to WHO policy and UMC Guidelines, ADR reports sent from the WHO PIDM member countries to VigiBase are anonymized, but they are still to be considered sensitive due to the nature of the data.

When receiving and using adverse reaction data ("Data"), the user agrees and acknowledges that it will be the controller of any such Data. Accordingly, the user shall adhere to all applicable legislation such as, but not limited to, EU and national legislation regarding protection of personal data (e.g. the Data Protection Directive 95/46/EC and Regulation (EC) No 45/2001, as applicable). Transfer of sensitive data to a third party is generally prohibited subject to limited exceptions explicitly stated in applicable legislation.

As the controller of the Data, the user shall be liable for any and all processing of the Data and shall indemnify and hold the UMC harmless against any claim from a data subject or any other person or entity due to a breach of any legislation or other regulation regarding the processing of the Data.

Non-permitted use of VigiBase Data includes, but is not limited to:

- patient identification or patient targeting
- identification, profiling or targeting of general practitioners or practice

Any publication, in whole or in part, of information obtained from UMC must include a statement:

(iv) regarding the source of the information
(v) that the information comes from a variety of sources, and the likelihood that the suspected adverse reaction is drug-related is not the same in all cases,
(vi) that the information does not represent the opinion of the World Health Organization.

Omission of this statement may exclude the responsible person or organization from receiving further information from VigiBase.

UMC may, in its sole discretion, provide further instructions to the user, responsible person and/or organization in addition to those specified in this statement and the user, responsible person and/or organization undertakes to comply with all such instructions.

Uppsala Monitoring Centre (UMC), Box 1051, SE-751 40, Uppsala, Sweden
Tel: +46-18-65 60 60, E-mail: info@who-umc.org, Web: www.who-umc.org

(End WHO Vigibase Terms of Use, 2016-05-01)

Prerequisite(s): In order to use this Oracle Cloud Service, you must first purchase Oracle Health Sciences Empirica Signal Cloud Service.

Service Level Targets:

The Service Level Targets, including Target System Availability, are provided with the Oracle Health Sciences Empirica Signal 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.