Oracle Life Sciences AI Agents Service Descriptions and Metrics

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METRIC DEFINITIONS

Trial is defined as each research project, study or procedure created, modified, tracked, planned and/or conducted by a sponsor using the Oracle services.

GLOSSARY

AI Agent is an autonomous entity that leverages artificial intelligence (AI) to perform assigned tasks, examine its environments, take actions as prescribed by its roles, and adjust based on its experiences.
AI Units (AU) is defined as credits that entitle customers to run AI Agents. Each AI Agent uses a defined number of AI Units (AU) that are counted each time the AI Agent is actioned as stated in the AI Unit Consumption Table.

Connected Clinical Research System is defined as an Oracle or third-party clinical research system that You use to provide Your Trial Content to the Cloud Service through supported integrations.

Digital Plan is defined as a structured operational representation of a Trial that may include Trial assumptions, timelines, milestones, resource planning elements, operational dependencies, and execution scenarios.

Health Summary is defined as a summarized view of operational Trial(s) indicators, metrics, trends, and risks derived from Connected Clinical Research Systems.

Key Performance Indicator (KPI) is defined as a metric presented by the Cloud Service designed to help support monitoring, planning, analysis, or oversight activities for a Trial.

Operational Plan is deifned as a structured representation of Trial planning activities, timelines, assumptions, resources, operational milestones, and execution strategies used to support Trial planning and oversight.

Protocol Amendment Recommendation is defined as informational outputs generated by the Cloud Services designed to recommend potential Trial protocol modifications based on identified operational patterns or trends for evaluation or consideration.

Protocol Conversion is defined as a process designed to transform protocol documents into a structured, machine-readable representation to a unified study definitions model standard to help with operational planning, analytics, and downstream workflow support of a Trial.

Site Insights is defined as informational outputs generated by the Cloud Services designed to help identify Trial site performance, enrollment activity, operational efficiency, study conduct, or site-level operational indicators.

Subject Insights is defined as informational outputs generated by the Cloud Services designed to identify Trial subject participation, enrollment, retention, engagement, or operational trends derived from connected systems.

Trial Insights is defined as informational outputs generated by the Cloud Service designed to help identify operational patterns, trends, opportunities, risks, or performance indicators related to Trial execution.



SERVICE DESCRIPTIONS – ORACLE LIFE SCIENCES AI AGENTS

Oracle Life Sciences AI Agent Cloud Service, Clinical Trial Pack

Part #: B113296 – Per Trial

Oracle Life Sciences AI Agent Cloud Service, Clinical Trial Pack

Oracle Life Sciences AI Agent Cloud Service, Clinical Trial Pack is a Cloud Service that uses AI Agents to provide access to dashboards, KPIs, and AI-driven insights to help support Trial planning, operations, and oversight. Users of the Oracle Life Sciences AI Agents Cloud Service are authorized to access the following AI Agents:

Trial Planning Agent

Oracle Life Sciences Trial Planning Agent is an AI Agent intended to be used by clinical development professionals prior to Trial execution to help support Protocol Conversion, Digital Plan generation, Operational Plan workflows, country and site selection, cost estimation, and schedule planning activities.

Trial Conduct Agent

Oracle Life Sciences Trial Conduct Agent is an AI Agent intended to be used by clinical trial operations teams responsible for executing and monitoring active clinical Trials. Oracle Life Sciences Trial Conduct Agent is designed to support Trial monitoring including Trial health summaries, overviews, and KPIs, Site Insights, Subject Insights, and Protocol Amendment Recommendations.

Trial Portfolio Agent

Oracle Life Sciences Trial Portfolio Agent is an AI Agent intended to be used by executive leadership and clinical development teams to support portfolio level operational oversight. Oracle Life Sciences Trial Portfolio Agent is designed to help summarize insights across a portfolio of Trials, providing Trial portfolio overviews with health summaries and KPIs, and Trial portfolio insights.

Environments

The Cloud Service includes one (1) Production Environment.

Prerequisites

For Trial Conduct Agent and Trial Portfolio Agent, a supported Connected Clinical Research System as set forth in the program documentation.

Delivery

You may access this Cloud Service through a web-based user interface using your tenant specific URL. AI capabilities are delivered through AI Agents operating within the Cloud Services and Oracle's models (including OCI Generative AI).

AI Agents

This Cloud Service includes AI agents. The AI agents may use Large Language Models through the Cloud Services. Your use of the LLM may be subject to additional terms as described in the Appendix to this document and by using such LLM, You acknowledge and agree to abide by the terms specific to that LLM. Oracle reserves the right to update the additional terms associated with a given LLM or to update the AI Unit decrement status associated with a given LLM during the Services Period upon notice.

Usage Limits

The Cloud Service is subject to usage limits based on:

- Up to a maximum of 210 AI Units
- Insights and outputs derived from the Cloud Services are not regulatory grade and are not approved for use in and should not be relied upon to support regulatory submissions, filings, obligations or decision-making or support regulated vigilance assessments, processes, or submissions.

AI Unit Consumption Table

ACTION	METRIC	AI UNITS CONSUMED
Onboarding of each Trial	AI Units	6 per Trial

Disaster Recovery and Service Availability

For purposes of Recovery Time Objective and Recovery Point Objective pursuant to Disaster Recovery and System Availability as described in the Oracle Cloud Policies referenced below, this Cloud Service has the following service level targets for the Environment:

RECOVERY TIME OBJECTIVE	RECOVERY POINT OBJECTIVE	TARGET SERVICE AVAILABILITY
12 hours	1 hour	99.5%

The Service Level Targets do not apply to non-production usage. The Target System Availability 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.

Oracle Cloud Policies and Pillar Documentation

Your order for this Oracle Cloud Service is subject to the *Oracle Cloud Hosting and Delivery Policies and Industry Cloud Services Pillar Document*, which may be viewed at www.oracle.com/contracts/cloud-services.

Your Responsibilities

- You are responsible for performing user management for Your Users and Administrator Users using the AI Agents User Management and Oracle Identity Domains.
- You are responsible for uploading protocol documents into the Cloud Services to be processed via the Cloud Services.
- You are responsible for building and maintaining integrations and connections to the Cloud Services to Your Connected Clinical Research System using Oracle-published APIs and schemas. Oracle consulting assistance is available under a separate agreement for an additional fee. You remain responsible for ensuring you have all rights necessary to integrated with third party cloud services, applications and/ or sources.
- AI-generated outputs are informational in nature and are subject to limitations inherent in machine learning and generative AI technologies and You are responsible for ensuring appropriate human review and approval prior to use of any AI-generated outputs for any purpose. Any recommendations are provided solely for consideration or evaluation, and You are solely responsible for determining whether to implement any recommendation.
- The Cloud Service is designed and authorized solely for the processing of non-identifiable information and is not intended for the receipt, storage, processing, or transmission of personally identifiable information or any other information that identifies, or could reasonably be used to identify, an individual. You will not input, upload, submit, transmit, or otherwise make available through this Cloud Service any such information and acknowledge that You are solely responsible for ensuring that any of Your Content provided to the Cloud Service has been rendered non identifiable in accordance with applicable law prior to submission.
- You are responsible for assessing the Cloud Services for and ensuring Your compliance with Your

regulatory, privacy, security, quality, and GxP obligations. You are responsible for Your compliance obligations, including obtaining consents and authorizations where necessary for Your Content and ensuring data that you provide to or connect with the Cloud Services complies with applicable law and contractual terms.

- You acknowledge and agree that data collected and/ or used by the Cloud Services may not comprise a complete patient medical record; such data may be incorrect because of transcription or other errors; the Services have not been reviewed or approved by regulators for use as "decision support" software for diagnosis or therapy or pharmacovigilance activities; and the Services and outputs are not intended to guide clinical treatment, determine patient eligibility at the point of care, or serve as a finalized regulatory or clinical document.
- You are responsible for, and the Services depend on, Your fulfillment of Your obligations under this service description, the order, and the agreement.

APPENDIX

As a condition of using the OpenAI LLM (GPT 4.1 and GPT-5.2; this Appendix does not apply to GPT-OSS), You acknowledge that Your use is limited to use of Your Custom AI Agent in support of Your Oracle Life Sciences AI Agents. In addition, You agree that You and Your Users will comply with the following terms:

1. You understand that the content of Your prompt (such as data, images, text) will be sent to an OpenAI end point that is outside of the Oracle managed datacenter associated with Your Oracle Life Sciences AI Agents. All OpenAI endpoints accessed via the Oracle Life Sciences AI Agents are enabled for "Zero Data Retention" which means that Your Content (a) will not be logged for human review and (b) will not be saved to disk or retained by OpenAI.

2. The Program Documentation includes mapping of the Custom AI Agent for Oracle Life Sciences AI Agents in a given Data Center Region and the location of the related Open AI endpoint.

3. In the event that OpenAI (i) removes an endpoint, (ii) ceases to offer an endpoint in a region, or (iii) deprecates a version of an OpenAI LLM, Oracle will provide at least 90 days notice.

4. Your Users of the Custom AI Agent for Oracle Life Sciences AI Agents must be located in a country or territory that is supported by OpenAI; the full list of supported countries and territories is available at https://help.openai.com/en/articles/5347006-openai-api-supportedcountries-and-territories.

5. Without limiting the applicability of other terms in Your order and Agreement, You agree that You will not and will not knowingly permit Your Users to use the OpenAI LLM in a way that violates OpenAI Policies, as described at the following links: Service-Specific Terms (https://openai.com/policies/service-terms), Sharing and Publication Policy (https://openai.com/policies/sharing-publication-policy), and Usage Policies (https://openai.com/policies/usage-policies). Further, You will not and will not knowingly permit Your Users to authorize or allow minors to use the OpenAI LLM without consent from their parent, guardian or instructor. You will not and will not knowingly permit Your Users to use Output from the OpenAI LLM to develop artificial intelligence models that directly compete with OpenAI's products and services.