ORACLE

Oracle Life Sciences

Cloud Consulting/ Professional Services

Service Descriptions and Metrics

12-Oct-2023

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PROFESSIONAL SERVICES DELIVERY POLICIES

The Oracle Professional Services Delivery Policies ("Policies") available at http://www.oracle.com/contracts apply to all professional services in your order.

Oracle's Professional Services Delivery Policies are subject to change, but such changes will not materially reduce the level of performance, functionality, security, or availability for the Services for the duration of Your order.

DEFINITIONS

Clinical One

"Clinical One" refers to Oracle Life Sciences Clinical One Cloud Services and may include the following Oracle Life Sciences Cloud Services purchased by You:

- *Single Trial Services*: Oracle Life Sciences Clinical One Cloud Service – Basic, Data Collection, Phase 1, Single Trial; Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Single Trial; Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Phase 1, Single Trial; Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Single Trial; Oracle Life Sciences Clinical One Cloud Service - Randomization & Supplies Management, Additional Sites, Single Trial; Oracle Life Sciences Clinical One Cloud Service – Randomization & Supplies Management, Up to 75 Sites, Single Trial; Oracle Life Sciences Clinical One Cloud Service - Randomization, Additional Sites, Single Trial; Oracle Life Sciences Clinical One Cloud Service - Randomization, Up to 75 Sites, Single Trial; Oracle Health Sciences Clinical One Cloud Service - Basic, Data Collection, >75 Patients, Single Trial; Oracle Health Sciences Clinical One Cloud Service - Basic, Data Collection, Up to 75 Patients, Single Trial; Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, >75 Patients, Single Trial; Oracle Health Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Up to 75 Patients, Single Trial; Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Basic Cloud Service; Oracle Health Sciences Clinical One Randomization and Data Collection Single Trial Plus Cloud Service; or Oracle Health Sciences Clinical One Randomization & Supplies Management Single Trial Cloud Service
- *Multiple Trial Services*: Oracle Life Sciences Clinical One Cloud Service - Basic, Data Collection, Multi-Trial; Oracle Life Sciences Clinical One Cloud Service - Plus, Data Collection and Randomization, Multi-Trial; Oracle Life Sciences Clinical One Cloud Service - Randomization, Multi-Trial; Oracle Life Sciences Clinical One Cloud Service - Supplies Management, Multi-Trial; Oracle Health Sciences Clinical One Randomization and Data Collection Multi-Trial Basic Cloud Service; Oracle Health Sciences Clinical One Randomization Cloud Service; or Oracle Health Sciences Clinical One Supplies Management Cloud Service

Data Point

A Data Point is a data field in the source system that corresponds to a data field in the target system.

InForm

"InForm" refers to Oracle Life Sciences InForm Cloud Services and may include the following Oracle Life Sciences Cloud Services purchased by You:

- *Single Trial Services*: Oracle Life Sciences InForm Cloud Service, Oracle Life Sciences InForm Direct Cloud Service, Oracle Health Sciences InForm Cloud Service, Oracle Health Sciences InForm Direct Cloud Service
- *Multiple Trial Services*: Oracle Life Sciences InForm Trial Capacity Cloud Service, Oracle Health Sciences InForm Trial Capacity Cloud Service

Trial

Trial is defined as each research project, study or procedure created, modified, tracked and/or conducted by a sponsor using the licensed programs or service(s).

CONSULTING/PROFESSIONAL SERVICE DESCRIPTIONS

Oracle Life Sciences Clinical One Data Collection Trial Configuration – Unique Form per Trial

Part #: B92509

Description of Services

Oracle Life Sciences Clinical One Data Collection Trial Configuration includes the following remote services related to the configuration of a Trial build design for the Data Collection component of Clinical One, (the "**Services**"). Oracle will:

1. Consult with Your trial team and project manager remotely to gather and review Your requirements for the build configuration for one (1) Trial ("**Your Trial**");
2. Consult with Your trial team and project manager remotely to confirm and finalize Your requirements, which may include, as required by Your Trial the total electronic case report forms ("**eCRFs**") for Your Trial ("**Total eCRFs per Patient**"), electronic data capture form content, rules and edit checks, schedule for time and events, Clinical One configurations, and database requirements, for Your Trial, subject to the Assumptions below, (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
3. Based upon Your Confirmed Requirements and the agreed-upon timelines and milestones, Oracle will create and provide to You a project plan in English and in a format determined by Oracle detailing the tasks, timelines, and milestones for which Oracle and You are responsible;
4. Based upon Your Confirmed Requirements, Oracle will configure and test the Cloud Services for Your Trial ("**Trial Build Configuration**"), provide specification documentation in English and in a format determined by Oracle describing the design of the Trial Build Configuration, and notify You that the Trial Build Configuration is ready for Your Testing (as defined under Your Cooperation);
5. Conduct a meeting with You to review the Trial Build Configuration and Your plan for Your Testing ("**Testing Kick-off Meeting**");
6. Consult with Your trial team and designated project manager remotely to address Your questions that arise during Your Testing and to review Your findings after completion of Your Testing;
7. Address issues raised by You with respect to the Trial Build Configuration during Your Testing and notify You that the Trial Build Configuration is ready for deployment to the Production mode of Clinical One;
8. Upon Your instruction, move the Trial Build Configuration to Approved status so that You can enable it in the Production mode of Clinical One.
9. Following movement of the Trial Build Configuration to Approved status, Oracle will provide a documentation package to You to help address Your record retention obligations. The documentation will contain records relating to the specification, verification, and acceptance of Your Trial Build Configuration.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that trial specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Use the Identity and Access Management Service ("**IAMS**") to perform user management, and ensure Oracle service team members are provided prompt access to Clinical One as necessary for Oracle to perform the Services.
3. Designate a project manager responsible for coordinating Your activities.
4. Designate a trial team responsible for Your Trial to participate in meetings and configuration reviews with Oracle and ensure that the trial team and project manager are present and/or involved in all key meetings and deliverables (such as requirements discussion and user acceptance testing), and that they adhere to the project plan.
5. Deliver clear and complete requirements and documentation (e.g. final/approved protocol, time & events schedule, copies of electronic case report forms, and/or other documents that describe the clinical study conduct operations and format for data entry) in accordance with the project plan.
6. Provide input into the creation and maintenance of the project planning document as requested by Oracle.
7. Ensure Trial Build Configuration versions created by the Oracle services team as part of the Services are not modified by You or Your Users during the Services and/or the duration of Your Trial.
8. Upon notification by Oracle that the Trial Build Configuration is ready for Your Testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following the Testing Kick-off Meeting. "**Testing**" means:
    i. Testing the Trial Build Configuration (e.g. conducting user acceptance testing) in the Test mode of Clinical One against Your own standard operating procedures and/or work instructions using Your own test cases, and
    ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle.
9. Approve the Trial Build Configuration and instruct Oracle to move the Trial Build Configuration to the Approved status within five (5) business days of the date Oracle notifies You that the Trial Build Configuration is ready for Production mode of Clinical One.

10. Deploy the Trial Build Configuration to Production by enabling Your Site Users to access the Approved Trial.

Project Assumptions

1. Oracle will perform the Services remotely from Oracle's site.
2. The Service is for the configuration of the Data Collection component of Clinical One and does not include configuration of any other components of the Cloud Service.
3. The Trial Build Configuration is limited to the quantity of Unique Forms You have ordered. A "**Unique Form**" is an eCRF for a clinical study which is intended to capture certain information for a specific purpose, as differentiated from other eCRFs for such clinical study. Unique Forms include new or reused Unique Forms.
4. A **"Visit"** is a collection of eCRFs for a particular visit by a patient for the clinical trial.
5. The total number of Visits included with the Trial Build Configuration is no more than 50.
6. **"Rule"** is defined as an aspect of the Trial Build Configuration that determines actions that Oracle Life Sciences Clinical One will perform based on certain specified conditions.
7. The Service includes up to 8 Rules per Unique Form that You have ordered.
8. The quantity of Unique Forms included in Your order is based upon the parameters that You provided to Oracle prior to execution of the order. A different combination of Unique Forms, Visits, and/or Rules may be necessary as the Services proceed, and such changes may require additional effort and fees.
9. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance, may be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the execution of Your order (**"Professional Services Period"**). For the purposes of Oracle Life Sciences Clinical One Data Collection Trial Configuration Service, this means that You must have met Your obligation to instruct Oracle to move the Trial Build Configuration to the Approved status within the Professional Services Period defined above.

Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences Clinical One RTSM Trial Configuration – Trial

Part #: B92510

Description of Services

Oracle will provide up to 120 hours of remote assistance related to the configuration of a Trial build design for the Randomization and/or Supplies Management components of Clinical One, (the "**Services**"). Such assistance may include the following:

1. Consult with Your trial team and project manager remotely to gather and review Your requirements for the build configuration for one (1) Trial ("**Your Trial**");
2. Consult with Your trial team and project manager remotely to confirm and finalize Your requirements for Your Trial, subject to the Assumptions below, (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
3. Based upon Your Confirmed Requirements and the agreed-upon timelines and milestones, Oracle will create and provide to You a project plan in English and in a format determined by Oracle detailing the tasks, timelines, and milestones for which Oracle and You are responsible;
4. Based upon Your Confirmed Requirements, Oracle will configure and test the Cloud Services for Your Trial ("**Trial Build Configuration**"), provide specification documentation in English and in a format determined by Oracle describing the design of the Trial Build Configuration, and notify You that the Trial Build Configuration is ready for Your Testing (as defined under Your Cooperation);
5. Conduct a meeting with You to review the Trial Build Configuration and Your plan for Your Testing ("**Testing Kick-off Meeting**");
6. Consult with Your trial team and designated project manager remotely to address Your questions that arise during Your Testing and to review Your findings after completion of Your Testing;
7. Address issues raised by You with respect to the Trial Build Configuration during Your Testing and notify You that the Trial Build Configuration is ready for deployment to the Production mode of Clinical One;
8. Upon Your instruction, move the Trial Build Configuration to Approved status so that You can enable it in the Production mode of Clinical One.
9. Following movement of the Trial Build Configuration to Approved status, Oracle will provide a documentation package to You to help address Your record retention obligations. The documentation will contain records relating to the specification, verification, and acceptance of Your Trial Build Configuration.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that trial specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;

c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;

d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and

e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

2. Use the Identity and Access Management Service (**"IAMS"**) to perform user management and ensure Oracle service team members are provided prompt access to Clinical One as necessary for Oracle to perform the Services.
3. Designate a project manager responsible for coordinating Your activities.
4. Designate a trial team responsible for Your Trial to participate in meetings and configuration reviews with Oracle and ensure that the trial team and project manager are present and/or involved in all key meetings and deliverables (such as requirements discussion and user acceptance testing), and that they adhere to the project plan.
5. Deliver clear and complete requirements and documentation (e.g. final/approved protocol, time & events schedule, etc.) in accordance with the project plan.
6. Provide input into the creation and maintenance of the project planning document as requested by Oracle.
7. Ensure Trial Build Configuration versions created by the Oracle services team as part of the Services are not modified by You or Your Users during the Services and/or the duration of Your Trial.
8. Upon notification by Oracle that the Trial Build Configuration is ready for Your Testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following the Testing Kick-off Meeting. "**Testing**" means:

    i. Testing the Trial Build Configuration (e.g. conducting user acceptance testing) in the Test mode of Clinical One against Your own standard operating procedures and/or work instructions using Your own test cases, and

    ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle.

9. Approve the Trial Build Configuration and instruct Oracle to move the Trial Build Configuration to the Approved status within five (5) business days of the date Oracle notifies You that the Trial Build Configuration is ready for Production mode of Clinical One.
10. Ensure that any live randomization schedule and/or medication kit list that You require is generated in or uploaded into the Approved status container by Your study personnel and that such study personnel are unblinded.
11. Deploy the Trial Build Configuration to Production by enabling Your Site Users to access the Approved Trial.

Project Assumptions

1. Oracle will perform the Services remotely from Oracle's site.

2. The Service is for the configuration of the Randomization and/or Supplies Management components of Clinical One and does not include configuration of any other components of the Cloud Service.
3. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance, may be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the execution of Your order (**"Professional Services Period"**). For the purposes of Oracle Life Sciences Clinical One RTSM Trial Configuration Service, this means that You must have met Your obligation to instruct Oracle to move the Trial Build Configuration to the Approved status within the Professional Services Period defined above.

Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences Clinical One Central Coding Trial Configuration – Trial

Part #: B93146

Description of Services

Oracle Life Sciences Clinical One Central Coding Trial Configuration covers the following remote services related to the Oracle Life Sciences Central Coding program configuration for the integration of Oracle Life Sciences Central Coding (**"Central Coding"**) with the Data Collection component of Clinical One (**"Clinical One Data Collection"**), (the **"Services"**). Oracle will:

1. Consult with Your designated project manager remotely for up to four (4) hours to gather, review, finalize, and confirm Your integration requirements to be included in the Central Coding setup and integration configuration for one (1) Clinical One Data Collection Trial (**"Your Trial"**) (subject to the limits below) (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
2. Based upon Your Confirmed Requirements, create and finalize a specification document in English and in a format determined by Oracle describing the setup and integration configurations (**"Final Integration Specification"**);
3. Based upon the Final Integration Specification, in Your user acceptance testing instance of Central Coding, configure one (1) integration between Central Coding and Your Trial (**"Central**

Coding Configuration"), which may include only the following:

a. Configuration of a coding algorithm

b. Configuration of coding definitions for up to two (2) standardized medical coding dictionaries

c. Configuration of assignment rules for coding work teams

d. Configuration of synonym lists and stopword lists

e. Configuration of Your Trial and the associated Central Coding job schedules, and/or

f. Configuration of one version of Medical Dictionary for Regulatory Activities (**"MedDRA"**) and one version of World Health Organization Drug Dictionary (**"WHODD"**) standardized medical coding dictionaries in Central Coding.

4. Verify the Central Coding Configuration in Your user acceptance testing instance of Central Coding and notify You that the Central Coding Configuration is ready for Your Testing (as defined below);
5. Address Test Feedback provided by You during the Testing Period with respect to the Central Coding Configuration (**"Final Central Coding Configuration"**);
6. Perform and verify the Final Central Coding Configuration in Your Production instance of Central Coding.
7. Following verification of the Final Central Coding Configuration in Your Production instance, Oracle will provide a documentation package to You to help address Your record retention obligations. The documentation will contain records relating to the specification, verification, and acceptance of Your Final Central Coding Configuration.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are involved in all key meetings, deliverables, and timelines.
3. Manage and oversee all third party vendors.
4. Upon notification by Oracle that the Central Coding Configuration is ready for Your testing,

perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following such notice from Oracle (**"Testing Period"**). **"Testing"** means:

i. Testing the Central Coding Configuration (e.g. conducting user acceptance testing) in Your user acceptance testing instance of Central Coding against Your own standard operating procedures and/or work instructions using Your own test cases, and

ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle (**"Test Feedback"**).

5. Obtain, prior to the commencement of the Services, all appropriate license rights for MedDRA and WHODD.

Project Assumptions

1. Any configurations required for the Trial Build will be the responsibility of the party performing the Trial Build. **"Trial Build"** means the Trial design and build configurations of the Data Collection component of Clinical One.
2. The Services are limited to configurations based on available standard features and functions in accordance with the Service Specifications for Clinical One and Central Coding and do not include custom configurations.
3. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance, will be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences Clinical One Central Coding, Single Dictionary Upgrade – Each

Part #: B93147

Description of Services

Oracle Life Sciences Clinical One Central Coding, Single Dictionary Upgrade covers the following remote services related to the upgrade of one (1) Standard Coding Dictionary in Oracle Life Sciences Central

Coding (**"Central Coding"**) for use with the Data Collection component of Clinical One, (the **"Services"**). Oracle will:

1. Consult with Your designated project manager remotely for up to one (1) hour to gather, review, finalize, and confirm Your requirements for **(a)** a new version of one (1) Standard Coding Dictionary based on the standard Central Coding product functionalities (the **"New Dictionary Version"**), and **(b)** one (1) set of configuration parameters to be used in conjunction with the New Dictionary Version and assignment rules to process incoming requests in Central Coding (a **"Coding Definition"**), (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
2. Based upon Your Confirmed Requirements, create and finalize a specification document in English and in a format determined by Oracle describing the New Dictionary Version and Coding Definition (**"Final Specification"**);
3. Based upon the Final Specification, perform the steps below (collectively the **"Impact Analysis Process"**) in Your user acceptance testing instance of Central Coding:
    a. Install the New Dictionary Version;
    b. Update the Central Coding configuration for the New Dictionary Version and Coding Definition;
    c. Perform synonyms lists upgrade;
    d. Run an update for the Coding Definition;
    e. Perform an impact analysis and prepare an impact analysis report designed to allow Your coder to review updated codes for existing verbatims before committing such updates;
    f. Assist Your coder in reconciling and accepting changed codes;
    g. Notify Your coder that the updates are ready for finalization; and
    h. Upon Your coder's instruction, finalize the updates (the **"Committed Updates"**).
4. Implement the Committed Updates in Your user acceptance testing instance of Central Coding and notify You that the Committed Updates are ready for Your Testing (as defined below);
5. Address Test Feedback provided by You during the Testing Period;
6. In Your Production instance of Central Coding, perform the Impact Analysis Process and implement the Committed Updates.

<u>Your Cooperation</u>

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your Trial(s) including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;

d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and

e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are involved in all key meetings, deliverables, and timelines.
3. Manage and oversee all third party vendors.
4. Ensure that Your dictionary coder works with Oracle on the Impact Analysis Process and instruct Oracle to finalize the updates within five (5) business days of the date Oracle notifies You that the updates are ready for finalization.
5. Upon notification by Oracle that the Committed Updates are ready for Your testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following such notice from Oracle (**"Testing Period"**). **"Testing"** means:

    i. Reviewing the Impact Analysis report and reconciling and accepting changed codes in Your user acceptance testing instance of Central Coding against Your own standard operating procedures and/or work instructions using Your own test cases, and

    ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle (**"Test Feedback"**).

6. Obtain, prior to the commencement of the Services, all appropriate license rights for the Standardized Coding Dictionary.

Project Assumptions

1. **"Standardized Coding Dictionary"** means either Medical Dictionary for Regulatory Activities (**"MedDRA"**) or World Health Organization Drug Dictionary (**"WHODD"**)
2. Any configuration updates required for the Trial build design(s) of the Data Collection component of Clinical One are not included.
3. The Dictionary Upgrade and Coding Definition may be associated with one or more Clinical One Data Collection Trials.
4. The required Clinical One Data Collection Trials will be configured prior to Oracle beginning the Impact Analysis Process in Your user acceptance testing instance.
5. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance will be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated

herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences Clinical One Digital Gateway Configuration Service – Integration per Trial

Part #:

B92664 Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points
B92665 Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 70 Data Points

Description of Services

Oracle Life Sciences Clinical One Digital Gateway Configuration Service includes the following remote services related to the configuration of a standard integration between Clinical One and a Separate Software Application (as defined in the Project Assumptions) (the "**Services**"). Oracle will:

1. Consult with Your project manager to gather and review Your requirements to identify one (1) Separate Software Application and the Data Point(s), as defined in the "Definitions" section above, to be included in the integration for one (1) Trial ("**Your Trial**");
2. Consult with Your designated project manager to confirm and finalize Your requirements, Separate Software Application, and Data Points (subject to the limits below) to be included in the integration for Your Trial ("**Your Confirmed Requirements & Data Points**"):
    a. If You have purchased Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 40 Data Points (part # B92664), up to 40 Data Points are included;
    b. If You have purchased Oracle Life Sciences Clinical One Digital Gateway Configuration Service, up to 70 Data Points (part # B92665), up to 70 Data Points are included;
3. Based upon Your Confirmed Requirements & Data Points, create a specification document in English and in a format determined by Oracle identifying the one (1) Separate Software Application for the integration and describing the integration configurations and Data Point(s) to be included in the integration ("**Integration Specification**");
4. Consult with Your project manager to review and finalize the Integration Specification ("**Final Integration Specification**");
5. Based upon the Final Integration Specification, configure one (1) integration between Clinical One and the one (1) Separate Software Application for Your Trial ("**Digital Gateway Configuration**");
6. If testing is available for the Separate Software Application, Oracle will perform the Digital Gateway Configuration in the Test mode of Clinical One and will assist in addressing issues raised by You with respect to the Digital Gateway Configuration during Your Testing (as

defined below);

7. Oracle will perform the Digital Gateway Configuration in the Production mode of Clinical One; and
8. Upon Your instruction, enable the Digital Gateway Configuration in the Production mode of Clinical One for the corresponding Production Trial.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are involved in all key meetings, deliverables, and timelines.
3. Manage and oversee all third party vendors.
4. Review the Integration Specification and provide feedback to Oracle within one (1) week following the date that Oracle provides the Integration Specification to You.
5. Use the Identity and Access Management Service (**"IAMS"**) to perform user management, and ensure Oracle service team members are provided prompt access to Clinical One and Digital Gateway as necessary for Oracle to perform the Services.
6. If testing is available for the Separate Software Application, coordinate with the Separate Software Application vendor to ensure that Oracle service team members are provided prompt access to the Separate Software Application Trial build design in a non-production test environment as necessary for Oracle to perform the Services.
7. If testing is available for the Separate Software Application, upon notification by Oracle that the Digital Gateway Configuration is ready for Your testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following such notice from Oracle. "**Testing**" means:
    i. Testing the Digital Gateway Configuration (e.g. conducting user acceptance testing) in the Test mode of Clinical One against Your own standard operating procedures and/or work instructions using Your own test cases, and
    ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle.

8. Instruct Oracle to enable the Digital Gateway Configuration in the Production mode of Clinical One within five (5) business days of the date Oracle notifies You that the Digital Gateway Configuration is ready to be enabled in Production mode.
9. Obtain, prior to the commencement of the Services, the Separate Software Application and all appropriate license rights necessary for Oracle to access the Separate Software Application on Your behalf.

Project Assumptions

1. "**Separate Software Application**" means a software application other than Clinical One and may be an Oracle software application or a third party software application.
2. Data Points to be included in the Digital Gateway Configuration must be finalized in Clinical One and the Separate Software Application Trial build designs before Oracle starts work on the Integration Specification.
3. The Clinical One Trial build design must be in the Clinical One Test container and, if testing is available for the Separate Software Application, the Separate Software Application Trial build design must be finalized for testing, and available in a test environment, before Oracle begins the Digital Gateway Configuration.
4. The Services are limited to configurations for eligible pre-built integrations in accordance with the Clinical One Program Documentation and do not include custom configurations. Not all pre-built integrations are eligible for this Service. The available pre-built integrations are described at the following link: https://docs.oracle.com/en/industries/health-sciences/clinical-one/clinicalio/index.html.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). For the purposes of Oracle Life Sciences Clinical One Digital Gateway Configuration Service, this means that You must have met Your obligation to instruct Oracle to enable the Digital Gateway Configuration in the Production mode of Clinical One within the Professional Services Period defined above.

Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences Clinical One Extended Dashboards Service – Each

Part #: B98946

Description of Services

Oracle Life Sciences Clinical One Extended Dashboards Service covers the following remote services related to the deployment of analytics dashboards within the Data Collection component of Clinical One, (the "**Services**"). Oracle will:

1. Upon receipt of access to Your Clinical One Cloud Service in accordance with Your Obligations below, deploy the following analytics dashboards for the Data Collection component of Clinical One in one (1) Clinical One tenant (the **"Clinical One Extended Dashboards"**):

    a. **Study Design Metadata Dashboard**

    This dashboard covers study metadata and design analytics, designed to assist with activity tracking and pattern identification, and consists of the following seven (7) reports and twenty-three (23) visualizations:

    1. ***Study Design Overview*** report, with the following visualizations:

        a. Key performance indicator metrics for Total Studies, Study Versions, Study Branches, Study Cycle Branches, Study Events, Study Form Counts, and Study Item counts.

        b. *Study Version by Design Status Bar Graph:* Presentation of study version distribution in the Draft, Test, Approved, and Archive modes of Clinical One across different studies.

        c. *Study Design Details Tablular Metrics*: Study elements (Event Count, Form Count, Branch Count, Required Items Count, etc.) across different studies, study modes, and versions.

    2. ***Study Version Over Months*** report, with the following visualizations:

        a. *Study Version Counts Over Months Line Graph*: Indicates total number of study versions created over months, for studies selected in the Clinical One Extended Dashboard.

        b. *Study Version Details Table:* Tabular listing of study level details for Study Phases, Therapeutic Area, Study Design Status, Study Version, Modified-by, Version Start, and Modification Month.

    3. ***Study Design Comparison*** report, with the following visualizations:

        a. *Study Design Details Horizontal Bar Chart*: Shows variations between two different versions of a study selected by You for Branch Count, Event Count, Form Count, and Item Count.

        b. *Visit Grid Heat Map*: Chart indicating visit differences between two different selected study versions.

        c. *Forms Grid Heat Map*: Chart showing form differences between two different selected study versions.

        d. *Repeating Form Grid Heat Map:* Chart indicating repeating form differences between two different selected study versions.

        e. *Branches Grid Heat Map*: Chart showing branch differences between two different selected study versions.

f. *Items Grid Heat Map*: Chart indicating form item differences between two different selected study versions.

4. ***Therapeutic Areas*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

   a. *Study Version Count in Therapeutic Area Stacked Bar Visualization:* Presents total study version distribution among the Draft, Test, Approved, and Archive modes across different therapeutic areas.

   b. *Study Versions in Different Therapeutic Area Grid Heat Map*: Chart showing the density of study versions across studies and therapeutic areas.

   c. *Total Study Versions by Therapeutic Area and Study Phase Donut Chart*: Shows distribution of study versions and their percentages for different therapeutic areas and study phases.

   d. *Study, Phase & Therapeutic Area Sankey Visualization*: Covers selected studies across different phases & therapeutic areas.

   e. *Study Therapeutic Area Details Table:* Tabular presentation of study, phase, and therapeutic level data details including Blinding Type, Total Study Versions, Draft Version Count, Test Version Count, Approved Version Count, and Archive Version Count.

5. ***Study Version Data Availability*** report, with the following visualizations:

   a. *Study Version Data Availability Timeline:* Shows a complete schedule of all available versions across months of a year for the studies selected by You in the Clinical One Extended Dashboard.

6. ***Study Phase Analysis*** report, with the following visualizations:

   a. *Study Phase Details Table:* Shows tabular metrics of a study and its phases with Event Count, Form Count, and Item Count.

   b. *Study Phase Analysis Vertical Bar Chart:* Presents total event count, form count, and item count across different phases for different selected studies.

7. ***Study Branch Details*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

   a. Average Cycle Count by Study Branch Horizontal Bar Chart: Shows cycle count at different branches.

   b. Study Branch Count by Cycle Branch Status Pie Chart: Includes counts and percentages of study branches differentiating Cycle Branch or Non-Cycle Branch.

   c. *Branch Count by Design Status Vertical Bar Chart:* Presents study branch count spread across study design status (in Draft, Test, Approved, and Archive modes).

   d. *Study Branch Details Table:* Tabular presentation of data with columns for Study Title, Study Version, Study Design Status, Study Branch, Is Cycle Brand, Cycle Count, and Assign Subject Using Form Question.

b. Study Progress Overview Dashboard

This dashboard provides reports related to site status and performance, subject recruitment and retention within the study-site, site monitoring, and tracking and consists of the following five (5) reports and twenty (20) visualizations:

1. ***Study Overview*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. Key performance indicator metrics for Total Screened, Current Screened, Screen Failed, Enrolled, Current Active, Randomized, Completed, and Early Terminated Subjects.
    b. *Total Enrollment Progress Over Time Line Chart:* Presents enrollment progress over months.
    c. *Screening vs Enrollment Progress Over Time Combo Chart:* Comparison of enrolled count (line) vs. screened count (bar) of subjects.
    d. *Subject Enrollment Details Table:* Presents data in a tabular format including columns for Investigator, Month, Total Screened, Current Screened, Screen Failed, Enrollment Count, Completed Count, and Dropout Counts of subjects at Study, Country, and Site level.
2. ***Trial Recruitment Status*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. *Subjects Geographical Distribution Map Chart:* Indicates the subject counts across different countries on the world map.
    b. *Number of Subjects by Study Bar Chart*: Presentation of the subject distribution and comparison.
    c. *Number of Subjects by State and Study Grid Heat Map*: Shows density of subjects in different states (New, Screened, Enrolled, Active, Completed, Withdrawn, etc.).
    d. *Number of Subjects by State Bar Chart*: Visual representation of progress and comparison of subject count vs subject states.
3. ***Outstanding Queries by Site and Visit*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. *Query Count by Country Map Chart*: Indicates the query counts across different countries/geographic locations on the world map.
    b. *Outstanding Queries by Visit Stacked Bar Visualization*: Presents queries spread across different visits with different query statuses (Opened, Answered, Closed, etc.).
    c. *Count and Duration of Open Queries by Site Vertical Bar Visualization*: Presents open queries within different durations (0-5 days, 6-10 days, 11-30 days, 31-60 days, >60 days) across Sites.
    d. *Outstanding Queries by Site and Visit Table:* Tabular metrics of Study, Country, Site, Subject, Event, Count of Open Queries, Answered Queries, Candidate Queries, Total Queries, 0-5 Days Opened, 6-10 Days Opened, 11-30 Days Opened, 31-60 Days Opened, and >60 Days Opened.
4. ***Form Status*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

a. Key performance indicator metrics for Total Forms, Forms Completed, Forms Frozen, Forms SDV (Source Data Verification), and Forms Signed.

b. *Frozen, Completed, Verified, and Signed Forms by Visit Vertical Bar Chart*: Identifies count of forms completed, forms frozen, forms sdv, and forms signed across visits.

c. *Completed vs Verified vs Signed Forms Timeline Line Chart*: Shows differences in total forms completed, forms signed, and forms verified across form visit month.

d. *Forms Status Details Table:* Tabular metrics of detailed data with columns for Study, Country, Site, Subject, Event, Visit Start Date, Total Forms, Count of Forms Completed, Forms Frozen, Forms Verified, and Forms Signed.

5. ***Forms Missing*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

a. Key performance indicator metrics for Total Forms, Forms Completed, Forms Missing, Forms Partially Completed, and Forms Overdue.

b. *Forms Status by Visit Type Stacked Bar Chart*: covers counts of Forms Completed, Forms Missing, Forms Partially Completed, and Forms Overdue across event types.

c. *Forms Status by Visit Horizontal Bar Chart*: Includes counts and comparisons of Forms Completed, Forms Missing, Forms Partially Completed, and Forms Overdue across visits.

d. *Forms Missing Details Table:* Tabular metrics of detailed data with columns for Study, Country, Site, Investigator, Subject, Visit Type, Event, Visit Start Date, Visit Status, Total Forms, Forms Completed, Forms Missing, Forms Partially Completed, and Forms Overdue.

c. Site and Region Overview Dashboard

This dashboard provides reports related to status and performance of study, site, and region for monitoring and tracking and consists of the following five (5) reports and twenty-six (26) visualizations:

1. ***Site Status*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

a. Key performance indicator metrics of Total Sites Count, Active Sites Count, and Retired Sites Count.

b. *Sites by Status Donut Chart*: Shows distribution of active vs. retired sites, with counts and percentages.

c. *Site Status by Study*, *Horizontal Bar Chart*: Shows statistics for Site counts and comparison of Sites by status (Active, Retired).

d. *Site Status by Countries Stacked Bar Visualization*: Presents total number of Sites across countries with Site status (Active, Retired).

e. *Site Status Details Table:* Includes tabular metrics of detailed data with columns for Study, Country, Site, Investigator, Site Status, Fist Screened, First Randomized, Total Sites, Active Sites, and Retired Sites.

2. ***Trial Recruitment & Status*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

a. Key performance indicator metrics of New Subjects, Total Screened, Current Screened, Screen Failure, Enrolled, Current Active, Randomized, Completed, and Withdrawn Subject Count.

b. *Subject Count by Status Vertical Stacked Bar Visualization*: Shows distribution of subjects across subject states (Active, Completed, Enrolled, New, Screen Failed, Screening Initiated, Withdrawn, etc.).

c. *Subject Count by Status by Site Grid Heat Map*: Chart showing the density of subjects across sites and subject state.

d. *Trial Recruitment Details Table:* Includes tabular metrics of detailed data with columns for Study, Country, Site, Investigator, Site Status, New Subjects, Total Screened, Current Screened, Screen Failed, Enrolled, Randomized, Randomized, Current Active, Completed Study, and Dropout.

3. ***Enrollment Status*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

   a. *Subject Enrollment Count by Site/Country Grid Heat Map*: Chart showing the density of enrolled subjects across Sites and country.

   b. *Subject Enrollment Count by Country Donut Chart*: Shows distribution of enrolled subjects with counts and percentages across countries.

   c. *Subject Enrollment Count by Site Vertical Stacked Bar Visualization:* Shows distribution of enrolled subjects at different sites .

   d. *Total Enrollment Progress Over Time Line Chart*: Presents enrollment progress over months.

   e. *Screening vs Enrollment Progress Over Time Combo Chart*: Comparison of enrolled count (line) vs. screened count (bar) of subjects.

   f. *Site Enrollment Details Table:* Shows tabular metrics of detailed data with columns for Study, Country, Site, Investigator, Site Status, Month, Total Screened, and Enrollment Count.

4. ***Form Status*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

   a. Key performance indicator metrics for Total Forms, Forms Completed, Forms Missing, Forms Overdue, Forms Frozen, Forms Verified, and Forms Signed.

   b. *Frozen Forms by Study/Site Grid Heat Map*: Chart showing the volume of Frozen Forms across sites .

   c. *Signed Forms by Study/Site*, *Grid Heat Map*: Chart showing the volume of signed forms across sites.

   d. *Verified Forms by Study/Site Grid Heat Map*: Chart showing the volume of verified forms across sites.

   e. *Number of Subjects by Study/Site Grid Heat Map*: Chart showing the volume of subject counts across sites.

f. *Forms Details Table:* Shows tabular metrics of detailed data with columns for Study, Country, Site, Subject, Visit Title, Form Name, Total Forms, Forms Completed, Forms Overdue, Forms Frozen, Forms Verified, and Forms Signed.

5. ***Query Status*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

   a. *Query Count by Country Map Chart*: Indicates the query counts across different countries/geographic locations on a world map.

   b. *Outstanding Queries by Visit Stacked Bar Visualization*: Shows queries spread across different visits with different query statuses (Opened, Answered, Candidate, etc.).

   c. *Outstanding Queries by Site Horizontal Stacked Bar Chart*: Visualization of the distribution of open and answered queries across different Sites.

   d. *Total Queries Distribution by Status Stacked Bar Chart*: Visualization presenting total queries spread across different query statuses (Opened, Answered, Candidate, etc.).

   e. *Outstanding Queries by Site and Visit Table*: Includes tabular metrics of data with columns for Study, Country, Site, Subject, Event, Count of Open Queries, Answered Queries, Candidate Queries, Total Queries, 0-5 Days Opened, 6-10 Days Opened, 11-30 Days Opened, 31-60 Days Opened, and >60 Days Opened.

d. CRA (Clinical Research Associate) Extension Dashboard

This dashboard provides reports related to site status and performance, subject recruitment and retention, site monitoring, and tracking and consists of the following nine (9) reports and thirty-four (34) visualizations:

1. ***Study-Enrollment Overview*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

   a. *Enrollment Progress Over Time Line Chart*: Presents enrollment progress over months.

   b. *Enrollment Count by Studies Pie Chart*: Shows counts and percentages of total enrollment counts.

   c. *Study Overview Details Table:* Tabular metrics of detailed data including columns for Study, Therapeutic Area, Study Phase, Blinding Type, Study Version, Country, Site and, Total Enrollment Count.

2. ***Enrollment*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

   a. *Trend Analysis of Enrollment Line Chart*: Presents enrollment percentage progress over months.

   b. *Enrollment Rate per Site Vertical Bar Chart*: Shows enrollment percentage across sites.

   c. *Enrollment % by Study Horizontal Bar Chart*: Shows enrollment percentage.

   d. *Subject Enrollment Details Table:* Tabular metrics of detailed data including columns for Study, Country, Site, Total Subject Count, Current Screened Count, Total Enrollment Count, Current Active Count, Randomized Count Completed Study Count, Screen Failed Count, Early Termination Count, and Dropout count.

3. ***Subject Drop Out Count by Reason*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

    a. *Total Subject Status Distribution Revealing Dropouts Like Screen Failed/Withdrawn Vertical Stacked Bar Visualization*: Shows distribution of subjects at different subject states (Active, Completed, Enrolled, New, Screen Failed, Screening Initiated, Withdrawn, etc.).

    b. Reasons of Screening Failure Tree Diagram Visualization: Displays pictorial view of different screen failure reasons available.

    c. Subject Dropout Count by Reason Details Table: Tabular metrics of detailed data including columns for Study, Country, Site, Site Status, Investigator, Subject State, Screen Failure Reason, and Dropout counts.

    d. *Screening Failure/Dropout Counts by Reason Table:* Tabular metrics of dropout counts for each screen failure reason.

4. ***Outstanding Queries by Site and Visit*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

    a. *How Long Since the Answered Queries Are Not Tracked to Closure Vertical Bar Chart*: Shows query counts against query age in days.

    b. *Query Counts by Question Type Horizontal Stacked Bar Chart*: Shows correlation between queries raised and question type with different query state (Open, Answered, Candidate, etc.).

    c. Top 10 Queries by Query Age Tree Map Chart: Shows the top 10 outstanding queries with query text, query age, and query counts.

    d. Outstanding Queries by Site and Visit Details Table: Tabular metrics of detailed data consisting of columns for Study, Country, Site, Visit, Visit Type, Scheduled Visit, Open Queries, Answered Queries, Candidate Queries, Total Queries, 0-5 Days Opened, 6-10 Days Opened, 11-30 Days Opened, 31-60 Days Opened, and >60 Days Opened.

5. ***Queries Status by Site and Subject*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

    a. *Number of Queries by Visit and Query Status Vertical Bar Chart*: Shows comparison of query counts against different query states (Open, Answered, Candidate, etc.) across visits.

    b. *Query and Subjects Count by Study Horizontal Bar Chart*: Shows correlation between total query counts and subject counts.

    c. Query Status Count by Mandatory Item Donut Visualization: Provides query counts and percentages for mandatory items with query status (Open, Answered, Candidate, etc.).

    d. Total Queries Distribution by Status Visualization: Shows metrics for open, answered, candidate, etc. query counts across countries.

    e. Query Status by Site and Subject Details Table: Tabular metrics of detailed data consisting of columns for Study, Country, Site, Subject Number, Subject State, Open Queries, Answered Queries, Candidate Queries, Closed Queries, Deleted Queries, Started Visits, and Percentage of Queries within Country.

6. ***Queries Management Detail*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

    a. *Queries Raised on Items, Vertical Stacked Bar Visualization*: Shows volume of queries with different query states (Open, Answered, Candidate, etc.) for different items.

    b. *Top 5 Queries Raised on Items Horizontal Bar Chart*: Shows correlation between Total Query Counts and items.

    c. Query Management Detail Report Table: Tabular metrics of detailed data consists of columns for Study, Country, Site, Subject Number, Visit, Form Name, Item Name, Query Comment, Query State, Query Age, and User Name.

7. ***Subject Counts with Outstanding Queries*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

    a. *Average Age of Queries Open by Site/Study Vertical Stacked Bar Visualization*: Compares average age of open queries on all available sites.

    b. *Subject Count with Query Status by Site, Vertical Stacked Bar Chart*: Shows correlation between query counts with status (Open, Answered, Candidate, etc.) and subject count for different sites.

    c. Subject Counts with Outstanding Queries Table: A tabular presentation of detailed data consisting of columns for Study, Country, Site, Subject Number, State, and Count.

8. ***Summary of Query Activity*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

    a. Key performance indicator metrics around Open Query Count, Answered Query Count, Candidate Query Count and Closed Query Count.

    b. *Top 5 Sites with Highest Number of Queries, Vertical Bar Visualization*: Shows the five Sites with the highest volume of queries.

    c. *% Queries by Status Donut Visualization*: Shows query volume with percentage distribution across query status (Open, Answered, Candidate, etc.).

    d. *Query Aging Buckets for Open, Answered and Closed State Bar Visualization*: Presents statistics around query volume with status (Open, Answered, Candidate, etc.) divided into query age categories (0-5 Days, 6-10 Days, 11-30 Days, 31-60 Days, >60 Days).

    e. Query Activity Details Table: Tabular metrics of detailed data including columns for Study, Country, Site, Subject Number, Visit, Open Query Count, Answered Query Count, Candidate Query Count, Deleted Query Count, Closed Query Count, 6-10 Days Opened, 11-30 Days Opened, 31-60 Days Opened and >60 Days Opened.

9. ***Top Investigators*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:

    a. *Top Investigators Compared to All Investigators for Study, Total Enrollment, Vertical Bar Visualization*: Presents comparison of patients enrolled by investigator.

    b. Enrollment by Investigators for Study Table: Tabular metrics of detailed data consisting of columns for Study, Country, Site, Investigator, Subject Number, Screening Date, and State.

e. Data Manager (DM) Extension Dashboard

This dashboard provides reports related to site status and performance, subject recruitment and retention, site monitoring, and tracking and consists of the following five (5) reports and twenty-one (21) visualizations:

1. ***Outstanding Queries by Site and Visit*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. *How Long since the Answered Queries are not Tracked to Closure Vertical Bar Chart*: Shows query counts against query age in days.
    b. *Query Counts by Question Type, Horizontal Stacked Bar Chart*: Shows correlation between queries raised and question type with different query state (Open, Answered, Candidate, etc.).
    c. *Top 10 Queries by Query Age Tree Map Chart*: Shows the top 10 outstanding queries with Query Text, Query Age, and Query Counts.
    d. *Outstanding Queries by Site and Visit Details Table:* Tabular metrics of detailed data consisting of columns for Study, Country, Site, Visit, Visit Type, Scheduled Visit, Open Queries, Answered Queries, Candidate Queries, Total Queries, 0-5 Days Opened, 6-10 Days Opened, 11-30 Days Opened, 31-60 Days Opened, and >60 Days Opened.
2. ***Queries Status by Site and Subject*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. *Number of Queries by Visit and Query Status Vertical Bar Chart*: Shows comparison of query counts against different query states (Open, Answered, Candidate, etc.) across visits.
    b. *Query and Subjects Count by Study Horizontal Bar Chart*: Shows correlation between total query counts and subject counts.
    c. *Query Status Count by Mandatory Item Donut Visualization*: Provides query counts and percentages for mandatory items with query status (Open, Answered, Candidate, etc.).
    d. *Total Queries Distribution by Status Visualization:* Shows metrics for Open, Answered, Candidate, etc. query counts across countries.
    e. *Query Status by Site and Subject Details Table:* Tabular metrics of detailed data consisting of columns for Study, Country, Site, Subject Number, Subject State, Open Queries, Answered Queries, Candidate Queries, Closed Queries, Deleted Queries, Started Visits, and % of Queries within Country.
3. ***Queries Management Detail*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. *Queries Raised on Items Vertical Stacked Bar Visualization*: Shows volume of queries with different query states (Open, Answered, Candidate, etc.) on different items.
    b. *Top 5 Queries Raised on Items Horizontal Bar Chart*: Shows correlation between total query counts and items.
    c. *Query Management Detail Report Table:* Tabular metrics of detailed data consisting of columns for Study, Country, Site, Subject Number, Visit, Form Name, Item Name,

Query Comment, Query State, Query Age, and User Name.

4. ***Subject Counts with Outstanding Queries*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. *Average Age of Queries Open by Site/Study, Vertical Stacked Bar Visualization*: Compares average age of open queries on all available Sites.
    b. *Subject Count with Query Status by Site, Vertical Stacked Bar Chart*: Shows correlation between query counts with status (Open, Answered, Candidate, etc.) and subject count for different Sites.
    c. *Subject Counts with Outstanding Queries Table:* Tabular presentation of detailed data consisting of columns for Study, Country, Site, Subject Number, State, and Count.
5. ***Summary of Query Activity*** report, with the following visualizations for the studies selected by You in the Clinical One Extended Dashboard:
    a. Key performance indicator metrics around Open Query Count, Answered Query Count, Candidate Query Count and Closed Query Count.
    b. *Top 5 Sites With Highest Number Of Queries Vertical Bar Visualization*: Shows the five Sites with the highest volume of queries.
    c. *% Queries by Status Visualization*: Shows query volume with percentage distribution across query status (Open, Answered, Candidate, etc.).
    d. *Query Aging Buckets for Open, Answered and Closed State Bar Visualization*: Presents statistics around query volume with status (Open, Answered, Candidate, etc.) divided in query age categories (0-5 Days, 6-10 Days, 11-30 Days, 31-60 Days, and >60 Days).
    e. *Query Activity Details Table:* Tabular metrics of detailed data including columns for Study, Country, Site, Subject Number, Visit, Open Query Count, Answered Query Count, Candidate Query Count, Deleted Query Count, Closed Query Count, 6-10 Days Opened, 11-30 Days Opened, 31-60 Days Opened, and >60 Days Opened.

2. Notify You that the Clinical One Extended Dashboards are available for Your use (**"Oracle's Notification"**).
3. Provide You with access to documentation on the Clinical One Extended Dashboards.
4. For ten (10) business days from the date of Oracle's Notification, assist in answering your questions regarding and provide technical support for the Clinical One Extended Dashboards (**"Dashboard Support"**). Thereafter standard Oracle Cloud Support applies.
5. These dashboards will be deployed "as-is" and with no customizations.

Your Cooperation

1. Regulatory Compliance:
    a. You are responsible for notifying Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You.
    b. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Use the Identity and Access Management Service (IAMS) to perform user management and ensure that Oracle service team members are provided prompt access to Clinical One as

necessary for Oracle to perform the Services.

Project Assumptions

1. The Clinical One Extended Dashboards may be used for all studies on one (1) Clinical One tenant.
2. The Services do not include custom configurations.
3. Once deployed, Your users with access to Analytics within Clinical One will also have access to the Clinical One Extended Dashboards.
4. The Dashboard Support will be available during standard Oracle business hours in the GMT time zone.
5. Standard Oracle Cloud Support is described in the *Oracle Cloud Hosting and Delivery Policies*, which are available at www.oracle.com/contracts.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Professional Services Period

The Services above must be used within twelve (12) from the signature date of Your order ("Professional Services Period"). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences Clinical One Study Build Instruction for Data Collection (private class) – Each

Part #: B93027

Description of Services

The Oracle Life Sciences Clinical One Study Build Instruction for Data Collection, private class consists of the following services related to Trial design and build configurations ("**Trial Builds**") of the Data Collection component of Clinical One ("**Clinical One DC**"), (the "**Services**"). Oracle will:

1. Conduct one (1) kick-off meeting of up to one (1) hour in duration via web conference that may be attended by up to eight (8) of Your participants to:
    a. Present a summary of the Services that will be performed and the topics and agenda for the Instruction Workshop;
    b. Provide You with the list of, and instructions on accessing, the pre-requisite self-paced online Clinical One courses (the "**Pre-Requisite Courses**"); and
    c. Determine the dates and times for the Instruction Workshop;

2. Set up a non-production environment for You within Oracle's Clinical One training environment and provide You with access;
3. Provide one (1) workshop, consisting of instruction, demonstrations, and hands-on exercises based on industry-recommended practices for Clinical One DC Trial Builds, for up to twenty-four (24) total hours in duration for up to eight (8) of Your participants (the "**Instruction Workshop**");

Your Cooperation

1. Designate up to eight (8) participants to attend the kick-off meeting and the Instruction Workshop.
2. Ensure that Your Instruction Workshop participants have the business, functional skills, and knowledge (including prior knowledge of, experience in, and responsibility for building, running and managing clinical trials) to support Oracle's performance of the Services and that they have completed the Pre-Requisite Courses before the start of the Instruction Workshop.
3. Ensure that Your designated participants attend the kick-off meeting and the Instruction Workshop.
4. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

Project Assumptions

1. The Pre-Requisite Courses will be completed by Your Instruction Workshop participants prior to the Instruction Workshop.
2. Oracle will perform the Services remotely. The Services may be performed by Oracle resources located globally. Oracle global resources will use commercially reasonable efforts to provide the Services in accordance with Your working hours.
3. Oracle will provide the Instruction Workshop via web conference (including video) over the course of six (6) consecutive half business days.
4. Oracle and You will mutually agree upon dates and times for the Instruction Workshop, which will be scheduled a minimum of eight (8) business days in advance.
5. One (1) business day is equivalent to eight (8) hours. A business day is Monday through Friday, excluding holidays, during Oracle local business hours.
6. The Instruction Workshop will be delivered using Oracle's Clinical One training environment on the then-current version of Clinical One. Your access to the training environment will be removed after completion of the Instruction Workshop.
7. All verbal and written communication, and related documentation, will be in English.
8. Configurations of Trial Builds or integrations, reports, ongoing support or troubleshooting, as well as make up sessions for any part of the Instruction Workshop that may have been missed by Your Instruction Workshop participants, and any other services not expressly identified in the Description of Services are excluded.

Professional Services Period

The Services must be used within twelve (12) months from the execution of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically

forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle each agree to designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences Clinical One Study Build Instruction for Randomization & Trial Supply Management (private class) – Each

Part #: B93026

Description of Services

The Oracle Life Sciences Clinical One Study Build Instruction for Randomization & Trial Supply Management, private class consists of the following services related to Trial design and build configurations ("**Trial Builds**") of the Randomization and Supplies Management component of Clinical One ("**Clinical One RTSM**"), (the "**Services**"). Oracle will:

1. Conduct one (1) kick-off meeting of up to one (1) hour in duration via web conference that may be attended by up to eight (8) of Your participants to:
    a. Present a summary of the Services that will be performed and the topics and agenda for the Instruction Workshop;
    b. Provide You with the list of, and instructions on accessing, the pre-requisite self-paced online Clinical One courses (the "**Pre-Requisite Courses**"); and
    c. Determine the dates and times for the Instruction Workshop;
2. Set up a non-production environment for You within Oracle's Clinical One training environment and provide You with access;
3. Provide one (1) workshop, consisting of instruction, demonstrations, and hands-on exercises based on industry-recommended practices for Clinical One RTMS Trial Builds, for up to twenty-four (24) total hours in duration for up to eight (8) of Your participants (the "**Instruction Workshop**");

Your Cooperation

1. Designate up to eight (8) participants to attend the kick-off meeting and the Instruction Workshop.
2. Ensure that Your Instruction Workshop participants have the business, functional skills, and knowledge (including prior knowledge of, experience in, and responsibility for building, running and managing clinical trials) to support Oracle's performance of the Services and that they have completed the Pre-Requisite Courses before the start of the Instruction Workshop.

3. Ensure that Your designated participants attend the kick-off meeting and the Instruction Workshop.
4. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

Project Assumptions

1. The Pre-Requisite Courses will be completed by Your Instruction Workshop participants prior to the Instruction Workshop.
2. Oracle will perform the Services remotely. The Services may be performed by Oracle resources located globally. Oracle global resources will use commercially reasonable efforts to provide the Services in accordance with Your working hours.
3. Oracle will provide the Instruction Workshop via web conference (including video) over the course of six (6) consecutive half business days.
4. Oracle and You will mutually agree upon dates and times for the Instruction Workshop, which will be scheduled a minimum of eight (8) business days in advance.
5. One (1) business day is equivalent to eight (8) hours. A business day is Monday through Friday, excluding holidays, during Oracle local business hours.
6. The Instruction Workshop will be delivered using Oracle's Clinical One training environment on the then-current version of Clinical One. Your access to the training environment will be removed after completion of the Instruction Workshop.
7. All verbal and written communication, and related documentation, will be in English.
8. Configurations of Trial Builds or integrations, reports, ongoing support or troubleshooting, as well as make up sessions for any part of the Instruction Workshop that may have been missed by Your Instruction Workshop participants, and any other services not expressly identified in the Description of Services are excluded.

Professional Services Period

The Services must be used within twelve (12) months from the execution of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle each agree to designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences Clinical One Study Build Instruction for Randomization & Trial Supply Management and Data Collection (private class) – Each

Part #: B93028

Description of Services

The Oracle Life Sciences Clinical One Study Build Instruction for Randomization & Trial Supply Management and Data Collection, private class consists of the following services related to Trial design and build configurations ("**Trial Builds**") of the Randomization, Supplies Management, and Data Collection components of Clinical One ("**Clinical One RTSM and DC**"), (the "**Services**"). Oracle will:

1. Conduct one (1) kick-off meeting of up to one (1) hour in duration via web conference that may be attended by up to eight (8) of Your participants to:
    a. Present a summary of the Services that will be performed and the topics and agenda for the Instruction Workshop;
    b. Provide You with the list of, and instructions on accessing, the pre-requisite self-paced online Clinical One courses (the "**Pre-Requisite Courses**"); and
    c. Determine the dates and times for the Instruction Workshop;
2. Set up a non-production environment for You within Oracle's Clinical One training environment and provide You with access;
3. Provide one (1) workshop, consisting of instruction, demonstrations, and hands-on exercises based on industry-recommended practices for Clinical One RTSM and DC Trial Builds, for up to thirty-two (32) total hours in duration for up to eight (8) of Your participants (the "**Instruction Workshop**");

Your Cooperation

1. Designate up to eight (8) participants to attend the kick-off meeting and the Instruction Workshop.
2. Ensure that Your Instruction Workshop participants have the business, functional skills, and knowledge (including prior knowledge of, experience in, and responsibility for building, running and managing clinical trials) to support Oracle's performance of the Services and that they have completed the Pre-Requisite Courses before the start of the Instruction Workshop.
3. Ensure that Your designated participants attend the kick-off meeting and the Instruction Workshop.
4. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

Project Assumptions

1. The Pre-Requisite Courses will be completed by Your Instruction Workshop participants prior to the Instruction Workshop.
2. Oracle will perform the Services remotely. The Services may be performed by Oracle resources located globally. Oracle global resources will use commercially reasonable efforts to provide the Services in accordance with Your working hours.

3. Oracle will provide the Instruction Workshop via web conference (including video) over the course of eight (8) consecutive half business days.
4. Oracle and You will mutually agree upon dates and times for the Instruction Workshop, which will be scheduled a minimum of eight (8) business days in advance.
5. One (1) business day is equivalent to eight (8) hours. A business day is Monday through Friday, excluding holidays, during Oracle local business hours.
6. The Instruction Workshop will be delivered using Oracle's Clinical One training environment on the then-current version of Clinical One. Your access to the training environment will be removed after completion of the Instruction Workshop.
7. All verbal and written communication, and related documentation, will be in English.
8. Configurations of Trial Builds or integrations, reports, ongoing support or troubleshooting, as well as make up sessions for any part of the Instruction Workshop that may have been missed by Your Instruction Workshop participants, and any other services not expressly identified in the Description of Services are excluded.

Professional Services Period

The Services must be used within twelve (12) months from the execution of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle each agree to designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences Clinical One Study Build Mentoring – Per Hour

Part #: B93029

Description of Services

During the Professional Services Period (as defined below), for up to the quantity of Hours You have ordered Oracle will provide the remote mentoring services described below related to Trial design and build configurations (**"Trial Builds"**) of the Randomization and Trial Supply Management (RTSM) and/or Data Collection (DC) components of Clinical One ("**Clinical One RTSM and/or DC**"), (the **"Services"**). Hours purchased may be used for some or all of the following activities. Upon your request, Oracle will:

1. Assist with answering questions from, and providing guidance to, Your Designated Resources in support of Trial Builds that You are performing for Your Clinical One RTSM and/or DC Trials.
2. Conduct the following at a time mutually agreed to by You and Oracle:

a. A workshop covering Central Coding configurations for up to 8 Designated Resources;

b. A workshop covering Clinical One Analytics for up to 8 Designated Resources;

c. A training session upon Oracle's release of each new Clinical One version covering product and feature changes and updates (**"Clinical One Delta Training Session"**) for up to 8 Designated Resources

3. Assist with answering questions from, and providing guidance to, Your Designated Resources relating to Oracle Product Validation Packages (PVPs) for Clinical One
4. Assist with requests and feedback from Your Designated Resources related to the functionality and features of Clinical One

Your Cooperation

1. Ensure that Your Designated Resources have the business and functional skills and knowledge (including prior knowledge of, experience in, and responsibility for building, running and managing clinical trials) to support Oracle's performance of the Services and that they are trained in Clinical One RTSM and/or DC prior to using the Services.
2. Ensure that Oracle service team members are provided prompt access to Your Oracle Life Sciences Clinical One Cloud Service, if required, and limit Oracle's access to the extent necessary for Oracle to perform the Services.
3. Request from Oracle any workshops and/or the Clinical One Delta Training Session that You require at least two weeks in advance of the date You require them.
4. Provide names and email addresses for Designated Resources who will attend workshops and/or the Clinical One Delta Training Session.
5. Ensure that Your Designated Resources have viewed any available training videos prior to requesting a Clinical One Delta Training Session.
6. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

Project Assumptions

1. Oracle will provide the Services remotely from Oracle's site.
2. All verbal and written communication and related documentation will be in English.
3. **"Your Designated Resources"** means Your users that You have authorized to use the Services.
4. Oracle's performance of configurations of Trial Builds or integrations, as well as any other services not expressly identified in this Service Description are excluded.
5. Remote Services may be performed by Oracle resources located globally. The Services are available for use on Oracle business days. A business day is Monday through Friday, excluding holidays, during Oracle local business hours. Oracle global resources will use commercially reasonable efforts to provide the Services in accordance with Your working hours.
6. The content covered in any workshops requested by You will be solely determined by Oracle.

Professional Services Period

The Services must be used within twelve (12) months from the execution of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle each agree to designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences InForm Trial Build Service

Part #s:

For Oracle Life Sciences InForm Cloud Service:

B91590 – Oracle Life Sciences InForm Trial Build Service, Base Build - Trial
B91591 – Oracle Life Sciences InForm Trial Build Service, New Unique Form - Form
B91592 – Oracle Life Sciences InForm Trial Build Service, Reused Unique Form - Form
B91593 – Oracle Life Sciences InForm Trial Build Service, Optional non-standard web language - Language

For Oracle Life Sciences InForm Direct Cloud Service:

B91600 – Oracle Life Sciences InForm Direct Trial Build Service, Base Build - Trial
B91601 – Oracle Life Sciences InForm Direct Trial Build Service, New Unique Form - Form
B91602 – Oracle Life Sciences InForm Direct Trial Build Service, Reused Unique Form - Form
B91603 – Oracle Life Sciences InForm Direct Trial Build Service, Optional non-standard web language - Language

Description of Services

Oracle Life Sciences InForm Trial Build Service includes the following remote services related to the Oracle Life Sciences InForm program configuration of a Trial design for InForm, ("**Services**"). Oracle will:

1. Consult with Your designated project manager remotely to gather and review Your functional requirements to be included in the Trial Build configuration for one (1) Trial ("**Your Trial**");
2. Consult with Your designated project manager remotely to finalize and confirm Your functional requirements, which may include, as required, the total number of forms for Your Trial **("Total Forms")**, electronic data capture (**"EDC"**) form content, rules and edit checks, schedule for time and events, InForm program configurations, and database requirements, to be included in the Trial Build configuration for Your Trial, subject to the Assumptions below, (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
3. Based upon Your Confirmed Requirements and the agreed-upon timelines and milestones, Oracle will create and provide to You a project plan in English and in a format determined by Oracle detailing the tasks, timelines, and milestones for which Oracle and You are responsible;

4. Based upon Your Confirmed Requirements, Oracle will configure and test the Cloud Services for Your Trial ("**Trial Build Configuration**"), provide specification documentation in English and in a format determined by Oracle describing the design of the Trial Build Configuration, and notify You that the Trial Build Configuration is ready for Your testing;
5. Consult with Your designated project manager remotely to address Your questions that arise during Your Testing and to review Your findings after completion of Your Testing;
6. Address issues raised by You with respect to the Trial Build Configuration during Your Testing and notify You that the Trial Build Configuration is ready for deployment to the Production instance of Your Oracle Life Sciences InForm Cloud Service;
7. Upon Your instruction, Oracle will deploy the Trial Build Configuration to the Production instance of Your Oracle Life Sciences InForm Cloud Service.
8. Following deployment of the Trial Build Configuration to the Production instance, Oracle will provide a documentation package to You to help address Your record retention obligations. The documentation will contain records relating to the specification, verification, and acceptance of Your Trial Build Configuration.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are present and/or involved in all key meetings and deliverables (such as requirements discussion and user acceptance testing), that they adhere to the agreed timelines.
3. Deliver clear and complete requirements in accordance with the agreed timeline planning.
4. Provide input into the creation and maintenance of the project planning document as requested by Oracle.
5. Upon notification by Oracle that the Trial Build Configuration is ready for Your testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following such notice from Oracle. "**Testing**" means:
    i. Testing the Trial Build Configuration (e.g. conducting user acceptance testing) in the UAT instance of Your Oracle Life Sciences InForm Cloud Service against Your own standard operating procedures and/or work instructions using Your own test cases, and

ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle.

6. Instruct Oracle to deploy the Trial Build Configuration to the Production instance of Your Oracle Life Sciences InForm Cloud Service within five (5) business days of the date Oracle notifies You that the Trial Build Configuration is ready for deployment to the Production instance.

Project Assumptions

1. Oracle will perform the Services remotely from Oracle's site.
2. The Trial Build Configuration is limited to the quantity of New Unique Forms, Reused Unique Forms, and Optional Non-Standard Web Languages You have ordered.
3. A "**Unique Form**" is an electronic case report form for a clinical study which is intended to capture certain information for a specific purpose, as differentiated from other electronic case report forms for such clinical study. For the purpose of the Trial Build Configuration, any Unique Form for Your Trial will either be a New Unique Form or a Reused Unique Form.
4. A "**New Unique Form**" is a Unique Form that requires development of completely new or substantially new design elements, as distinguished from a Reused Unique Form.
5. A "**Reused Unique Form**" is a Unique Form created for Your previous Oracle Life Sciences InForm Trial(s) or a Unique Form from Your existing form library that requires no or minimal (as described herein) additional development work. Minimal additional development work may only include the following: updating the year range for a date field; deleting items that do not impact Rules, reports, or integrations; or other minor updates to text that do not impact Rules, reports, or integrations. Any Unique Form that is not a Reused Unique Form is a New Unique Form.
6. An "**Optional Non-Standard Web Language**" is any language other than English or Japanese. Some languages may not be available.
7. The total number of Unique Forms included with the Oracle Life Sciences InForm Trial Build Service is equal to the total quantity of New Unique Forms and Reused Unique Forms You have ordered ("**Total Unique Forms**").
8. "**Rule**" is defined as an aspect of the Trial Build Configuration that determines actions that Oracle Life Sciences InForm will perform based on certain specified conditions. A data-entry Rule checks whether data is valid or sets the value of an item based on a calculation. A workflow Rule tests data values to determine the group of visits (study element), visit (study event), or form to which a subject progresses next. A global condition Rule determines whether a study object will appear for a particular subject.
9. The total number of Rules included with the Oracle Life Sciences InForm Trial Build Service is up to the sum of: (the Total Unique Forms (as defined above) multiplied times 5.8) plus (the Total Forms (as defined above) multiplied times 1.4).
10. The quantities of New Unique Forms, Reused Unique Forms, and Optional Non-Standard Web Languages included in Your order are based upon the parameters that You provided to Oracle prior to execution of the order. A different combination of Forms, Languages, and/or Rules may be necessary as the Services proceed, and such changes may require additional effort and fees.

11. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance, may be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). For the purposes of Oracle Life Sciences InForm Trial Build Service, this means that You must have met Your final obligation to instruct Oracle to deploy the Trial Build Configuration to the Production instance of Your Oracle Life Sciences InForm Cloud Service within the Professional Services Period defined above.

Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences InForm, Central Coding Configuration – Trial

Part #s:

B91595 – Oracle Life Sciences InForm, Central Coding Configuration - Trial
B91605 – Oracle Life Sciences InForm Direct, Central Coding Configuration - Trial

Description of Services

Oracle Life Sciences InForm Central Coding Configuration includes the following remote services related to the Oracle Life Sciences Central Coding program configuration for the integration of Oracle Life Sciences Central Coding Cloud Service (**"Central Coding"**) with InForm, ("**Services**"). Oracle will:

1. Consult with Your designated project manager remotely to gather, review, finalize, and confirm Your integration requirements to be included in the Central Coding setup and integration configuration for one InForm (1) Trial ("**Your Trial**"), subject to the Assumptions below, (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
2. Based upon Your Confirmed Requirements, consult with Your designated project manager to create and finalize a specification document in English and in a format determined by Oracle describing the integration configurations to be included in the integration (**"Final Integration Specification**");
3. Based upon the Final Integration Specification, in Your user acceptance testing instance of Central Coding, configure one (1) integration between Central Coding and InForm ("**Central Coding Configuration**"), which may include only the following:
    a. Creation and/or configuration of a coding algorithm

b. Creation and/or configuration of coding definitions for up to two (2) standardized medical coding dictionaries

c. Set up of assignment rules for coding work teams

d. Configuration of synonym lists and stopword lists

e. Configuration of InForm with InForm Adapter and the associated Central Coding job scheduler, and/or

f. Configuration of one version of Medical Dictionary for Regulatory Activities (**"MedDRA"**) and one version of World Health Organization Drug Dictionary (**"WHODD"**) standardized medical coding dictionaries in the Central Coding program.

4. Test the Central Coding Configuration in Your user acceptance testing instance of Central Coding and notify You that the Central Coding Configuration is ready for Your Testing (as defined below);
5. Address issues raised by You with respect to the Central Coding Configuration during Your Testing and perform and test the Central Coding Configuration in Your Production instance of Central Coding;
6. Following availability of the Central Coding Configuration in Your Production instance, Oracle will provide a documentation package to You to help address Your record retention obligations. The documentation will contain records relating to the specification, verification, and acceptance of Your Central Coding Configuration.
7. During the Services Period of Your InForm Trial, provide up to thirty-two (32) hours of assistance to You for standard dictionary upgrades of MedDRA and WHO Drug Dictionary, including impact analysis in preparation for an upgrade (if applicable). You may request such upgrades up to two (2) times per calendar year, and Oracle will perform the upgrades per a mutually agreed schedule between You and Oracle.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;

    b. Ensure that specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;

    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;

    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and

    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are involved in all key meetings, deliverables, and timelines.

3. Manage and oversee all third party vendors.
4. Upon notification by Oracle that the Central Coding Configuration is ready for Your testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following such notice from Oracle. "**Testing**" means:
    i. Testing the Central Coding Configuration (e.g. conducting user acceptance testing) in Your user acceptance testing instance of Central Coding against Your own standard operating procedures and/or work instructions using Your own test cases, and
    ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle.
5. Obtain, prior to the commencement of the Services, all appropriate license rights for MedDRA and WHODD.

Project Assumptions

1. Any Central Coding mappings required for the InForm Trial Build will be the responsibility of the party performing the InForm Trial Build.
2. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance, may be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences InForm CRF Submit – Each

Part #s:

B91598 – Oracle Life Sciences InForm CRF Submit
B91588 – Oracle Life Sciences InForm Cloud Service, InForm CRF Submit Additional Runs
B91589 – Oracle Life Sciences InForm Direct Cloud Service, InForm CRF Submit Additional Runs

Description of Services

Oracle Life Sciences InForm CRF Submit includes the following remote services related to the CRF Submit component of InForm, ("**Services**"). Oracle will:

1. Based on Your requirements as documented in Oracle's CRF Submit Request Form and Oracle's CRF Submit requirements document (and subject to Your Cooperation below), provide one (1) archive or study submission PDF file of Your InForm Trial Data ("**CRF Submit File**"). These files are intended to document Your data as it existed in Your Production instance of InForm upon generation of the CRF Submit File.
2. Provide the CRF Submit File via secure file transfer and notify You that the CRF Submit File is available for download by You.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Requesting the CRF Submit File and providing Your clear and complete requirements, including required data elements and output types for the CRF Submit File, by completing and submitting to Oracle the CRF Submit Request Form and Oracle's CRF Submit requirements document in a manner specified by Oracle. Your requirements may not exceed the available choices in Oracle's CRF Submit requirements document. You may request the CRF Submit File during the Trial or following Database Lock and prior to submission of Your Request for Decommission of Your Trial.
3. If required, provide Your InForm Trial Data to Oracle in a format specified by Oracle.
4. Downloading the CRF Submit File via Oracle's secure file transfer service within the CRF Submit File Retrieval Period (as defined below). The CRF Submit Files will be deleted or otherwise rendered inaccessible by Oracle upon the end of the CRF Submit File Retrieval Period.
5. Distribute the PDFs, as appropriate.
6. You are responsible for ensuring that You do not submit Your Request for Decommission for Your InForm Trial until You and Your Sites have requested, downloaded, and reviewed the CRF Submit File(s) that You and Your Sites require.
7. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

Project Assumptions

1. It is recommended that You request the CRF Submit File at least ninety (90) calendar days prior to the end of the InForm Services Period to allow time for CRF Submit File generation and Your review prior to submission of Your Request for Decommission of Your InForm Trial. Failure to request the CRF Submit File in the recommended timeframe may require You to extend the InForm Services Period.
2. The CRF Submit File will be available for download by You for 60 calendar days from the date Oracle notifies You that the CRF Submit File is available ("**CRF Submit File Retrieval Period**"). The CRF Submit File will be deleted or otherwise rendered inaccessible by Oracle upon the end of the CRF Submit File Retrieval Period.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences InForm Integration Configuration – Integration Per Trial

Part #s:

B91597 – Oracle Life Sciences InForm Integration Configuration - Integration Per Trial
B91607 – Oracle Life Sciences InForm Direct Integration Configuration - Integration Per Trial

Description of Services

Oracle Life Sciences InForm Integration Configuration covers the following remote services related a Standard File-Based Integration (as defined below) between InForm and a third party system ("**Services**"). Oracle will:

1. Consult with Your designated project manager remotely to review, finalize, and confirm Your data integration requirements, which are limited to data mapping, data restrictions, or notifications, to be included in the configuration of a Standard File-Based Integration for one (1) InForm Trial ("**Your Trial**"), subject to the Assumptions below, (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
2. Based upon Your Confirmed Requirements, consult with Your designated project manager to create and finalize a specification document in English and in a format determined by Oracle describing the integration configurations to be included in the integration (**"Final Integration Specification**"). Specifications may include only form data element mappings, data types, data

element restrictions, and/or notification information;

3. Based upon the Final Integration Specification, create and provide to You a project plan detailing the tasks, timelines, and milestones for which Oracle and You are responsible and create a communication plan document listing team members, responsibilities, and contact information;
4. Based upon the Final Integration Specification, in Your user acceptance testing instance of InForm, configure components for one (1) Standard File-Based Integration between InForm and one (1) third party system ("**InForm Integration Configuration**"), which is limited to the following:
    a. Up to a maximum of 20 data fields across up to 5 InForm Unique Forms (as defined below)
5. Test the InForm Integration Configuration in Your user acceptance testing instance of InForm. Oracle's testing includes performing formal testing of the InForm Integration Configuration; testing of clinical data files provided by You or the third party system vendor for up to 20 data fields; and conducting an independent validation of the InForm Integration Configuration by verifying components against the Final Integration Specification.
6. Notify You that the InForm Integration Configuration is ready for Your Testing (as defined below);
7. Address issues raised by You with respect to the InForm Integration Configuration during Your Testing and notify You that the InForm Integration Configuration is ready for deployment to Your Production instance of InForm;
8. Upon Your instruction, Oracle will install and configure the InForm Integration Configuration in Your Production instance of InForm.
9. Following availability of the InForm Integration Configuration in Your Production instance, Oracle will provide a documentation package to You to help address Your record retention obligations. The documentation will contain records relating to the specification, verification, and acceptance of Your InForm Integration Configuration.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are involved in all key meetings, deliverables, and timelines.
3. Deliver clear and complete requirements in accordance with the agreed timeline planning.
4. Provide input into the creation and maintenance of the project plan and communication plan documents as requested by Oracle.
5. Manage and oversee all third party vendors, including but not limited to ensuring that the third party system vendor adheres to the Final Integration Specification and provides necessary files for Testing.
6. Upon notification by Oracle that the InForm Integration Configuration is ready for Your testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following such notice from Oracle. "**Testing**" means:
    i. Testing the InForm Integration Configuration (e.g. conducting user acceptance testing) in Your user acceptance testing instance of InForm against Your own standard operating procedures and/or work instructions using Your own test cases, and
    ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle.
    iii. For data imported into InForm, correct and resubmit (or ensure that the third party system vendor corrects and resubmits) records that are rejected.
7. Instruct Oracle to deploy the InForm Integration Configuration to Your Production instance of InForm within five (5) business days of the date Oracle notifies You that the InForm Integration Configuration is ready for deployment to the Production instance.

Project Assumptions

1. A **"Standard File-Based Integration"** integrates data between InForm and a third party system via a flat file transfer. Three types of Standard File-Based Integrations are available: an inbound integration, an outbound integration, or a two-way integration.
2. An **"Inbound Integration"** imports data from a third party system to InForm.
3. An **"Outbound Integration"** exports data from InForm to a third party system.
4. A **"Two-Way Integration"** imports data from a third party system into InForm and exports data from InForm into the same third party system.
5. An **"InForm Unique Form"** is an electronic case report form for a clinical study configured within InForm which is intended to capture certain information for a specific purpose, as differentiated from other electronic case report forms for such clinical study.
6. For data to be imported into InForm, the file format will be specified by Oracle. The third party system will initiate a process to extract data and transmit the data to Oracle via sFTP for upload into InForm. The following requirements must be met for all third party system data files to be imported into InForm:
    a. Data files must be formatted according to the Oracle's MedML file format or pipe-delimited format (note that screening, enrollment, and patient transfer cannot be done using pipe-delimited format).
    b. Data files must contain only incremental records.

c. Separate data files must be created for each InForm visit-form combination. For example, if there are two forms that will receive uploaded data for a given Trial, the third party system vendor must create two separate data files for transfer to Oracle. If the same form is used for several visits, a separate data file is required for each instance of this form.

d. Each record must contain the subject number, subject initials (or equivalent if initials are not used), and Site number in order to be loaded.

e. Records will be rejected if subject number, subject initials, or Site are incorrect or if subject is not enrolled.

f. Screening failures can be loaded, provided they are identified as screen failures in the record.

g. MedML format has tags to accommodate screening, enrollment, adding patient data, editing patient data, and transferring patient.

h. MedML format has a tag called DUPLICATEORDER which is a number specifying the order in which patients with the same patient initials are enrolled. This tag is required when two or more patients with the same initials are present at a Site. The value of this tag can be supplied by the third party system vendor or automatically calculated by the third party system.

i. If the third party system will generate the DUPLICATEORDER value, the screen and enroll transactions must be sent within the same file.

j. Data files must adhere to specific file naming conventions, which will be determined by Oracle.

7. For data to be imported into a third party system, the file format will be agreed upon between You and Oracle. InForm will initiate a process to extract data and transmit the data to the third party via sFTP for import into the third party system.
8. The Services require coordination between You, the third party system vendor, and Oracle.
9. Specifications for integration data must be incorporated into the InForm Trial Build and form layout prior to Oracle beginning the Services.
10. **"InForm Trial Build"** refers to the design and configuration of the InForm program for a Trial, whether performed by You or provided by Oracle with the Oracle Life Sciences InForm Trial Build Service.
11. All data file transfers must be done using sFTP in accordance with Oracle's Cloud Hosting and Delivery Policies and the Oracle Global Business Unit Cloud Service Pillar document. Third party system vendors must have a supported sFTP client to access the Oracle sFTP.
12. Performance of the Standard File-Based Integration is dependent on the number and size of files being imported into or exported from InForm at any one time.
13. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance, may be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences InForm, Lab Normals Management Tool Configuration – Trial

Part #s:

B91596 – Oracle Life Sciences InForm, Lab Normals Management Tool Configuration - Trial
B91606 – Oracle Life Sciences InForm Direct, Lab Normals Management Tool Configuration – Trial

Description of Services

Oracle Life Sciences InForm Lab Normals Management Tool Configuration includes the following remote services related to the configuration of Oracle Life Sciences InForm Lab Normals Management Tool (**"LNMT"**) for InForm ("**Services**"). Oracle will:

1. Consult with Your designated project manager remotely to review, finalize, and confirm Your data integration requirements to be included in the configuration of LNMT for one (1) InForm Trial ("**Your Trial**"), subject to the Assumptions below, (**"Your Confirmed Requirements"**) and to agree upon timelines and milestones;
2. Based upon Your Confirmed Requirements, consult with Your designated project manager to create and finalize a specification document in English and in a format determined by Oracle describing the integration configurations to be included in the integration (**"Final LNMT Specification**"). Specifications are limited to form data element mappings, data types, data element restrictions, and/or notification information;
3. Based upon the Final Integration Specification, create and provide to You a project plan detailing the tasks, timelines, and milestones for which Oracle and You are responsible and create a communication plan document listing team members, responsibilities, and contact information;
4. Based upon the Final Integration Specification, in Your user acceptance testing instance of InForm, configure the LNMT components ("**LNMT Configuration**");
5. Test the LNMT Configuration in an Oracle development instance. Oracle's testing covers documenting test cases needed for the LNMT Configuration and performing formal testing of the LNMT Configuration.
6. Test the LNMT Configuration in Your user acceptance testing instance of InForm, limited to smoke testing by entering values for up to five (5) data points; and verifying the LNMT

Configuration;

7. Notify You that the LNMT Configuration is ready for Your Testing (as defined below);
8. Address issues raised by You with respect to the LNMT Configuration during Your Testing and notify You that the LNMT Configuration is ready for deployment to Your Production instance of InForm;
9. Upon Your instruction, Oracle will install and configure the LNMT Configuration in Your Production instance of InForm.
10. Following availability of the LNMT Configuration in Your Production instance, Oracle will provide a documentation package to You to help address Your record retention obligations. The documentation will contain records relating to the specification, verification, and acceptance of Your LNMT Configuration.

Your Cooperation

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are involved in all key meetings, deliverables, and timelines.
3. Deliver clear and complete requirements in accordance with the agreed timeline planning.
4. Provide input into the creation and maintenance of the project plan and communication plan documents as requested by Oracle.
5. Manage and oversee all third party vendors.
6. Upon notification by Oracle that the LNMT Configuration is ready for Your testing, perform Testing, as described below, for a period of no longer than two (2) consecutive calendar weeks following such notice from Oracle. "**Testing**" means:
    i. Testing the LNMT Configuration (e.g. conducting user acceptance testing) in Your user acceptance testing instance of InForm against Your own standard operating procedures and/or work instructions using Your own test cases, and
    ii. Providing Oracle with clear, reproducible, and actionable test feedback in a format specified by Oracle.
7. Instruct Oracle to deploy the LNMT Configuration to Your Production instance of InForm within

five (5) business days of the date Oracle notifies You that the LNMT Configuration is ready for deployment to the Production instance.

Project Assumptions

1. The eCRFs (electronic case report forms) for the InForm Trial must be designed using LNMT specifications for capturing lab data. In conjunction with the eCRF design, the InForm Trial Build must include a set of Trial-specific edit checks used to auto-generate InForm queries.
2. **"InForm Trial Build"** refers to the design and configuration of the InForm program for a Trial, whether performed by You or provided by Oracle with the Oracle Life Sciences InForm Trial Build Service.
3. All lab tests and units have been pre-identified for each Trial for entering normal ranges through the LNMT user interface.
4. Changes introduced by You following finalization of Your Confirmed Requirements or additional Services that may be required for Your regulatory compliance, may be subject to additional fees.

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced after performance of the Services.

Oracle Life Sciences Small and Mid-Size Market Argus Enhanced Managed Service – Each

Part #: B90746

Description of Services

Oracle Life Sciences Small and Mid-Size Market Argus Enhanced Managed Service includes up to forty (40) person days of remote assistance with one (1) or more of the following activities related to Your production version of Argus (as defined below) ("**Services**"):

1. Consult periodically with Your designated project manager to review the process by which Services will be delivered to You and provide periodic status updates.
2. Provide a monthly written status report to You of all Services completed on Your behalf.
3. Perform configurations related to products, studies, licenses, workflow, user group access,

code lists, reporting rules, and reporting destinations.

4. Perform updates to the configurations on Your non-production environment and promote the updated configurations to Your production environment.
5. Prepare updates to Your Argus Configuration Specification Document.
6. Support testing activities, including but not limited to, investigation of test deviations, test script creation, and assisting Your users with test script execution.
7. Perform production troubleshooting and issue mitigation.
8. Coordinate Your My Oracle Support requests for environment related issues and resolution.
9. Support Your users with ad-hoc inquiries and training requests.

Your Cooperation

1. Limit Oracle's access to any production environments or shared development environments to the extent necessary for Oracle to perform Services.
2. Participate in meetings and configuration reviews with Oracle and ensure that key personnel are involved in all key meetings and timelines.
3. Manage and oversee all third-party vendors.

Project Assumptions

1. The parties acknowledge and agree that the performance of Services does not require or involve the processing of personal data.
2. A person day is defined as one (1) resource working for up to eight (8) hours.
3. The Services will be performed during Your normal business hours Monday through Friday, excluding Your and Oracle's holidays, except as otherwise mutually agreed upon in writing by You and Oracle.
4. **"Argus"** refers to "Oracle Life Sciences Argus Advanced Cloud Service" or "Oracle Life Sciences Argus Basic Cloud Service".

Professional Services Period

The Services above must be used within twelve (12) months from the signature date of Your order (**"Professional Services Period"**). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

Oracle Life Sciences Study Project Management and Advisory Services for InForm and Clinical One – Hours

Part #: B92938

Description of Services

During the Professional Services Period below, Oracle will make available to You a project manager to provide remote assistance upon Your request with the Trial-Related activities below for Your Oracle InForm/Clinical One Trial(s) for up to the quantity of hours You have purchased (the "**Services**").

The Oracle project manager will:

1. Act as Your Oracle point of contact for guidance on Your Trial-Related queries including but not limited to coordination of communications between You and Oracle, regulatory requests, and product feature review and discussions between You and Oracle;
2. Track, record, and communicate any mutually agreed metrics and/or trends for Your Trial;
3. Prepare and provide any mutually agreed status reports;
4. Facilitate and participate in Your Trial-Related meetings, at a mutually agreed-to time, including but not limited to preparing for and attending meetings with Your third-party vendors and following up on meeting actions, if reasonable and required;
5. Assist with coordination of Oracle input on the impact and feasibility of potential configuration changes that may be required for Your Oracle InForm/Clinical One Trial(s), including but not limited to assisting with Your questions on Trial design, form design, workflow, and rule design.

Your Cooperation

1. Regulatory Compliance:
    a. You are responsible for notifying Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You.
    b. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Contact Your Oracle project manager to request the Services and coordinate with Your project manager for the delivery of Services.
3. Participate in meetings with Oracle and ensure that key personnel are involved in all key meetings.
4. Manage and oversee all third party vendors.

Project Assumptions

1. **"Trial-Related"** means the activities performed by Oracle are directly related to services that Oracle provides for Your Oracle InForm/Clinical One Trial(s), excluding activities related solely to the hosting, support, maintenance, or availability of the underlying Cloud Services.
2. **"Your Oracle InForm/Clinical One Trial(s)**" means Your Trial(s) which use InForm and/or Clinical One.
3. Oracle will perform the Services remotely.

4. The time used to perform the Services will be deducted from the quantity of available Hours You have purchased.
5. The Services are limited to use for InForm or Clinical One and may not be used for any other Cloud Services or applications.
6. Configuration services, including but not limited to customizations or changes to the scope of InForm or Clinical One Trial Build Services or any integration configurations, and all services not expressly stated are specifically excluded.

Professional Services Period

The Services above must be used within the applicable **Professional Services Period** below:

(a) If Clinical One Single Trial or InForm Single Trial Cloud Service (identified on Your order by a Protocol Number) or Clinical One Multiple Trial and/or InForm Multiple Trial Cloud Services, (the "**Underlying Cloud Services**"), are specified on Your order for the Services, the Services must be used by the end of the then-current Services Period for the Underlying Cloud Services (excluding any subsequent extensions to the Services Period); or

(b) If no Underlying Cloud Services are specified on Your order, the Services must be used within twelve (12) months from the signature date of Your order.

Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Consulting/Professional Services Payment Frequency

The fees for the Services will be invoiced upon Your execution of and Oracle's acceptance of the order in advance of performance of the Services.

RETIRED OFFERINGS

SERVICE DESCRIPTIONS FOR RETIRED OFFERINGS

Oracle Health Sciences InForm Cloud Service, Study Project Management – Trial

Part #s:

B91619 – Oracle Health Sciences InForm Cloud Service, Study Project Management - Trial
B91620 – Oracle Health Sciences InForm Direct Cloud Service, Study Project Management – Trial

Description of Services

During the Services Period specified in Your order, Oracle will make available to You a project manager to provide remote assistance for one (1) Oracle Health Sciences InForm Cloud Service Trial (**"InForm Trial"**) related to the activities outlined below ("**Services**").

Oracle will:

1. Assist with tracking of metrics and milestones which have been mutually agreed with You;
2. Assist with issue and risk management;
3. Coordinate communications between You and Oracle related to the InForm Trial;
4. Assist with governance, limited to planning and coordinating governance meetings associated with:
    a. Oracle's delivery of services for the InForm Trial
    b. Review of critical issues and incidents related to the InForm Trial
    c. Process changes related to the InForm Trial
5. Responding to Your information requests for regulatory audits related to the InForm Trial as provided under, and subject to, the terms of Your Agreement (excluding audits or regulatory inspections of You by regulatory agencies or other parties).

Your Cooperation

Subject to the terms in the Policies, the following obligations apply in addition to those in the Policies:

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your InForm Trial including without limitation such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of

the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and

e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.

2. Participate in meetings with Oracle and ensure that key personnel are involved in all key meetings, deliverables, and timelines.
3. Provide input into the creation and maintenance of the project plan as requested by Oracle.
4. Manage and oversee all third party vendors.

Project Assumptions

1. Oracle will perform the Services remotely from Oracle's site.
2. The Services are limited to one (1) InForm Trial.
3. Configuration services, including but not limited to customizations or changes to the scope of Oracle Health Sciences InForm Trial Build Services or any integration configurations, are specifically excluded.

Professional Services Period

The Services above must be used within the Services Period of Your order ("Professional Services Period"). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.

Oracle Health Sciences InForm Cloud Service, Study Project Management and Advisory Services – Per Hour

Part #s:

B91599 – Oracle Health Sciences InForm Cloud Service, Study Project Management and Advisory Services - Per Hour
B91608 – Oracle Health Sciences InForm Direct Cloud Service, Study Project Management and Advisory Services - Per Hour

Description of Services

During the Services Period specified in Your order, Oracle will make available to You Oracle resources for up to the quantity of hours You have ordered to provide remote assistance for one (1) Oracle Health Sciences InForm Cloud Service Trial (**"InForm Trial"**) related to the activities outlined below ("**Services**").

Oracle will:

1. Provide Project Management (PM), Design Consultant (DC), and Technical Consultant (TC) resources to assist You with questions regarding InForm Trial design, form design, workflow and rule design, deployment packages, data extract setup, and data extract usage for Your InForm Trial;
2. Assist with project status reporting for Your InForm Trial;
3. Assist with coordination of communications between You and Oracle related to Your InForm Trial;

Your Cooperation

Subject to the terms in the Policies, the following obligations apply in addition to those in the Policies:

1. Regulatory Compliance – You are responsible for the following:
    a. Notify Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You;
    b. Ensure that specifications meet the regulatory requirements for Your InForm Trial including such requirements laid out in the clinical protocol and subsequent clinical protocol amendments;
    c. Ensure that any required regulatory approvals are in place prior to using the Services in Your Production environment;
    d. Provide to Oracle the approved clinical protocol prior to Oracle's commencement of the Services and, as applicable, provide to Oracle any subsequent clinical protocol amendments; and
    e. You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
2. Participate in meetings with Oracle and ensure that key personnel are involved in all key meetings and timelines.
3. If applicable, provide input into the creation and maintenance of a project plan as requested by Oracle.
4. Manage and oversee all third party vendors.
5. Contact Your Oracle Project Manager at least two (2) days in advance to request use of the Services.

Project Assumptions

1. Oracle will perform the Services remotely from Oracle's site.
2. The Services are limited to one (1) InForm Trial.
3. The Services include Project Management (PM), Design Consultant (DC) & Technical Consultant (TC) resources only.
4. Configuration services, including but not limited to customizations or changes to the scope of Oracle Health Sciences InForm Trial Build Services or any integration configurations, are specifically excluded.

5. If You use all Hours ordered prior to the end of the Services Period, You may purchase additional Hours.
6. Hours not used by the end of the Services Period expire without refund and are not available for future use or use for other services.

Professional Services Period

The Services above must be used within the Services Period of Your order ("Professional Services Period"). Any Services not used within the Professional Services Period will be automatically forfeited by You, with no further action required of either party, and You will not be entitled to a refund, or any credit toward additional or other services, for any unused portion of the fees paid for any unused Services. You may not use the fees for any services other than the Services stated herein.

Project Management

You and Oracle further agree to each designate a project manager who shall work together with the other party's project manager to facilitate an efficient delivery of the Services.