ORACLE

Oracle Health Sciences

IRT Cloud Service

Service Descriptions and Metrics

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METRIC DEFINITIONS

Integration Per Trial

Integration Per Trial is defined as each distinct integration with another application

Language

Language is defined as enabling the use of the study in a language other than the standard languages. For IRT - standard language is English.

Patient

Patient is defined as a person receiving healthcare related treatment such as receiving drug(s), medical device or alternate treatment/therapy and/or enrolled/participating in a clinical study. For the purposes of licensing, maximum number of patients enrolled in the study must be counted.

Site

Site is defined as a single location from which the system will be accessed (e.g., an investigator site or a customer location). A customer location includes (a) any location from which the system will be accessed and can also include (b) individuals or organizations that will access the system; for both (a) and (b), the customer location must have a contract with You (i.e., the customer location is a third party).

Trial

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

REGULATORY COMPLIANCE

Information on Oracle's practices for regulatory standards applicable to the handling or processing of data for the Cloud Services or delivery of Trial Build and Configuration Services as described in this Service Description may be viewed at support.oracle.com (Doc ID 2256629.1).

SERVICE DESCRIPTIONS

Oracle Health Sciences IRT Cloud Service – Base Fee – Trial

Part #s: B91581; B91584; B91686; B91687

The IRT Cloud Service will be deployed in a hosting facility and will be maintained and managed by Oracle. The deployment of the IRT Cloud Service will consist of two instances: one Production instance and one User Acceptance Testing (UAT) instance for Non-Production use. The Production instance is the instance which will be used to capture the clinical study data ("Data"). The UAT instance will be used to perform user acceptance testing prior to Production go-live and will be used to test changes and fixes after Production go-live.

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

- IRT

Users and Access by Users

Your use of the Services is limited to personnel related to Your Trial as authorized by You. This consists of two main groupings of personnel: Sponsor and Site. The Sponsor group consists of Your personnel and may also include other sub-contracted personnel such as Contract Research Organization personnel, depots, monitors, and data managers. The Site personnel typically consist of the Site coordinator (clinical research coordinators) and study investigators (principal investigators and sub-investigators).

Deliverables and Customer Dependencies

The deliverables for a given Trial are dependent upon the components included in that Trial. Not all Trials will produce all of the deliverables and entitlements listed below. Some common deliverables and entitlements that apply to most Trials include:

- If requested, online training for IRT for Users using Your named Trials.
- Maintenance of the Services Environments – Oracle will maintain the UAT and Production instances in accordance with support services detailed in the *Oracle Cloud Hosting and Delivery Policies* document and *Oracle Industries Cloud Services Pillar Document*, including product upgrades to new releases (hot fixes, service packs, and minor releases only) and in-place upgrades and migrations in accordance with the *Oracle Life Sciences Cloud Services – GA and EOL Dates* document. Migrations typically include a Trial move to a new server. Upgrades and migrations are scheduled with You and are performed during the maintenance window. Data migration services between versions and upgrades between major product versions will be scoped and contracted separately and may require an additional fee.
- Fixes to the Production IRT Application – Related documents are created and maintained by Oracle in Oracle's standard format and approved by You.
- Changes to the Production IRT Application – The Change Management process will be followed (including additional fees if applicable). Related documents are created by Oracle and approved by You.

- Final Data Extract – Oracle will provide a final data extract, upon request by You, at the end of the Trial.
    - The standard data extract is limited to the following:
        - File Types:
            - Text (txt, rtf)
            - Comma Separated (csv)
            - Excel (xls, xlsx)
            - XML
        - Data:
            - Subject data, subject visit data, and drug unit dispensation data.
            - Audit trail data
        - Transport Mechanism:
            - The final data extract file will be posted to an Oracle sFTP location. Secure access to the Oracle sFTP location will be granted to You for the sole purpose of You manually retrieving the file from such sFTP location.
- A decommissioning package (i.e. archival study database and associated files related to hosting the study Production instance including integrations, if any) will be provided to You for download after decommissioning.
- Archival documentation related to Oracle services (e.g. trial build specifications, Scope Changes, document for trial fix, and service request tickets) will be provided to You for download periodically during the Services Period.
- Oracle Project Management
    - Project Management services include coordination of professional services requests and communications and Trial planning (project plan containing key milestones to be mutually agreed with You).
    - Project Management specifically excludes contractual additions, such as Scope Changes
    - A Project Manager will be assigned as the primary contact to You for Services activity.

Your responsibilities for a given Trial are dependent upon the components included in the Trial. Examples of Your responsibilities include but are not limited to:

- Regulatory Compliance – You are responsible for the following:
    - Notifying Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You throughout the Services Period. Oracle will cooperate with Your efforts to determine whether use of the standard Oracle Services offering is consistent with those requirements. Additional fees may apply to any additional work that is required to be performed by Oracle to comply with such requirements.
    - Ensuring that specifications meet the regulatory requirements for the Trial including such requirements laid out in the Protocol and subsequent Protocol Amendments.
    - Ensuring that any required regulatory approvals are in place prior to moving the configured Trial Build to Production or enabling Your Site Users to access the Services. This applies to the initial release and any subsequent releases that may occur as a result of modifications to the configured Trial Build.

    - Providing the final clinical protocol and, as applicable, any subsequent final protocol amendments.
    - You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
- Adding the Site and User information directly in the IRT program via an upload utility or directly in the Oracle-provided tool (User Management Tool (UMT)) for studies integrated with InForm™.
- Ensuring that all Users are properly trained prior to accessing the Production instance of the Cloud Service. This includes maintaining all training records.
- Reviewing and approving documents related to live IRT program changes and fixes.
- Approving the IRT program database lock and decommissioning.
- Submitting the Request for Decommission prior to the end of the Services Period.
    - If You require additional time beyond Your Services Period, You will be required to execute an extension to Your order.
    - If You fail to meet Your obligation to submit the Request for Decommission prior to the end of the Services Period and You have not contracted for an extension to the Services Period, Your Trial will be decommissioned upon the end of the Services Period.
    - If You submit the Request for Decommission no later than thirty (30) days prior to the end of the Services Period, then, following Your written request, Oracle will provide You with a credit of any recurring fees actually paid to Oracle for the period following Oracle's receipt of Your Request for Decommission.
- Reviewing and accepting the following deliverables within sixty (60) calendar days of Oracle's notice that the deliverables are available to you (the "acceptance period") by providing written acknowledgement within the acceptance period. If You fail to provide written notice of non-acceptance to Oracle within the acceptance period, as provided above, the deliverables shall be deemed accepted as of the end of the acceptance period and Oracle may permanently delete or otherwise render inaccessible the deliverables and Your Data in Your instance(s):
    - the decommissioning package
    - relevant archival documentation related to Oracle services
- Distributing decommissioning package and archival documentation, as appropriate

Usage Limits – The Cloud Service is subject to usage limits based on:

- One Trial
- The number of Patients defined in Your order

- The following usage limits apply:

Metric	Database Storage (Records)	File Storage (GB)	Bandwidth	# of Instances included
Trial	25 GB per Trial	N/A	N/A	1 UAT for Non-Production use and 1 Production

Service Level Targets – The Cloud Service has the following service level targets:

Cloud Service	Recovery Time Objective (RTO)	Recovery Point Objective (RPO)	Target System Availability
IRT Cloud Service	90 days	48 hours	99%

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

Oracle Cloud Policies

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

Oracle Health Sciences IRT Cloud Service – Patient

Part #s: B91582; B91685

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

- Oracle Health Sciences IRT Cloud Service

Usage Limits: The Cloud Service is subject to usage limits based on:

- One Trial
- The quantity of Patients defined in Your order
- Oracle Health Sciences IRT Cloud Service – Patient is subject to the Usage Limits for Oracle Health Sciences IRT Cloud Service – Base Fee.

Service Level Targets:

The Service Level Targets for this Oracle Cloud Service are provided with the Oracle Health Sciences IRT Cloud Service – Base Fee.

Oracle Cloud Policies:

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

Oracle Health Sciences IRT Cloud Service – End User Helpdesk

Part #s: B91583; B91693

Users of the IRT Cloud Service End User Helpdesk are able to perform the following activities:

- Provide Help Desk support via local Toll-Free numbers.
- Escalate calls to You.
- Routine User Management
    - User activation/inactivation requests
    - User termination/Addition
    - Site or User addition or change
- Management of User Management Tool (UMT) accounts
- Creation/change of rights, roles, and groups

IRT Cloud Service End User Helpdesk is available in the following languages during normal Oracle business hours in the GMT time zone, except where noted:

- English (available 24x7)
- Spanish
- French
- German
- Italian

Usage Limits – The IRT Cloud Service End-user Helpdesk is subject to usage limits based on:

- One Trial
- The quantity of Sites defined in Your order

IRT Cloud Service End-user Helpdesk – Service Level Targets. The IRT Cloud Service End-user Helpdesk has the following service level targets:

- Severity Level 1 issues will be responded to within one hour of the User logging a ticket.

For the purpose of IRT Cloud Services End user Helpdesk, Severity Level 1 is a catastrophic issue impacting multiple system Users of an active Production system. The issue may be perceived as presenting potential data integrity risks or Patient safety risks**.**

Oracle Cloud Policies

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

Oracle Health Sciences IRT Cloud Service – Base Randomization and Oracle Health Sciences IRT Cloud Service – Base Supply Management

Part #s: B91618; B91741; B91688; B91362; B91735; B91691; B91614; B91736; B91692

The Oracle Health Sciences IRT Cloud Service – Base Randomization is designed for the use of randomization using a secure web browser to provide access to clinical study data. Additional information on features and functionality for Base Randomization is included in the IRT Cloud Service Product Functionality Guide, which may be accessed through My Oracle Support at this link.

The Oracle Health Sciences IRT Cloud Service – Base Supply Management is an option to the Oracle Health Sciences IRT Cloud Service – Base Randomization and is designed to assist the management of clinical trial drug supplies using a secure web browser to provide access to clinical study data. Additional information on features and functionality of Base Supply Management is included in the IRT Cloud Service Product Functionality Guide, which may be accessed through My Oracle Support at this link.

Deliverables and Customer Dependencies

The deliverables for a given Trial are dependent upon the components included in that Trial. Not all Trials will produce all of the deliverables and entitlements listed below. Some common deliverables and entitlements that apply to most Trials include the following.

Oracle will:

- Write specifications in English and in a format determined by Oracle to document the design of the IRT program configurations.
- Create and maintain a timeline plan outlining the key tasks, timelines, and milestones for which Oracle and You are responsible, as applicable.
- Create and maintain a communication plan describing the team members, their responsibilities, and their contact information.
- If requested, set up integration with Oracle Health Sciences InForm.
- Prepare web prompts, and a site user manual in English. You may contact Oracle for non-site user manual(s) in English for which there may be additional cost.
- Configure the IRT Program for Base Randomization, and if ordered, Base Supply Management.
- Load one (1) randomization schedule (list) and 1 drug schedule (list) for setup.
- Upon Your instruction, release the configured IRT program in Your UAT instance that You may use to conduct UAT activities.
- Assist You with Your User Acceptance Testing (up to 1 round) as follows:
    - If requested, provide optional UAT script for Base Randomization for You to test the IRT program configuration. (A UAT script for Base Supply Management is available for an additional fee.)
    - If requested, load optional UAT data.
    - One (1) user acceptance testing findings meeting.

- Respond to questions that You raise during user acceptance testing.
- If required, deploy a new configuration to the UAT instance for You to re-test Your user acceptance testing findings.
- If additional rounds of user acceptance testing are required, the Change Management process will be followed (including additional fees and time).

- Upon Your instruction, release the configured IRT program in Your Production instance that Your Users may access.

Your Obligations

Your responsibilities for a given Trial are dependent upon the components included in the Trial. Examples of Your responsibilities include but are not limited to:

- Regulatory Compliance – You are responsible for the following:
  - Notifying Oracle of any requirements or responsibilities imposed on Oracle arising from regulatory approvals granted to You throughout the Services Period. Oracle will cooperate with Your efforts to determine whether use of the standard Oracle Services offering is consistent with those requirements. Additional fees may apply to any additional work that is required to be performed by Oracle to comply with such requirements.
  - Ensuring that specifications meet the regulatory requirements for the Trial including such requirements laid out in the Protocol and subsequent Protocol Amendments.
  - Ensuring that any required regulatory approvals are in place prior to moving the configured Trial Build to Production or enabling Your Site Users to access the Services. This applies to the initial release and any subsequent releases that may occur as a result of modifications to the configured IRT program.
  - Providing the final clinical protocol and, as applicable, any subsequent final protocol amendments.
  - You remain solely responsible for Your regulatory compliance in connection with Your use of the Services.
- Managing and overseeing third party vendors (e.g. supply chain management, central labs, CTMS, external partners, Your subcontractors, etc.).
- Delivering clear and complete requirements in accordance with the agreed timeline planning. These may include clinical requirements, web language requirements, and test (dummy) randomization, and/or drug schedules. If the final protocol is not available, You and Oracle may mutually agree to begin study design from Your requirements based on a draft protocol; however any changes to Your requirements on receipt of the final protocol may be subject to additional fees in accordance with the Change Management process.
- Providing input into the creation and maintenance of the timeline and milestone planning as requested by Oracle.
- Negotiating in good faith an estimated timetable for any revised or additional milestone dates that are introduced after the initial timeline agreement.

- Ensuring that all key stakeholders, decision-makers, and team members are present and/or involved with all key meetings and deliverables (e.g. planning and review of the IRT program specifications, User Acceptance Testing, etc.) and that they adhere to the agreed timelines.
- Reviewing draft specifications prior to specification review meetings with Oracle team.
- Acceptance of design specifications in a timely manner.
- Instruct Oracle to release the configured IRT program in Your UAT instance and for release to Production go-live.
- Testing the UAT instance (e.g. conducting user acceptance testing) to Your own standard operating procedures and/or work instructions and for creating and testing Your own test cases. This includes capturing user acceptance testing feedback that is clear, reproducible, and actionable in the Oracle provided template. If changes are introduced during user acceptance testing, the Change Management process will be followed (including additional fees and time).
- Instruct Oracle to release the configured IRT program in Your Production instance.

Your Obligations for User Requirements Specifications:

You are responsible for performing the following with respect to alerts and notifications in Your User Requirements Specifications:

- Review the User Requirements Specifications (URS) document and confirm that it correctly identifies all IRT alerts and notifications for Your IRT Trial;
- Identify the alerts and notifications in the URS that will not be transmitted but will instead be made available for review only within the IRT program. Note the End User will be notified in email to retrieve the information through the IRT program with a link contained in the body of the communication;
- Specify the alerts and notifications in the URS that will be transmitted unencrypted (the data will be present in the body of an email); and
- Review each alert and notification in the URS and ensure that there is no data contained in any alert or notification that is required under applicable law or regulation to be encrypted during transmission.

You acknowledge and agree that with respect to the alerts and notifications that are transmitted in the URS:

- Any alerts or notifications that are sent unencrypted are subject to intercept and access by unauthorized third parties, which creates a security risk for the data contained in the alerts and notifications;
- You are solely responsible for ensuring that there is no data contained in any alert or notification that is required under applicable law or regulation to be encrypted during transmission; and
- You are responsible for all damages and liabilities that result from transmitting the data unencrypted.

Usage Limits. This Service is subject to usage limits based on:

- One Trial
- This Service utilizes the IRT Cloud Service environment(s) and is subject to the Usage Limits and Service Level Targets for IRT Cloud Service.
- The Services above must be used within twelve (12) months from the signature date of Your order. For the purposes of Oracle Health Sciences IRT Cloud Service – Base Randomization and/or Oracle Health Sciences IRT Cloud Service – Base Supply Management, this means that You must have met Your final obligation to instruct Oracle to the configured IRT program to the Production instance of Your Oracle Health Sciences IRT Cloud Service within the timeframe defined above. Any Services not used within this timeframe 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.

Oracle Cloud Policies

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

Oracle Health Sciences IRT Cloud Service – Non-Standard Web Language

Part #s: B91615; B91695; B91740

Deliverables and Customer Dependencies

- Oracle will configure the Oracle Health Sciences IRT Cloud Service to facilitate translation of Your web prompts and Site user manuals into non-English languages, subject to the Usage Limits herein.

Usage Limits – This Service is subject to usage limits based on:

- One Trial
- The number of Languages defined in Your order
- This Service utilizes the IRT Cloud Service environment(s) and is subject to the Usage Limits and Service Level Targets for IRT Cloud Service.

Oracle Cloud Policies

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

Oracle Health Sciences IRT Cloud Service – IRT Integration

Part #s: B91616; B91694; B91738

Deliverables and Customer Dependencies

Oracle will:

- For each Integration You have ordered, configure or build components to integrate Your Oracle Health Sciences IRT Cloud Service with a third party system.
- Set up a standard one or two way integration to Your Oracle Health Sciences IRT Cloud Service, limited to the following requirements:
    - Third party Integration types:
        - Supply Vendor/Depot
        - Electronic Data Capture Systems
        - Clinical Trial Management Systems
        - Sponsor/Contract Research Organization (CRO) Systems
        - Lab Vendors
        - IRT Systems
    - Transport Mechanism
        - The data transfer file(s) will be posted to an Oracle sFTP location by the source application and picked up from the Oracle sFTP by the destination application.
        - Secure access will be granted to the third party to access the Oracle sFTP location for the purpose of posting and/ or picking up (as applicable) the data transfer file(s).
    - File Types:
        - Text (txt, rtf)
        - Comma Separated (csv)
        - Excel (xls, xlsx)
        - XML
    - Data contained for inbound/outbound files:
        - By Blinding:
            - Blinded: the file does not include any unblinding data
            - Un-blinded: the file includes unblinding data
        - By Type:
            - Subject data (including but not limited to subject demographical data, randomization data, visit record data, dispensation record data, lab result data)
            - Drug data (including but not limited to depot inventory data, dispensation data, Site inventory data, drug ordering data)
            - Site data (including but not limited to Site contact details, enrollment summary data)

        - By Volume:
            - Up to 15 columns per file
    - Exclusions:
        - Computed data points (dose formulas, dose/treatment mappings)
        - IRT program audit data
        - Statistical Analysis System (SAS) datasets and transport files
        - Web service based integrations

Usage Limits: This Service is subject to usage limits based on:

- The quantity of Integrations Per Trial defined in Your order
- Implementation on one Production and one UAT instance per Trial for each Integration purchased
- The Services above must be used within twelve (12) months from the signature date of Your order. Any Services not used within this timeframe 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.

Oracle Cloud Policies

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

Oracle Health Sciences IRT Cloud Service – Additional IRT Standard Options

Part #: B91617; B91689; B91734

The Additional IRT Standard Options include standard optional services or standard optional functionality related to randomization and clinical trial supply management. The IRT Cloud Service – Base Randomization offering is a prerequisite in order to purchase any of the IRT Cloud Services. This section describes the features that are unique to the Additional IRT Standard Options and not already included in the Base Randomization or Base Supply Management features.

STANDARD OPTIONAL SERVICES

For IRT Cloud Service - Base Randomization:

Statistician - Generate Randomization Schedule

An Oracle statistician will provide services for generating one randomization schedule/list. The services include the provisioning of one test randomization schedule for User Acceptance Testing (UAT) purposes and one final randomization schedule.

For IRT Cloud Service - Base Supply Management:

Base Supply UAT (User Acceptance Testing) Scripts

You will be provided with a UAT script in Oracle's standard format that includes up to 200 UAT scenarios covering the drug supply management functionalities.

Statistician - Generate Drug Schedule

An Oracle statistician will provide services for generating one drug schedule/list. The services include the provisioning of one test drug schedule for UAT purposes and one final drug schedule.

STANDARD OPTIONAL FUNCTIONALITY

For IRT Cloud Service - Base Randomization:

RE-SCREENING:

- Allows a user to re-screen a subject, with the option for the subject to keep their original screening/subject number or to receive a new screening/subject number, and the option for including a frequency (one time; multiple times) of re-screenings allowed.
- The same data points will be captured as in the initial screening transaction.
- Permits subject's status called 'Re-screen' on the 'Subject Details 'report.
- Creation of a new 'IRT Re-screening Confirmation' notification.
- Re-screening will not include any changes to the 'Study Limits' nor any other reporting. If the 'Roll-back' feature is utilized, it will be modified to allow the rolling back of a re-screening transaction. This includes the standard edit of the re-screening date.

  Note: Not available when the Site is closed.

RE-RANDOMIZATION

- Allows for a user to perform a secondary randomization of a subject, obtaining a new randomization code (number) which will be used to dictate subsequent visit drug assignments.
- Creation of a new 'IRT Re-randomization Confirmation' notification.
- Change to the 'Unblinded IRT Randomization Report' to include a record on the re-randomization captured data.
- If the 'Roll-back' functionality is utilized, it will be modified to allow the rolling back of a re-randomization transaction. This includes the standard edit of the re-randomization date.

  Note: Not available when the Site is closed.

DYNAMIC STRATIFICATION

- A change to standard randomization to calculate in the background subject strata based on captured subject data points during the randomization transaction.

- The calculation may not include more than two data variables and will be limited to a range check on the captured data points.

FOLLOW-UP VISIT (without Dispensation)

- Allows for a user to register a scheduled 'Follow-up visit'. This includes the creation of a new 'IRT Follow-up visit Confirmation' notification.
- If the 'Roll-back' functionality is utilized, it will be modified to allow the rolling back of a Follow-up visit transaction. This includes the standard edit of the follow-up visit date.

Note: Not available when the Site is closed.

ADDITIONAL REPORT

- Web report based on the standard IRT program reporting framework
- Report includes collected study Data only and includes up to a maximum of 10 columns of Data.
- You will have the option to specify the name and content of the report during the User Requirements Specifications review and prior to finalization.
- Development and implementation of a customer provided template is not included.

ADDITIONAL ALERT

- Alert reporting on collected study Data only based on the standard IRT program reporting framework.
- You will have the option to specify the name and collected study data points of the alert during the User Requirements Specifications review and prior to finalization.

For IRT Cloud Service - Base Supply Management:

FORCED RANDOMIZATION

- A change to standard randomization forcing a subject to one of the treatment arms for which drug supplies are available when a subject was initially to be randomized to a treatment arm for which the IRT Site inventory is showing no or insufficient supplies available.
- Creation of a new 'IRT forced randomization' alert.
- Does not include the implementation of a forced randomization limit.

RUN-IN/LEAD-IN DISPENSING

- Allows for a user to register one scheduled visit with drug dispensation prior to the randomization visit
- Creation of a new 'IRT Run-in/Lead-in dispensing Confirmation' notification.
- If the 'Roll-back' functionality is utilized, it will be modified to allow the rolling back of a run-in/lead-in transaction. This includes the standard edit of the Run-in/lead-in dispensing

date.

- The user may register a subject as a screen-failure after a subject has been registered for a Run-in /Lead-in visit.
- This excludes the drug supply projection calculation for this run-in/lead-in dispensing visit.

Note: Not available when the Site is closed.

PARTIAL DISPENSING

- A change to the standard dispensation visit allowing a user to register a dispensation visit even when there is insufficient drug supply required for the visit according to the IRT Site inventory. The IRT program will allocate the drug supply quantities that are available. The user will obtain the remaining supplies through the 'IRT Unscheduled Dispensing' at a later point.
- Creation of a new 'IRT Partial Dispensation' alert

UNSCHEDULED DISPENSING

- Allows for a user to register a non-scheduled visit (also known as unscheduled visit) with the purpose of obtaining drug dispensation in between scheduled visits.
- Creation of a new 'IRT Unscheduled Visit Confirmation' notification.
- If the 'Roll-back' functionality is utilized, it will be modified to allow the rolling back of an Unscheduled Visit transaction. This includes the standard edit of the unscheduled dispensing date.

Note: Not available when the Site is closed.

FOLLOW-UP VISIT (with Dispensation)

- Allows for a user to register a scheduled 'Follow-up visit', including drug dispensation.
- Creation of a new 'IRT Follow-up visit Confirmation' notification.
- If the 'Roll-back' functionality is utilized, it will be modified to allow the rolling back of a Follow-up visit transaction. This includes the standard edit of the follow-up visit date.

Note: Not available when the Site is closed.

COMBINATION SERIALIZED AND NON-SERIALZED (BULK) SUPPLIES

- The 'IRT Drug Supply Management' module and functionalities allows a mixture of serialized and non-serialized supplies (also known as bulk).
- No other changes are included.

ADDITIONAL SUPPLY MANAGEMENT REPORT

- Web report based on the standard IRT program reporting framework
- The Report includes collected study Data only (specific to supply management data) and

includes up to a maximum of 10 columns of Data.

- You may specify the name and content of the report during the User Requirements Specifications review and prior to finalization.
- Development and implementation of a customer provided template is not included.

ADDITIONAL SUPPLY MANAGEMENT ALERT

- An alert reporting on collected study Data (specific to supply management) only based on the standard IRT program reporting framework
- You will have the option to specify the name and collected study data points (specific to supply management) of the alert during the User Requirements Specifications review and prior to finalization.

STANDARD DRUG ORDER FORM MODIFICATIONS

- Change to the standard IRT program drug order form
- Formatting changes, adding static text, and adding collected study Data relevant to the drug order.
- You will have the option to specify the name and content of the drug order form during the User Requirements Specifications review and prior to finalization.
- Development and implementation of a customer provided template is not included.

STANDARD IP RETURN FORM MODIFICATIONS

- Changes to the standard IRT program IP return form
- Formatting changes, adding static text, and adding collected study Data relevant to the IP drug return.
- You will have the option to specify the name and content of the IP return form during the User Requirements Specifications review and prior to finalization.
- Development and implementation of a customer provided template is not included.

Usage Limits. This Service is subject to usage limits based on:

- The quantity of Additional IRT Standard Options defined in Your order
- This Service utilizes the IRT Cloud Service environments and is subject to the Usage Limits and Service Level Targets for those environments.
- The Services above must be used within twelve (12) months from the signature date of Your order. Any Services not used within this timeframe 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.

Oracle Cloud Policies

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

Oracle Health Sciences IRT Cloud Service – Additional IRT Trial Specific Options

Part #: B91350; B91690; B91739

Each Additional IRT Trial specific Option is specified in Your order and is in addition to the Base Randomization, Base Supply Management, and the Additional IRT Standard Options services you may have ordered.

Deliverables and Customer Dependencies

The deliverables and Customer dependencies for Additional IRT Trial Specific Options are described in and subject to the terms of Your order.

Usage Limits. This Service is subject to usage limits based on:

- The Services must be used within twelve (12) months from the signature date of Your order. Any Services not used within this timeframe 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.

Oracle Cloud Policies

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

ACCEPTANCE OF DELIVERABLES

Upon Oracle's completion of any deliverable, You will be responsible for any additional review and testing of such deliverable in accordance with any mutually agreed review criteria or test scripts. If the deliverable does not conform with any such review criteria or test scripts, You will have five (5) business days after Oracle's submission of the deliverable ("Acceptance Period") to give Oracle written notice which shall specify the deficiencies in detail. Oracle will use reasonable efforts to promptly cure any such deficiencies. After completing such cure, Oracle will resubmit the deliverable for Your review and testing as set forth above. Upon accepting any deliverable submitted by Oracle, You must provide Oracle with written acceptance of such deliverable. If You fail to provide written notice of any deficiencies within the Acceptance Period, as provided above, such deliverable will be deemed accepted at the end of the Acceptance Period. This section does not apply to Oracle Health Sciences IRT Cloud Service – Base Fee – Trial, Oracle Health Sciences IRT Cloud Service – Patient, or Oracle Health Sciences IRT Cloud Service – End User Helpdesk.

CHANGE MANAGEMENT

If either party determines that any changes to the services ordered are required (including changes to the scope of services, Your protocol, the study parameters, supporting detail, or non-standard development work), a Scope Change order may be required. Each Scope Change order will document the change(s) to the specific Services to be performed, to either party's responsibilities or obligations, and/or to the applicable fees. Oracle is not obligated to perform tasks related to changes in scope, cost, or contractual obligations until You and Oracle mutually agree to and execute a Scope Change order.