InForm On Demand Single Trial Services Description

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This is the *Services Description for Oracle InForm On Demand Single Trial (*"Schedule") to Your Study Order for Oracle InForm On Demand Single Trial services ("Study Order"). This Schedule describes the services provided by Oracle (the "Services") for the Trial listed in the Study Order. Additional services ordered in Your Study Order (e.g., integration services, etc.) may be described in other schedules. Further details of the Services are shared at the commencement of the Services.

Table of Contents

1.0 Overview of Services

InForm is a web-based data collection system designed for clinical studies. Oracle will provide You with Services for Your Trial in three phases: FastStart, FastForward, and FastLock. The activities related to these Services are bounded by the parameters in the Study Order and described in more detail below.

During the FastStart phase ("Study Setup"), Oracle provides Services related to project initiation and application set-up tasks to prepare the InForm Services environment for user acceptance testing.

During the FastForward phase ("Study Conduct"), Oracle provides Services related to user acceptance testing, InForm program usage, and the management of contracted changes. The FastForward phase starts at the delivery of the InForm program for user acceptance testing and concludes upon confirmation by You of Database Lock.

During FastLock ("Study Closure"), Oracle provides Services leading to decommission of the InForm Services environment.

Regulatory Compliance: Information on Oracle's practices for certain regulatory standards applicable to 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 2158526.1). References therein to Oracle's design, development, testing, or validation as they relate to Trial Build and Configuration Services apply only where You have ordered Trial Build or other Configuration services from Oracle.

2.0 Optional Services

In addition to the standard Services that Oracle provides to You, optional services are also available, such as:

- Custom Requests – Custom requests will be per quotation and may include services such as database imports, database exports, custom reports, etc.
- IVRS Integration - The IVRS Integration Solution integrates InForm GTM Trial data with external vendor Interactive Voice Response Systems (IVRS) and Interactive Web Response Systems (IWRS) to screen and enroll patients, perform randomization, add/update clinical patient data and transfer patient data.
- Dedicated Hosting Environment – A hosting service which can be ordered based on Your hosting needs. Additionally, when a contracted InForm Trial reaches a threshold of 5 million data items consumed, You must pay for increased hosting fees. Such fees will be calculated and contracted as a Dedicated Hosting Environment.

3.0 Deployment and Environments

Your InForm Services environment will be deployed in a hosting facility and will be maintained and managed by Oracle. The deployment of the Services environment will consist of an instance for production use ("**Production instance**"), a non-production instance for user acceptance testing ("**UAT instance**"), and if requested by You, a non-production instance for training ("**Training instance**"). The Production instance is the instance which will be used to capture the clinical 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. The Training instance may be used by You to conduct training. You may also contact Oracle for additional training options, more information is here.

4.0 Users and Access by Users

The Services are intended to be used by personnel related to Your Trial as authorized by You. Normally this consists of two main groupings of personnel: sponsor and Site. The sponsor group typically consists of personnel from Your company and may also include other sub-contracted personnel such as Contract Research Organization personnel, monitors, and data managers. The Site personnel typically consist of the

Site coordinators (clinical research coordinators) and study investigators (principal investigators and sub-investigators).

Identity and Access Management Service (IAMS): Oracle Health Sciences Identity and Access Management Service (IAMS) provides Oracle single sign-on (SSO) functionality for IAMS-enabled versions of InForm. IAMS manages identity and access requests by Users and roles. IAMS uses coarse-grained authentication to evaluate if Users have been assigned privileges to open an InForm page that they are trying to access. For IAMS-enabled versions of InForm, Users may access an InForm page to which they are provided privileges using a single sign-on account. Once an InForm page is accessed by a User using a single sign-on account, the User will automatically be signed into such InForm page for future access. IAMS is supported for development, UAT, and Production instances in newly deployed in environments of InForm 6.1 or later. IAMS will not be supported for Training instances. Fine-grained privilege access control features may be accessed through the InForm program as described in the InForm program documentation.

5.0 Deliverables and Customer Dependencies

The deliverables for a given project are dependent upon the components included in that project. Not all projects will produce all of the deliverables listed below. Some common deliverables that apply to projects include:

- Specifications – These are written by the Oracle project team to document the design of the InForm program configurations. Specifications may include EDC form content, rules and edit checks, InForm program configurations, and database requirements.
- Project Plan – This plan will be created and maintained by the Oracle Project Manager. It will detail the tasks, timelines, and milestones for which Oracle and You are responsible, as applicable.
- Team List – This document is created and maintained by the Oracle Project Manager. It describes the team members, their responsibilities, and their contact information.
- InForm Program Release for UAT – This is the initial release by Oracle of the configured InForm program in the UAT instance of Your InForm Services environment that You may use to conduct user acceptance testing activities.
- InForm Program Release for Go-Live – This is the Production release by Oracle of the configured InForm program in the Production instance of Your InForm Services environment that Your approved Users may access.
- Changes and Fixes to the Production InForm Program – Related documents are created by Oracle and approved by You.
- Database Extracts – These database extracts may be used by You to analyze and report on Your Data captured by the configured InForm program. It is Your responsibility to request an export online and to download the export.
- Archives for Your Trial
    - **InForm Trials with CRF Submit** – For InForm Trial(s) with CRF Submit installed and enabled in the Cloud Service ("**CRF Submit Self-Service Trial(s)**"), You and Your Sites must generate, download, and maintain any archive and/or study submission PDFs, as well as any reports ("**CRF Submit Self-Service Files**") that You or Your Sites may require for Your Trial through CRF Submit. You, and Your Sites, are responsible for fulfilling the obligations stated in the Services Description with regard to generating and downloading these CRF Submit Self-Service Files through CRF Submit.
        - There is no limit on the number of CRF Submit Self-Service Files which may be generated by You and Your Sites through CRF Submit during the Trial up to Your Request for Decommission.

        - CRF Submit Self-Service Files will be deleted or otherwise rendered inaccessible by Oracle upon the earlier of 120 calendar days after they were generated or decommissioning of the Cloud Service, and the CRF Submit Self-Service Files will not be available for download after such time. Additionally, CRF Submit, including the CRF Submit Self-Service Files, will not be available after decommission. Your Request for Decommission confirms both Your and Your Sites' acceptance of the CRF Submit Self-Service Files.
        - For an additional fee, You may request that Oracle generate archive and/or study submission PDFs on Your behalf in accordance with the Service Description for InForm CRF Submit within the *Oracle Health Sciences InForm Cloud Service - Service Descriptions and Metrics*.
    - **InForm Trials without CRF Submit** – For InForm Trial(s) without CRF Submit installed and enabled in the Cloud Service ("**CRF Submit Non-Self-Service Trial(s)**"), You may request that Oracle generate Your PDFs up to two times during the Trial through Your Request for Decommission. Oracle may generate and deliver the PDFs to You on encrypted physical media or as otherwise designated by Oracle. You, and Your Sites, are responsible for fulfilling the obligations stated in the Services Description with regard to requesting PDFs.
    - These archive files are intended to document the Data as it existed in Your Production instance of the configured InForm program. Generation of additional set(s) of output with different output requirements, such as a subset of Data for auditing purposes, is not covered by this Services Description and must be ordered separately.
- Help Desk Support – User support will be accessible via email or via local phone numbers (toll-free where available at Oracle's discretion).
- User Management Tool (UMT) Non-Production Environment – Except for critical patch updates, the latest generally available release of UMT will be released in the UMT non-production environment prior to release in the UMT production environment. Your UMT Users are entitled to access the latest generally available release of UMT in the UMT non-production environment to try new features, to update sponsor internal standard operating procedures, and to train sponsor end users to perform common trial administration tasks (including import of Users, Sites, and roles) prior to accessing the latest generally available release of UMT in the UMT production environment. The UMT non-production environment has no connectivity to InForm or Identity and Access Management Service (IAMS). Except for critical patch updates, the latest generally available release of UMT will be deployed in the UMT non-production environment, at Oracle's discretion, approximately three calendar weeks to 60 calendar days prior to release in the UMT production environment. The release preview timeframe will vary depending on the content of the release and the significance of new features.
- Maintenance of the Cloud Services **–** Oracle will maintain the Cloud Services, including upgrades, in accordance with the *Oracle Cloud Hosting and Delivery Policies and Oracle Global Business Unit Cloud Services Pillar Document*. Upgrades are applied per InForm server and all Trials on the same server are upgraded at the same time. Migrations will be in accordance with the *Oracle Health Sciences Cloud Services – GA and EOL Dates* document, which is available at www.oracle.com/contracts. Migrations typically include a Trial move to a new server. Oracle will coordinate change management requests required for upgrades and migrations.
    - Maintenance of the Production instance **–** Upgrades and migrations are scheduled with You and are performed during the maintenance window.
    - Maintenance of the UAT instance
        - Upon request, Oracle will update the UAT instance with a fresh extract of the Production instance each time a change or fix to the InForm program configuration requires testing. This involves removing the UAT instance (including UAT Data) and

replacing it with a fresh extract of the Production instance containing all the Data as it exists in the Production instance.

- Upgrades and migrations are scheduled with You and are performed during business hours for UAT instances.

- Maintenance of the Training instance
  - If requested by You, Oracle will set up a Training instance using Trial implementation files similar to those used for the Production instance. You may request that the Training instance be updated to reflect subsequent changes or fixes within the Production instance. Copying Data from the Production instance to the Training instance is not allowed.
  - Upgrades and migrations are scheduled with You and are performed during business hours for Training instances.

- Production Instance Backups – The terms of the *Oracle Cloud Hosting and Delivery Policies* and *Oracle Global Business Unit Cloud Services Pillar Document* apply for the purpose of Production instance backups. Backups are not intended for and cannot be used for purposes of archiving a Trial. Oracle will make the following backups of Your Data hosted by Oracle in the Production instance.
  - Daily backups of hosted application system and database files.
  - On four-hour intervals, backups are made of the Oracle Database Archive files where applicable.
  - Daily replication of backups to an offsite facility
- A decommissioning package (i.e. archival study database and associated files related to hosting the Production instance including integrations, if any) will be sent to you after decommissioning.
- Archival documentation related to Oracle services (e.g. trial build specifications, change orders, document for trial fix, and service request tickets) will be sent to You via Oracle sFTP periodically during the Services Period.
- Optional services as described in the parameters table in the Study Order.

Your responsibilities related to the above services are dependent upon the components included in the project, including but 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.

- If You require a Training instance for Your Trial, You are responsible for requesting that Oracle deploy a Training instance.
- Delivering clear and complete requirements in accordance with the agreed timeline planning. These may include form, edit check, Trial configuration, and database requirements.
- Providing input into the creation and maintenance of the project plan as requested by the Oracle Project Manager.
- 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. requirements discussion and user acceptance testing, etc.) and that they adhere to the agreed timelines.
- Acceptance of the configured InForm program for release to the UAT instance and for release to the Production instance.
- Providing names of individuals who will require access to the UAT instance.
- In accordance with Your standard operating procedures and/or work instructions, testing the InForm program (e.g., conducting user acceptance testing) as well as creating and testing Your own test cases. This includes capturing UAT feedback that is clear, reproducible, and actionable in the Oracle-provided template. If changes are introduced following finalization of the documented requirements, the change management process will be followed (including additional fees and time, as appropriate).
- Adding Site and User information into User Management Tool (UMT) and/ or for the initial creation of the Sites and Users, providing a completed Oracle template listing the Site and User information to be loaded into UMT if Oracle is contracted to provide End User Help Desk support.
- Performing testing and training in the UMT non-production environment in accordance with Your standard operating procedures and/or work instructions as well as creating and testing Your own test cases.
- Ensuring that all users are trained prior to accessing the system. This includes maintaining all training records.
- All Data management activities for the Trial, including but not limited to dictionary coding, query resolution, Serious Adverse Event ("SAE") reconciliation, and Database Lock.
- Managing and overseeing third party vendors (e.g., lab vendors, external partners, Your subcontractors, etc.). If Oracle will not supply End User Help Desk support then You must ensure Your End User Help Desk vendor is aware they need to administer Oracle users where appropriate.
- While InForm may be used to assist in adverse event notification, InForm is not designed to be a comprehensive safety case handling system. Should You decide to use the Cloud Service for collection and reporting of serious adverse events, You remain responsible for ensuring that all applicable regulatory obligations are met.
- Reviewing and approving documents related to Production instance changes and fixes.
- Approving the InForm program Database Lock by completing the FastForward completion forms.
- Archives for Your Trial
    - **For CRF Submit Self-Service Trials**, You and Your Sites are responsible for generating, downloading, and maintaining any CRF Submit Self-Service Files You and/or Your Sites may

require during the Trial and/or following Database Lock, prior to Your Request for Decommission.

- You may choose to generate CRF Submit Self-Service Files on behalf of Your Sites, however You are responsible for ensuring that Your Sites download their CRF Submit Self-Service Files directly using CRF Submit.
- CRF Submit Self-Service Files will be deleted or otherwise rendered inaccessible by Oracle upon the earlier of 120 calendar days after they were generated or decommissioning of the Cloud Service, and CRF Submit Self-Service Files will not be available for download after such time. CRF Submit, and the CRF Submit Self-Service Files, will not be available after decommission.
- You are responsible for making Your Sites aware of the services and their obligations hereunder.
- If at any time there is a failure in the storage drive that stores CRF Submit Self-Service Files and storage cannot be restored after commercially reasonable effort, then You are responsible for regenerating the files using CRF Submit.
- Your Request for Decommission confirms both Your and Your Sites' acceptance of the CRF Submit Self-Service Files. You are responsible for ensuring that You do not submit Your Request for Decommission until You and Your Sites have requested, downloaded, and reviewed the CRF Submit Self-Service Files that You and Your Sites require. It is recommended that the final CRF Submit Self-Service Files be generated and downloaded by You and Your Sites in a manner that permits sufficient time for review prior to the end of the FastLock Period. You are responsible for executing any extensions to Your order that You and Your Sites may require due to Your failure to submit Your Request for Decommission by the end of the FastLock Period.

  - **For CRF Submit Non-Self-Service Trials**, You and Your Sites are responsible for submitting Your PDF archive requirements and requesting that Oracle generate any PDFs You and/or Your Sites may require during the Trial and/or following Database Lock, within 7 calendar days of Database Lock and prior to Your Request for Decommission.
    - You are responsible for reviewing the archival PDFs and signing and returning to Oracle a Request for Decommission within 30 calendar days of receipt of the archival PDFs.
    - You are responsible for making Your Sites aware of the services and their obligations hereunder.
    - You are also responsible for distributing PDFs, as appropriate.

- Reviewing and accepting the following deliverables within sixty (60) calendar days of delivery by returning to Oracle the designated Oracle forms within such 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 Trial Data in Your instance(s):
  - the decommissioning package
  - relevant archival documentation related to Oracle services
- The FastLock phase is expected to take a total of 90 calendar days between Your confirmation of Database Lock and decommission. From the completion of FastForward, Oracle will keep the Trial available in a read-only status for 90 calendar days (or as otherwise indicated in Your order) (the

"FastLock Period") to perform close down activities. Should this timeframe extend beyond the FastLock Period due to delays on Your part, Oracle reserves the right to charge additional fees as outlined in the Study Order.

6.0 Acceptance of Deliverables

Upon completion of any deliverable, Oracle may provide a copy thereof to You. You will be responsible for any additional review and testing of such deliverable in accordance with any mutually agreed review criteria or specifications. If the deliverable does not conform with any such review criteria or specifications, unless stated otherwise in Your obligations above, You shall 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 shall use reasonable efforts to promptly cure any such deficiencies. After completing such cure, Oracle shall resubmit the deliverable for Your review and testing as set forth above. Upon accepting any deliverable submitted by Oracle, You shall 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 shall be deemed accepted at the end of the Acceptance Period.

7.0 FastStart

FastStart consists of activities prior to the availability of the configured InForm program for user acceptance testing (UAT).

Project Management
Oracle will: • Create a project plan detailing Trial tasks and milestones. • Coordinate Oracle project team efforts. • Track and keep You informed of Trial/project progress. • Change Order initiation, as needed. • Endeavor to archive key milestones, for example: Release for User Acceptance Testing (UAT)
Study Design and Build
Oracle will: • Lead discussions to understand and document Your Trial requirements • Configure or build Trial components in support of the mutually agreed Trial requirements
Formal Testing
Oracle will: • Conduct an independent test of Your Trial by testing Trial components against the mutually agreed Trial requirements
Help Desk
If Oracle is contracted to provide End User Help Desk support, Oracle will: • Set up sites and users in the InForm program. • Manage user accounts in the InForm program.

8.0 FastForward

FastForward consists of activities from availability of the configured InForm program for user acceptance testing through confirmation by You of completion of Database Lock.

Project Management
Oracle will: • One (1) User Acceptance Testing (UAT) findings meeting. • Status meetings (teleconference) at mutually agreed intervals and times

• Change Order initiation, as needed. • Discussion regarding Change Order deliverables, as needed.
User Acceptance Testing
Oracle will: • Assess and address any design that You find in UAT that does not support the mutually agreed Trial requirements • If required, deploy the new build to the UAT environment for You to re-test Your findings
Help Desk
If Oracle is contracted to provide End User Help Desk support, Oracle will: • Provide Help Desk support via email or via local phone numbers (toll-free where available at Oracle's discretion). • Set up sites and users in the InForm program and manage user accounts. • Deliver an (End-User) Satisfaction Survey questionnaire. • Escalate calls to You, as appropriate.
Study Hosting and Application Management
Oracle will: • Add user accounts to the Training instance with passwords that will expire according to the parameters defined in the Production instance and as per Oracle's standards.

9.0 FastLock

FastLock services consist of those relating to the management of the Production instance from confirmation by You of completion of Database Lock to Trial decommission.

Project Management
Oracle will: • Liaise with Your team for activities needed to close out the Trial. • If applicable, progress Your archive requirements as described under Deliverables
Formal Testing
Oracle will: • If applicable, perform formal testing of the archival PDFs
Help Desk
Oracle will: • Modify end-users to "Read Only" status.
Study Hosting and Application Management
Oracle will: • Decommission and recycle the Trial environment.

10.0 Oracle Cloud Policies and Pillar Documentation

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

11.0 Service Level Targets

InForm On Demand has the following service level targets:

Cloud Service	Recovery Time Objective (RTO)	Recovery Point Objective (RPO)	Target System Availability
Oracle Health Sciences InForm On Demand	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.