System Support Plan

For

Eclipse Coding Tool, V 2.7

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| Signature by the approvers indicates that they have read and understood the content of the document; that they agree the document is complete and accurate, and that they support its intent. | | |
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Revision History

| **Version No.** | **Date** | **Description of Change** | **Name / Title / Department** |
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| 1.0 | 19-Oct-2017 | New Document (Final) | Thirumurugan Rajamoorthy, Support Member – DataSciences (Managed Service Provider, HCL), OIT-Global R&D, OPDC |
| 2.0 | 13-Oct-2020 | Migration of Eclipse servers from Canary on-premise data center to AWS Cloud (CHG0012196).  As part of this Change request the following sections are updated.   * Updated Section 4 to list current roles and responsibilities. * Updated section 5 to update the System Backup and Disaster Recovery related information. * Replaced IOS with I&H throughout the document. * Updated section 11.1 to include AWS backup details. * 12-Patching. * 13-System Failure. * As per updated RACI, Reviewer & approver details are updated. * Updated and moved Acronyms and Definition section to end. | Mohanraj Gangatharan,  Support Member – DataSciences (Managed Service Provider, HCL), OIT-Global R&D, OAPI |
| 3.0 | 16-Sep-2022 | Following sections are updated/added as authorized by Change Request: RLSE0010463   * Updated the Reviewers & Approvers section   Updated the application version from 2.4.1 to 2.7.0 throughout the document.  Added the responsibilities for I&H role in Section 4  In Section 6.2- Updated Support environment details  In Section #7 added Google Chrome, Microsoft edge and Firefox as browsers  and removed IE explorer 11.  Updated Section #8 to include user account setup in Canary SSO  Updated AWS definition in Acronyms &  Definitions Table | Suganthi Rajendran,  Support Member – Data Sciences (Managed Service Provider, HCL), OIT-Global R&D, OAPI |

**Note:** The version number in ‘Revision History’ section should be in sync with version of the document in GQ-EDMS after approval.

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# Purpose

The purpose of this System Support Plan (SSP) is to outline the service and support to be provided for the Eclipse Coding Tool (Application version 2.7.0) that will be used by Data Management department (Clinical Coding), Canary Pharmaceutical Development and Commercialization Inc. (OPDC).

# Scope

## In Scope

The scope of this SSP is limited to Accessibility, Security, Communication, Support and Maintenance of the Eclipse Coding Tool System for its current implementation at OPDC. Further, the System Owner will be responsible for the management of this SSP.

## Out Of Scope

Detailed procedures and instructions followed by Application Support teams during the support process are out of scope for this document, as they are already covered in SOP and Working Practices listed in “References” section below.

# References

## System Life Cycle Procedures (SOPs & WPs)

| Reference Number | Title | Version |
| --- | --- | --- |
| PRC-0000778 | IT System Support and Operations | 3.0 |
| PRC-0000788 | IT System Access & Vulnerability Management | 2.0 |
| PRC-0000789 | IT System Incident & Problem Management | 2.0 |
| PRC-0000790 | IT System Support Plan | 2.0 |
| PRC-0000997 | Periodic Review of Validated IT Systems | 2.0 |
| PRC-0000776 | IT Change Management | 2.0 |
| PRC-0000775 | IT System Deployment | 2.0 |

Table 1: SOP References

## 

## Project References

| Val Number | Name & Title | Version |
| --- | --- | --- |
| VAL-0022968 | Document Name: System Assessment (SA)  Document Title: Eclipse Coding Tool\_v2.7.0\_RLSE0010463\_SA | 4.0 |
| VAL-0024238 | Document Name: Validation Plan  Document Title: Eclipse Coding Tool\_V1.0\_PR9601-17589\_VP | 2.0 |
| VAL-0024237 | Document Name: Infrastructure Configuration Specification  Document Title: Eclipse Coding Tool\_V2.5\_ICS | 3.0 |

Table 2: Project References

# Responsibilities

| Role | Department | Responsibilities |
| --- | --- | --- |
| System Owner | OIT-Global R&D, OAPI | System Owner is responsible for:   * The Review and Approval of System Support Plan document |
| Business Information Manager (BIM) | OIT-Global R&D, OAPI | BIM is responsible for:   * The Review and Approval of System Support Plan document |
| Project Manager | OIT-Global R&D, OAPI | Project Manager is responsible for:   * Ensuring that the System Support Plan is established and it’s in align with overall project objectives and track activities in this project phase * Ensuring that the tasks are happening on schedule as planned |
| Support Team | OIT-Global R&D, OAPI | Support Team is responsible for:   * Tier 1 and Tier 2 support on incidents reported by users * Analyzing and troubleshooting the reported incidents. * Resolving Tier 1 and Tier 2 incidents / issues reported in a timely manner * Escalating Tier 3 incidents / issues to Eclipse Product support Team * Management of user access based on necessary approvals * Coordinating / Collaborating with Vendor to identify suitable solutions for Business reported issues * Licenses management to ensure that adequate licenses are available to accommodate user access requests * Monitoring/analyzing server logs for any issues and assist * Managing and/or Assisting with any patches/updates to the application as per Canary’s applicable procedures (SOPs / WP) when implementing changes * Update known error database (KEDB) with incident / issue details and resolution * Ensuring this SSP document is kept current, reflecting the latest |
| Infrastructure & Hosting (I&H) | IT – I&H, OAPI | I&H team is responsible for:   * Review and approval of this document * Network connectivity * SSO implementations, environment support and   maintenance |
| Amazon Web Services (AWS) | Amazon - Vendor | AWS team is responsible for:   * Infrastructure components (i.e. network, hardware, etc.) |

Table 3: Roles & Responsibilities

# Constraints, Assumptions and Dependencies

* The system is treatable in Production environment for the licensed number of users and meets all current business needs as documented in User Requirements specification (with any acceptable exceptions/deviations noted in the Validation Summary Report).
* Infrastructure (Hardware & Supporting Software for application) is maintained as stated in the current Infrastructure Configuration Specification and any updates required are performed as per Canary’s SOPs and Work Practices and Governing documents of the application.
* Required level of access (if not granted already) is provided to identified Support team personnel investigating into any issues reported by users.
* I&H team member(s) is/are identified to assist investigating Support team personnel (if required).
* Workarounds are available for any open application issues identified during the testing/validation phase.
* In case of disaster, System is recovered / restored timely from the last backup. The current solution didn’t consider Load Balancing, Clustering, High availability as they were not identified as requirements. However, if a need is identified later due to an issue or poor performance of current solution then that will result in Change Request and may undergo a Major / Minor change depending on the additional business needs identified.
* The I&H group will be following the procedures laid out in the “ANC-0000081, Data Center Recovery Plan Job Aid “document for the System Backup and Disaster Recovery related to the Canary systems internally managed. The I&H will follow the AWS data center procedure for system servers hosted in AWS Cloud.
* The system shall be used with only the supported Browsers that Canary has validated.
* Support team assumes the users shall use one of the supported Browsers.
* Workarounds are followed by users as documented in relevant documentation for any known issues / limitations.
* Users are expected to follow the provided instructions for accessing system or performing any business operations within the system.

# System Details

## Support Strategy

Support team will monitor day to day business operations in the Eclipse Coding Tool (Application version 2.7) and will provide their assistance whenever necessary. Primarily the support team assisting to business users for creating jobs, uploading various dictionaries, creating reports, exporting data in various file formats and make sure the business as usual. Support team is responsible and responding, resolving the issues as per the agreed Service levels. Support team shall leverage necessary technical assistance from Eclipse vendor and also escalate / follow-up the critical application issues. All system issues will be tracked via the Service-Now system.

The team shall strive to lessen the impact of any significant issues encountered and associated risks. Any new change requests or required maintenance updates to the system will follow appropriate and/or applicable Working Practice and defined Canary Change / Release management process.

The support team will secure and maintain sufficient licenses for users and will ensure users are activated/de-activated as per Canary’s processes.

## Support Environment Details

|  |  |
| --- | --- |
| **Application Name** | Eclipse Coding Tool, (Application version 2.7) |
| **Environments** | Development, Test and Production |
| **Hardware** | Refer to Infrastructure Configuration Specification (ICS). |
| **Software** | JDK 1.8 Update 11.1, Tomcat 8.5, Oracle 19c |
| **Data Exchange** | Not Applicable |

# Accessibility

The system is accessible via compatible and supported web browsers by utilizing the URL ([http://j1eclipseap01v:8080/eclipseCoding/coding#](http://j1eclipseap01v:8080/eclipseCoding/coding)) (https://www.google.com/?client=safari) provided. All system users are provided with documented instructions on how they could access the system utilizing Google Chrome, Microsoft Edge and Firefox browsers (Canary recommended). The Vendor recommended and validated the Eclipse system in Google Chrome, Microsoft Edge and Firefox browsers. However, the system shall support the recent versions of any browsers. The browser compatibility issues shall be reported / recorded to vendor whenever it occurs.

# Security

System Administrator (Support Team) is responsible to creating user accounts, assigning roles and system privileges. The system access requests shall be submitted by the supervisor of the account recipient using the User Request Form. Support team will be performed user account creation activity in Canary SSO and Eclipse Coding Tool application. The system access shall be provided by System Administrator (Support Team) based on the completed User Request Form and it stored in Support Team SharePoint portal for system audit purpose.

Support Team SharePoint portal link: Click “[Here](https://collaboration.otsuka-us.com/teams/HCL-MSP/Shared%20Documents/Forms/AllItems.aspx?RootFolder=%2Fteams%2FHCL%2DMSP%2FShared%20Documents%2FBiometrics&FolderCTID=0x012000D8D7AA088018BF46B769F972A15AD575&View=%7B0ED79668%2D2DEA%2D4A1D%2DAC62%2D2B5A4096144F%7D)”

# Communication

The System unavailability (scheduled or unscheduled) will be monitored by support team and essential outage notifications and communications shall be initiated to necessary business groups ([Biometrics-Support@Canary-us.com](mailto:Biometrics-Support@otsuka-us.com)). Phone: 603 294 4580

All Eclipse system users will be notified when an outage occurs. Support team shall make all attempts to send out a notification within 30 minutes of any unplanned outage due to any issue. Depending on how significant / critical the outage and its impacts are on the business, periodic update notifications will be sent to users if the unscheduled outage is exceeding 30 minutes’ time during normal business hours. This notification transmitted to the user community will provide appropriate details pertaining to the disruption, a potential estimate of the outage duration, or at a minimum, an Estimated Time of Availability (ETA) for the next status update.

# Support

Support team will provide traditional and customary support for the system in the following manner: User support is defined as: “instructional and defect related support, of the end user, for the application.”

## Issues Tracking

All system issues will be tracked via the Service-Now system. All end user support events will be captured in the Service-Now system.

## Support Hours

The application support is running on 24\*7 for Canary OPDC Global users. The Support team is responsible for providing the support to the users of this system. The supporting period excludes company holidays as defined by OAPI Human Resources.

## Periodic Review

The periodic review of user accounts will be performed every six months. The support team will generate the active user account report and send to business owner for review. Based on business owner review   
note/confirmation, the users account will be modified\disabled by support team in Eclipse system.  
The details of performed tasks, email communications and evidence will be documented and stored in team location.

## Helpdesk Details

**10.4.1 STANDARD REQUESTS** – TIER 1(ex: user account management, ad-hoc reports, and functionality issues). Requests of this type should be communicated to the Helpdesk in one following manners:

* Send an e-mail message to [Biometrics-Support@Canary-us.com](mailto:Biometrics-Support@otsuka-us.com)
* Internally, dial extension 3333
* Externally, dial 1-877-4CANARY (1-877-468-7852)

For emergency support after business hours, dial extension **3335** internally or dial **240-683-3335** externally to notify an Information Technology Manager.

### ESCALATION (TIER 2)

All issues classified as ‘Tier 2 will be communicated to the appropriate Support Team by the CANARY Helpdesk personnel.

Tier 2 issues are listed below:

* Coding job creation
* Coded report
* Synonym list import and export
* Dictionary load
* Synonym list up version

### ESCALATION (TIER 3)

Issues meriting Tier 3 classification typically require the assistance from the vendor or developers. Such issues will be reported to Eclipse Product Support personnel by the Support team. The Support team will coordinate with the Vendor until a resolution is identified and the issue is resolved for the Business user. See vendor contact details below:

**Vendor:** Eclipse

Current point of contact: Leslie Bihari (President & CEO)

Phone: (603) 294-4580

[lbihari@eclipsesol.com](mailto:lbihari@eclipsesol.com), [support@eclipsesol.com](mailto:support@eclipsesol.com).

[www.eclipsesol.com](http://www.eclipsesol.com)

# Maintenance

AWS and Application Support teams will provide traditional and customary maintenance for the physical equipment and application for Eclipse system.

## Backups

### Server

The Eclipse Coding system servers are hosted in AWS and system backup/patching/restore activities performed by AWS team based on the standard schedules.

Canary data center backup/patching/restore procedures not applicable for Eclipse Coding system servers.

**AWS:** The standard backups schedule is as follows:

| **AWS Server backup details** | | | |
| --- | --- | --- | --- |
| **Server Category** | Bronze | Silver | Gold |
| **Backup** | Daily | 12 hours | 4 hours |
| **Backup Retained** | 35 days | 35 days | 35 days |

The Eclipse Server Backup fall under Bronze Category.

### Database

Servers backup activities will be performed as per AWS standard back-up process / cycle for Eclipse coding Tool system.

# Patching

## Operating System Patching on Servers

Refer to “Server Patching Process (VAL-0034944)” document.

## Application

Support team will apply the patches and verify them prior to applying them in the Production environment. Application patches will be applied in a test environment and verified. Following successful verification of patches in Test environment, patches are applied in Production environment. Support Team will closely monitor the Production environment after patches have been applied and will roll-back the patch if any potential issues are observed / reported by users.

## Database

Refer to section 11.1.2.

# System Failure

Following table define team responsibility when the system failure.

|  |  |  |
| --- | --- | --- |
| **Role** | **Department** | **Responsibilities** |
| Support Team | IT-BAS, R&D, OAPI | * System Failure * Application issues (Tier 1, 2 and above) |
| Support Team and Application Vendor | IT-BAS, R&D, OAPI and ICS | * Application Configuration Changes |
| Support Team and Database Vendor | IT-BAS, R&D, OAPI and OCI | * Database issues |
| AWS | Amazon – Vendor | * Hardware |

## Hardware

Hardware issues will be addressed by AWS Team.

## Primary Application

Eclipse Coding application issues (Tier II, and above) will be addressed by OAPI-IT’s Delivery and Eclipse Coding Support group.

## Supporting Applications

Supporting application issues (Tier II, and above) will be addressed by Delivery System Support group, and/or ICS (Application Vendor) team, when applicable.

## Restoration

The restoration effort/support will be addressed by AWS team on the standard procedures.

# Issue Tracking

All issues related to this system will be captured via support calls fielded by OIT Helpdesk/ServiceNow. Issues that require escalation to Eclipse will be tracked in ServiceNow.

# Performance Monitoring

The Support team will closely monitor and investigate the system performance if any issues with the system response are reported by multiple users, after go live. The expectation is current system architecture should cater to all the current business needs.

The periodic review of “Eclipse Coding Tool” system will be held on every 2 years based on the “Periodic Review of Validated IT Systems” SOP.

# Acronyms & Definitions

| Acronym or Abbreviation | Expansion or Definition |
| --- | --- |
| **AWS** | Amazon Web Services |
| **BPSS** | Business Production Support Services |
| **CEO** | Chief Executive Officer |
| **ETA** | Estimated Time of Availability |
| **GQ-EDMS** | Global Quality – Electronic Document Management System |
| **GQS** | Global Quality Solutions |
| **I&H** | Infrastructure & Hosting |
| **ICS** | Infrastructure Configuration Specification |
| **IOS** | Infrastructure & Operations Services |
| **IT** | Information Technology |
| **JDK** | Java Development Kit |
| **KEDB** | Known Error Database |
| **NJ** | New Jersey |
| **OAPI** | Canary America Pharmaceutical Inc. |
| **OIT** | Canary Information Technology |
| **OPDC** | Canary Pharmaceutical Development & Commercialization Inc. |
| **PRC** | Project Code |
| **SA** | System Assessment |
| **SOP** | Standard Operating Procedure |
| **SSP** | System Support Plan |
| **UATP** | User Acceptance Test Protocol |
| **URL** | Uniform Resource Locator |
| **VP** | Validation Plan |
| **WP** | Working Practice |