**Vaccines Business Unit-Electronic Lab Notebook**  
**U005**

**VBU-ELN – Audit Trail & eSignature Script**

**Document Version: 1.0**

# Document Control

*All signatures and dates can be captured electronically via SignIT or other approved tool*

This document is created and maintained with the provided individuals and uses the standardized SOPs for accuracy and maintenance.

## Authored By:

By signing this document, I am in agreement for approval.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Amanda Lashua |  |  |  | 14/11//2018 |
| Signature: |  | Author |  | Date: |
|  |  |  |  | dd-mmm-yyyy |

## Pre-Approvals

IT SDLC Lead signatory indicates the approval that this script may be used for UAT testing and that the prescribed testing satisfies the stated test case objective.

Business Lead signatory indicates approval the prescribed test steps technically correct, address the test case, and are executable.

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| Signature: |  | Business Lead |  | Date: |
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| Signature: |  | IT SDLC Lead |  | Date: |
|  |  |  |  | dd-mmm-yyyy |

## Version History

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Version | Author | Description of Change |
| 10 Apr 2018 | 1.0 | Terri Martell | Initial Release |

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# Script Testing Instructions

|  |  |
| --- | --- |
| Script Notes: | * **Test Action / Instructions**   + The step **Test Action / Instructions** column outlines the general process to be followed, by a tester experienced with ELN, to demonstrate a specific result that is defined in the Expected Results column.   + All steps designed to meet a requirement, or test objective, must capture objective evidence (ex. screen print) that supports the decision to pass or fail the step. A reference to the captured objective evidence must be documented in the Actual Results column. * **Expected Results**   + The result that is expected to be generated by following the process outlined in the **Test Action / Instructions** column. * **Requirement ID(s)**   + List of the User Requirement Specification (URS) Ids addressed by the test script. * **Status**   + **PASS-** indicates the step executed as stated in the Expected Results.   + **FAIL -** indicates that the expected result was not achieved or an error occurred and the step did not execute as intended. Upon a failed step provide a Test Incident Id reference in the Actual Results column and a description of the failure in the script Comments section. * **Actual Results** * If a result is not as expected, indicate the actual result in the Actual Results field. * If a result failed enter the Test Incident Id in the Actual Results field. * When the Actual Results are equivalent to the Expected Results the check box “Meets Expected Results” in the Actual Results column can be utilized in place repeating the verbiage in the Expected Results column in the Actual Results column. * When a result is not as expected, check “Other” in the Actual Results field and document the actual result. * When a screen capture is equivalent to a screen capture that was captured earlier, in the same script, the tester may reference the earlier screen capture in the Actual Results column. * **Comments**    + Comments fields are not required but if not utilized the comments section must be crossed off with a diagonal line and initial and dated.   + Comments must be clear and only Takeda approved, or previously defined, abbreviations utilized. * **All screen captures or Attachments must have the following:**   + The tester must capture all the required data indicated in the **Test Action / Instruction** column   + Also Script number, Step number, Tester’s Name, Test Date, Page X of Y   + A separate Screen Print Template is used to capture cut and pasteable objective evidence and the required information listed above may be documented in that template page headers. |
|  | **Additional Comment:** If the Test Script is not to be fully re-executed, specify test steps will be re-executed and include rationale in the script comments section. |

## Test Script Title: VBU-ELN – Audit Trail & eSignature Script

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Test Script ID:** | U005 | **Test Environment:** | Development  X Test | | Production  Other: \_\_Model\_\_\_\_\_\_\_\_ | |
| **Test Script Objectives:** | VBU-ELN – Audit Trail & eSignature Script  This script is designed to verify if ELN satisfies Audit Trail and Electronic Signature requirements. | | | | | |
| **Test Data Specification** |  | | | | | |
| **Pre-requisites:** | Two Testers with the ability to create and edit experiments.  Testers have access to Electronic Lab Notebook (ELN) for the execution environment.  Testers are trained and experienced in using ELN.  Record the URL for execution environment below:  URL: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
| **Requirement IDs :** | Individual steps cover the URS IDs being tested in that step | | | **Execution:** | | Initial Execution  Re-Execution  Run #: |

| **Step** | **Test Action / Instructions** | **Expected Results** | **Actual Results** | **Status** |
| --- | --- | --- | --- | --- |
|  | **First tester (create and edit experiments)**  Open Google Chrome browser and navigate to the URL recorded in Pre-requisites section.  Click on Sign in. | The tester is logged into ELN and is directed to the Dashboard screen. | X Meets Expected Results  Other: | X Pass  Fail |
|  | **ATES-0010**  Create a new experiment by clicking on “NEW+” from the Experiments section on the left panel.  Populate all the mandatory fields and hit “Click to publish now”.  Add an attachment to the same experiment and hit “Click to publish now” again.  **Capture a screen print** of History section on the left panel **and attach** | The tester is able to see 3 versions of the experiment (one created time stamp and two saved time stamps) in the history section on lower left side of screen. | X Meets Expected Results  Other:  Attachment #: \_\_\_\_\_\_\_\_\_ | X Pass  Fail |
|  | Check out the file (attachment) added in the step above, make a change and hit Save.  Check in the file and hit “Click to publish now”.  Ensure that a new version of the experiment is created in the History section. | A new version of the experiment is created in the History section. | X Meets Expected Results  Other: | X Pass  Fail |
|  | **ATES-0011**  Navigate to the most recent version of the experiment and open the attachment.  **Capture a screen print** **and attach** | The tester is able to verify that the attachment contains changes made in step 3. | X Meets Expected Results  Other:  Attachment #: \_\_\_\_\_\_\_\_\_ | X Pass  Fail |
|  | **ATES-0011**  Navigate to the second most recent version of the experiment and open the attachment.  **Capture a screen print** **and attach** | The tester is able to verify that the attachment does not contain edits made in step 3 in the historical version of the experiment. | X Meets Expected Results  Other:  Attachment #: \_\_\_\_\_\_\_\_\_ | X Pass  Fail |
|  | Populate/Select values for all mandatory fields if not already selected.  Click on Sign option and select a Witness.  Check the box for “Checking the box and entering your authentication credentials indicates that you have performed the work as described.”  Click on Sign. | The tester is able to select a witness for an experiment. | X Meets Expected Results  Other: | X Pass  Fail |
|  | **ATES-0013**  Enter your username and click on Sign On.  **Capture a screen print** of the error message **and attach** | The tester is prompted to enter a password to move the experiment to the next state. | X Meets Expected Results  Other:  Attachment #: \_\_\_\_\_\_\_\_\_ | X Pass  Fail |
|  | Enter your password and click on Sign On. | The tester is able to successfully sign off on the experiment. | X Meets Expected Results  Other: | X Pass  Fail |
|  | Create a new experiment by clicking on “NEW+” from the Experiments section on the left panel.  Populate all the mandatory fields.  Select second tester’s name for the field Collaborator(s).  Hit “Click to publish now” again. | The tester is able to create a new experiment and save the changes made. | X Meets Expected Results  Other: | X Pass  Fail |
|  | **Second tester (create and edit experiments)**  Open Google Chrome browser and navigate to the URL recorded in Pre-requisites section.  Click on Sign in. | The tester is logged into ELN and is directed to the Dashboard screen. | X Meets Expected Results  Other: | X Pass  Fail |
|  | **WRK-0012**  Search and navigate to the experiment created in step 9.  Update value for one of the mandatory fields.  Hit “Click to publish now”.  **Capture a screen print** **and attach** | The tester is able to make changes to an experiment created by another tester. | X Meets Expected Results  Other:  Attachment #: \_\_\_\_\_\_\_\_\_ | X Pass  Fail |
|  | **ATES-0014**  Hover over the most recent experiment in the History section.  **Capture a screen print** **and attach** | Name of the second tester is displayed verifying the system identifies changes made by a particular user in the audit trail. | X Meets Expected Results  Other:  Attachment #: \_\_\_\_\_\_\_\_\_ | X Pass  Fail |
|  | Log out of ELN.  Close the browser. | The tester is successfully logged out. | X Meets Expected Results  Other: | X Pass  Fail |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test Script ID:** | |  | | **Test Environment:** | Development  Test | | Production  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Comments:** |  | | | | | | |
| **Test Script Executed By:** | | | | | | | |
|  | | |  | | |  | |
| **Name Amanda Lashua** | | | **Signature** | | | **Date (14-11-2018)** | |

# Test Incidents

## Test Incidents Table

|  |  |  |
| --- | --- | --- |
| Test Incident Id | Step Number | Test Incident Description |
|  |  |  |
|  |  |  |
|  |  |  |

# 

# Execution Review & Post Approval

## Execution Review

Signatures below signify review and post-approval of the contents of this test script.

|  |  |
| --- | --- |
| **Test Script Status** | X Pass  Fail |
| **Comments :** | |
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## Post-Approval

I have reviewed this document and approve the provisions as stated.

Amanda Lashua 14-11-2018

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|  |  |  |  |  |
| Printed Name |  | IT SDLC Lead or Test Lead Signature |  | Date: <dd-mmm-yyyy> |