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| Group Informatics  Smoke Test |
| Kit Label Database (KLD) |
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Document Information

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Document History

| **Version** | **Changes** | **Effective Date** |
| --- | --- | --- |
| 1.0 | This version supersedes version 2.0 of the KLD Smoke Test:   * Section 3: Added text “is an” to “The Kit Label Database is an in-house developed system application that supports the generation of Kit Labels used on Genentech and Roche clinical trials”. * Section 5.3: Added minimum group membership requirements. * Replaced Appendix B with Section 7. * Added Test Evidence Section 8. * Section 7.3, Test Case 3: updated numbering from 9th position corrected to end of test case. * Section 7.3, Test Case 3, Step 19, updated “Sequence” to “Sequence No.”. * Section 7.4, Test Case 4, Step 3, updated length of specified Protocol Number to fit available field length. * Section 7.4, Test Case 4, Step 3, inserted specification for a second Kit Code, Number of Kit IDs = 10. * Section 7.4, Test Case 4, Step 8, updated “Block size” to “block size”. * Section 7.4, Test Case 4, Step 10, inserted confirmation step. * Section 7.5, Test Case 5, Steps 8 and 12, changed “Treat. Code” to “Treatment Code”. | 05-APR-2011 |
| 2.0 | * Section 2: Updated the document scope to Kit Label Database and its relevant components. Removed references to SAT and UAT. * Section 4: Updated Definitions with more comprehensive system related terms. * Section 5: Updated the Test Setup to a ‘Smoke Test Approach’; moved Environment Variables to Section 6.1. * Section 5.2: Moved to 6.1. * Section 5.3: Moved to Section 6.1 as Pre-requisites for performing test cases in Section 7. * Section 7.1: Combined steps to initiate SQL session. * Section 7.2: Combined steps for testing the application’s accessibility. * Section 7.3: Combined steps for testing of Scrambled Kit List. * Section 7.4: Combined steps for testing of Blocked Kit List. * Section 7.5: Combined steps for Subject Treatment List. * Section 7.6: Added Regulatory and Emergency Unblinding test case. | 17-JUN-2013 |
| 3.0 | * Section 7.4: Blocked Kit List has been updated to exclude protocol setup steps. * Section 7.4: Subject Treatment List: Added part of testing transmitting protocol – Email notifications and Zip attachment sending. * Section 7.6: Valicert connection verification has been added. | 19-FEB-2015 |
| 4.0 | * Section 6.1: <TEST PROTOCOL> added. * Section 7.3: Added Test Case Set-up/Prerequisites section. * Section 7.3.15 - 7.3.16: Added steps related with Scrambled Kit Lists verification. * Section 7.5: <TEST PROTOCOL> variable added. * Section 7.6: Removed emergency Unblinding. * Section 7.7: Removed whole section with Valicert connection verification. | 30-MAY-2016 |
| 5.0 | * Document has been moved to new PMM template. * Updated name of the Valicert folder which will be used for testing and file name in test case steps. * Added links to screenshots that refer to Appendix B. * Added new step in section 7.3.11. * Updated screenshot in 7.3.17. * Removed sections ‘Scope’ and ‘System Overview’. | 02-NOV-2016 |
| 6.0 | * Section 5.0: checkbox “This section is not applicable to this execution” has been moved to Section 5.1. * Updated header in Appendix C – ‘Signature Log’ section. | 09-FEB-2017 |
| 7.0 | * Moved document to new template. * Update messages displayed in steps: 5.3.23 and 5.5.6. | 20-APR-2017 |
| 8.0 | * Document Information section: Document Owner – “Service Delivery Manager” changed to “Delivery Service Manager”. * Section 1 – HPSM has been replaced by ServiceNow for Change Requests from April 2018. * Added additional column for “Initial/Date” as it is in the last approved Test Case template v.5.0 * Overall grammar/spelling mistakes were corrected. * Information about screenshots has been updated and removed from “Actual Result”. * Removed entries from section 2, as they are not applicable to this test case. * Updated ”Reference Number” for each section, it applies to User Requirements Specification document. * Changed “Appendix A - Smoke Test Variables for KLD” to “Appendix A - Variables”. * JBOSS SERVER for PROD and QA in “Appendix A - Variables” have been updated with new names. * Changed “Appendix B - Test Evidence (screenshots)” to “Appendix B - Test Evidence”. * Checkbox with “As expected” label has been added to “Actual Result” column. | 19-JUL-2018 |
| 9.0 | Update:   * Section 2, added new definitions * Section 3, modified hyperlinks in Test Section (table) * Section 4.1, Variables * Section 4.2, removed Valicert details for Jboss Server, * Section 5.1-5.6 Updated Reference Number, Instruction and Expected Result sections * Appendix A – Variables; Appendix B – Test Evidence   Added:   * Section 3.1, Test Execution, Section 7, Post-Approval | Date of last signature |

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# Purpose

The purpose of this Smoke Test is to ensure and verify that the Kit Label Database (KLD) continues to operate as expected after implemented system changes. If executed in its entirety, key KLD system components will have been tested.

This Smoke Test is performed per the ServiceNow Change Request / Disaster recovery exercise / other reference recorded below:

**Reference #:** CHG0901575

# Definitions

The following additional terms and abbreviations used in this document:

| **Term** | **Definition** |
| --- | --- |
| Block | Set of Kit IDs/Subject IDs defined to contain a particular quantity of each Kit Type or Treatment Group, within which the IDs are randomized to those Kit Types/Treatment Groups. See also *Permuted Blocks*. |
| Blocked Kit List | A list of sequential numeric Kit IDs randomly assigned to Kit Types in blocks with user-defined quantities per block for a single study. A single study can contain multiple Kit Lists each with a potentially different block configuration. Kit Types are assigned to Kit IDs in a random manner within a block, using permuted blocks, such that the Kit Type cannot be ascertained from the Kit ID. |
| DR | Disaster Recovery environment |
| FS | Functional Specification document |
| Kit | Package containing a single treatment for a single study subject. |
| Kit ID | Kit identification string (series of alphanumeric characters) used for printing Kit labels. |
| Kit Type | Type of drug treatment contained in a Kit (package); the types of drug (or placebo) administered to subjects in a study. Kit Types are identified by Kit Code and Kit Description. Kit Description is the key component for matching with other systems, such as CLARA and IxRS.  Note: Kit Types are often in a 1-to-1 correspondence with Treatment Groups, but not always. |
| List | Set of Kit IDs or Subject IDs with their associated randomized Kit Types for a protocol number. |
| PROD | Production environment |
| QA | Test environment |
| Scrambled Kit List | A list of randomly generated Kit IDs and their associated Kit Code and Kit Description generated for a single study. Kit Codes and Kit Descriptions are assigned to Kit IDs in a random manner such that the Kit Type cannot be ascertained from the Kit ID. |
| ServiceNow | A cloud-based solution that offers usability based on simplicity combined with an intuitive and engaging user experience. ServiceNow enables consistent and scalable IT processes throughout Group Informatics, while at the same time transitioning us to leaner and more efficient process management and execution. |
| Subject Treatment List | A complete list of Subject IDs and their assigned Treatment Groups generated in user-defined blocks for a single study. A single study can be divided into multiple Sub-studies, each with their own sub-list. A Sub-study can contain multiple Cohorts (i.e. multiple lists of Subject IDs) each with a potentially different block configuration. Treatment Groups are assigned to Subject IDs in a random manner within each block, using permuted blocks, such that the Treatment Group cannot be ascertained from the Subject ID. The lists are distributed to study sites for administering treatment to subjects enrolled in the study. |
| Unblind | Determine a Subject’s Treatment Group by revealing the Kit Type associated with a particular Kit or Subject ID, in the case of the Scrambled Kit List, Blocked Kit List or Subject Treatment List, respectively. |
| Valicert | A Roche server that uses SFTP to transfer file to/from Roche/Genentech. |
| Verification | A KLD process by which CMO and IVRS Kit Types are matched against the database records. A Protocol is assigned a ‘Verified’ status when all of its mapped or unmapped Kit Types have been successfully matched. |

# Smoke Test approach

This Smoke Test aims to test the KLD modules. Successful execution of these tests will demonstrate that the core KLD functions are operating as expected.

It is recommended to create a small to medium size Kit Lists (<= 10000) for the purposes of this test. If used, content and size of large kit lists must be verified with the appropriate tools. Please check with system admin for further information on creating large Kit Lists.

The following table summarizes tests in *subsequent* sections:

|  |  |  |
| --- | --- | --- |
| System Module | Test Objective | Test Section |
| Database Availability | Test connectivity and availability of the backend database. | 5.1 |
| Global Navigation | KLD Application is accessible. | 5.2 |
| Scrambled Kit List | Test the functionality (including verification) of the Scrambled Kit List. | [5.3](#SKL) |
| Blocked Kit List | Test the functionality of the Blocked Kit List. | 5.4 |
| Subject Treatment List | Test the functionality of the Subject Treatment List. | [5.5](#STL) |
| Regulatory Unblinding | Test the accessibility of regulatory Unblinding pages. | 5.6 |

## Test Execution

All pre-requisites need to be met prior this test execution.

* All test cases should be performed in order.  
  Exception: Test Evidence (Screenshot 7) from Actual Result in step 5.3.17 can be provided later due to the Valicert email notification schedule in KLD. It is acceptable, as it does not impact the Actual Results in the further steps.
* It is recommended that tester maintain opened the same session for the entire execution.
* If needed, only applicable sections may be executed. If step was defined as not needed relevant section should be marked ‘Not Applicable’ (‘N/A’).
* All dates should appear in DD-MMM-YYYY format.
* The real results received during the test execution should be documented in ‘Actual Result’ section and assessed against the ‘Expected Results”. The tester should decide whether the step has Passed or Failed.
* The evidence of the test results must be captured with date and time visible on the screenshot.
* All executed Test Cases should be reviewed and approved by relevant person (refer to Kit Label Database (KLD) - Roles and Responsibilities, PL ID: [13895653](https://projectlibrary.bas.roche.com/projectlibrary/livelink.exe?func=doc.ViewDoc&nodeid=13895653&vernum=5) and Kit Label Database (KLD) - Allocation of People, PL ID: [22941641](https://projectlibrary.bas.roche.com/projectlibrary/livelink.exe/Open/22941641))
* If there is a date/time difference noted on the generated file, it is acceptable due to time zone differences set for Kit Label Database application server and the time zone in tester’s location.
* All defects associated with failed test cases should be recorded in Section ‘6. Assessment’ and appropriately assessed, mitigated, and closed in accordance to the Incident/Problem Management process.

# Test Setup

## Environment Variables

KLD environment details can be found in [Appendix A](#_Appendix_A_-).

Prior to starting the execution of this test case, please record KLD environment and its corresponding variables where the testing will be performed in the tables below:

|  |  |  |
| --- | --- | --- |
| **KLD Environment** | | |
| QA: | Production: | DR: |

Please enter the corresponding KLD variable from [Appendix A](#_Appendix_A_-), where appropriate and remaining values used for testing:

|  |  |
| --- | --- |
| **Variables used in the instructions** | **Test specific value** |
| URL / JBOSS SERVER URL | https://vcorpjbqa04.gene.com:8543/kld/ |
| DATABASE INSTANCE | kldu1 |
| JBOSS SERVER | vcorpjbqa04.gene.com |
| VALICERT VENDOR DIRECTORY | \\ridnsg801.nala.roche.com\valicert\_temp\SFTP\PGL\PDI\Randomisation\corpjbqa01\FORTEST\ToRoche |
| BROWSER\* | Google Chrome |
| TEST PROTOCOL\*\* | IT0002 |

**\*** Internet Explorer is the recommended browser for Kit Label Database.

\*\*Test Protocol is defined in section [Appendix A – Variables](#_Appendix_A_–).

## Prerequisites

The following are the prerequisites that must be in followed and verified prior to the execution of this Smoke Test:

* Tester must have Oracle SQL/PLUS installed, or an equivalent SQL client.
* Tester must have TNS NAMES entry setup for <DATABASE INSTANCE>.
* Tester must know password for KLD DATABASE SCHEMA.
* Tester must have permission to use Kit Label Database in the environment that is being tested through membership of the following groups:
  + kld\_skl\_admin,
  + kld\_bkl\_admin,
  + kld\_stl\_admin,
  + kld\_unblind.
* Tester must have access to KLD Valicert root directory: [\\ridnsg801.nala.roche.com\valicert\_temp\SFTP\PGL\PDI\Randomisation](file:///\\ridnsg801.nala.roche.com\valicert_temp\SFTP\PGL\PDI\Randomisation).

# Test Cases

## Database Availability

This section is not applicable to this execution. Initial & Date: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Case Number:** | 1 | **Reference Number:** | N/A |

|  |  |
| --- | --- |
| **Test Objective:** | Connectivity and availability of the Oracle backend database. |
| **Test Case Set-up / Prerequisite:** | See [Prerequisites](#_Prerequisites) section of this document. |

| **Step** | **Instruction** | **Expected Result** | **Actual Result** | **Pass**  **/ Fail** | **Initial**  **/ Date** |
| --- | --- | --- | --- | --- | --- |
|  | Initiate an SQL client session and Logon to KLD account using required password against <DATABASE INSTANCE>.  Take a **screenshot** and attach it to [Appendix B.](#_Appendix_B_–) | SQL client session to database successfully created. | SQL client session to database is successfully created.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | Exit SQL session. | SQL session closed. | SQL session is closed. | Pass | AM / 03-APR-2023 |

## Global Navigation

This section is not applicable to this execution. Initial & Date: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Case Number:** | 2 | **Reference Number:** | FS 5.2 |

|  |  |
| --- | --- |
| **Test Objective:** | KLD application accessibility. |
| **Test Case Set-up / Prerequisite:** | See [Prerequisites](#_Prerequisites) section of this document. |

| **Step** | **Instruction** | **Expected Result** | **Actual Result** | **Pass**  **/ Fail** | **Initial**  **/ Date** |
| --- | --- | --- | --- | --- | --- |
|  | Open browser and set URL to <URL> / <JBOSS SERVER URL>. | Browser opened successfully and Kit Label Database login window displayed username and password fields. | Browser openes successfully and Kit Label Database login window displays username and password fields. | Pass | AM / 03-APR-2023 |
|  | Enter username, password and click on *Login* button.  Take a **screenshot** and attach it to [Appendix B.](#_Appendix_B_–) | The Main Menu displayed successfully. | The Main Menu displays successfully.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |

## Scrambled Kit List

This section is not applicable to this execution. Initial & Date: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Case Number:** | 3 | **Reference Number:** | FS 6 |

|  |  |
| --- | --- |
| **Test Objective:** | 1. User can view active Scrambled Kit Lists. 2. User can view details for a specific Scrambled Kit List. 3. User can open Scrambled Kit Lists for the protocol. 4. User can access and verify Scrambled Kit List files. 5. User can create Scrambled Kit Lists. 6. User can verify Scrambled Kit Lists. 7. Administering KLD protocols. |
| **Test Case Set-up / Prerequisite:** | Create a file for cKLF Verification according to the VKLF format, so that it does **not** contain any correct verification data.  You may use a notepad for that purpose. Protocol number name should be set to the one used in the test script.   |  |  | | --- | --- | | **Header row:** | Protocol Number, Sequence Number, Kit ID, Kit Code, Kit Description | | **Content:** | SMKTST<DDMMMYY>,1,ABC12345,A,Smktst |   **Note:** Here is an example of a file content that can be used for testing.    File name should comply with the right naming convention:  IVRS\_FORTEST\_SMKTST<DDMMMYY>\_<YYYYMMDD>.CSV  e.g. IVRS\_FORTEST\_SMKTST06JUL15\_20160223.CSV  For remaining prerequisites, please see [Prerequisites](#_Prerequisites) section of this document. |

| **Step** | **Instruction** | **Expected Results** | **Actual Result** | **Pass**  **/ Fail** | **Initial**  **/ Date** |
| --- | --- | --- | --- | --- | --- |
|  | Click on *Scrambled Kit Lists* link. | Active Scrambled Kit Lists window opened to display a list of the active Scrambled Kit Lists. | Active Scrambled Kit Lists window opens to display a list of the active Scrambled Kit Lists. | Pass | AM / 03-APR-2023 |
|  | Click on a selected Protocol Number. | The Edit Scrambled Kit List window opened to display the details for the selected Protocol Number. | The Edit Scrambled Kit List window opens to display the details for the selected Protocol Number. | Pass | AM / 03-APR-2023 |
|  | Click on the *Back* button to return to the Active Scrambled Kit List window. | User returned to the Active Scrambled Kit List window. | User returns to the Active Scrambled Kit List window. | Pass | AM / 03-APR-2023 |
|  | Select a protocol using radio button.  Enter selected Protocol Number:  BN29552  Click on the *Production Kit List File (PKLF)* button to download and Save the Production Scrambled Kit List.  Enter PKLF file number:  BN29552\_RCHE\_KLD1\_PROD\_V1.0\_RESTRICT\_20230403032438.csv  Verify the PKLF file label is according to the following format:  <PROTOCOL\_NUMBER>\_KLD\_PROD\_KLD\_RESTRICTED\_KLD\_<YYYYMMDDHHMMSS> | The PKLF file downloaded and saved successfully.  File label format was correct. | The PKLF file downloads and saves successfully.  File label format is correct. | Pass | AM / 03-APR-2023 |
|  | Open the PKLF downloaded for the selected protocol in this test case. | File opened as expected. | File opens as expected. | Pass | AM / 03-APR-2023 |
|  | Verify that the file contains corresponding protocol data:   * Protocol Number * Kit Code * Kit Description * Kit ID   Take a **screenshot** and attach it to [Appendix B.](#_Appendix_B_–) | File contained the correct data format. | File contains the correct data format.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | While on Active Scrambled Kit Lists window, using radio button select existing protocol.  Click the *Scrambled Kit List File (SKLF)* button. | Kit List Download for CLARA page opened. | Kit List Download for CLARA page opens. | Pass | AM / 03-APR-2023 |
|  | From the Kit List Download for CLARA click the *Download Entire List* button to download and save the Entire List file. | The Entire List file downloaded and saved successfully. | The Entire List file downloads and saves successfully. | Pass | AM / 03-APR-2023 |
|  | Open the Entire List file downloaded for the selected protocol in this test case. | File opened as expected. | File opens as expected. | Pass | AM / 03-APR-2023 |
|  | Verify that file contains corresponding data for protocol selected:   * Protocol Number * Export Date * Kit ID * Sequence Number * Block * Kit Code * Kit Description   Take a **screenshots** of first and last page and attach it to [Appendix B](#_Appendix_B_–). | File contained the correct data format. | File contains the correct data format.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | Click *Back* button. | User returned to the Active Scrambled Kit List window. | User returns to the Active Scrambled Kit List window. | Pass | AM / 03-APR-2023 |
|  | Click on a Protocol Number that you have downloaded files. | The Edit Scrambled Kit List window opened to display the details for the Protocol Number clicked on. | The Edit Scrambled Kit List window opens to display the details for the Protocol Number clicked on. | Pass | AM / 03-APR-2023 |
|  | Click *Back* button. | User returned to the Active Scrambled Kit List window. | User returns to the Active Scrambled Kit List window. | Pass | AM / 03-APR-2023 |
|  | Click the *Create Kit List* button. | A Create Scrambled Kit List window opened. | A Create Scrambled Kit List window is opened. | Pass | AM / 03-APR-2023 |
|  | Fill the following fields with values:  Study Requester User ID: <TESTER ID>  Study Requester User ID: matacza  Study Biostatistician: <TESTER>  Study Biostatistician: matacza  Protocol Number: SMKTST<DDMMMYY>  Protocol Number: SMKTST03APR23  Protocol Title: SMKTST<DDMMMYY>  Protocol Title: SMKTST03APR23  Kit ID Format: ABC12345  Kit Code1 = A  Kit Code2 = B  Kit Description1 = drug A  Kit Description2 = drug B  Number of Kit IDs = 5  Number of Kit IDs = 5  Click *Save* and then again *Save* button on Kit List Confirmation.  Take a **screenshot** and attach it [to Appendix B](#_Appendix_B_–). | Scrambled Kit List created successfully. | Scrambled Kit List is created successfully.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | Upload the prerequisite test file to <VALICERT\_VENDOR DIRECTORY>.  Print a name of the file used for testing:  IVRS\_FORTEST\_SMKTST03APR23\_20230403.CSV | File successfully uploaded. | File is successfully uploaded. | Pass | AM / 03-APR-2023 |
|  | Wait up to 20 minutes for the email notification with the results of verification.  Example of email notification:    Take a **screenshot** and attach it to [Appendix B](#_Appendix_B_–). | The email notification received successfully.  Title of the email contained following phrase:  “IVRS Kit List Discrepancies”  Copy of the email attached. | The email notification is received successfully.  Title of the email contains the following phrase:  “IVRS Kit List Discrepancies”.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | Click on *Admin* button. | Admin menu window opened. | Admin menu window opened. | Pass | AM / 03-APR-2023 |
|  | Click on *Deactivate* *Kit List*. | Deactivate Kit List window opened. | Deactivate Kit List window opens. | Pass | AM / 03-APR-2023 |
|  | Find SMKTST<DDMMMYY> and click on Deactivate button on the right.  Then on the Deactivate Confirmation screen click on *Deactivate* button. | A message is shown:  “Study SMKTST<DDMMMYY> was successfully deactivated” | A message shows:  “Study SMKTST03APR23 was successfully deactivated” | Pass | AM / 03-APR-2023 |
|  | Click on *Admin* button. | Admin menu window opened. | Admin menu window opens. | Pass | AM / 03-APR-2023 |
|  | Click on *View Deactivated Kit Lists*. | Deactivated Kit List window opened. | Deactivated Kit List window opens. | Pass | AM / 03-APR-2023 |
|  | Find SMKTST<DDMMMYY> and click on Delete button on the right.  Then on the Delete Confirmation screen click on *Delete* button. | A message is shown:  “Study SMKTST<DDMMMYY> was successfully Deleted” | A message shows:  “Study SMKTST03APR23 was successfully Deleted”. | Pass | AM / 03-APR-2023 |
|  | Click on the *Main* *Menu* button to return to the Main Menu of the Kit Label Database. | User returned to the Main Page. | User returns to the Main Page. | Pass | AM / 03-APR-2023 |

## Blocked Kit List

This section is not applicable to this execution. Initial & Date: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Case Number:** | 4 | **Reference Number:** | FS 7.1, 7.3.1, 7.3.7 |

|  |  |
| --- | --- |
| **Test Objective:** | User can view Blocked Kit Lists. |
| **Test Case Set-up / Prerequisite:** | See [Prerequisites](#_Prerequisites) section of this document. |

| **Step** | **Instruction** | **Expected Result** | **Actual Result** | **Pass**  **/ Fail** | **Initial**  **/ Date** |
| --- | --- | --- | --- | --- | --- |
|  | Click on the *Blocked Kit Lists* link.  Take a **screenshot** and attach it to [Appendix B](#_Appendix_B_–). | Blocked Kit Lists by Protocol Window opened. | Blocked Kit Lists by Protocol Window opens.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | Click the *Create List for New Protocol* button. | A Create Blocked Kit List window opened. | A Create Blocked Kit List window opens. | Pass | AM / 03-APR-2023 |
|  | Click on the *Back* button. | Blocked Kit Lists by Protocol by Window opened. | Blocked Kit Lists by Protocol by Window opens. | Pass | AM / 03-APR-2023 |
|  | Click on the *Main Menu* button to return to the Main Menu of the Kit Label Database. | User returned to the Main Page. | User returns to the Main Page. | Pass | AM / 03-APR-2023 |

## 

## Subject Treatment List

This section is not applicable to this execution. Initial & Date: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Case Number:** | 5 | **Reference Number:** | FS 8.7 |

|  |  |
| --- | --- |
| **Test Objective:** | 1. User can view Subject Treatment List. 2. User can view details for a specific Subject Treatment List. 3. User can open Subject Treatment Lists for the protocol. 4. User can access and verify Subject Treatment List files. |
| **Test Case Set-up / Prerequisite:** | See [Prerequisites](#_Prerequisites) section of this document. |

| **Step** | **Instruction** | **Expected Result** | **Actual Result** | **Pass**  **/ Fail** | **Initial**  **/ Date** |
| --- | --- | --- | --- | --- | --- |
|  | Click on the *Subject Treatment Lists* link. | Subject Treatment Lists by Protocol screen opened. | Subject Treatment Lists by Protocol screen opens. | Pass | AM / 03-APR-2023 |
|  | Using radio button select the approved STL <TEST PROTOCOL> by clicking on the radio button next to it.  Click *Download/Transmit* button. | Download Subject Treatment List screen is opened. | Download Subject Treatment List screen opens. | Pass | AM / 03-APR-2023 |
|  | Click *Download As CSV* button to download and save the Subject Treatment List. | The Subject Treatment List file downloaded successfully. | The Subject Treatment List file is downloaded successfully. | Pass | AM / 03-APR-2023 |
|  | Open the downloaded file and verify that it contains following fields for each Sub Study from the step 3:   * Protocol Number * Abbrev. Protocol Title * Sub-Study Name * Approved Date * Site Name * Cohort Name * Stratification * Block * Subject ID * Treat. Code * Treatment Description   **Note:** the files may contain 1 or more Replacement Sets.  Take a **screenshot** and attach it to [Appendix B](#_Appendix_B_–). | File contained the correct data. | File contains the correct data.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | Navigate to Subject Treatment Lists By Protocol. Using radio button select the approved STL <TEST PROTOCOL> by clicking on the radio button next to it.  Click *Download/Transmit* button.  **Note:** Tester must be a member of recipient group for this STL test protocol. | Downloaded Subject Treatment List for selected Protocol page displayed. | Download Subject Treatment List for selected Protocol page is shown. | Pass | AM / 03-APR-2023 |
|  | Click on *Transmit* button. | Message:  “Subject Treatment List has been transmitted to recipients as Zip file '<TEST PROTOCOL\_<YYYYMMDD>.zip'” displayed. | Message “Subject Treatment List has been transmitted to recipients as Zip file “<TEST PROTOCOL\_<YYYYMMDD>.zip“ is displayed. | Fail | AM / 03-APR-2023 |
|  | Expect an email notification sent to STL test protocol’s recipient inbox.  Email should have a password protected ZIP file attached.  Take a **screenshot** and attach it to [Appendix B](#_Appendix_B_–). | Email notification with ZIP attachment delivered to STL test protocol’s recipient inbox. | Email notification with ZIP attachment is delivered to STL test protocol’s recipient inbox.  Refer to Appendix B for Test Evidence. | Pass | AM / 03-APR-2023 |
|  | Click on the *Main Menu* button to return to the Main Menu. | User returned to the Main Page. | User returns to the Main Page. | Pass | AM / 03-APR-2023 |

## Unblind Subject

This section is not applicable to this execution. Initial & Date: \_\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **Test Case Number:** | 6 | **Reference Number:** | FS 9 |

|  |  |
| --- | --- |
| **Test Objective:** | 1. User can get access to Unblind Subject. 2. User can see studies on Unblind Subject list. |
| **Test Case Set-up / Prerequisite:** | See Prerequisites section of this document. |

| **Step** | **Instruction** | **Expected Result** | **Actual Result** | **Pass**  **/ Fail** | **Initial**  **/ Date** |
| --- | --- | --- | --- | --- | --- |
|  | Click on the *Unblind Subject* link.  Check box and click *I agree* button. | Unblind Subject confirmation window displayed. | Unblind Subject confirmation window is shown. | Pass | AM / 03-APR-2023 |
|  | Click on one of the protocols from the list. | Protocol selected successfully. | Protocol is selected successfully. | Pass | AM / 03-APR-2023 |
|  | Click on the *Main Menu* button to return to the Main Menu of the Kit Label Database. | User returned to the Main Page. | User returns to the Main Page. | Pass | AM / 03-APR-2023 |
|  | Click *Logout* to log off. | Logout was successful. | Logout is successful. | Pass | AM / 03-APR-2023 |

# Assessment

| **Step** | **Assessment** |
| --- | --- |
| From step 5.3.17 | Next steps were executed while waiting for SKL verfication email. It does not impact the actual results in the further steps. |
| 5.3.6 | Discrepancy with column names – column names changed within KLD 4.5 release. This is a test case issue, actual results are corrected. Smoke Test template will be updated. |
| 5.3.10 | Discrepancy with column names – column names changed within KLD 4.5 release. This is a test case issue, actual results are corrected. Smoke Test template will be updated. |
| 5.5.6 | Message “Subject Treatment List has been transmitted to recipients as Zip file “<TEST PROTOCOL\_<YYYYMMDD>.zip“ is not displayed, but protocol has been transmitted properly, email from 5.5.7 has been received. Despite the fact that test step was failed, test objective is fulfilled. |

# Post-Approval

|  |  |  |
| --- | --- | --- |
| **Execution** | **Name** | **Date** |
| **Executed by** | Aleksandra Matacz | 03-APR-2023 |
| **Reviewed by** | Sławomir Gahl | Electronically signed |
| **Approved by** | Monika Kondyjowska | Electronically signed |

# 

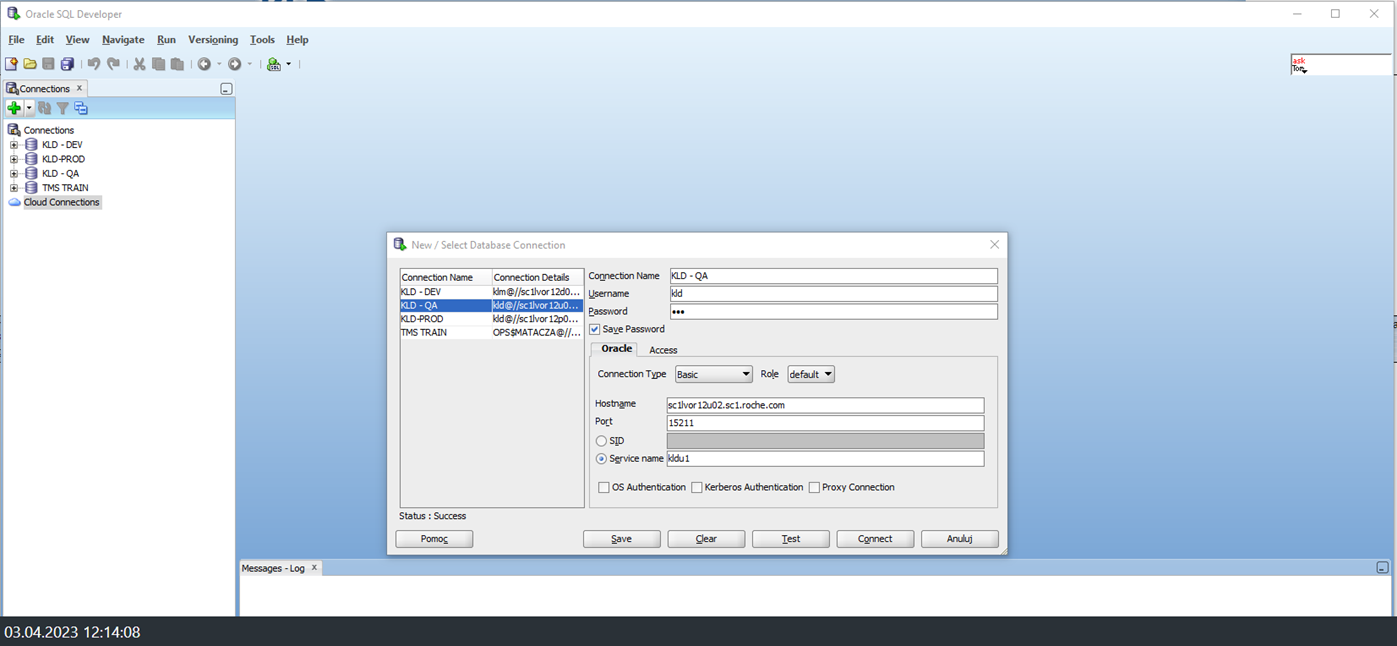
# Appendix A – Variables

The following table gives the values for the variables used during testing:

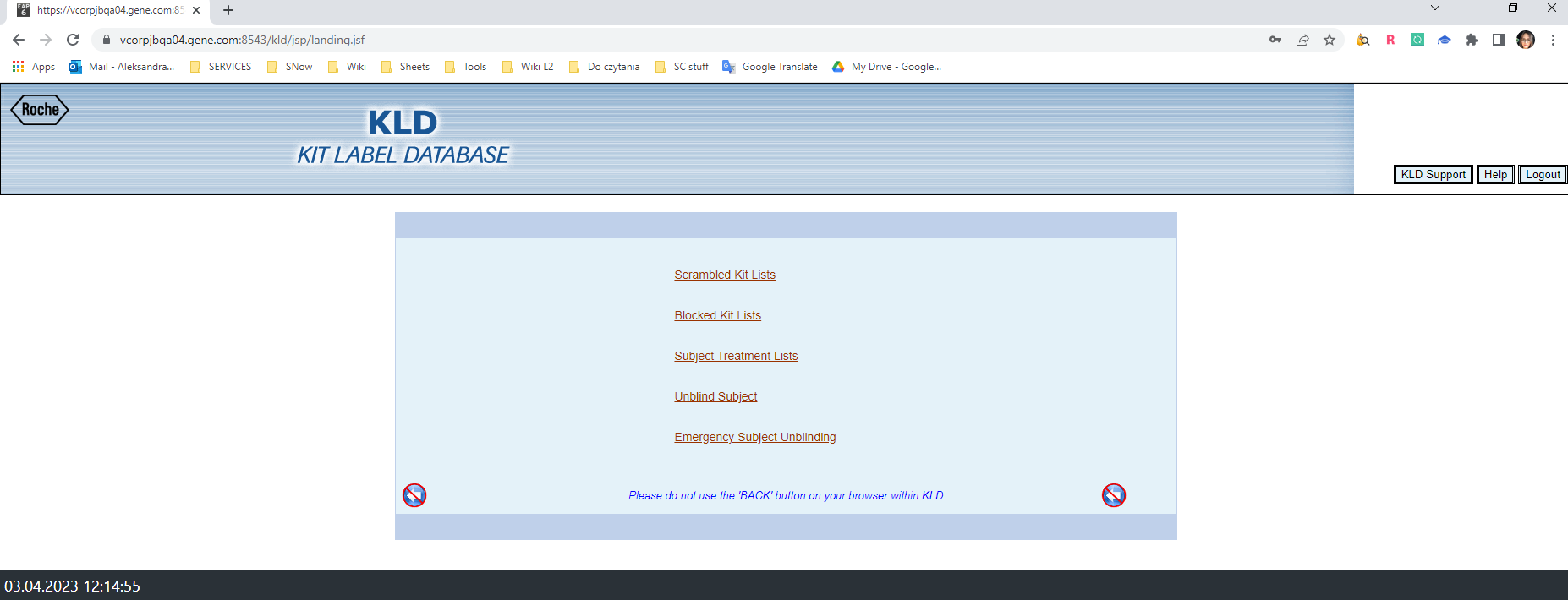
| **Variables used in test case** | **Value for specific environment** | | |
| --- | --- | --- | --- |
| **PROD** | **QA** | **DR** |
| <URL> | <http://pdapps.gene.com/kld> | <http://pdappsqa.gene.com/kld> | <http://vcorpjbprd06.gene.com:8180/kld> |
| <JBOSS SERVER URL> | <http://10.37.17.42:8180/kld>  (vcorpjbprd04.gene.com) | <https://vcorpjbqa04.gene.com:8543/kld/> (vcorpjbqa04.gene.com) | N/A |
| <http://10.37.17.43:8180/kld> (vcorpjbprd05.gene.com) | <https://vcorpjbqa05.gene.com:8543/kld/> (vcorpjbqa05.gene.com) |
| <JBOSS SERVER> | vcorpjbprd04.gene.com / vcorpjbprd05.gene.com | vcorpjbqa04.gene.com / vcorpjbqa05.gene.com | vcorpjbprd06.gene.com |
| <DATABASE INSTANCE> | kldp1 | kldu1 | klds1 |
| <TEST PROTOCOL> | IT0002 | | |
| <VALICERT VENDOR DIRECTORY> | \\ridnsg801.nala.roche.com\Valicert\_temp\SFTP\PGL\PDI\Randomisation\FORTEST\ToRoche | \\ridnsg801.nala.roche.com\Valicert\_temp\SFTP\PGL\PDI\Randomisation\corpjbqa01\FORTEST\ToRoche | \\ridnsg801.nala.roche.com\Valicert\_temp\SFTP\PGL\PDI\Randomisation\FORTEST\ToRoche |

# Appendix B – Test Evidence

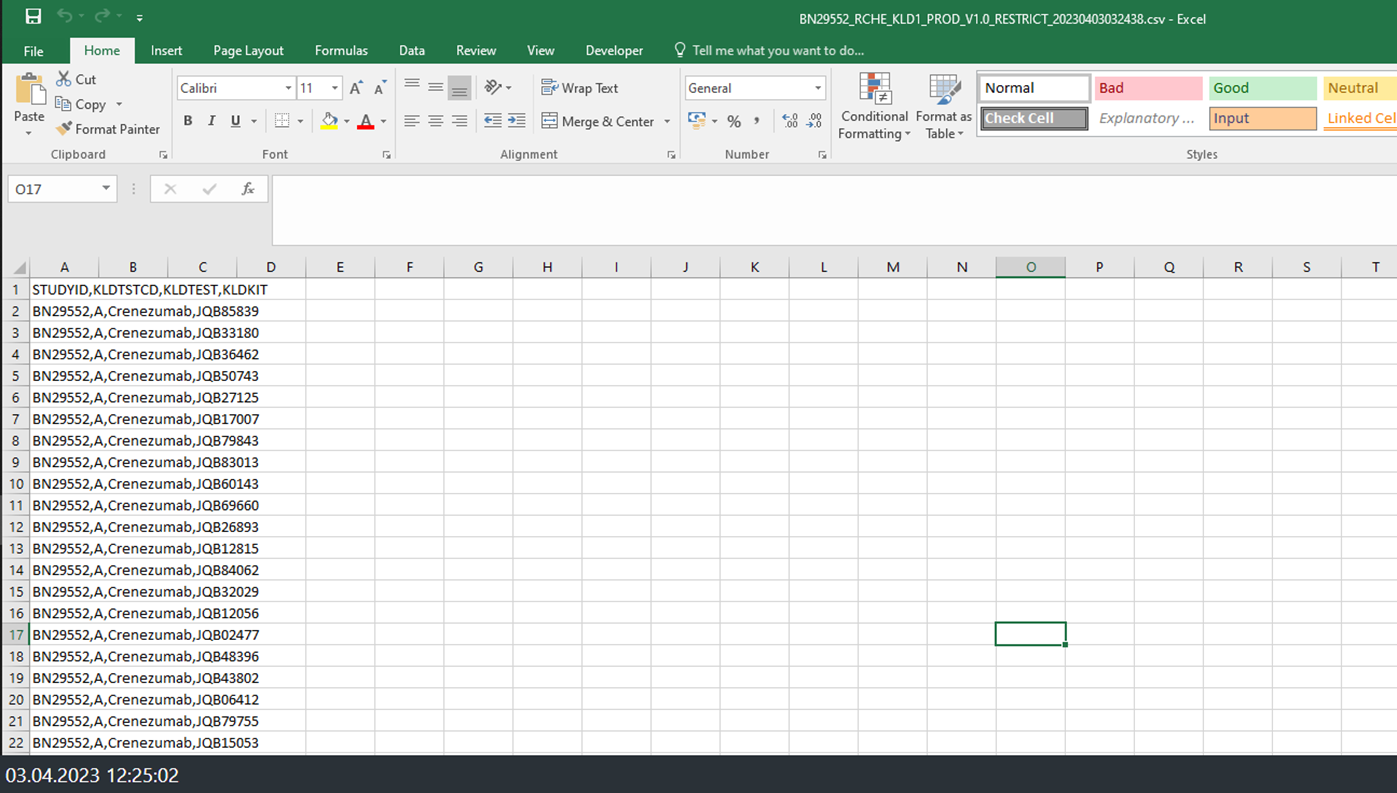
Add screenshots as required in this test case document execution from section 5.

Screenshot step 5.1.1: 

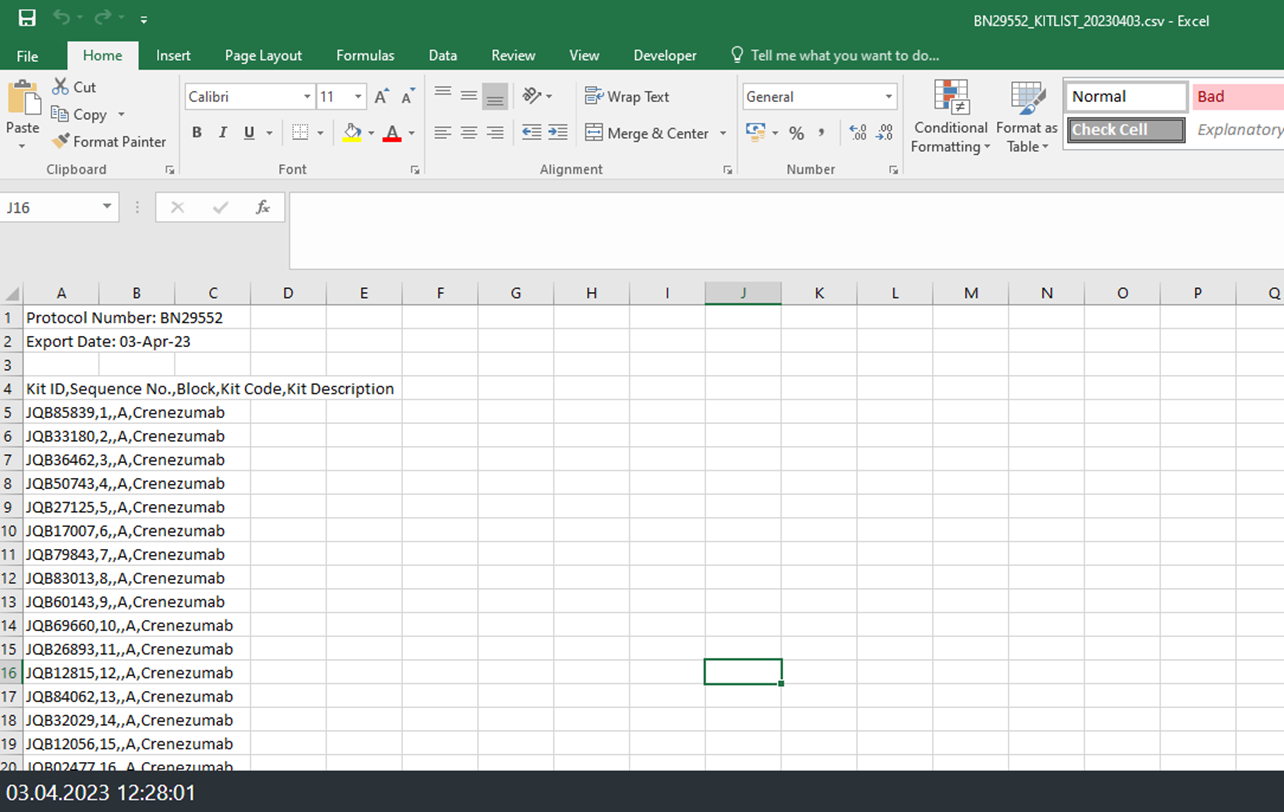
Screenshot step 5.2.2:



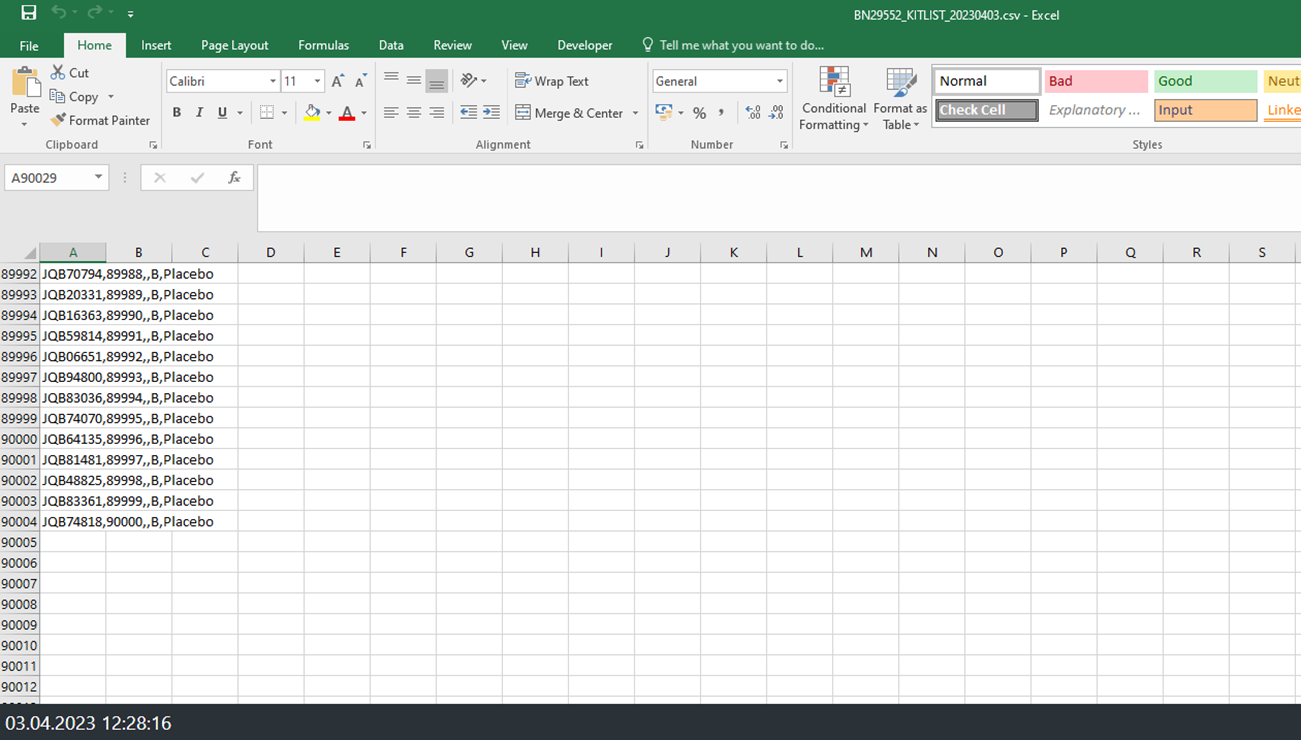
Screenshot step 5.3.6:



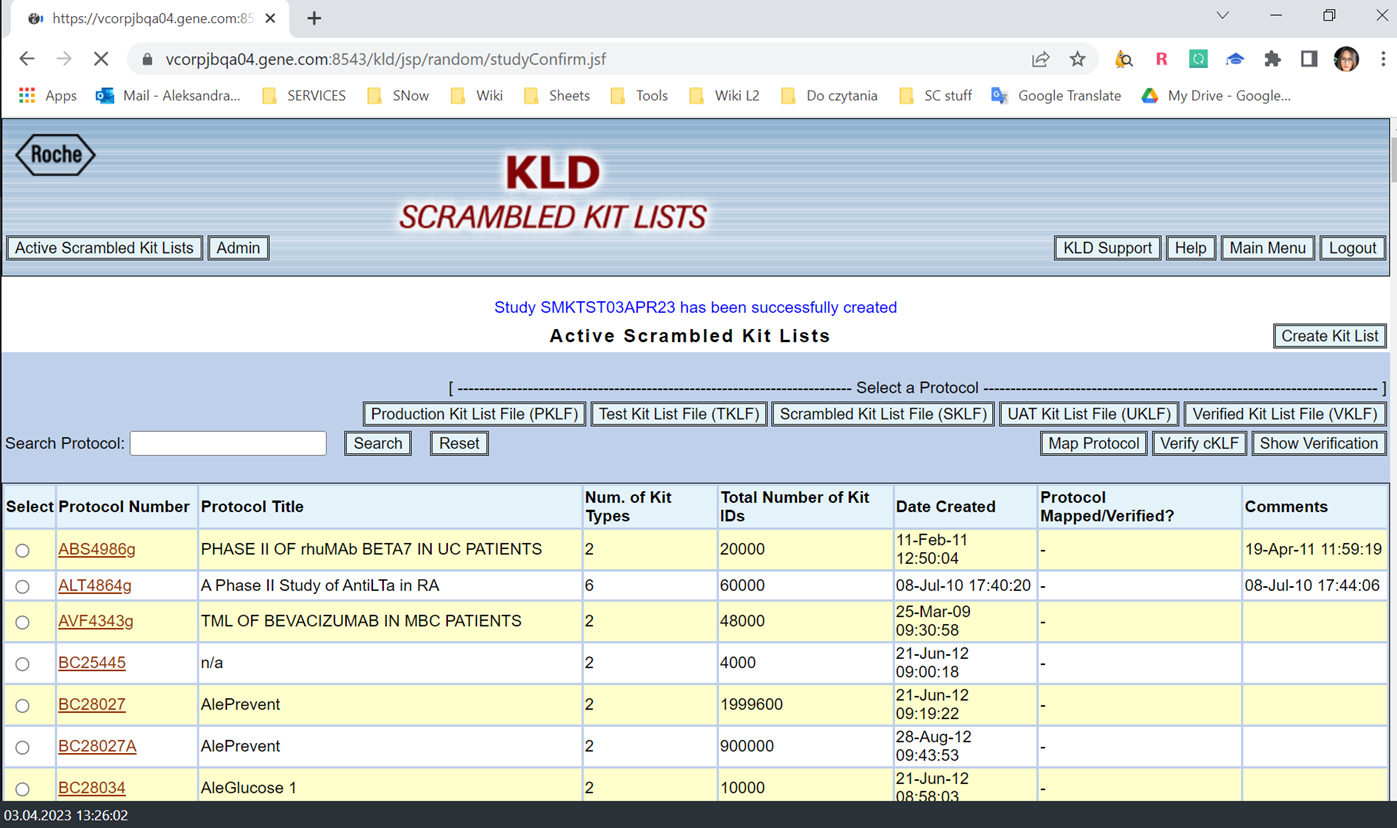
Screenshot step 5.3.10:



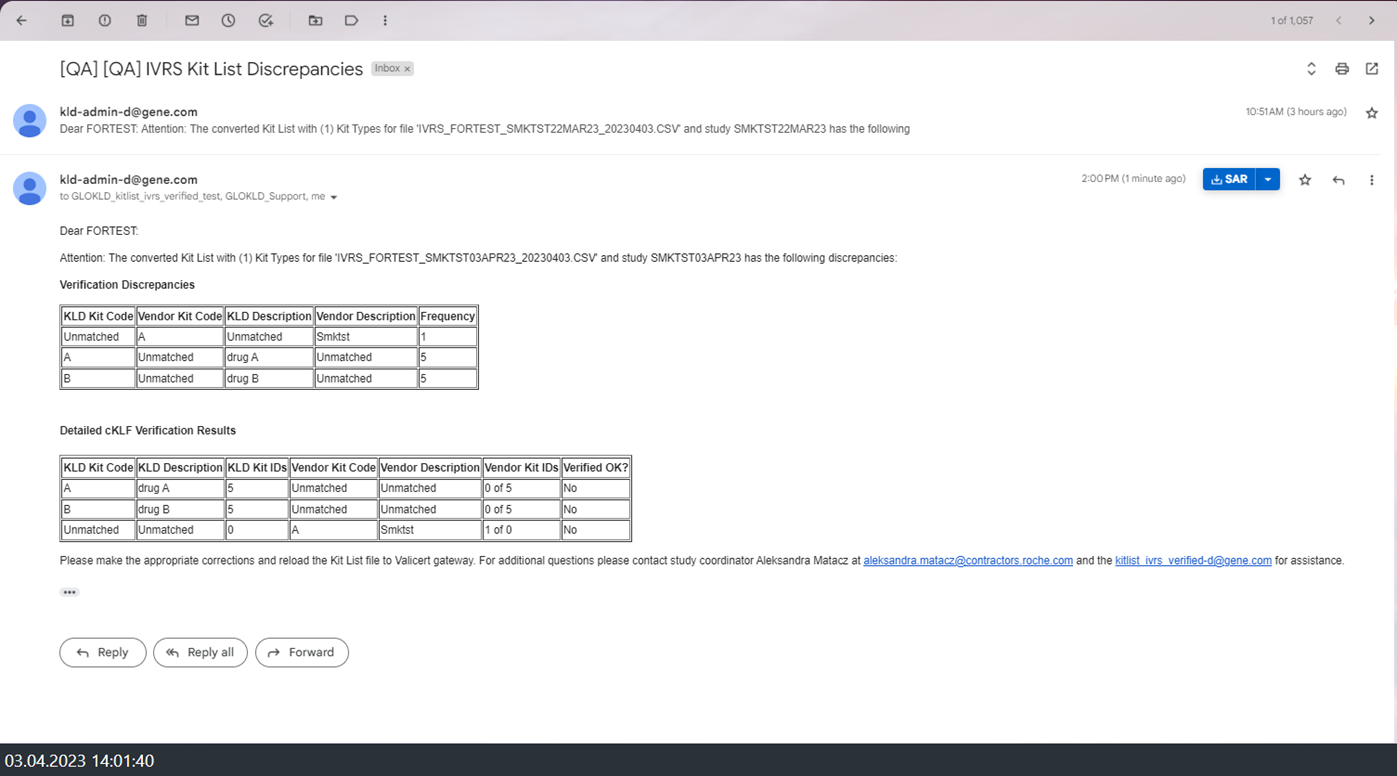
Screenshot step 5.3.10:



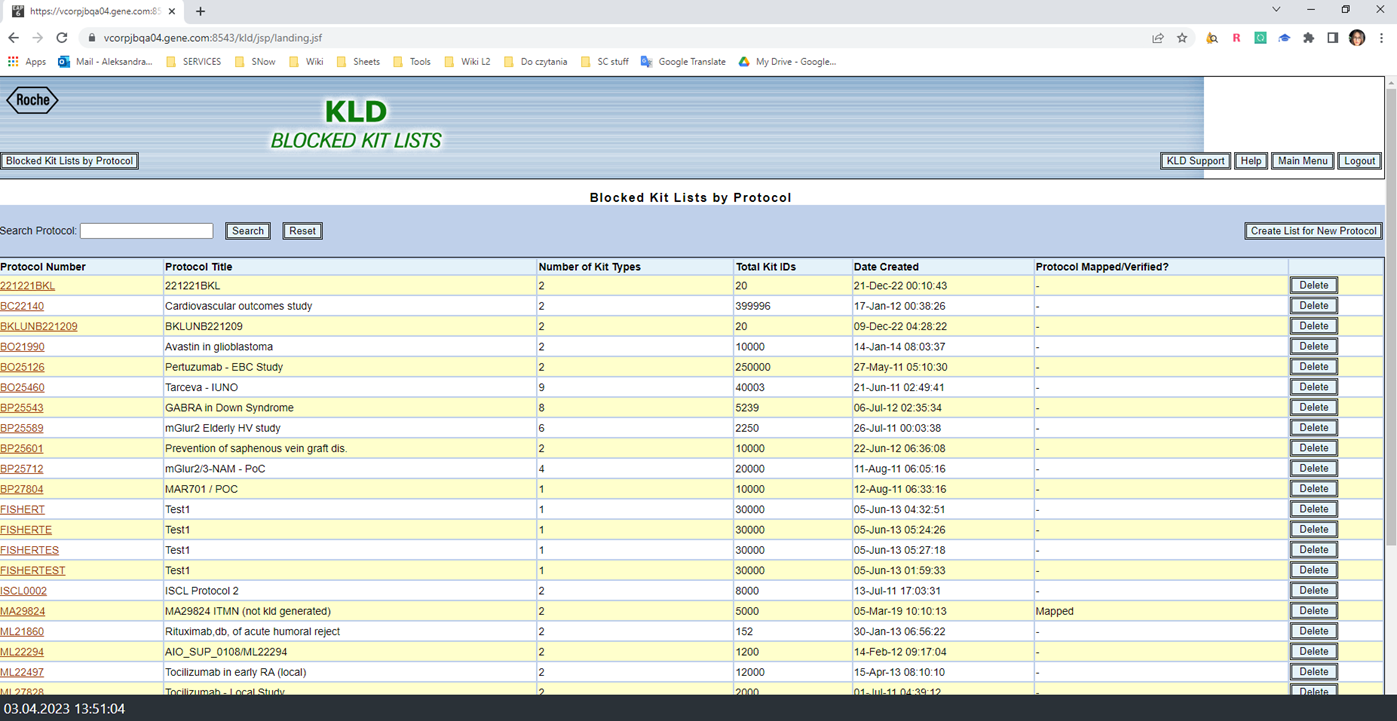
Screenshot step 5.3.15:

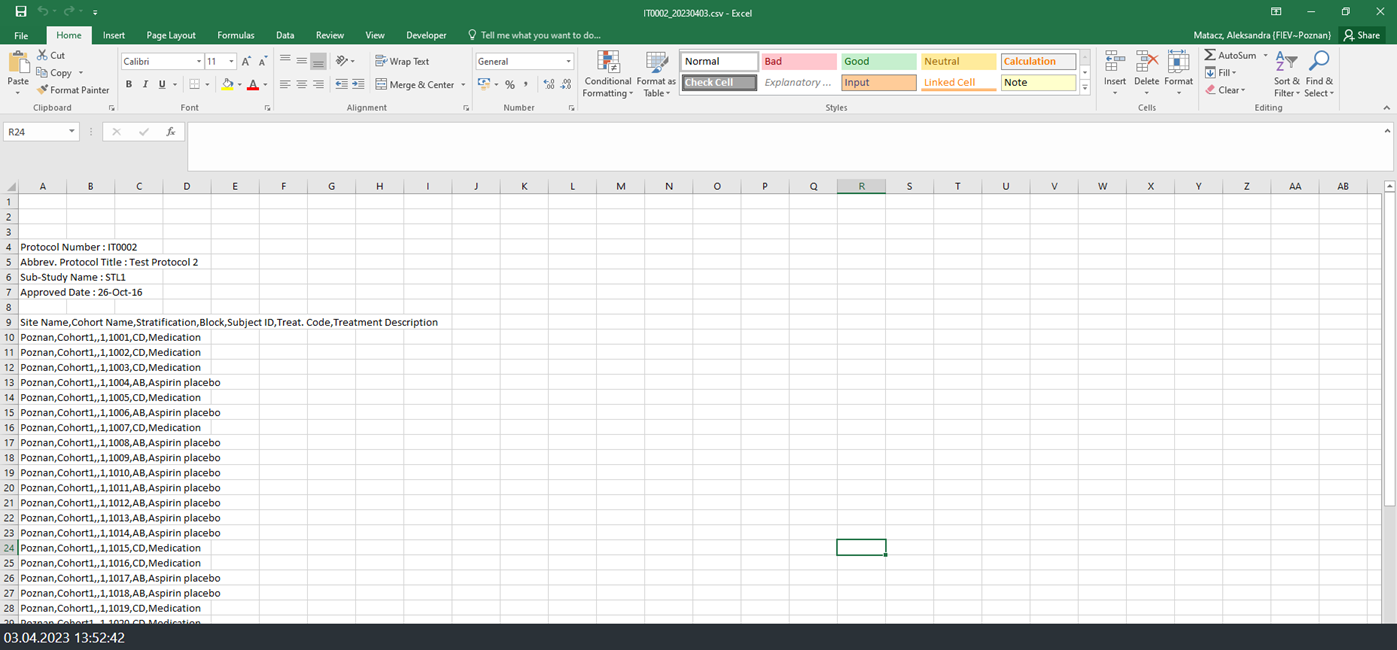


Screenshot step 5.3.17:

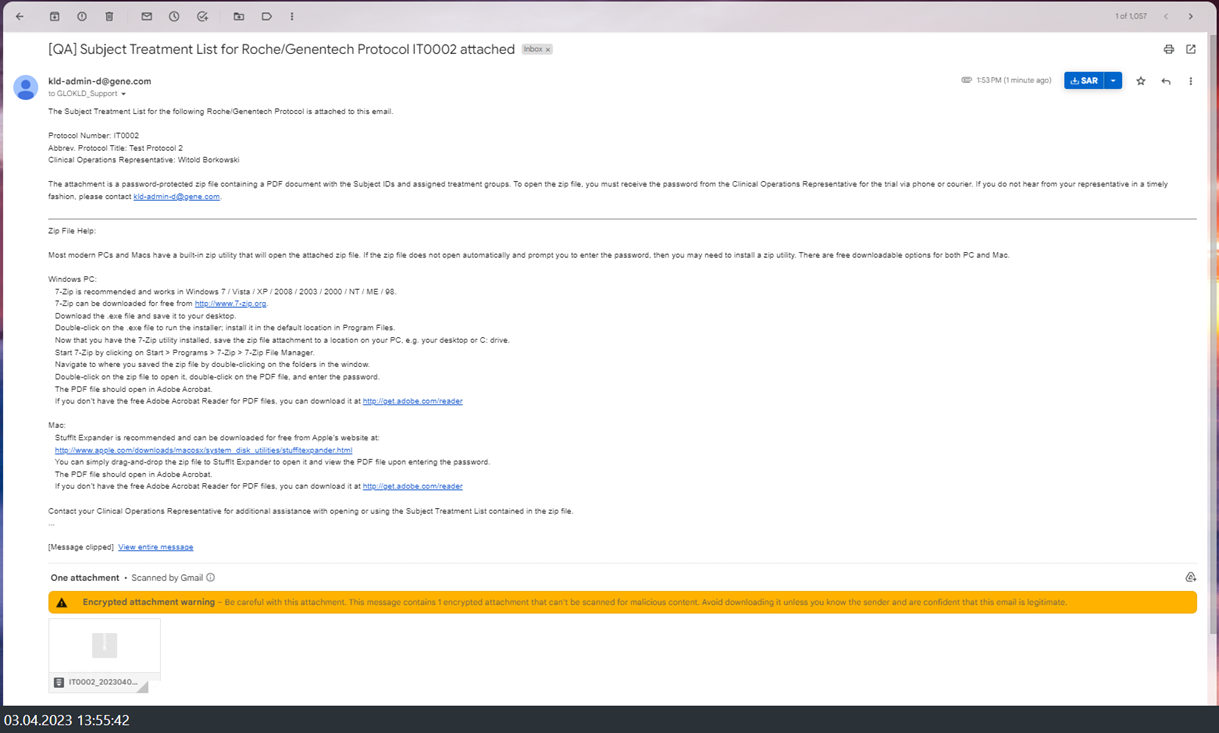


Screenshot step 5.4.1:



Screenshot step 5.5.4: 

Screenshot step 5.5.7:



# Appendix C – Signature Log

All individuals who have executed any part of this document or made entries within the scope of this document must make an entry in the table below for identification purposes.

| **Name of individual** (Print or Type) | **Signature** | **Initial** | **Department** |
| --- | --- | --- | --- |
| Aleksandra Matacz | Electronically signed | AM | FIEV |