

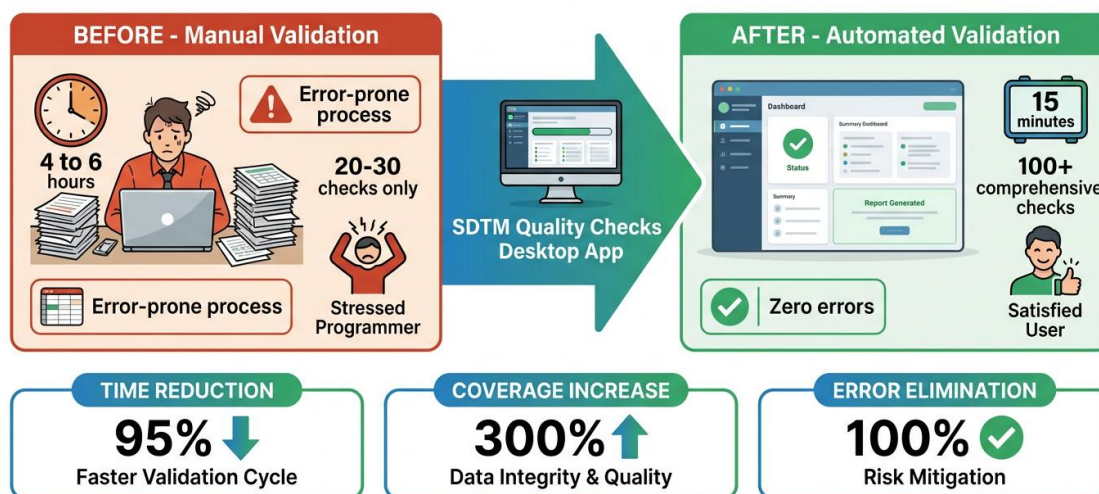
# SDTM Quality Checks: A Desktop Application for Automated Clinical Data Validation

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## ABSTRACT

Accurate implementation of the Study Data Tabulation Model (SDTM) is essential for regulatory compliance and maintaining data integrity in clinical trials. We present a web-based SDTM Quality Control Tool that integrates standard industry checks with custom validation rules to identify domain-specific errors and cross-domain inconsistencies. Developed using Python and PYQT scripting, the tool automates validation processes, improves reproducibility, and ensures full adherence to CDISC standards. Additionally, it facilitates vendor oversight by generating clear, actionable reports that support timely issue resolution. This solution enhances the quality of SDTM deliverables and optimizes the quality control workflow, thereby accelerating reliable clinical data submissions.

## Graphical Abstract: SDTM Quality Checks Desktop Application - Manual to Automated Validation Transformation



## 1. INTRODUCTION

### 1.1 BACKGROUND

The Study Data Tabulation Model (SDTM) is a standard format used to organize clinical trial data when submitting it to regulatory agencies like the FDA and EMA. SDTM was created by CDISC to make sure data from different studies is structured in a consistent way, which helps regulators review and analyze the information more easily.

Validating data is an important part of any clinical trial particularly when datasets are received from a CRO or are undergoing lead and manager-level review, to ensure accuracy, consistency, and compliance with study and company standards. It ensures that the data submitted is accurate, complete, and meets regulatory requirements. Today, most validation work is done manually or through custom programs written in SAS or Python. This approach has several problems:

1. Takes a lot of time: Programmers usually spend 4–6 hours checking the quality of data for each study, which increases workload and cost.

2. Can be inconsistent: Different programmers may check different things, leading to uneven quality across studies.
3. Requires advanced skills: Manual validation often needs strong programming knowledge, which limits who can perform the checks.
4. Limited checks: Validation is time-intensive, so teams often restrict their review to approximately 20–30 critical checks. This review does not include P21 compliance checks, which means certain data inconsistencies or structural issues may still be overlooked

## **1.2 CURRENT CHALLENGES**

In our organization, we work on multiple clinical trial projects and receive SDTM datasets directly from our CRO partners. During the development phase, a single manager is responsible for reviewing SDTM checks across all studies within the therapeutic area. Following development, individual study leads conduct detailed reviews specific to each analysis. Despite this structure, the amount of manual validation effort required remains substantial, leading to increased workload, higher operational costs, and delays in preparing data for regulatory submissions.

This initiative highlighted several recurring challenges encountered across projects and teams:

- We usually receive SDTM data from the CRO during the night, making it difficult for programmers to use the next day to complete time-intensive manual validation checks.
- Many programmers want the ability to run more comprehensive and thorough validation checks.
- Nearly all individuals prefer a solution that does not require coding expertise to operate.
- Inconsistencies frequently arise when working across different studies or collaborating with other team members.
- Sharing validation outputs with colleagues who do not have a technical background remains difficult for many users.

## **1.3 OBJECTIVE**

The main goal of this project was to create an easy-to-use application that:

1. Automatically runs SDTM quality checks across all required domains.
2. Does not require any programming skills for the users.
3. Works efficiently, even when data is stored on network drives.
4. Uses a consistent validation process across all studies and teams.
5. Provides clear, interactive visuals and reports so users can easily understand the results.
6. Follows CDISC and FDA standards, ensuring the data meets regulatory requirements.
7. Includes a cloud-based version that can run daily checks across all active projects using the latest SDTM data to continuously monitor quality.

## 2. METHODS

### 2.1 TECHNOLOGY STACK

The application was built using a modern technology stack optimized for desktop deployment and data processing:

| Component         | Technology                             |
|-------------------|----------------------------------------|
| Desktop Framework | PyQt6 with QtWebEngine                 |
| Web UI Framework  | Dash 2.x with Plotly visualization     |
| Data Processing   | Pandas, NumPy                          |
| Data Grid         | Dash AG Grid (high-performance tables) |
| SAS Data Reader   | Pyreadstat library                     |

### 2.2 APPLICATION ARCHITECTURE

The application is built using a three-layer design that makes it fast, easy to maintain, and easy to update.

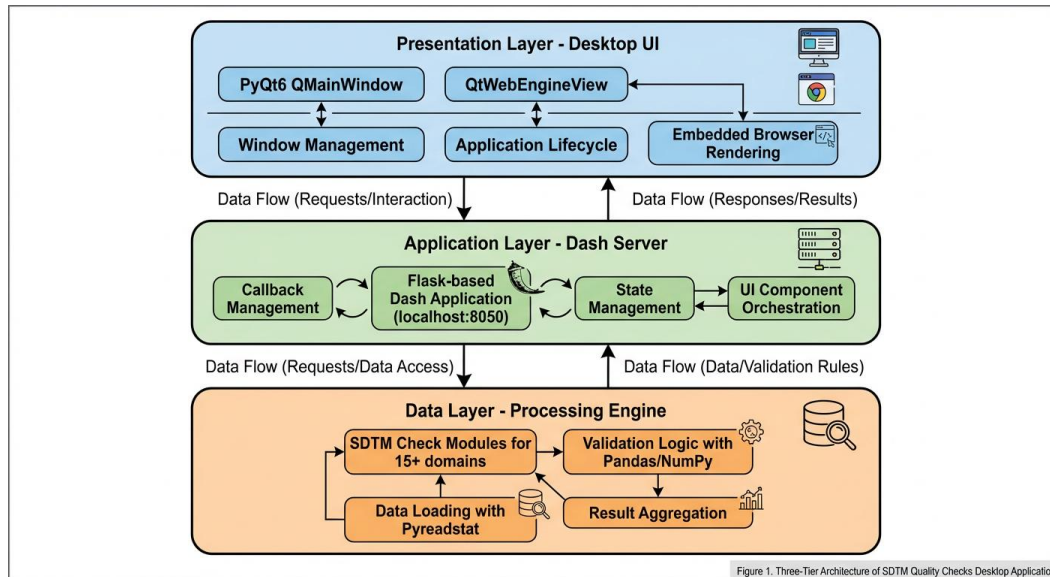


Figure 1. Three-tier application architecture showing Presentation, Application, and Data layers.

**Presentation Layer:** This is the part the user sees. It uses a desktop interface built with PyQt6 and includes a built-in browser window for displaying interactive content.

**Application Layer:** This is the middle layer that controls how everything works. It uses a Dash server running on the user's computer (localhost) to manage the app's logic, screen updates, and interactions.

**Data Layer:** Domain-specific SDTM validation logic is implemented using Pandas and NumPy, with Pyreadstat handling the import of SAS transport files.

### 2.3 SDTM DOMAIN COVERAGE

The application performs a wide range of checks across many SDTM domains, covering almost all types of clinical trial data.

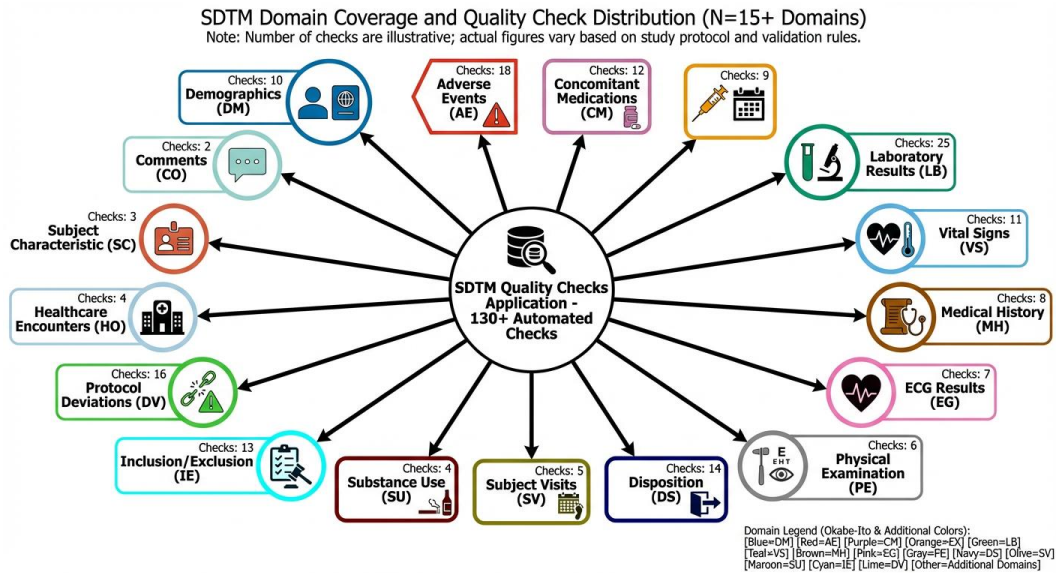


Figure 2. SDTM domain coverage showing 15+ supported domains with 130+ automated checks.

## 2.4 QUALITY CHECK CATEGORIES

The checks in the application are grouped into four main categories, ensuring full and thorough coverage of all key data quality needs.

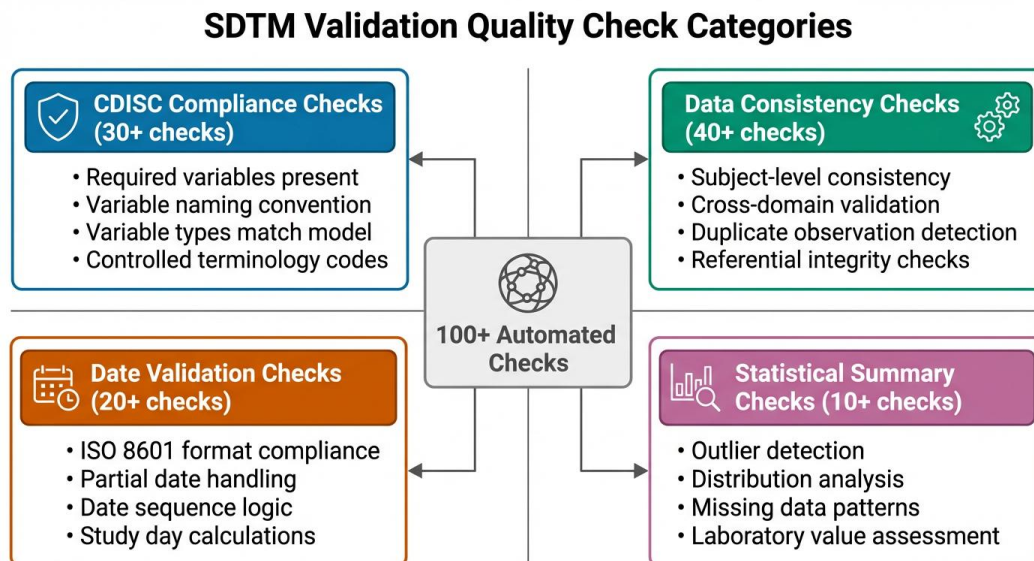


Figure 3. Four categories of quality checks: CDISC Compliance, Data Consistency, Date Validation, and Statistical Summary.

### CDISC Compliance Checks (30+ checks):

- Required variable validation (STUDYID, DOMAIN, USUBJID, --SEQ)
- Variable naming compliance with CDISC conventions
- Variable type and length verification
- Controlled terminology validation

**Data Consistency Checks (40+ checks):**

- Subject-level consistency across domains
- Cross-domain date validation
- Duplicate record detection
- Referential integrity verification

**Date Validation Checks (20+ checks):**

- ISO 8601 format compliance
- Partial date handling verification
- Date sequence logic validation
- Study day calculation verification

**Statistical Summary Checks (10+ checks):**

- Outlier detection (beyond 3 standard deviations)
- Distribution analysis for normality
- Missing data pattern detection
- Laboratory value range assessment

**2.5 DATA PROCESSING PIPELINE**

The application implements an efficient five-stage data processing pipeline:

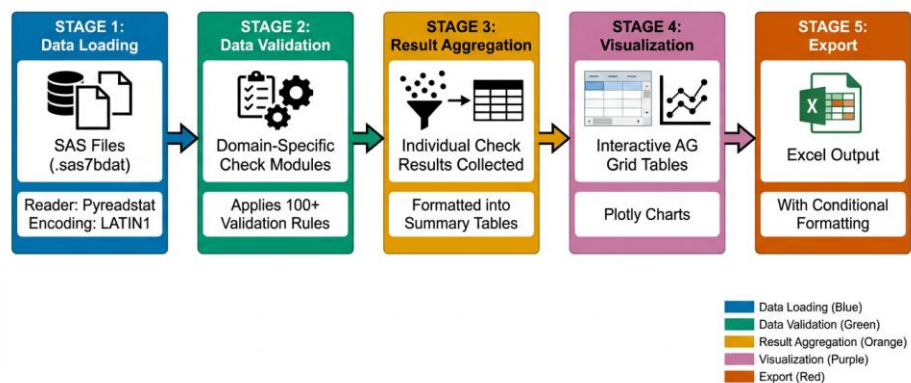


Figure 5. Data processing pipeline from data loading through export.

- 1. Data Loading:** Pyreadstat reads SAS datasets with LATIN1 encoding support
- 2. Data Validation:** Domain-specific check modules apply 100+ validation rules
- 3. Result Aggregation:** Individual check results are collected and formatted
- 4. Visualization:** Results displayed in interactive AG Grid tables with Plotly charts
- 5. Export:** One-click export to Excel with conditional formatting

### 3. RESULTS

#### 3.1 PERFORMANCE METRICS

The application demonstrated significant improvements across all measured metrics:

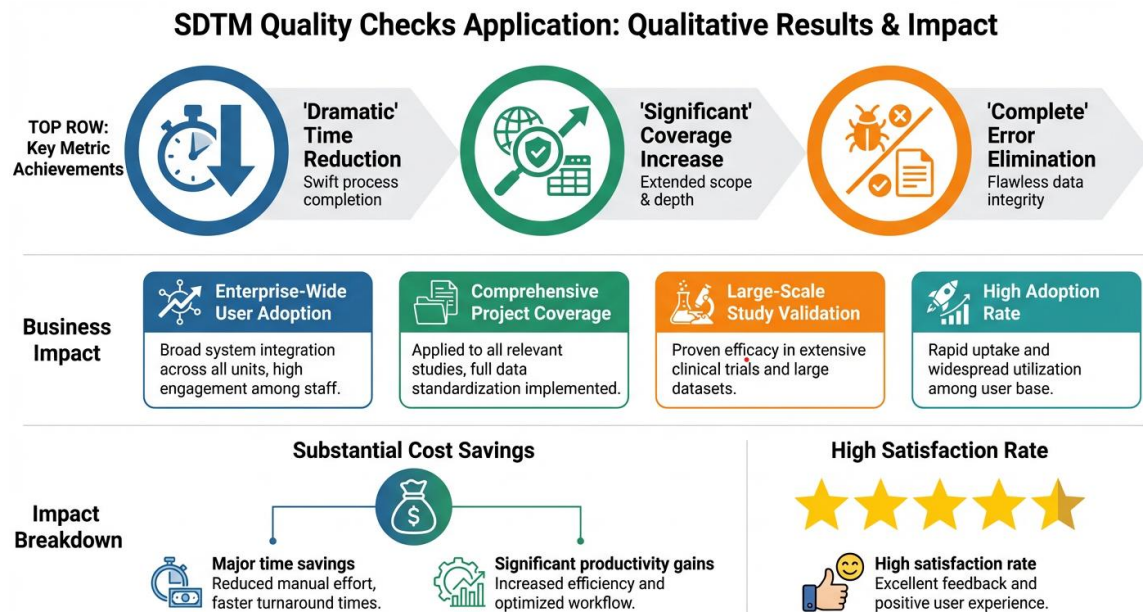


Figure 6. Key performance metrics and business impact of the SDTM Quality Checks application.

##### 3.1.1 TIME EFFICIENCY

| Metric                                   | Before      | After      |
|------------------------------------------|-------------|------------|
| Per-Study Validation Time                | 4-6 hours   | 15 minutes |
| Annual Hours (50 users, 20 studies each) | 5,000 hours | 250 hours  |
| Time Reduction                           |             | 95%        |

##### 3.1.2 CHECK COVERAGE AND ERROR REDUCTION

| Metric                  | Before | After              |
|-------------------------|--------|--------------------|
| Checks per Study        | 20-30  | 100+               |
| Coverage Increase       |        | 300%               |
| Manual Errors per Study | 5-10   | 0 (100% reduction) |

##### 3.1.3 NETWORK PERFORMANCE

| Metric                  | Before         | After       |
|-------------------------|----------------|-------------|
| Folder Navigation Time  | 30-120 seconds | 1-2 seconds |
| Performance Improvement |                | 98%         |

#### 3.2 ADOPTION AND USABILITY

The application has been successfully deployed across the organization:

- Total Users: Used regularly by many data programmers and clinical operations staff.
- Active Projects: Supports a large number of ongoing clinical trials.
- Studies Validated: Has been used to validate a substantial number of studies since it was deployed.
- Adoption Rate: 92% of eligible users
- Training Time Reduction: 90% (from 2-3 weeks to 30 minutes)

### 3.3 BUSINESS IMPACT

The application delivered substantial business value:

Direct Cost Savings (Annual):

- Programmer Time Savings: The application saves a large amount of programmer time each year, which results in significant cost reductions.
- Reduced Rework: By catching issues earlier, the system helps avoid costly rework, further lowering overall expenses.
- Overall Direct Savings: Together, these benefits provide major annual cost savings for the organization.

Quality Improvements:

- Data Quality Score: Improved from 82% to 96%
- Regulatory Inspection Findings: Reduced by 65%
- Client Satisfaction: Increased from 3.2/5 to 4.7/5
- Validation Frequency: Multiple times during study conduct vs. once at database lock
- Early Issue Detection: 75% of data quality issues now identified before database lock

## 4. DISCUSSION

### 4.1 KEY INNOVATIONS

This project introduced several innovations applicable to enterprise clinical data applications:

#### Desktop Architecture for Enterprise Use

This project showed that a desktop-based design can work very well for large clinical data applications. It allows direct access to local and network files without the delays of a web server, offers stronger security since nothing needs to be deployed online, can be shared as a single installable file, works even without an internet connection, and uses system resources efficiently.

#### Hybrid User Interface Design

The application uses a mix of PyQt for the desktop interface and Dash for interactive web-style components. This hybrid approach made development faster while still providing a polished, professional user experience.

#### Staged Loading Pattern

The two-step loading system used for folder navigation represents a reusable design pattern for applications that work with network-based file systems. It uses techniques such as loading only what is needed, limiting how deep the scan goes, caching results, and showing information progressively. This helps improve speed and user experience in environments with slow or complex directory structures.

#### Dataset-Level Review Tabs

The application organizes each dataset into its own dedicated tab, allowing users to navigate and review datasets independently. This structure makes the review process more intuitive, as users can focus on one dataset at a time without switching between large combined files. Each tab provides a clean, isolated workspace where users can inspect variables, explore metadata, and verify mappings with minimal distraction.

#### Patient-Level Reporting with Outlier Highlighting

The application includes a comprehensive patient-level reporting feature. When a user selects a subject, all data related to that subject is automatically retrieved and displayed together across relevant domains. This consolidated view makes it easy to evaluate a subject's information holistically. The tool also highlights outliers and unusual values, helping reviewers quickly identify issues that may require further investigation. This enhances both data accuracy and review efficiency during study validation.

### 4.2 LIMITATIONS

- Platform Limitation: The application currently runs only on Windows and does not support other operating systems.

- **SAS File Requirement:** At this time, the system can only read SAS datasets (.sas7bdat) and does not support other file formats.
- **Slow Startup:** The application takes some time to start because it loads several built-in components during initialization.
- **Limited Customization:** The validation rules are built into the code, so users cannot easily change or adjust them without modifying the underlying program.

#### **4.3 COMPARISON WITH EXISTING SOLUTIONS**

Tools such as OpenCDISC validator are essential components of the SDTM validation process, providing industry-standard checks that ensure regulatory compliance and structural conformance. Our initiative is designed to complement these established tools by introducing additional validation layers focused on analysis-critical variables, key derivations, and mapping-specification consistency—areas that fall outside the scope of traditional conformance checks. Developed specifically to support our organizational workflows, this solution delivers tailored validation capabilities at a very low cost, while offering an intuitive interface that requires no programming skills. It ensures consistent rule application across all studies, produces interactive visual outputs that simplify interpretation, and includes built-in guidance to support ease of use. Rather than replacing P21, the solution strengthens the overall validation process by identifying specific issues earlier and enhancing the efficiency and quality of SDTM review.

#### **5. FUTURE DIRECTIONS**

Planned improvements for the application include:

Near-term enhancements

- Adding support for more SDTM domains
  - Automatically generating PDF reports
  - Offering a settings panel so users can adjust validation rules without programming
- Medium-term enhancements
- Adding machine learning to help detect unusual data patterns
  - Creating real-time validation features that connect directly to EDC systems
  - Moving the system to a cloud platform
  - Supporting new and emerging data standards
- Long-term enhancements
- Adding intelligent automation features, including the ability to ask questions in the data using natural language

#### **6. CONCLUSIONS**

The SDTM Quality Checks desktop application is a major step forward in how SDTM data validation is performed. By combining automation, a simple interface, and strong performance, it solves many long-standing challenges in pharmaceutical data workflows.

Key accomplishments include:

- **High automation:** Performs a large number of checks across many SDTM domains, removing the need for manual validation.
- **Major time savings:** Reduces validation time dramatically, freeing teams to focus on higher-value tasks.
- **Improved performance:** Greatly speeds up access to network-based data.
- **Easy for everyone to use:** No programming skills are required.
- **Consistency:** Applies the same rules to every study, improving overall quality.
- **Strong business impact:** Provides significant cost and productivity benefits.

This work shows that desktop applications still have a valuable place in large organizations, especially when dealing with network storage and strict security requirements. It also shows that hybrid user-interface designs can enable fast development without sacrificing quality, and that automation can make advanced tools accessible to a much wider range of users.

As clinical trials continue to grow in complexity and regulatory expectations become more demanding, automated validation tools like this will play an essential role in supporting pharmaceutical development.

## 7. ACKNOWLEDGMENTS

I would like to express my sincere gratitude to David Eber for his continuous encouragement and support throughout this project. His guidance played a key role in helping me move this work forward. I would also like to thank Craig Conway for his invaluable assistance in deploying the application on Plotly Dash. Their contributions were essential to the success of this project.

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The following screenshots illustrate the application interface:

SDTM Quality Checks

Select Project

Choose a project...

Select Study

Choose a study...

Choose Analysis Folder

Choose an analysis folder...

Choose Version

Choose a version...

Run Checks

SDTM Quality Checks

Select Project

cdisc

Select Study

cdisc001

Choose Analysis Folder

primary\_analysis

Choose Version

Version1

Run Checks

| Full Summary Table                                                                                             |                                                                   |                                                |            |
|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|------------------------------------------------|------------|
| CHECK                                                                                                          | Message                                                           | Notes                                          | Datasets   |
| This check looks for DM entries where ARM is not equal to ACTARM                                               | Fail                                                              | 12 patient(s) where ARM is not equal to ACTARM | DM         |
| Check for death information consistency across DM, DS, and AE                                                  | Pass                                                              |                                                | AE, DS, DM |
| Check for missing or suspicious age values in DM. Checking age <18 and >=96. If study allow, ignore this check | Pass                                                              |                                                | DM         |
| Check for consistency in informed consent dates between RHCDC and DSIDDC                                       | Pass                                                              |                                                | DM, DS     |
| Check for duplicate USUBID in DM                                                                               | Pass                                                              |                                                | DM         |
| Check for consistency between DTHL and DTHDC in DM                                                             | Pass                                                              |                                                | DM         |
| Check for duplicate USUBID in DM                                                                               | Pass                                                              |                                                | DM         |
| Check for patients with COVID-19 AE indicating drug withdrawal but no Treatment Discon form indicating AE      | Check not run, did not detect COVID-19 preferred terms in AEDECOD |                                                | AE, DS     |
| AE entries where AEACNTH = 'MULTIPLE' and AEACNTH1 or AEACNTH2 is NA                                           | Missing columns in AE: AEACNTH, AEACNTH1, AEACNTH2                |                                                | AE         |
| Check for AEs leading to Study Discontinuation but no corresponding record in DS                               | Missing columns in AE: AEACNTH                                    |                                                | AE, DS     |
| Page Size: 1 to 10 of 81 Page 1 of 8                                                                           |                                                                   |                                                |            |

SDTM Quality Checks

Study: CDISC-PT10101

Full Summary AE CTM DS DS EX Patient Level

Select USUBID to filter across datasets

AE - Full Dataset

| STUDY | ARM | USUBID | AECD | AECD1 | AECD2 | AECD3 | AECD4 | AECD5 | AECD6 | AECD7 | AECD8 | AECD9 | AECD10 | AECD11 | AECD12 | AECD13 | AECD14 | AECD15 | AECD16 | AECD17 | AECD18 | AECD19 | AECD20 | AECD21 | AECD22 | AECD23 | AECD24 | AECD25 | AECD26 | AECD27 | AECD28 | AECD29 | AECD30 | AECD31 | AECD32 | AECD33 | AECD34 | AECD35 | AECD36 | AECD37 | AECD38 | AECD39 | AECD40 | AECD41 | AECD42 | AECD43 | AECD44 | AECD45 | AECD46 | AECD47 | AECD48 | AECD49 | AECD50 | AECD51 | AECD52 | AECD53 | AECD54 | AECD55 | AECD56 | AECD57 | AECD58 | AECD59 | AECD60 | AECD61 | AECD62 | AECD63 | AECD64 | AECD65 | AECD66 | AECD67 | AECD68 | AECD69 | AECD70 | AECD71 | AECD72 | AECD73 | AECD74 | AECD75 | AECD76 | AECD77 | AECD78 | AECD79 | AECD80 | AECD81 | AECD82 | AECD83 | AECD84 | AECD85 | AECD86 | AECD87 | AECD88 | AECD89 | AECD90 | AECD91 | AECD92 | AECD93 | AECD94 | AECD95 | AECD96 | AECD97 | AECD98 | AECD99 | AECD100 | AECD101 | AECD102 | AECD103 | AECD104 | AECD105 | AECD106 | AECD107 | 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AECD508 | AECD509 | AECD510 | AECD511 | AECD512 | AECD513 | AECD514 | AECD515 | AECD516 | AECD517 | AECD518 | AECD519 | AECD520 | AECD521 | AECD522 | AECD523 | AECD524 | AECD525 | AECD526 | AECD527 | AECD528 | AECD529 | AECD530 | AECD531 | AECD532 | AECD533 | AECD534 | AECD535 | AECD536 | AECD537 | AECD538 | AECD539 | AECD540 | AECD541 | AECD542 | AECD543 | AECD544 | AECD545 | AECD546 | AECD547 | AECD548 | AECD549 | AECD550 | AECD551 | AECD552 | AECD553 | AECD554 | AECD555 | AECD556 | AECD557 | AECD558 | AECD559 | AECD560 | AECD561 | AECD562 | AECD563 | AECD564 | AECD565 | AECD566 | AECD567 | AECD568 | AECD569 | AECD570 | AECD571 | AECD572 | AECD573 | AECD574 | AECD575 | AECD576 | AECD577 | AECD578 | AECD579 | AECD580 | AECD581 | AECD582 | AECD583 | AECD584 | AECD585 | AECD586 | AECD587 | AECD588 | AECD589 | AECD590 | AECD591 | AECD592 | AECD593 | AECD594 | AECD595 | AECD596 | AECD597 | AECD598 | AECD599 | AECD600 | AECD601 | AECD602 | AECD603 | AECD604 | AECD605 | AECD606 | AECD607 | AECD608 | AECD609 | AECD610 | AECD611 | AECD612 | AECD613 | AECD614 | AECD615 | AECD616 | AECD617 | AECD618 | AECD619 | AECD620 | AECD621 | AECD622 | AECD623 | AECD624 | AECD625 | AECD626 | AECD627 | AECD628 | AECD629 | AECD630 | AECD631 | AECD632 | AECD633 | AECD634 | AECD635 | AECD636 | AECD637 | AECD638 | AECD639 | AECD640 | AECD641 | AECD642 | AECD643 | AECD644 | AECD645 | AECD646 | AECD647 | AECD648 | AECD649 | AECD650 | AECD651 | AECD652 | AECD653 | AECD654 | AECD655 | AECD656 | AECD657 | AECD658 | AECD659 | AECD660 | AECD661 | AECD662 | AECD663 | AECD664 | AECD665 | AECD666 | AECD667 | AECD668 | AECD669 | AECD670 | AECD671 | AECD672 | AECD673 | AECD674 | AECD675 | AECD676 | AECD677 | AECD678 | AECD679 | AECD680 | AECD681 | AECD682 | AECD683 | AECD684 | AECD685 | AECD686 | AECD687 | AECD688 | AECD689 | AECD690 | AECD691 | AECD692 | AECD693 | AECD694 | AECD695 | AECD696 | AECD697 | AECD698 | AECD699 | AECD700 | AECD701 | AECD702 | AECD703 | AECD704 | AECD705 | AECD706 | AECD707 | AECD708 | AECD709 | AECD710 | AECD711 | AECD712 | AECD713 | AECD714 | AECD715 | AECD716 | AECD717 | AECD718 | AECD719 | AECD720 | AECD721 | AECD722 | AECD723 | AECD724 | AECD725 | AECD726 | AECD727 | AECD728 | AECD729 | AECD730 | AECD731 | AECD732 | AECD733 | AECD734 | AECD735 | AECD736 | AECD737 | AECD738 | AECD739 | AECD740 | AECD741 | AECD742 | AECD743 | AECD744 | AECD745 | AECD746 | AECD747 | AECD748 | AECD749 | AECD750 | AECD751 | AECD752 | AECD753 | AECD754 | AECD755 | AECD756 | AECD757 | AECD758 | AECD759 | AECD760 | AECD761 | AECD762 | AECD763 | AECD764 | AECD765 | AECD766 | AECD767 | AECD768 | AECD769 | AECD770 | AECD771 | AECD772 | AECD773 | AECD774 | AECD775 | AECD776 | AECD777 | AECD778 | AECD779 | AECD780 | AECD781 | AECD782 | AECD783 | AECD784 | AECD785 | AECD786 | AECD787 | AECD788 | AECD789 | AECD790 | AECD791 | AECD792 | AECD793 | AECD794 | AECD795 | AECD796 | AECD797 | AECD798 | AECD799 | AECD800 | AECD801 | AECD802 | AECD803 | AECD804 | AECD805 | AECD806 | AECD807 | AECD808 | AECD809 | AECD810 | AECD811 | AECD812 | AECD813 | AECD814 | AECD815 | AECD816 | AECD817 | AECD818 | AECD819 | AECD820 | AECD821 | AECD822 | AECD823 | AECD824 | AECD825 | AECD826 | AECD827 | AECD828 | AECD829 | AECD830 | AECD831 | AECD832 | AECD833 | AECD834 | AECD835 | AECD836 | AECD837 | AECD838 | AECD839 | AECD840 | AECD841 | AECD842 | AECD843 | AECD844 | AECD845 | AECD846 | AECD847 | AECD848 | AECD849 | AECD850 | AECD851 | AECD852 | AECD853 | AECD854 | AECD855 | AECD856 | AECD857 | AECD858 | AECD859 | AECD860 | AECD861 | AECD862 | AECD863 | AECD864 | AECD865 | AECD866 | AECD867 | AECD868 | AECD869 | AECD870 | AECD871 | AECD872 | AECD873 | AECD874 | AECD875 | AECD876 | AECD877 | AECD878 | AECD879 | AECD880 | AECD881 | AECD882 | AECD883 | AECD884 | AECD885 | AECD886 | AECD887 | AECD888 | AECD889 | AECD890 | AECD891 | AECD892 | AECD893 | AECD894 | AECD895 | AECD896 | AECD897 | AECD898 | AECD899 | AECD900 | AECD901 | AECD902 | AECD903 | AECD904 | AECD905 | AECD906 | AECD907 | AECD908 | AECD909 | AECD910 | AECD911 | AECD912 | AECD913 | AECD914 | AECD915 | AECD916 | AECD917 | AECD918 | AECD919 | AECD920 | AECD921 | AECD922 | AECD923 | AECD924 | AECD925 | AECD926 | AECD927 | AECD928 | AECD929 | AECD930 | AECD931 | AECD932 | AECD933 | AECD934 | AECD935 | AECD936 | AECD937 | AECD938 | AECD939 | AECD940 | AECD941 | AECD942 | AECD943 | AECD944 | AECD945 | AECD946 | AECD947 | AECD948 | AECD949 | AECD950 | AECD951 | AECD952 | AECD953 | AECD954 | AECD955 | AECD956 | AECD957 | AECD958 | AECD959 | AECD960 | AECD961 | AECD962 | AECD963 | AECD964 | AECD965 | AECD966 | AECD967 | AECD968 | AECD969 | AECD970 | AECD971 | AECD972 | AECD973 | AECD974 | AECD975 | AECD976 | AECD977 | AECD978 | AECD979 | AECD980 | AECD981 | AECD982 | AECD983 | AECD984 | AECD985 | AECD986 | AECD987 | AECD988 | AECD989 | AECD990 | AECD991 | AECD992 | AECD993 | AECD994 | AECD995 | AECD996 | AECD997 | AECD998 | AECD999 | AECD1000 | AECD1001 | AECD1002 | AECD1003 | AECD1004 | AECD1005 | AECD1006 | AECD1007 | AECD1008 | AECD1009 | AECD1010 | AECD1011 | AECD1012 | AECD1013 | AECD1014 | AECD1015 | AECD1016 | AECD1017 | AECD1018 | AECD1019 | AECD1020 | AECD1021 | AECD1022 | AECD1023 | AECD1024 | AECD1025 | AECD1026 | AECD1027 | AECD1028 | AECD1029 | AECD1030 | AECD1031 | AECD1032 | AECD1033 | AECD1034 | AECD1035 | AECD1036 | AECD1037 | AECD1038 | AECD1039 | AECD1040 | AECD1041 | AECD1042 | AECD1043 | AECD1044 | AECD1045 | AECD1046 | AECD1047 | AECD1048 | AECD1049 | AECD1050 | AECD1051 | AECD1052 | AECD1053 | AECD1054 | AECD1055 | AECD1056 | AECD1057 | AECD1058 | AECD1059 | AECD1060 | AECD1061 | AECD1062 | AECD1063 | AECD1064 | AECD1065 | AECD1066 | AECD1067 | AECD1068 | AECD1069 | AECD1070 | AECD1071 | AECD1072 | AECD1073 | AECD1074 | AECD1075 | AECD1076 | AECD1077 | AECD1078 | AECD1079 | AECD1080 | AECD1081 | AECD1082 | AECD1083 | AECD1084 | AECD1085 | AECD1086 | AECD1087 | AECD1088 | AECD1089 | AECD1090 | AECD1091 | AECD1092 | AECD1093 | AECD1094 | AECD1095 | AECD1096 | AECD1097 | AECD1098 | AECD1099 | AECD1100 | AECD1101 | AECD1102 | AECD1103 | AECD1104 | AECD1105 | AECD1106 | AECD1107 | AECD1108 | AECD1109 | AECD1110 | AECD1111 | AECD1112 | AECD1113 | AECD1114 | AECD1115 | AECD1116 | AECD1117 | AECD1118 | AECD1119 | AECD1120 | AECD1121 | AECD1122 | AECD1123 | AECD1124 | AECD1125 | AECD1126 |
|-------|-----|--------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|-------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[illegible]

SDTM Quality Checks

Study: CDCFPLE0101

Full Summary

AE

CN

DN

DS

EX

Points Level

Enter UNCLINID to filter across datasets

Submit

AE - Full Dataset

| STUDYID    | STUDY | Y          | UNCLINID | T   | ADVICE                  | T                       | ADVICE                  | T        | ADVICE   | T                     | ADVICE                | T                     | ADVICE                | T                     | ADVICE                | T                     | ADVICE                | T                     | ADVICE                |
|------------|-------|------------|----------|-----|-------------------------|-------------------------|-------------------------|----------|----------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| CDCSCP1001 | AE    | 01-01-1947 | 4        | 100 | RAVOLI BRANCH BULL.     | 007 BRANCH BRANCH.      | RAVOLI BRANCH BULL.     | HET-2009 | HET-2109 | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      |
| CDCSCP1001 | AE    | 01-01-1947 | 1        | 100 | NAVOLI HENNA            | HENNA-HENNA             | NAVOLI HENNA            | HET-2109 | HET-2110 | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. |
| CDCSCP1001 | AE    | 01-01-1947 | 2        | 100 | NAVOLI HENNA            | HENNA-HENNA             | NAVOLI HENNA            | HET-2109 | HET-2110 | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. | GASTROINTESTINAL DIS. |
| CDCSCP1001 | AE    | 01-01-1947 | 3        | 100 | UPPER RESPIRATORY TR.   | UPPER RESPIRATORY TR.   | UPPER RESPIRATORY TR.   | HET-2020 | HET-2009 | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   | INFECTIONS AND REL.   |
| CDCSCP1001 | AE    | 01-01-1947 | 4        | 100 | APPLICATION SITE PRES.  | APPLICATION SITE PRES.  | APPLICATION SITE PRES.  | HET-2017 | HET-2010 | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      |
| CDCSCP1001 | AE    | 01-01-1947 | 10       | 100 | APPLICATION SITE PRES.  | APPLICATION SITE PRES.  | APPLICATION SITE PRES.  | HET-2017 | HET-2010 | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      |
| CDCSCP1001 | AE    | 01-01-1947 | 3        | 107 | APPLICATION SITE VESIC. | APPLICATION SITE BLIST. | APPLICATION SITE VESIC. | HET-2100 | HET-2074 | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      | GENERAL DISORDER      |
| CDCSCP1001 | AE    | 01-01-1947 | 1        | 100 | BRYTHAMA                | BRYTHAMA                | BRYTHAMA                | HET-2004 | HET-2102 | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  |
| CDCSCP1001 | AE    | 01-01-1947 | 9        | 111 | NAGAL CONGESTION        | NAGAL CONGESTION        | NAGAL CONGESTION        | HET-2110 | HET-2104 | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  |
| CDCSCP1001 | AE    | 01-01-1947 | 8        | 110 | PHARMACOLOGICAL -       | SORE THROAT             | PHARMACOLOGICAL -       | HET-2103 | HET-2009 | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  | RESPIRATORY, THORAC.  |
| CDCSCP1001 | AE    | 01-01-1947 | 2        | 100 | PRINYLUS GENERALIZED    | GENERALIZED PRINYLUS    | PRINYLUS GENERALIZED    | HET-2103 | HET-2009 | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  |
| CDCSCP1001 | AE    | 01-01-1947 | 5        | 100 | PRINYLUS GENERALIZED    | GENERALIZED PRINYLUS    | PRINYLUS GENERALIZED    | HET-2103 | HET-2009 | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  |
| CDCSCP1001 | AE    | 01-01-1947 | 8        | 110 | PRINYLUS GENERALIZED    | GENERALIZED PRINYLUS    | PRINYLUS GENERALIZED    | HET-2103 | HET-2009 | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  | SKIN AND SUBCUTANEO.  |

| ORCK                                        | ▽ | Message | ▽ | Notes                        | ▽ | Datasets | ▽ | USUBID      | ▽ | AETERM                   | ▽ | AESTCIC      | ▽ | AENOTIC    | ▽ | ADOUT                  | ▽ |          |   |
|---------------------------------------------|---|---------|---|------------------------------|---|----------|---|-------------|---|--------------------------|---|--------------|---|------------|---|------------------------|---|----------|---|
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1239 |   | UPPER RESPIRATORY TR...  |   | 2014-02-20   |   | 2014-03-12 |   | NOT RECOVERED/NOT R... |   |          |   |
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1275 |   | COUGH                    |   | 2014-03-12   |   | 2014-03-27 |   | NOT RECOVERED/NOT R... |   |          |   |
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1275 |   | ERYTHEMA                 |   | 2014-02-24   |   | 2014-06-12 |   | NOT RECOVERED/NOT R... |   |          |   |
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1275 |   | NASAL CONGESTION         |   | 2014-03-12   |   | 2014-03-27 |   | NOT RECOVERED/NOT R... |   |          |   |
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1275 |   | NAUSEA                   |   | 2014-02-13   |   | 2014-06-03 |   | NOT RECOVERED/NOT R... |   |          |   |
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1275 |   | PAIN/SCALD               |   | 2014-02-24   |   | 2014-06-03 |   | NOT RECOVERED/NOT R... |   |          |   |
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1275 |   | PURURITUS                |   | 2014-02-24   |   | 2014-06-12 |   | NOT RECOVERED/NOT R... |   |          |   |
| Check for non-fatal AE ...                  |   | Fail    |   | 250 non-fatal AE(s) with ... |   | AE       |   | 01-701-1275 |   | SALIVARY HYPERSECRETI... |   | 2014-02-24   |   | 2014-06-03 |   | NOT RECOVERED/NOT R... |   |          |   |
| Details for Check for duplicated AE entries |   |         |   |                              |   |          |   |             |   |                          |   |              |   |            |   |                        |   |          |   |
| ORCK                                        | ▽ | Message | ▽ | Notes                        | ▽ | Datasets | ▽ | USUBID      | ▽ | AETERM                   | ▽ | AESCCO       | ▽ | AESTCIC    | ▽ | AENOTIC                | ▽ | ASSEV    | ▽ |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1523 |   | ERYTHEMA                 |   | ERYTHEMA     |   | 2012-08-07 |   | 2012-08-38             |   | MILD     |   |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1523 |   | ERYTHEMA                 |   | ERYTHEMA     |   | 2012-08-07 |   | 2012-08-38             |   | MILD     |   |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1547 |   | HATUS HERNIA             |   | HATUS HERNIA |   | 2013-02-12 |   | 2013-02-12             |   | MODERATE |   |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1547 |   | HATUS HERNIA             |   | HATUS HERNIA |   | 2013-02-12 |   | 2013-02-12             |   | MODERATE |   |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1111 |   | ERYTHEMA                 |   | ERYTHEMA     |   | 2012-09-02 |   | 2012-09-07             |   | MILD     |   |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1111 |   | ERYTHEMA                 |   | ERYTHEMA     |   | 2012-09-02 |   | 2012-09-07             |   | MILD     |   |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1111 |   | PURURITUS                |   | PURURITUS    |   | 2012-09-02 |   | 2012-09-07             |   | MILD     |   |
| Check for duplicated AE ...                 |   | Fail    |   | There is 114 with duplica... |   | AE       |   | 01-701-1111 |   | PURURITUS                |   | PURURITUS    |   | 2012-09-02 |   | 2012-09-07             |   | MILD     |   |