
DataFax Validation (Upgrading to 3.7-001)

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Get ready!

Validation can be both time consuming and a pain at the same time BUT if the validation is not done correctly, a company can be exposing itself to a huge risk.

In 2004 Synteract had approximately 16 audits that involved database information, ranging from 1-5 days in length.

These audits included DF software validation binders and individual database development binders.



Validation Project Team

Develop and approve Validation Documents

1. Validation Plan
2. Functional Requirements
3. Traceability Matrix
4. Test Protocols for IQ, OQ, PQ and "Secondary" PQs
5. Validation Summary Report



Come up with a plan...

Validation Plan

This document will identify:

- The validation activities to be undertaken.
- The roles and responsibilities involved in the validation project.
- The methods by which the validation activity will be undertaken.



What is in the Validation Plan?

- Validation Plan Approval
- Document History
- Purpose and Overview
- Definitions
- Scope
- System Description
- Responsibilities
- Validation Process
- Test Execution
- Validation Execution Order
- Documentation Practices
- Validation Plan Deviation Form



Functional Requirements

The scope of this document is to detail such requirements in a manner that provides a foundation for developing and executing test protocols for the validation of this system.

OR

Listing of the intended functions of the system or portion of the system to be validated (*Risk Assessment).



Traceability Matrix

The scope of the Traceability Matrix (TM) is to provide documented evidence that all the Functional Requirements of the DataFax version 3.7-001 system (DataFax), are adequately tested during the validation process.

OR

Table that traces each functional requirement to the test protocol(s) to be executed in validating that requirement



Test Protocol

Description of a test and its expected result, including an area for the tester to incorporate actual results and whether the test meets the criteria (Pass or Fail indication); Used as a verification measure in performing qualification.

The IQ, OQ and PQ!



Installation Qualification (IQ)

This qualification testing ensures that the **installation and environment** for DataFax have been properly performed to justify proceeding with additional tests to **verify the functionality of the software**.



Operational Qualification (OQ)

This qualification testing ensures that **the implementation of DataFax system features and functions** have been properly performed to justify proceeding with additional tests to **verify the performance of the software**.



Performance Qualification (PQ)

This qualification testing **ensures that certain aspects of the DataFax system work properly**, and is the last step of validation testing, thereby completing the formal testing of DataFax v3.7-001 implementation.

OR

The PQ checks that DataFax functions as expected within the environment of intended operation for pre-defined and/or user-specific parameters. It performs checks on our studies that are currently running, i.e., DataFax integrity reports as well as snapshots of study data before an upgrade and after an upgrade.



Don't forget the "Secondary" PQs

Our Validation Team came up with "Secondary" PQs in addition to the ATK in order to test that all study configurations were functioning as intended.

Secondary PQs:

- Ensure that study setup and the clinical data are successfully transferred from one validated software system to another validated software system
- Ensure that no data are lost, modified, or corrupted during the upgrade.
- Covers validation testing for ongoing study databases (databases opened prior to the current software version release).



Secondary PQ. Step 1

Save pre-upgrade DataFax study state. All of output generated was saved to text files in a part1 directory.

- Verify configuration of visit map using DF_SSvisitmap
- Obtain pre-installation exports running DFlistplates.rpc combined with DFexport.rpc
- Obtain Integrity reports: DF_ICvisitmap, DF_ICrecords, DF_ICschema
- Get a list of study user permissions using DFuserPerms



Secondary PQ. Step 2

- Save post-installation DataFax study state. All reports generated in step 1 were generated again in a part2 directory
- Verify the DataFax visit scheduling is correct. We broke this out into a separate section due to its complexity.



Secondary PQ. Step 2.1 and 2.2

We added a separate section because of the upgrades to the DataFax Visit Scheduling. What were some of the upgrades that effected the visit map in DF v-3.7002?

- Conditional visit, plate, and cycle specifications for CRF requirements were enhanced
- DFX_schedule was amended to include target visit date and visit status
- Visit Map limitations were removed.
- Scheduling specifications were rewritten. The most significant change was the way DataFax now uses cycles to group visits.



Secondary PQ. Step 2.1 and 2.2 cont.

Step 2.1

- We ran DF_ICvisitmap and DF_PTschedule, saving the output to a text file
- The initial state of the DFvisit_map and related files (DFcplate_map, DFcvisit_map, etc.) were saved

Step 2.2

- Any irregularities in the visit scheduling found in step 2.1 were corrected
- DF_ICvisitmap and DF_Ptschedule were rerun.
- The final state of the visit map was saved. The UNIX diff command was run for both versions of the file to detail the corrections made.



Secondary PQ. Step 3

- The UNIX diff command was run against the part1 and part2 directories created for PQ parts 1 and 2 respectively
- Database configuration and setup integrity was verified



Validation Summary Report

Summary report of the execution of the IQ, OQ, and PQ test protocols and any other related information concerning the validation and its execution

All discrepancies and script errors will be noted in the Validation Summary Report



PAQ ~ Patch Qualification for DF 3.7-002

Upgrading to a patch
(Mini-Validation)

The Patch Qualification document (PAQ) will serve as the Validation Plan, Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ). Additionally, the features which were added or modified in this release and the associated script steps are outlined in the Traceability Matrix (TM).



Validation Lessons Learned for 3.7-001

- Due to some formatting changes in the DataFax reports, some comparisons of pre and post database snapshots reported failures.
- DF_ICvisitmap reported errors in character lengths of labels. In order to suppress errors, we allowed DataFax character descriptions of 40.
- Consider developing a 'Validation Style Guide' so that test scripts written by different people use similar wording.



Validation Lessons Learned for 3.7-001 cont.

- Allow time for a validation test run before validation is done on a production server. Then IQ, OQ, or PQ script errors are identified and the process is streamlined. This also allows for less DataFax down time, when doing validation on production.
- Allow time for Data Managers to review the scheduling reports for inconsistencies.
- Pick a time to do validation where all team members are present. Don't schedule validation during summer vacations or company holidays! (right...)



General Feedback from Auditors

- Don't use pens with water-soluble ink
- The person who wrote the test script should NOT execute that script.
- Provide some indication on supporting output, that it was reviewed and contained appropriate data (i.e., tick marks on the output)
- Don't write on supporting output at all; any tick marks are considered to be stray marks



Questions?

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