

DataFax Clinical Trials Management System

Traceability Matrix

The following table links requirements, risks, designs and tests. The following abbreviations are used to reference other documents:

- ATK = DataFax Acceptance Test Kit
- DQ = Daily Qualification Checklist
- IQ = Installation Qualification Checklist
- PQ = Production Qualification Checklist
- OO = Operational Qualification Checklist
- SD = System Design

The following categories describe risk severity:

1. **Critical:** It will be impossible to demonstrate data integrity if this system fails to function as required.
2. **Serious:** Significant additional work will be required to demonstrate data integrity if this system fails to function as required.
3. **On-Hold:** The system will be unusable until the problem is resolved, but no data is at risk because no changes to at least one portion of the system will be possible.
4. **Inconvenient:** The requirement is not met, but there is another way to accomplish the task.

| Requirement | Risk | Design Elements | Test |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|------------------------|---------------------|
| 5. Operational Requirements | | | |
| 5.1 Organizational Need | | | |
| 5.1.1. Database administrators to define databases capable of storing, displaying and exporting all data necessary to establish the endpoints defined for a clinical protocol; | 2 | SD 4.4.1 SD 5.5.2 | ATK 3.2 |
| 5.1.2.Database administrators to create programmed edit checks designed to verify the consistency of data elements; | 1 | SD 5.5.3 SD 5.5.2.6 | ATK 6.3.2 |
| 5.1.3.Clinical sites to submit Case Report Forms as electronic images via fax or email; | 2 | SD 5.6 | ATK Chapter 5 |
| 5.1.4.ORG management to define normal pattern(s) of review so that each CRF is processed by specific staff titles in an expected order | 1 | SD 5.7.4 | ATK 3.2 (View Only) |

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| 5.1.5. Automate certain aspects of data entry; | 1 | SD 4.4.3, SD 4.4.4 | ATK 6.3 |
| 5.1.6. Data management staff to view the CRF images and enter data which accurately represents the CRF, including | 2 | SD 5.7.3 | ATK Chapter 6 |
| 5.1.6.1. visual cues which alert reviewers to data which | 1 | SD 5.7.5 | ATK 4.9, 6.4.2 |
| 5.1.6.1.1. lie outside of established legal ranges, or | 1 | SD 5.7.5.1 | ATK 4.9, 6.4.2.a |
| 5.1.6.1.2. have been queried during previous reviews. | 1 | SD 5.7.5.2 | ATK 6.4.2.d |
| 5.1.6.2. system classifications which enable reviewers to indicate whether potential data problems have been identified | 3 | SD 5.7.3.3 | ATK 4.5.6, 4.7.4 |
| 5.1.7. Data management staff to query data items which they judge to be inconsistent, illegible or otherwise insufficient to meet standards set forth in CRF instructions or the study protocol; | 1 | SD 4.4.6 SD 5.7.3.2 | ATK 3.5, 6.3.1, |
| 5.1.8. Database administrators to create expectations for the submission of Case Report Forms, based on participant enrollment, according to the clinical protocol; | 1 | SD 5.5.4.1 | ATK 3.2 |
| 5.1.9. Data management staff to communicate queries regarding missing forms, and inconsistent or illegible data items to clinical sites; | 1 | SD 5.7.7 | ATK 8.4, 8.5 and 8.11 |
| 5.1.10. Data management staff to document the resolution of all queries based upon site response; | 1 | SD 5.7.7 | ATK 8.13 |
| 5.1.11. staff to manage images which were not recognized by the system; | 1 | SD 5.2 | ATK 5.3, 5.4 |
| 5.1.12. export of existing data to other systems, including SAS; | 2 | SD 4.7 | ATK Chapter 12 |
| 5.1.13. Systems administrators to start and stop data management processes as necessary to respond to environmental or regulatory circumstances according to appropriate SOPs and commonly accepted practices; and | 3 | SD 5.1.5 | IQ 8.e |
| 5.1.14. Systems administrators to review system events in order to verify system operation or troubleshoot specific problems encountered by ORG staff or clinical sites. | 2 | SD 5.5.1 | PQ 3. |
| 5.2 Organizational Responsibilities | | | |

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|------------------------------------------------------|-----------------------|
| 5.2.1.Meeting the definition of a closed system under 21 CFR 11 in that | 4 | SD 3 | ATK Chapter 1 |
| 5.2.1.1. the hardware and software which comprise the system are wholly contained on an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system, | 4 | SD 3.1.1 SD 3.1.2 | IQ 1.b |
| 5.2.1.2. a unique user ID / password combination is required for each system login, | 4 | SD 4.1.1 | ATK 1.5, 1.6 |
| 5.2.1.3. SOPs prohibit logging on with another individual's ID; and | 4 | SOP?? | Training Records (??) |
| 5.2.1.4. the operating system maintains a log of any instance in which the administrator (root) has found it necessary to temporarily switch to another user ID. | 4 | SD 4.1.1.3 | PQ 1.b |
| 5.2.2.Generating accurate and complete copies of records in both human readable and electronic form suitable for inspection, review and copying by | 2 | SD 5.2.3 SD 5.2.4 | ATK Chapters 6 and 12 |
| 5.2.2.1. linking each data record with a CRF image; | 3 | SD 5.2.3 | PQ 11. |
| 5.2.2.2. enabling export raw data as ASCII text. | 2 | SD 5.3.2 | ATK 12.2 - 12.5 |
| 5.2.2.3. Enabling the accurate and ready retrieval of the above throughout the records retention period by | 1 | SD 5.7.3.1 | ATK Chapter 5 |
| 5.2.2.3.1. maintaining all records online in an active state; | 1 | SD 5.2.2 and SD 5.7.3.1 | PQ 9. |
| 5.2.2.3.2. providing adequate hardware, software and related procedures to allow restoration in the event of unexpected system failure | 4 | SD 2.1.5, SD 4.3 and SOP?? (Events or Continuity) | PQ 8.a or PQ 8.b |
| 5.2.3.Providing the following facilities necessary to accurately recognize and record dates and times: | 4 | SD 5.2.5 | |
| 5.2.3.1. The system is configured to avoid confusion as to whether the time recorded for a particular event was based on the time zone of the server or that of the client. | 4 | SD 5.2.5.1 | |
| 5.2.3.2. End users are unable to control or alter date/time stamps created by the system. | 4 | SD 5.2.5.2 | |
| 5.2.3.3. The system is not constrained by | | SD 5.5.2.4 | |

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| 5.2.3.3.1. Any inability to recognize or manage 4-digit years; | 4 | SD 5.5.2.4.1 | ATK Chapter 11 |
| 5.2.3.3.2. Cultural conventions regarding the relative placement of day month and year; or | | SD 5.5.2.4.2, SD 5.5.2.4.3 | ATK 11.7 and 11.8 |
| 5.2.3.3.3. other factors, such as the UNIX 2037 problem, which are anticipated to require correction prior a particular date in order to preclude confusion of computers or human beings. | | SD 5.2.6 | |
| 5.2.4. Automatically creating an audit trail which | 3 | SD 5.2.4 | PQ 9. |
| 5.2.4.1. Captures the date and time of any data change; | 4 | SD 5.2.4.1 | PQ 9. |
| 5.2.4.2. Captures the user ID responsible for any data change; and | 4 | SD 5.2.4.2 | PQ 9. |
| 5.2.4.3. does not obscured previously entered data. | 4 | SD 5.2.4.3 | PQ 9. |
| 5.2.5. Controlling access to the private information of study participants by restricting access to authorized ORG staff. | 4 | SD 4.1.1 SD 5.1.2 | PQ 1.a |
| 5.2.6. Providing utilities for checking the integrity of the database, including | 1 | SD 5.7.6.2 | |
| 5.2.6.1. Comparison between the number of fields in each data record and the number of fields defined in the study database. | 1 | SD 5.7.6.2.1 | PQ 12. |
| 5.2.6.2. Verification of a one-to-one relationship between data records and CRF images. | 1 | SD 5.7.6.2.2 | PQ 11. |
| 5.2.6.3. Verification that each data query is attached to a single data field. | 3 | SD 5.7.6.2.3 | PQ 13. |
| 5.2.6.4. Verification that there are no unresolved queries on records which have been marked "clean". | 3 | SD 5.7.6.2.3 | PQ 13. |
| 5.2.7. Restricting the use of the DataFax software to a single server for a limited time in conformance with ORG's contractual obligations to Clinical DataFax Systems, Inc. | 1 | SD 5.1.4 | IQ 8.c |
| 6. Functional Requirements | | | |
| 6.1 Hardware | | | |
| 6.1.1. Data Management Server | | SD 2.1 | |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-----------------|------------|
| 6.1.1.1. A CPU capable of running the Solaris 7 Operating System or better; | | SD 2.1.1 | |
| 6.1.1.2. 1 MB of hard drive space for each 40 CRF images transmitted by clinical sites in addition what is required for the operating system and user accounts; | 2 | SD 2.1.2 | DQ 2. |
| 6.1.1.3. At least one fax modem capable of processing Group 3 images; | 2 | SD 2.1.3 | IQ 1.d |
| 6.1.1.4. Connections between the server and each fax modem established by | 2 | SD 2.1.5 | IQ 1.d |
| 6.1.1.4.1. Serial cables connected to | 2 | SD 2.1.4.1.1 | IQ 1.d.i |
| 6.1.1.4.2. Disabled serial ports; | 2 | SD 2.1.4.1.2 | IQ 1.d.ii |
| 6.1.1.5. Working telephone lines associated with known phone number(s); | 2 | SD 2.1.4.1.2 | IQ 1.e |
| 6.1.1.5.1. voice conversations can be successfully conducted | 2 | SD 2.1.4.2.1 | IQ 1.e.ii |
| 6.1.1.5.2. "Roll-over" is established so that the second modem is used if the first is busy, etc. | 1 | SD 2.1.4.2.2 | IQ 1.e.iii |
| 6.1.1.6. Keyboard | 2 | SD 2.1.7 | IQ 3.b |
| 6.1.1.7. Monitor | 2 | SD 2.1.8 | IQ 3.c |
| 6.1.1.8. Mouse | 2 | SD 2.1.9 | IQ 3.b |
| 6.1.2.Network Information (NIS) server | 2 | SD 2.3 | IQ 3.a.i |
| 6.1.2.1. A CPU capable of running a Solaris 7 Operating System or better | 2 | SD 2.3.1 | IQ 3.a |
| 6.1.2.2. Network card | | SD 2.3.2 | |
| 6.1.3.Postscript Capable Printer | 2 | SD 2.2 | IQ 4.g |
| 6.1.4.Remote Access Server | 2 | SD 2.1 | IQ 3.a |
| 6.1.4.1. Network Card to provide system connection from the public internet; | | SD 2.1.10 | IQ 3.a |
| 6.1.4.2. 8 MB random access memory to support processes created by each active client. | 2 | SD 2.1.4 | IQ 3.a |

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|------------------------------------------------------------------------------------------------------|------|-----------------------|------------------------|
| 6.1.4.3. The remote access server utilizes the same computer hardware as the Data Management server. | 1 | SD 2.1 | IQ 3.a |
| 6.2 Business Continuity Devices | 4 | SD 2.1.5 and SD 2.1.6 | IQ 3.e |
| 6.2.1.Tape Backup Device | 4 | SD 2.1.5 | IQ 3.e |
| 6.2.1.1. full backups at least month | 4 | SOP?? | IQ 8. |
| 6.2.1.2. incremental backups each business night | 4 | SOP?? | DQ 8. |
| 6.2.1.3. connecting cables | 1 | SD 2.1.5.1 | IQ 3.e.i |
| 6.2.1.4. one month's worth of tape media | 1 | SD 2.1.5.2 | IQ 3.e.ii |
| 6.2.2.Emergency Power Source | 3 | SD 2.1.6 | IQ 4.f.i |
| 6.2.3.Documentation and Help Systems | 1 | SD 6 | |
| 6.2.3.1. Copies of key software components, including | 1 | SD 6.1 | |
| 6.2.3.1.1. Solaris | 1 | SD 6.1.1 | IQ 5.a |
| 6.2.3.1.2. DataFax and HylaFAX | 1 | SD 6.1.2 | IQ 5.c |
| 6.2.3.2. Contract and telephone numbers, email addresses, User IDs and related passwords for | 1 | SD 6.2 | IQ 5.d, IQ 5.e, IQ 5.f |
| 6.2.3.2.1. Operating System support for the DataFax Server and related hardware support | 1 | SD 6.2.1 | IQ 5.c |
| 6.2.3.2.2. DataFax and HylaFAX software support | 1 | SD 6.2.2 | IQ 5.e |
| 6.2.3.3. DataFax License Number | 1 | SD 6.2.3 | IQ 5.d |
| 6.2.3.4. Phone numbers for each modem line. | 1 | SD 6.2.4 | IQ 1.e.iv |
| 6.3 Client Systems | | SD 2.4 | |
| 6.3.1.Desktop Systems | | SD 2.4.1 | |
| 6.3.1.1. Pentium II/III CPU capable of running Windows 95, Windows 98 or NT 4 | | SD 2.4.1 | |

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| 6.3.1.2. 64 MB RAM | | SD 2.4.2 | |
| 6.3.1.3. 1280x1024 display with 2 MB of video memory | | SD 2.4.6 | |
| 6.3.1.4. Network Card | | SD 2.4.3 | |
| 6.3.1.5. Keyboard | | SD 2.4.4 | |
| 6.3.1.6. Mouse | | SD 2.4.5 | |
| 6.3.2.Fax Machines | | SD 2.5 | |
| 6.3.2.1. receiving and transmitting Group 3 tiff images | | SD 2.5.1 | |
| 6.3.2.2. storing at least 50 pages in memory for later transmission | | SD 2.5.2 | |
| 6.3.3.Wide Area Network Connection (WAN) | | SD 3.3.1 | |
| 6.3.3.1. Authorized users can access the DataFax Clinical Trials Management System. | | SD 3.3 | |
| 6.3.3.2. Sufficient bandwidth exists to quickly update the X-Windows display on the client desktop each time the user selects a new data record. | | SD 3.3.2 | |
| 6.3.3.3. Unauthorized users are prevented from accessing the DataFax Clinical Trials Management System. | | SD 3.1.1, SD 3.1.2 and SOP?? | |
| 6.4 Software | | SD 4 | |
| 6.4.1.DataFax Server | | SD 4.4 | |
| 6.4.1.1. Solaris 7 Operating System (or better) installed and functioning as designed | | SD 4.1 | |
| 6.4.1.2. DataFax 3.6 or better. | | SD 4.4 | |
| 6.4.1.2.1. The location of the DataFax software within the file system is documented. | | SD 4.4 | |
| 6.4.1.2.2. The DataFax software installs successfully | | SD 4.4 | |
| 6.4.1.2.3. An administrator can successfully start the DataFax Software. No errors are reported. | | SD 5.1.5 | |

DataFAX Traceability Matrix

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------|-----------------|------|
| 6.4.1.3. HylaFAX 4.1.8 as bundled with DataFAX by CDSI. | | SD 4.5 | |
| 6.4.1.3.1. The location of the HylaFAX software is documented | | SD 4.5 | |
| 6.4.1.3.2. The DFaddmodem utility completes successfully for each modem. | | SD 5.3.3 | |
| 6.4.1.3.3. An administrator can successfully start the HylaFAX Software. All modems are reported as "Running and idle". | | SD 4.5 | |
| 6.4.1.4. Sendmail | | SD 4.2 | |
| 6.4.1.4.1. Ordinary pages submitted by facimile to (??) ###-#### appear in the unidentified fax router. | | SD 4.2.1 | |
| 6.4.1.4.2. Ordinary pages submitted by email to (??) datafax@_____ appear in the unidentified fax router. | | SD 4.2.2 | |
| 6.4.2.Windows Clients | | SD 2.4 | |
| 6.4.2.1. running a Windows operating system, ORG requires | | SD 2.4.1 | |
| 6.4.2.2. installation of X Windows display software, such as eXceed or Reflection X. | | SD 4.6 | |
| 6.5 System Accounts | | SD 4.1.1 | |
| 6.5.1."root" provides the ability to perform any function possible within the Solaris operating system | | SD 4.1.1.2 | |
| 6.5.2."datafax" is the login under which the DataFAX software is designed to run. DataFAX 3.7 can not be configured to operate under any other identity | | SD 4.1.1.4 | |
| 6.6 Group Identification | | SD 4.1.1.5 | |
| 6.6.1.All files created by DataFAX 3.7 belong to the group "studies". DataFAX software will not operate properly unless this group is defined within NIS. | | SD 4.1.1.5.1 | |
| 6.6.2.Ordinary users must belong to group "studies" in order to use the DataFAX Clinical Trials Management System. | | SD 4.1.1.5.2 | |
| 6.7 Environmental factors | | SD 3.2 | |

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| 6.7.1.The ambient temperature for all hardware must always remain between +10 degrees C to +35 degrees C (+50 degrees F to +90 degrees F). | | SD 3.2.1 | |
| 6.7.2.5 amps of 120v power for each server or desktop workstation | | SD 3.2.2 | |
| 6.7.3.Computer hardware must not be exposed to water | | SD 3.2.3 | |
| 6.7.4.Computer hardware must not be subject to excessive vibration | | SD 3.2.4 | |