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EMMES Data Management System Overview

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COMM-QA-056
EMMES DATA MANAGEMENT SYSTEM OVERVIEW

1.   Computer System/Program Development, QA, and Maintenance

The programs and systems that make up the EMMES software are well designed and documented and have been developed following EMMES guidelines and procedures. Software development and maintenance for data collection, data review and analysis, and database management for new and ongoing studies are performed on EMMES in-house network by its staff of full-time programmer analysts, system engineers, data managers, and statisticians. All system work performed is controlled and monitored by the IT management, whose role is to ensure that all projects have the appropriate level of technical support based on their need and schedules.

2.   Standard Operating Procedures

EMMES adheres to current regulations and guidelines, specifically in the areas of information security risks and data quality control for applications and software systems supporting clinical trials. EMMES has developed and continues to refine a set of internal Standard Operation Procedures (SOPs) that govern the design and development processes, including the required review and testing steps associated with the initial deployment of any computer-based system, as well as periodic upgrades to existing systems.

EMMES SOPs are introduced to new staff members to ensure they understand EMMES design, development and deployment style. These SOPs are reviewed periodically for adherence to the most current regulatory guidelines and employ the latest technologies available for computer systems supporting clinical trials. As part of EMMES internal software development quality control program, their Computer Systems Support Group has developed the following set of SOPs, working documents, and guidelines:

SOP#	Name
SOP-ADV-01.01 v1	Advantage Configuration, Testing, and Deployment
SOP-ADV-02.01 v1	Advantage Maintenance
SOP-ADV-03.01 v1	Advantage Manual Data Changes
SOP-VAL-02.01 v5	Corporate Software Development Life Cycle (SDLC)
SOP-VAL-03.01 v2	System Request Submission and Change Control
SOP-VAL-04.01 v2	Corporate User Acceptance Testing (UAT)
SOP-VAL-05.01 v1	Project-Level Software Customizations and Validation

3. Computer System and Program Validation

Specifically, as it relates to the critical issue of validation, EMMES performs exhaustive testing of all operational systems. Dedicated workstations and separate network test areas have been established permitting EMMES to emulate full systems in a controlled environment. Test data sets and test scenarios are created to mimic the standard and the non-standard activities of the centers and exercise the system to the fullest extent possible. Independent testing by the data managers, who are also responsible for certifying the new release and updating user documentation, follows unit testing by the programmers and formal testing by the QC group. All updates, regardless of their size, are peer-reviewed and documented prior to test initiation. After a systems initial deployment, there are two types of system updates. Product releases add new functionality to all projects that share the same platform while project releases implement or modify a study or protocol. For major upgrades in which new functionality is added, EMMES typically releases the software to a selected test site for beta testing prior to full system deployment. EMMES utilizes the same software validation processes for this project that have been used successfully for other EMMES studies. Documentation of the testing process, including test plans, tests scenarios, test data, and test results, are available for each system release.

4. Computer System Capacity

The EMMES Data Center is used to host the CCBB and Duke Stem Cell Laboratory System. Dedicated web, application and database servers provide the capacity and responsiveness necessary to service all EMMES supported projects. As new projects are added and as ongoing projects grow in size and usage, the capacity of the EMMES Data Center is systematically increased to ensure the highest levels performance are achieved. These routine upgrades occur on a scheduled basis and are typically transparent to the user community.

5. Back Up Procedures

The EMMES data and systems are backed up incrementally each day and the entire system is backed up weekly. Tapes generated at the end of each month are kept off-site and retained indefinitely. Incremental tape backups, performed at the end of each business day, contain files created or modified since the previous backup and are stored on-site in a fireproof safe. Daily backup tapes are rotated so that they overlap with weekly backups. All tapes are kept secure and private, subject to the non-disclosure, non-release provisions of EMMES contracts. Physical access to archived tapes is strictly limited.

6. REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	R. Bryant	Updated EMMES SOP table and document footer.

Signature Manifest

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