Cell Therapy Data Management

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Cell Therapy Data Management

- Introduction
- Database Design
  - How to get started?
  - Microsoft Access
  - Security Considerations
- Demo/Example
  - DocTrak(1.1.2)

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Database Design

- How do I get started?
  - Take a look around!
  - Consult your staff
  - Research your software options
    - Microsoft Office
    - StemSoft
    - ChemSW
  - Document development process!

Database Design

- Microsoft Access
  - UMMC Cell Therapy Database systems are designed using Entity Relationship (E-R) modeling, Normalization and Verification techniques, which are implemented in a relational database management system (RDBMS), MS Access 2000.

Database Design

- Microsoft Access
  - Advantages
    - Allows for streamlined relational data-mining vs spreadsheet-like data storage
    - Very User-Friendly GUI
    - Can be secured to a level compliant with 21CFR11
    - Software is most likely already available
      - Comes bundled with MS Office Professional
    - Very abundant knowledge base for referencing
    - Built in reporting capability

Database Design

- Microsoft Access
  - Disadvantages
    - Requires a "Developer" or "Power User"
    - No Support Contracts
    - The database does not have a continuous transaction log
    - Scalability
      - Not a problem unless you have terrabytes of data

Security Considerations

- Security should be a "Multi-Level" approach
  - Building
    - Access Card
  - Operating System / Server
    - Username / password required
    - Complex passwords required
    - Security Lockouts
    - Designated Data Directory
  - Access
    - Username / Password required
    - Password ageing, length requirement, etc.
- Work with your IS department to establish criteria that is appropriate for your needs!!

Cell Therapy Databases

- AlloNK(1.4)
- ARC(2.2.3)
- AssayMgr(1.0)
- CellTherapy(1.4)
- CFU(1.0)
- Coriell(1.3.1)
- CTDev(1.4)
- DCDev(1.2)
- LMI(2.0)
- TimeStudy(1.1)
- LabelMaker(1.1)
- DocTrak(1.1.2)

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Demonstration (UMMC)

- DocTrak(1.1.2)
  - Tracks critical documents (SOPs, Manuals, etc…)
  - Tracks employee training

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CAGT Databases

- Developed In House
  - SOPTRAK
  - CryoTRAK (clinical and research)
  - QAQCTRAK
  - LogiTRAK
  - Patient Label Database
  - Coulter Database
  - Environmental Monitoring
  - ShipRec
  - invyTrack

Database Design (CAGT)

- Microsoft Access
  - BCM-CAGT database systems are designed much like those at UMMC utilizing a source code control program for software version control and combination of Microsoft SQL Server and Access 2000 as the back end databases.

Database Design Goals (CAGT)

- **Goals of Database Development and Design**
  - Simplicity
    - All of the databases at CAGT have been developed in order to create an easy, reproducible, method to achieve the same result of an overly complex process.
  - Usability
    - Due to the diverse backgrounds of our staff we needed applications that would be easy to use and understand.
  - Speed

Database Design Process (CAGT)

- **Requirements Gathering (informal)**
  - Review of the 'business processes'
  - Determine the eventual output that users will want. (reports)
- **Design of the Data Model (tables)**
  - Acts as the foundation on which to build the application.
  - A solid data model will drive the development process
- **Develop the Prototype Application**
- **Review and Testing**
  - Users review and test the prototype
  - Typically discover some missed requirements
- **Application Redesign**
  - Mostly Minor updates and feature requests
- **Secondary Review**
- **Implementation**

Demonstration (CAGT)

- SOPTRAK(3.0)
  - Tracks critical documents (SOPs, Manuals, etc…)
  - Tracks employee training

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Thanks for listening!

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21CFR11 Checklist

Key: C = Conforms to Requirement, NC = Non-Conformance, N/A = Not Applicable, IP = In Process

Requirements	21 CFR Part 11 Requirements	Status	Explanation
	SUB-PART B: ELECTRONIC RECORDS		
11.10 General	**Closed System**		
11.10a	Validation - The computerized system shall be validated to ensure accuracy reliability, consistent intended performance and the ability to discern invalid or altered records		
11.10b	Ability to generate accurate complete copies in both human and electronic form		
11.10c	Protection of records to enable their accurate and ready retrieval throughout the record retention period		
11.10d	Limiting access to authorized individuals		
11.10e	**Audit Trails**		
	Be secure		
	Be computer generated		
	Be time and date stamped		
	Independently record the date/time of operator entries and actions that….		
	create electronic records		
	modify electronic records		
	delete electronic records		
11.10f	Use of operational system checks to enforce permitted sequencing of steps and events as appropriate		
11.10g	Authority checks shall ensure that only authorized individuals can…		
	use the system		
	electronically sign a record		
	access the operation or computer system input of output system		
	alter a record		
	perform the operation at hand		
11.10h	Device or teminal checks shall determine validity of the source of input or operation		
11.10i	Personnel Qualifications - Determination that the follow ing persons have the education, training, and experience to perform their assigned tasks:		
	Developer(s) of electronic record/signature systems		
	Maintainer(s) of electronic record/signature systems		
	User(s) of electronic records/signature systems		

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Requirements	21 CFR Part 11 Requirements	Status	Explanation
11.10j	**Documentation Controls** - Establishment and use of appropriate controls over written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures to deter record and signature falsification.		
11.10k	Use of appropriate controls over systems documentation:		
	(1) Adequate controls over the distribution of, access to and use of documentation for systems operation		
	(2) Revision and change control procedures to maintain an audit trail that documents time sequenced development and modification of systems documentation.		
11.3	Controls for Open Systems		
11.5	**Signature Manifestations**		
11.50a	Signed electronic signatures shall contain information associated with the signing that clearly indicates the following:		
11.50a cont.	(1) The printed name of the signer		
	(2) The date and time when the signature was executed		
	(3) The meaning associated with the signature		
11.50b	All items included in 11.50a(1), 11.50a(2), 11.50a(3) above shall be:		
	Subject to the same controls as for electronic records		
	Included as part of any human readable for of the electronic record (such as electronic display and/or printout or report)		
11.7	**Signature / Record Linking** - Electronic signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by o		
	SUB-PART C: ELECTRONIC SIGNATURES		
11.1	General Requirements		
11.100a	Each signature shall be unique to one individual and shall not be reused by, or reassigned to anyone else		
11.100b	The identity of the individual shall be verified prior to the organization establishing, assigning, certifying, or otherwise sanctioning that individual's electronic signature		
11.100c	Certification of electronic signatures to the FDA		
11.2	**Electronic Signatures and Controls**		
11.200a	Electronic signatures not based on biometrics shall:		
	(1) Employ at least two distinct identification components such as an identification code and password		

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Requirements	21 CFR Part 11 Requirements	Status	Explanation
	(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual		
	(ii) When an individual executes one or more signings not performed during a single continuous period of controlled system access, each signing shall be executed using all of the electronic signature components		
	(2) Be used only by their genuine owners		
	(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals		
11.200b	Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners		
11.3	**Controls for Identification Codes and Passwords** - Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity		
11.300a	Maintaining the uniqueness of each combine identification code and password, such that no two individuals have the same combination of identification code and password		
11.300b	Ensure that identification code and password issuances are periodically checked, recalled, or revised (to cover such events as password aging)		
	Electronically deauthorize passwords that have been lost, stolen or potentially compromised		
	Issue temporary or permanent replacements using suitable, rigorous controls		
11.300d	Detect any attempt at unauthorized use of identification code and passwords. Report any such attempt to to the Network Administrator and as appropriate to the organizational management.		
11.300e	Initial and periodic testing of devices that bear and generate identification or password information		

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