Considerations For Using Electronic Medical Records (EMR) In Clinical Trials

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The views expressed in this presentation are my own and does not represent the views of GlaxoSmithKline.
Evolution of the Clinical Trial Data Collection

Verification

EMR

eCRF

Clinical Database
Why the emphasis on EMR?
USA: Hospital data breach patients to receive settlement – March 2016


China: China investigating data leak and swindling of HIV patients – July 2016
Considerations for using EMR in clinical trials
1. Assessing the risks of EMR
Risks of using EMR in clinical trials

Root causes:

• Complex and diverse data standards used by the institutions
• Varying EMR systems across institutions and countries
• Diverse ownership of data
• Inherent inter-operability issues in the EMR system
• Lapse in security controls and discipline by EMR users
• Unknown process of validation and maintenance of EMR
• Limited training on required standards of EMR
2. Training on EMR required standards
Regulations and Standards

- Good Clinical Practice
- 21 CFR Part 11
- Industry Guidance
- Laws
GCP 5.5.3: Requirements for Computer Systems

5.5.3 When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

(a) Ensure and document that the electronic data processing system(s) conforms to the sponsor’s established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).

(b) Maintains SOPs for using these systems.

(c) Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail).

(d) Maintain a security system that prevents unauthorized access to the data.

(e) Maintain a list of the individuals who are authorized to make data changes (see 4.1.5 and 4.9.3).

(f) Maintain adequate backup of the data.

(g) Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing).

21 CFR Part 11

- Technical and procedures requirements
- Industry’s gold standard on principles of EMR System

Industry Guidance


Laws

- Privacy Act
- Personal Data Protection Act
- Health Record Act
3. Evaluating the EMR
Characteristics of EMR

An Electronic Medical Record is:

- A computerised medical record created by a healthcare provider
- Serves as a Health Information System
- Electronic record that is created, stored, retrieved and modifiable
- Usually stand alone
- Access is controlled and requires login details
- Use of Electronic Signatures

∴ A Closed System
Part 11 – Electronic Records: Controls for Closed System

Authenticity

Data Integrity

Confidentiality
4. Alternatives to EMR
Decision on EMR

PASS

FAIL

FAIL
Creating Certified Hard Copies: Process

- A hospital SOP (or equivalent documentation) on:
  - The need for maintaining hard copies of electronic documents
  - The methods for certification of hard copies as true and complete copies of electronic documents

- Requirements for the certification process*:
  1. Qualified individual
  2. A signature of the individual making the photocopy/printing
  3. The date the copy was made
  4. A written statement attesting to the accuracy and completeness of the copy
  * These requirements must be traceable to all pages copied (e.g. Pg 1 – 20)

- CRAs should at least be able to view/review the study records in EMR to check for accuracy and completeness of the hard copies made
Conclusions

- It is important to ensure data integrity and quality of clinical trials:
  - Risk assessment of EMR
  - Training on required standards
  - Evaluation of the EMR
  - Alternatives to EMR
Thank You

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