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

Combined CRCS-CRP Forum (Aug 2016)

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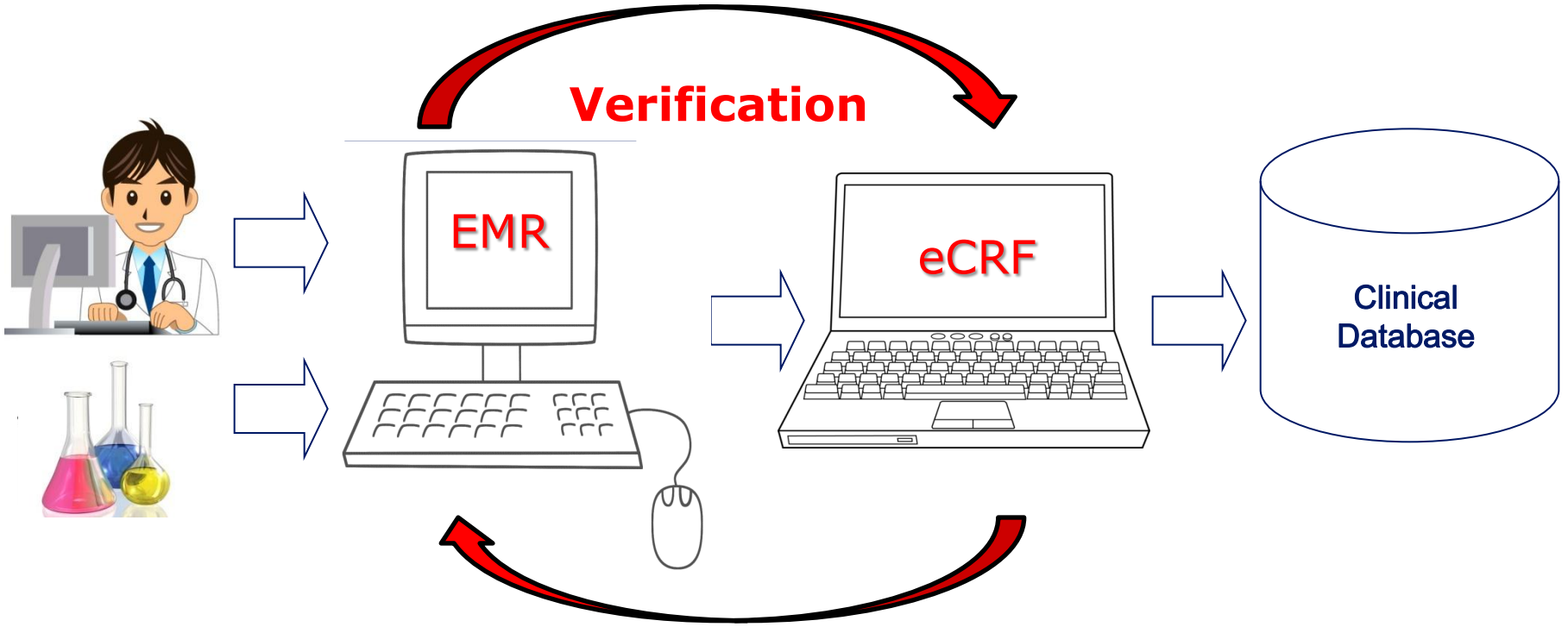
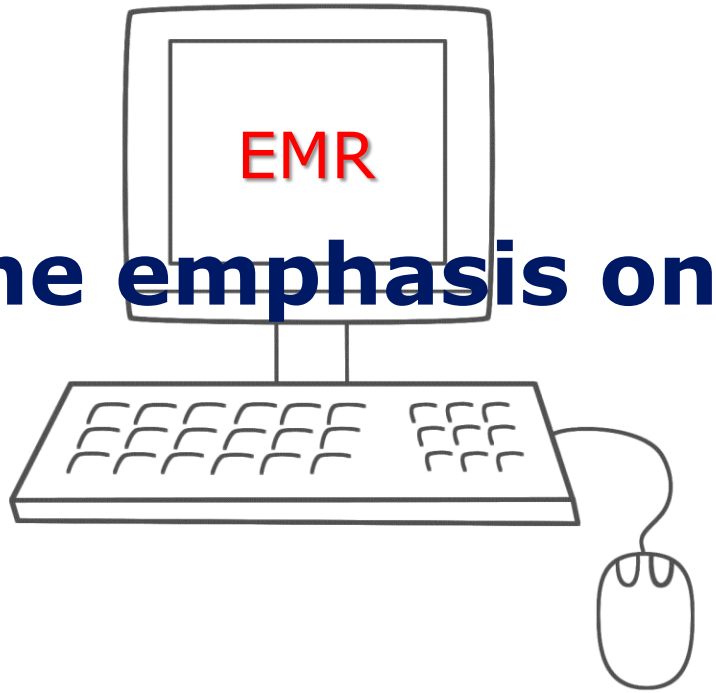
The views expressed in this presentation are my own and does not represent the views of GlaxoSmithKline.

Evolution of the Clinical Trial Data Collection



Why the emphasis on EMR?



DAILY NEWS

USA: Hospital data breach patients to receive settlement – March 2016

Singapore: Uni. Professor fired for data falsification – July 2016

China: China investigating data leak and swindling of HIV patients – July 2016


Construction
Database
Reliability
Assuring
Stability
Records
Accuracy
Facts
Data
Corporate
Maintaining
Transfers
Integrity
Computing
Consistency
Flow
Life Cycle
Indicators
Institution
Archiving
Trustworthy

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).

ICH Harmonised Tripartite Guideline. 1996. Guideline for Good Clinical Practice. pp21.

21 CFR Part 11

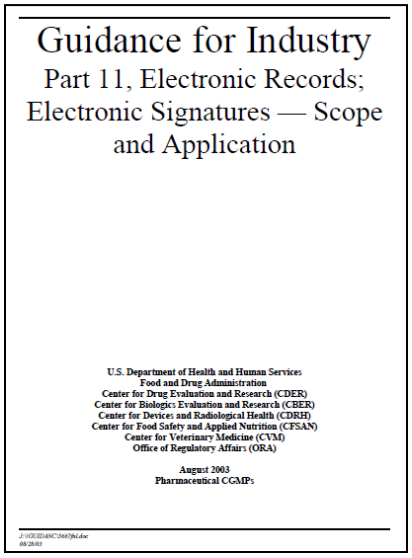
Part 11: Electronic Records and Electronic Signatures (1997)

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

US Food and Drug Administration. Code of Federal Regulations Title 21. FDA. [Online]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. [Jul 2016].

Industry Guidance

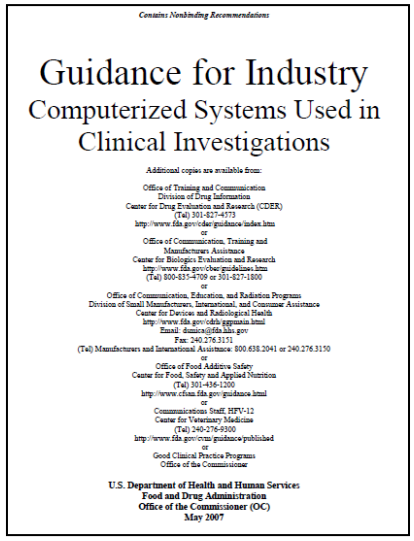
1. Part 11, Electronic Records; Electronic Signatures – Scope and Application (2003)
2. Computerized System Used In Clinical Investigations (2004)
3. Electronic Source Data in Clinical Investigations (2013)
4. Use of Electronic Health Record Data in Clinical Investigations – Draft (2016) – NEW


Guidance for Industry

Part 11, Electronic Records; Electronic Signatures — Scope and Application

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
Office of Regulatory Affairs (ORA)

August 2003
Pharmaceutical CGMPs


Contains Nonbinding Recommendations

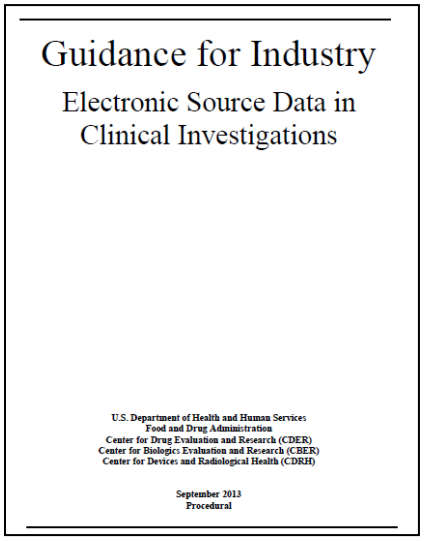
Guidance for Industry

Computerized Systems Used in Clinical Investigations

Additional copies are available from:

Office of Training and Communication
Division of Drug Information
Center for Drug Evaluation and Research (CDER)
(Tel) 301-827-4573
http://www.fda.gov/cder/guidance/index.htm
or
Office of Communication, Training and Manufacturers Assistance
Center for Biologics Evaluation and Research
http://www.fda.gov/cber/guidelines.htm
(Tel) 800-835-4709 or 301-827-1800
or
Office of Communication, Education, and Radiation Programs
Division of Small Manufacturers, International, and Consumer Assistance
Center for Devices and Radiological Health
http://www.fda.gov/cdrh/ggpmain.html
Email: dsmica@fda.hhs.gov
Fax: 240.276.3151
(Tel) Manufacturers and International Assistance: 800.638.2041 or 240.276.3150
or
Office of Food Additive Safety
Center for Food, Safety and Applied Nutrition
(Tel) 301-436-1200
http://www.cfsan.fda.gov/guidance.html
or
Communications Staff, HFV-12
Center for Veterinary Medicine
(Tel) 240-276-9300
http://www.fda.gov/cvm/guidance/published
or
Good Clinical Practice Programs
Office of the Commissioner

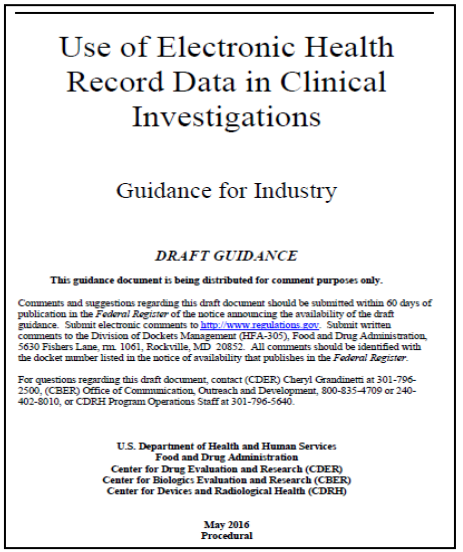
U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
May 2007


Guidance for Industry

Electronic Source Data in Clinical Investigations

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

September 2013
Procedural


Use of Electronic Health Record Data in Clinical Investigations

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Cheryl Grandinetti at 301-796-2500, (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010, or CDRH Program Operations Staff at 301-796-5640.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

May 2016
Procedural

US Food and Drug Administration. Code of Federal Regulations Title 21. FDA. [Online]. Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. [Jul 2016].

Laws

- Privacy Act
- Personal Data Protection Act
- Health Record Act

3. Evaluating the EMR

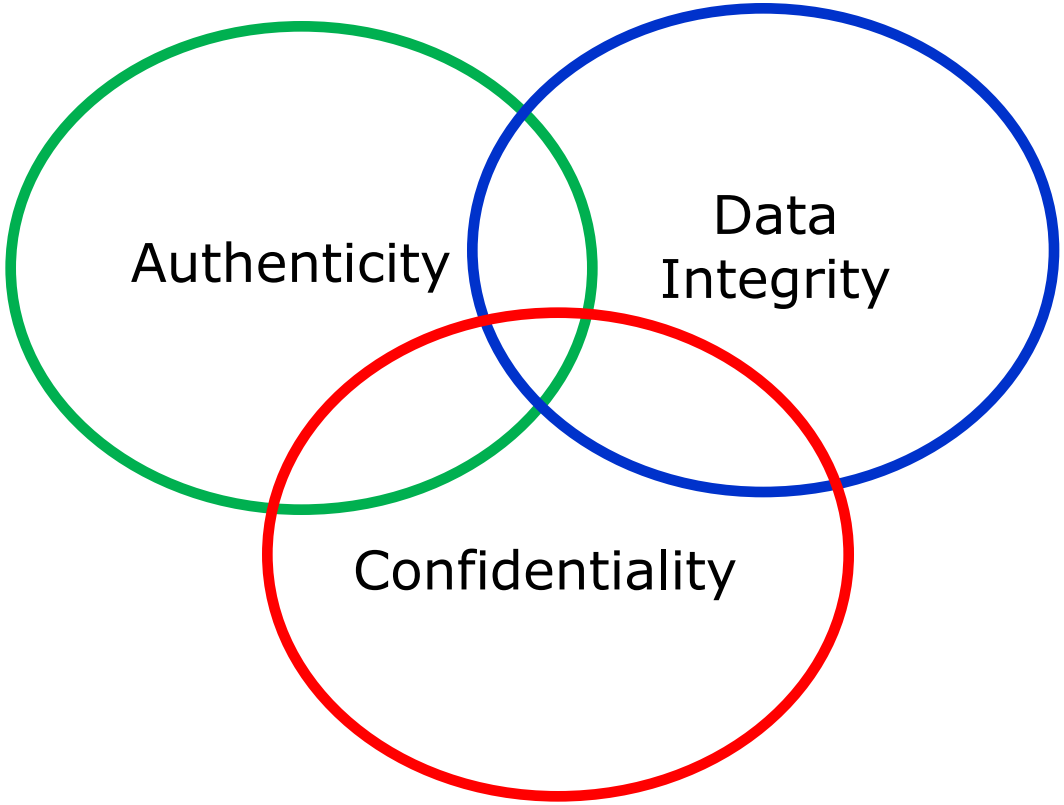
Characteristics of EMR

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

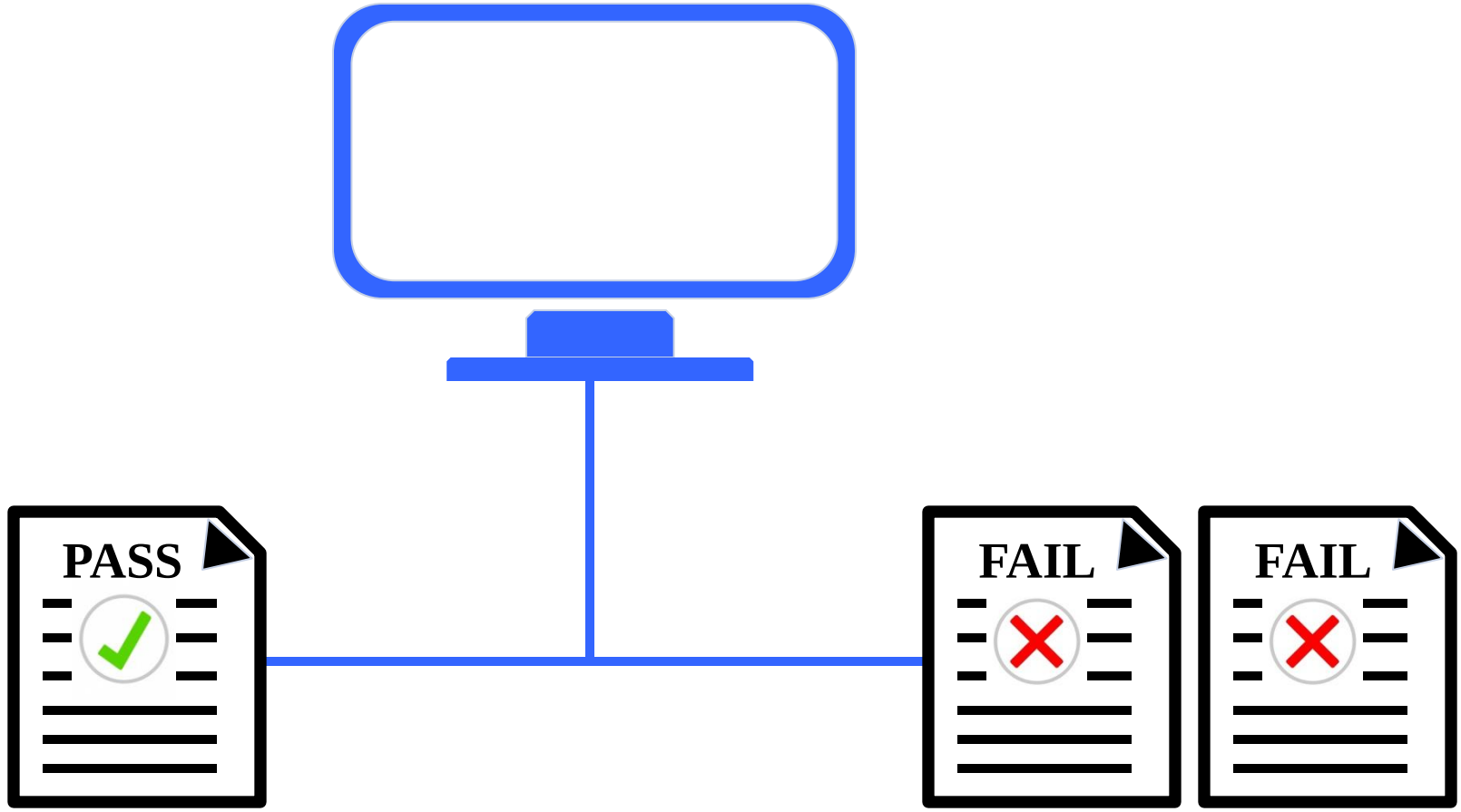
∴ **A Closed System**

Part 11 – Electronic Records: Controls for Closed System



4. Alternatives to EMR

Decision on EMR



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

For questions, further discussions, contact:

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