Bridging the Chasm

A Paradigm Shift in Source Documentation for Clinical Trials

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Topics

• Source Data
• Pathway to Electronic
• Data Capture
• Challenges
• Q & A
How many of you use EHR in your clinic?
How many are involved in clinical trials?
How many use EHR for data capture?

HELP!

FDA

CLINIC

SPONSOR

The SPONSOR wants it that way
The FDA regulations say . . . .
In reality, this is what WE have to work with

How does it all fit together?
Why eSource?

Final Guidance on Electronic Source Data in Clinical Investigations

Promoting eSource Data Capture

Guidance for Industry

Electronic source data in clinical investigations

...promotes capturing source data in electronic form...

[assists] in ensuring the reliability, quality, integrity, and traceability of electronic source data.

www.fda.gov

FDA Compliance and Public Health

CDRH

Leonard Saeks, Office of Medical Policy
Ron Hafemstein, Office of Strategic Programs

CBER

Chaco Kemen, Bioresearch Branch

CDRH

TFA Webinar

30 January 2014

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4/8/2014

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**Source Data**

All information in original (or certified copies) records of clinical findings, observations or other activities in a clinical investigation. (p.2, source: 21 CFR 312.62(b))

Access to source data is critical to the review and inspection of the study...

...So Know Your Source!

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**Source Data should be...**

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate


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**ALCOA**

- Attributable
  - Who entered the data?
  - Audit trail
- Legible
  - Electronic data & metadata in human-readable form
  - Modifications should not obscure prior entries
  - Audit trail
**ALCOA**

- **Contemporaneous**
  - The time of data entry into the eCRF should be close proximity to the time of clinical activity.
  - Audit trail!

- **Original**
  - Earliest record
  - Changes and/or corrections should not obscure prior entries.
  - Audit trail!

**eSource Data Capture:** Key Definitions (1)
- **eCRF**
  - Generally, an eCRF is an EDC system used by a clinical site to collect data on study subjects.

  - For this guidance, the eCRF is not a concept but rather it is viewed as clinical system, i.e., an electronic record.

  - The capture, review, management, analysis, and reporting on a clinical study does not occur in any single system, such as the eCRF.
**ELECTRONIC HYBRID**

- EHR
- DIGITAL IMAGES
- ELECTRONIC CRFs
- PAPER REPORTS

(Manual entry of data to eCRF)

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**ELECTRONIC**

- ELECTRONIC REPORTS
- DIGITAL IMAGES
- EHR
- eCRF

(Manual entry of data to eCRF)

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**ELECTRONIC TRANSFER**

- DIRECT TRANSFER OF SOURCE DATA TO SPONSOR eCRF
**Data Capture: Source Data Capture**

3. Automatic Transmission of Data from Devices or Instruments Directly to the eCRF
   - No paper required
   - Improved data quality and availability
   - Documentation of Source is important (e.g., interventional data management process)
   - Best Case!

4. Transmission of Data from PRO Instruments to the eCRF
   - No paper required
   - Improved data quality and availability
   - Documentation of Source is important (e.g., interventional data management process)
   - Best Case!

5. Direct Transmission of Data from the Electronic Health Record to the eCRF
   - Virtually, no paper required.
   - Improved data quality and availability.
   - Documentation of Source is important (e.g., interventional data process).
   - EHRs are not regulated by FDA.
   - FDA does not intend to assess compliance of EHRs with 21 CFR part 11.
   - Best Case!

**Computerized Systems Used in Clinical Investigations**

Regardless of the jurisdiction of the regulatory authority (in some cases none), there should be adequate controls to ensure confidence in the reliability, quality, and integrity of the source data.
Challenges

- EHR as source
  - Histories
  - Medications
  - Protocol specific examinations
  - Custom EHR Forms
  - Sponsor /monitor access
  - Electronic Signatures

Challenges

- Previous medical /hospital records
  - Obtaining records
  - Ambiguous data
  - Current information reported by subject
So Where Does That Leave Us?

CONUNDRUM!

QUESTIONS?
RESOURCES

   http://www.fda.gov/Training/GuidanceWebinars/ucm382198.htm

FDA Guidance for Industry, Electronic Source Data in Clinical Investigations_September 2013


Association of Clinical Research Personnel, The Monitor, August 2013_Fortunes and Misfortunes
   http://www.acrpnet.org/MainMenuCategory/Resources/TheMonitor/August-2013.aspx


Websites are current as of the date of this presentation
Fortunes and Misfortunes
Assorted Reflections on the Use of Regulatory Affairs

In 7th grade, I was competing in the final match to be the New Orleans On-Sets Novice Tournament Champion (“On-Sets” being an academic game based on mathematical set-theory designed for, and played by, nerds like me). In this rookie year of mine, I had made it all the way to the final match (even beating those who had been playing for several years) without knowing a specific and obscure “optional” rule that happened to be in effect at this tournament. I learned about this rule during this final championship match, when my opponent (whose name I still remember to this day) utilized it much to my disadvantage.

Confused during play, I called the moderator over, but the moderator backed my opponent and thus, before I really got to assimilate this newly learned rule into my offensive and defensive strategy, I lost the match. That very much smaller “Second Place” trophy (that I still have today) greatly reinforced to me that knowledge of the rules is crucial not just for understanding the field of play in order to stop from being penalized, but is also essential for success. To this day, I still credit my loss of the really big trophy to my not knowing all the rules and assimilating them into both an offensive and defensive strategy.

What Might Have Been and Too-Rosy Outlooks

Fast forward to today, and in my time in the clinical research industry, I have seen good medical products and services that will never make it to patients and providers. The unfortunate demise of these initiatives often has nothing to do with safety and efficacy, but with bad business plans. One key component to that business plan making or breaking the advancement of medicine is a solid regulatory affairs strategy.

Please note that I put my money (and other people’s money) where my mouth is on this. I often interact with private equity companies who invite me to sit in on deals regarding products or services in development with the potential to improve medical care.

Like being on the television show “Shark Tank” (similar to “Dragon’s Den” in non-U.S. countries), I sit and listen to the pitch from the entrepreneurs or inventors with an eager ear for even a hint of a regulatory affairs strategy. While the entrepreneurs and inventors are passionate about the product (and rightly so in many cases), they are often deluded into thinking that all they need is for everyone to hear about their product/
service and the practice of medicine will change.

All too often I hear, “We don’t have to worry about this or that with the Food and Drug Administration because blah, blah, blah.” Sometimes they’re pretty close to being right, but sometimes they are dead wrong and, to quote former U.S. heavyweight boxing champion Mike Tyson, “Everyone has a plan until they’re punched in the mouth.”

Essentially, good plans get funded and bad plans (despite how good the dream is] don’t.

### Core Rules, with Variations

We can see how the concept of regulatory affairs works in other walks of life—such as surrounding the game Monopoly. Over the past 80 years, even under the countless regional-, hobby-, 

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**A Quick Bit About EHRs and FDA’s Part 11**

**by David M. Vulcano, LCSW, MBA, CIP, RAC, and Susan M. Radtke, RN, MA, CCRP**

*Editor’s Note: This article has been reviewed by subject matter experts at the U.S. Food and Drug Administration (FDA).*

As we surge forward into the age of electronic health records (EHRs), we continue to create and face new challenges in all aspects of healthcare, including the clinical research component. Setting aside the complexities of implementing such systems in our healthcare delivery settings alone (including the simple issues, i.e., getting our word processors to stop autocorrecting “EHR” into “HER”), we in the clinical research industry are faced with additional operational challenges.

These challenges include balancing privacy and security issues with monitoring access and many other things, but one of the most frustrating challenges for sites is dealing with the varying interpretations on how FDA’s Part 11 in the *Code of Federal Regulations* applies to EHRs. As in other aspects of life, well-motivated traditions are being applied in inappropriate ways and in domains for which they were never designed. This is certainly the case of EHRs and Part 11.

There are only a handful of essential documents concerning Part 11, specifically the regulation itself and its two primary guidance documents on “Electronic Records; Electronic Signatures—Scope and Application” and “Computerized Systems Used in Clinical Investigations.” There is also a guidance still under development entitled “Electronic Source Data in Clinical Investigations” and debated hotly enough that the FDA published a second draft for comments.

These documents have been used and abused by those, for whatever reason, trying to justify that Part 11 applies to EHRs. This is mostly fueled by the fact that interpretations are all over the map on this issue, primarily because none of these documents offer any decision trees, flowcharts, or other clear and unambiguous answer to the question as to *if and when* an EHR system has to be Part 11 compliant.

Many people have confused portions of Part 11 compliance (or desirable characteristics of Part 11) as “full Part 11 compliance.” This has led to many sponsors requiring full Part 11 compliance via site contracts; the creation of lengthy questionnaires and other “EHR Mini Audits” and “Part 11 Gap Analysis”; and other onerous requests. Even EHR vendors have picked up on this and will make claims that their systems are Part 11 compliant, whether they realize or not that it is impossible to buy a fully compliant system “out of the box.”

Unfortunately, our hyper-paranoid industry is rapidly making this issue the next big black hole we all have to throw lots of money and time into.

What is needed is clear and unambiguous guidance from the FDA available to those who do not attend the conferences where representatives of the agency have addressed this topic verbally. Interestingly, the FDA has already issued such a clear and unambiguous statement, but is it simply not widely known because of the way it was issued—as correspondence through the Office of Good Clinical Practices (OGCP).

The correspondence was a response to an inquiry by ACRP member and coauthor of this message Susan Radtke who, in the face of receiving more and more onerous requests from sponsors/contract research organizations (CROs) dictating that EHRs be Part 11 compliant, asked OGCP to validate, in writing, the FDA’s statements to the contrary during the audiences at the ACRP Global Conferences. The key point of FDA’s response is captured in its opening paragraph:
and job-themed variations, there remains little difference in the core rules. [Personal note: My family has four, yes four different themes of the game, including the “Clinical Trials” version put out by a subject recruitment company several years ago.]

Regardless of the version you are playing, Monopoly’s rules can also be supplemented by self-regulated house rules (such as putting $500 on Free Parking, an option I personally loathe but agree to since I wish to be thought of as a good dad and husband). Also note that, through campaigning and market forces, the basic rules and infrastructure had minor changes, such as by the introduction of the third “Speed Die” as an option in 2007 to accelerate game play (noting that the Speed Die is required in official tournaments), and with things like additional note-to-files certifying that there was no missing information between visits, principal investigators having to initial and date each page of the printout of the entire medical record and certifying it is accurate, and other dubious expectations we hear are going on in our evolving, risk-based, yet hyper-paranoid world.

The main point about electronic medical records (EMRs) is that they are developed and maintained by the “institution” for general patient medical records. As such, they are a part of the practice of medicine and FDA does not regulate the practice of medicine. [The Department of Health and Human Services] does have an office which is specifically working on a national system for electronic health records—the Office of National Coordinator for Health Information Technology, referred to simply as ONC. [They have a website at www.healthit.gov if you are interested in them.] Hopefully the system(s) they help develop will have the major elements found in Part 11 that are pertinent to the integrity of data. [Emphasis Added] However, since FDA does not regulate the practice of medicine, we cannot dictate the ground rules for EMRs, even when they hold data relevant to clinical studies. Right now that is mainly information pertinent to inclusion/exclusion criteria and/or in-patient information about a study subject. It is expected that such information will be useable as collected and maintained in the institution’s EMRs. [Emphasis Added] We do not expect study sites to provide validation of these systems or any evidence relevant to Part 11. We only ask that FDA investigators be given the ability to review any information in them that is source data for the study in question.5

Although OGCP responses are not regulation or officially published guidance, this is the only written document from the FDA directly answering the direct question.

Based on anecdotal experience and comments, providing copies of this correspondence has helped dispel the myth many sponsors/CROs have that EHRs must be evaluated for Part 11 compliance, but many others still ask, as do different teams within the same sponsor/CRO. Perhaps future guidance or directions from the FDA or ONC will alter the course of this discussion, but until then, let’s not create additional burdens to ourselves.

We need to stand in the treestops and shout aloud for all in our industry to have clarity on this issue. It is hoped that this FDA OGCP informal communication can be more widely distributed and used to alleviate a lot of confusion, so that resources may be better used elsewhere.

Hopefully, this issue can be resolved and we can move to address the tangential requests, such as requiring printouts of the entire medical record with things like additional note-to-files certifying that there was no missing information between visits, principal investigators having to initial and date each page of the printout of the entire medical record and certifying it is accurate, and other dubious expectations we hear are going on in our evolving, risk-based, yet hyper-paranoid world.

References
5. The complete communication associated with this inquiry can be found and downloaded from www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliesToInquiriesToFDAonGoodClinicalPractice/default.htm. The document is found under the heading “Computer Questions” in the 2011 file and titled “21 CFR Part 11 Compliance.pdf.”

David M. Vulcano, LCSW, MBA, CIP, RAC (see main message for biographical statement)

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by the replacement of the Iron token with a Cat, effective this year after a public vote (although my family did unanimously vote for the Iron as the one to remove, we unanimously voted for the Robot as its replacement).

One key component to that business plan making or breaking the advancement of medicine is a solid regulatory affairs strategy.

You should easily see several parallels to our regulatory affairs concepts here (noting that, unlike in the real world, in Monopoly sometimes going to jail is a good strategy).

What’s in Store

In this issue, you will hopefully see examples of the full cycle of regulatory affairs, as well as a bit about regulatory affairs as a profession itself. This includes a little on how regulations affect us in terms of privacy and drug/device/biologic-specific issues; and on how to embrace the opportunities and parameters of regulations in a more sophisticated way, such as in risk-based monitoring. There are also examples of how advocacy in regulatory affairs contributes to improving what we do and regulations themselves.

I cannot emphasize enough that final point about the importance of advocacy in regulatory affairs, and not just viewing regulatory affairs as the department or person existing to protect a company’s “Chief Jailable Officers.” Back in 1998, the editor of the Washington Post’s “Science on the Ethical Frontier” series astutely stated, “as science speeds ahead, it often pushes the edges of society’s readiness to cope with consequences. Increasingly, research creates possibilities before the accompanying ethical, social, and legal ramifications have been resolved.”

With this thought in mind, we should note that as clinical researchers challenge the status quo of evidence-based medicine, they also, often unknowingly, pose challenges to the status quo of healthcare regulations and ethics. This is where regulatory affairs advocacy is so important, and you can see from the included article how ACRP/APCR is growing to be a respected voice in that process.

The Ropes Theme on the Cover

As to the cover of this issue, we settled on the ropes theme, as I believe this is an extremely appropriate allegory. Since prehistoric times, ropes have been used, among many other things, for protecting, restraining, rescuing, moving, supporting, exploring, building, destroying, competing, communicating, playing, entertaining, beautifying, and much more. When ropes work together among themselves and with other tools, the results are exponentially better. When ropes do not work together among themselves or with other tools, they may create knots or other hindrances toward the mission.

The concept of “rope” remains a constant over time, yet the makeup of rope has evolved. One strand is not as strong as the combined rope. Rope also needs to be replaced (ask sailors if they throw away rope that looks perfectly good to the naked eye), updated with the times and technology (ask rock climbers if they would switch out today’s dynamic kernmantle for twisted water reed fibers), and its source must be trusted (ask rappellers if they buy their rope from eBay).

Words of Wisdom

So with my very small “Second Place” trophy and four versions of Monopoly at home (sans Robot token), I leave you with my final quote describing my vision for this issue (and life)—one of my all-time favorites—from actor John Wayne, who stated, “Life’s tough, but it’s tougher when you’re stupid.”

As clinical researchers challenge the status quo of evidence-based medicine, they also, often unknowingly, pose challenges to the status quo of healthcare regulations and ethics.

You will have a very tough career life if you don’t have an understanding of and appreciation for regulatory affairs. Instead of viewing the realm of regulatory affairs as an obstacle, learn how it can not only be a protector, but also an enabler for your success, because your success contributes to the desired benefit of the populations we are privileged to serve. ACRP

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Clinical Study Data, Electronic Medical Records, and Privacy

By Jeanne M. Mattern

The Affordable Care Act requires all U.S. healthcare providers to digitize all patient records by 2014 and place them in electronic medical records (EMRs). This requirement is a boon to clinical research since it will, in theory, make all patient data (including certain clinical research data) accessible in a meaningful (structured and useable) form across the entire healthcare system. Clinical researchers can use this data to identify and screen potential research subjects, as well as to obtain health data during a study, e.g., about adverse events. This article will discuss privacy and other issues involved in making clinical research data accessible through EMRs.

An EMR can include data on all aspects of a patient’s health history, including diagnoses (including STDs), disabilities, laboratory test results, prescriptions, treatments, progress notes, social/family history, sexual history, substance abuse and mental illness. Most patients thus prefer their EMR data to remain private. Since EMR records are often linked with a person’s Social Security number, this data, in the wrong hands, could easily affect a person’s health insurance availability and rates, credit, and educational and employment standing and opportunities. Further, medical records can include intimate details about a person’s life and relationships that, if disclosed, could disrupt personal relationships or result in humiliation. As a result, healthcare organizations are required to protect the privacy of health information by multiple federal (and state) laws, including HIPAA, CFR 21 Part 11, ERISA, GCP, the Freedom of Information Act, the Gramm-Leach-Bliley Act, CLIA and others.

Just as data from clinical care can be useful for clinical research, data from clinical research can be useful for clinical care, and subject to the same privacy concerns. For example, study data that should be included in the EMR includes the following:

- Information about the patient’s clinical study participation
- Clinically significant data, e.g., diagnosis, treatment, laboratory and imaging results
- Clinical data initially recorded in the EMR (i.e., not specifically collected for research purposes)

Clinicians need access to their patients’ clinical research data to provide appropriate treatment. They also need this information to determine whether a patient is a candidate for a clinical study. They need data from past clinical studies and information about current clinical studies. The obvious place to store this information is in the EMR, which is a repository of health-related information that provides tools for sharing clinically relevant data. Understanding how research data fits into the EMR helps clarify the role of research in the larger healthcare context.

Institutions should have clear policies and procedures on including study data in the EMR. The institutional review board (IRB) or privacy board should help create the policies and procedures, and review their application to specific instances. Prior to conducting a study, the study team should review the protocol for potential information of clinical significance and determine whether and how it will be recorded in the EMR.
Factors to Consider
Determining what study information should be recorded in a patient’s EMR depends on multiple factors:

Studies and Patients Differ
At one extreme is the patient who participates in a very safe study that collects biospecimens to establish baseline data for a diagnostic device. At the other extreme is the advanced cancer patient who participates in a long series of clinical studies of various treatment combinations, with extensive adverse events. The privacy concerns of these patients also varies and in unpredictable ways. For example, the diagnostic device study might be for HIV/AIDS patients, some of whom care a great deal about privacy, while the advanced cancer patient might not care at all who knows about his condition. The data that can and should be recorded in the EMR for each patient thus also differs. However, if it is impractical to tailor the system for each patient, a general policy for the study is required.

EMR Systems Differ
The security and privacy of patient data within EMRs can vary. An EMR system consists of the EMR software plus the policies and procedures for its use. For example, institutions can implement different rules for who can access which patient data under which circumstances. The rules can be enforced by the software or just policies and procedures, to varying degrees of reliability, depending on institutional culture and training programs.

One option is to create a secure section of the EMR for recording some or all clinical study information. This section might require special permission to access or just present a warning that it contains confidential or proprietary clinical study information. Data captured in accordance with what is required pursuant to the protocol should be noted in the EMR with a summary of results.

Data Differs
Not all clinical research data belongs in an EMR. For example, data from an experimental or unvalidated lab test could mislead clinicians. Non-standard or partial data can mislead. Genetic data, in particular, is often speculative and, thus, inappropriate for use by clinicians who are not expert in its interpretation.

The “golden rule” for including data in an EMR is whether it will benefit the patient, especially his or her safety. This rule can conflict with contractual obligations to a study sponsor. The sponsor might be concerned about potential liability if the use of study data contributes to an injury to the patient. Or, it might be developing a new lab test that requires nondisclosure to protect its intellectual property. Such concerns should be addressed with the study sponsor and might require special arrangements.

“Incidental findings” occur when data from a clinical study reveals an unrelated medical condition of importance to the patient. Clear evidence of a serious heart condition should be disclosed to the patient’s physician. However, it may or may not be appropriate to disclose speculative evidence or data about an untreatable condition. An institution’s policy on incidental findings should be consistent with its policy on including study data in the EMR.

Usefulness is Difficult to Predict
Information that appears inconsequential at present might prove later to be very important. For example, the half-life of a study drug in a patient’s blood could be important if that drug interacts with another drug that the patient subsequently receives in combination. An EKG reading could provide useful baseline information years later for a cardiology patient.
absence of an adverse reaction to an active control drug might later be useful to know when the patient’s physician is deciding which drug to prescribe.

**Genetic Data**

Clinical studies can generate genetic data, e.g., the presence of a BRCA gene in a tumor, that have clear clinical significance and should be recorded in the patient’s EMR, as well communicated directly to the patient’s physician. However, other genetic data have uncertain or no clinical significance, and so should not be recorded in the EMR. Examples of such data include the following:

- Data generated solely as scientific information about genes or the genetic basis of a disease
- Data for which relevance to the disease and/or treatment is unknown or uncertain below a reasonable level
- Data obtained by genetic testing with inadequate sensitivity or specificity
- Data pertaining to an incurable and untreatable condition (that the patient does not want to know)

The privacy laws afford special protections to genetic data. Since recording any data in an EMR inherently makes it more vulnerable to disclosure or misuse, extra precautions should be taken for genetic data. For example, genetic data files could be encrypted, with a special procedure for gaining access.

**Information about the Study**

In addition to study data about the patient, a clinician might want information about the study itself, e.g., drug mechanism of action, known interactions, potential adverse reactions, and contact information for the investigator.

The EMR could thus include the protocol, consent form, and investigator’s brochure. Such documents are usually the study sponsor’s confidential information, so access to them should be limited to persons who need the information and have signed and understood the appropriate confidentiality agreements. Only one copy of the documents should be stored in the EMR, so it is necessary to reference them from patient records.

**Voluminous Data**

Study data — source documents, patient diaries, questionnaires, X-ray scans, device event logs, etc. — can be too voluminous or otherwise impractical to store in an EMR. However, the EMR can record their existence and document how to obtain access to them from the study archives. Such access might require partitioning the study records into those that have clinical significance and those that do not, or are confidential to the study sponsor. It might be necessary to store clinically significant records beyond the period required by the study sponsor.

**CMS Medical Record Documentation Standards**

The Affordable Care Act aims to improve healthcare and reduce the burden on covered entities and clinicians by requiring ICD-10 re-coding, standardization of quality measures, structured data for “meaningful use,” and health information exchange (HIE) compatibility. New CMS medical record documentation standards are imminent and will affect the recording of study data in EMRs.
Conclusion

EMRs are powerful tools for healthcare providers. However, like other powerful tools, they require proper training, maintenance and use. In particular, EMRs must balance the benefits of sharing information against the risks of disclosure or misuse of that information. Given the diversity of institutions, EMRs, studies and patients, the principles discussed above must be applied intelligently to specific circumstances to gain the healthcare benefits without sacrificing patient privacy or study sponsor confidentiality. The Affordable Care Act aims to create an EMR for every patient by 2014, so healthcare institutions that conduct clinical research should address these issues soon.

References

2. 21 CFR 50
3. 21 CFR 52
4. 21 CFR 56
5. 21 CFR 11
6. 21 CFR 213.62
7. 21 CFR 812.140
8. 45 CFR 2
9. 45 CFR 46
11. EPIC: Medical Record Privacy. http://epic.org/privacy/medical
12. ICH GCP Guideline, Sect. 1.51
13. ICH Guideline, Sect. 1.52
16. Cleveland Clinic policies, standard operating procedures, and guidance documents.

Author

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Managing CRA Access to Electronic Medical Records
By Pamela Strohmeyer

Electronic medical records (EMRs) can lower healthcare costs, reduce medical errors, improve patient care, and facilitate subject recruitment in clinical research. However, they also create problems when site monitors who are not permitted to access the protected health information (PHI) of patients and subjects in other studies perform clinical research source document verification (SDV).

The following incident, which took place at a clinical trial site in the Midwest, illustrates the need to determine best practices for study monitoring and SDV when EMRs are used:

The healthcare facility uses a hybrid system of paper and electronic medical records. The site's standard practice is for the clinical research associate (CRA) to review paper charts independently. The study coordinator then gives the CRA access to EMR records by logging into the EMR system, pulling up each subject’s record, and directly supervising the CRA’s viewing at all times. This cumbersome process was designed to prevent unauthorized access to restricted PHI.

Recently, a CRA who was dissatisfied with this process exploited loopholes in the system to obtain her own account from the information systems (IS) department by suggesting that she was an authorized employee. The new account gave the CRA employee-level access to the site’s EMR system.

Fortunately, before the CRA accessed the system and breached any patient’s privacy, she disclosed her actions to the study coordinator, who instructed the IS department to close the account. Procedures were immediately strengthened to prevent future security breaches.

The problem of EMR access arises because there are two conflicting regulatory requirements:

- CRAs have a right and obligation to review source documents. (21 CFR 312.53(d))
- Sites have a right and obligation to control access to their records. (21 CFR 11, HIPAA)

However, meeting these requirements simultaneously can be a challenge. EMR platforms are many and varied, and most of them do not feature user-friendly mechanisms for providing limited, temporary access to CRAs. Unfortunately, the “solutions” that have been implemented each introduce serious problems:

- Study coordinator accesses his or her own EMR account and supervises all viewing by the CRA.
  - Consumes site person’s time, increasing the cost of the study.
  - Scheduling can be problematic.
  - May strain professional relationship between site person and CRA.
- Study coordinator gives unsupervised access to his or her EMR account to the CRA.
  - Violates 21 CFR 11 and HIPAA.
  - Creates a risk of PHI disclosure that cannot be undisclosed after the fact.
  - Renders audit trail meaningless.
- Site creates an EMR account for the CRA; CRA agrees to access only study subject records, verifiable through the audit trail.
Violates 21 CFR 11 and HIPAA.
Creates a risk of PHI disclosure that cannot be undisclosed after the fact.

Site creates a multi-user dummy account for all CRAs.
Violates 21 CFR 11 and HIPAA.
Renders audit trail meaningless.
Creates a risk of PHI disclosure that cannot be undisclosed after the fact.

Site produces copies of complete EMR records for CRA review.
Creating, storing and eventually destroying copies is time-consuming and costly, especially if copies are certified.
Defeats the purpose of a paperless system.
Copies do not include audit trail data and possibly other information in the EMR.
It may be impossible to create incremental records for review at subsequent monitoring visits.

Site produces shadow charts (excerpts from the complete medical chart) for CRA review.
Important information may be intentionally or inadvertently omitted by the study coordinator and go undetected by the CRA.
Creating, storing and eventually destroying copies is time-consuming and costly, especially if copies are certified.
Defeats the purpose of a paperless system.
Copies do not include audit trail data and possibly other information in the EMR.

Automatically move EMR data into EDC system (like central lab reports).
Because the data is excerpted, important information may be excluded.
(Few commercially available EMR systems can feed information directly into the sponsor’s EDC system.)

Conclusion
The only practical way to provide limited access to EMR data for SDV is to build the functionality into the EMR system. However, this functionality is a low priority for developers of EMR systems since clinical research is a very small part of the activity at most healthcare providers. Further, a limited access feature requires additional system validation under 21 CFR 11. However, it is possible to have such a system, since at least one company, Greenway Medical Technologies, markets an EMR system that supports secure remote access for study-specific source document verification, with an audit trail. Over time, this feature may become more common.

Disclaimer
The author has no relationship with Greenway Medical Technologies or experience with its products.

References
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