Driving Access: Electronic Medical Record (eMRs) Systems at Research Sites

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Objective

- Learn how to access and review research data, using a risk-based approach, to ensure accurate, complete, and high quality data and reduce site non-compliance

Agenda

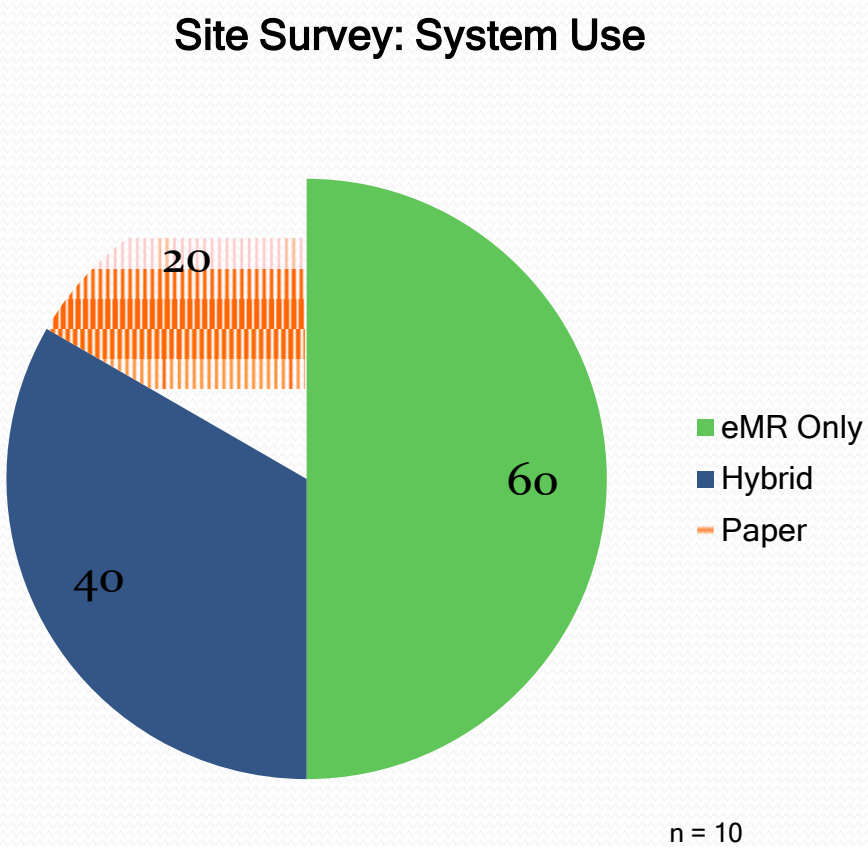
- Introduction
- eMR Systems
- eMR Regulation
- Impact on Research
- Monitoring Obstacles
- Ensuring Compliance

Introduction

- Electronic Medical/Health Records (eMR) are becoming more prevalent.
  - The federal stimulus package has pushed medical sites to implement eMRs, with a payment of greater than $50,000 for implementation

- Research use of eMR in research is an afterthought!
  - Typically site eMRs are established prior to determining logistical needs for research access and availability
  - Creates challenges for use in research

Site Use of eMRs



Results from a survey of site professionals revealed that most sites use eMRs exclusively

eMR Systems

- eMRs data capture methods:
  - Where paper records are scanned into a viewing application
  - Where data is directly entered into the system
  - Transcribed from another source prior to entry
- Few commercially available eMR systems can feed information directly into EDC systems. If they could this would minimize the effort required for source data verification (SDV) and eliminate transcription

eMR Regulation

- Draft Guidance: Electronic Source Documentation in Clinical Investigations – mentions eMRs as a source for clinical data inputs
- The EMA reflection paper: Expectations for Electronic Source Data and Data Transcribed to Electronic Data Collection Tools in Clinical Trials - also discusses the use of eMRs in clinical research
- The FDA has repeatedly stated that they will not assert jurisdiction over eMRs and therefore they are not assessing eMRs for compliance with 21 CFR Part 11
  - In 2011, Dr. Toth-Allen stated that the FDA does not "have oversight of the electronic health records" and therefore "has no control and cannot require that electronic health records are compliant with Part 11"

eMR Oversight

- Although not requiring compliance with Part 11, there are regulatory actions:
  - FDA Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) letters
  - Warning letters
  - FDA Form 483s

- A Clinical Investigator, Dr. Zabalgoitia, was cited within his NIDPOE letter for not controlling the access to the eMR which "jeopardized the integrity of data"
  - Others include: no direct access to source documentation or the lack of integrity within the eMR system cited under
    - 312.60 Failure to adequately supervise the clinical investigations
    - 312.62 Failure to maintain adequate and accurate case histories that record all observations

How Does Non-Compliance Affect Research?

- Sponsors, CROs, and sites must be aware of the compliance challenges
- Assess the level of risk associate with the site use of eMRs
- Communicate risk to sponsor
- Develop workable mitigation strategies

Focused Areas of Risk

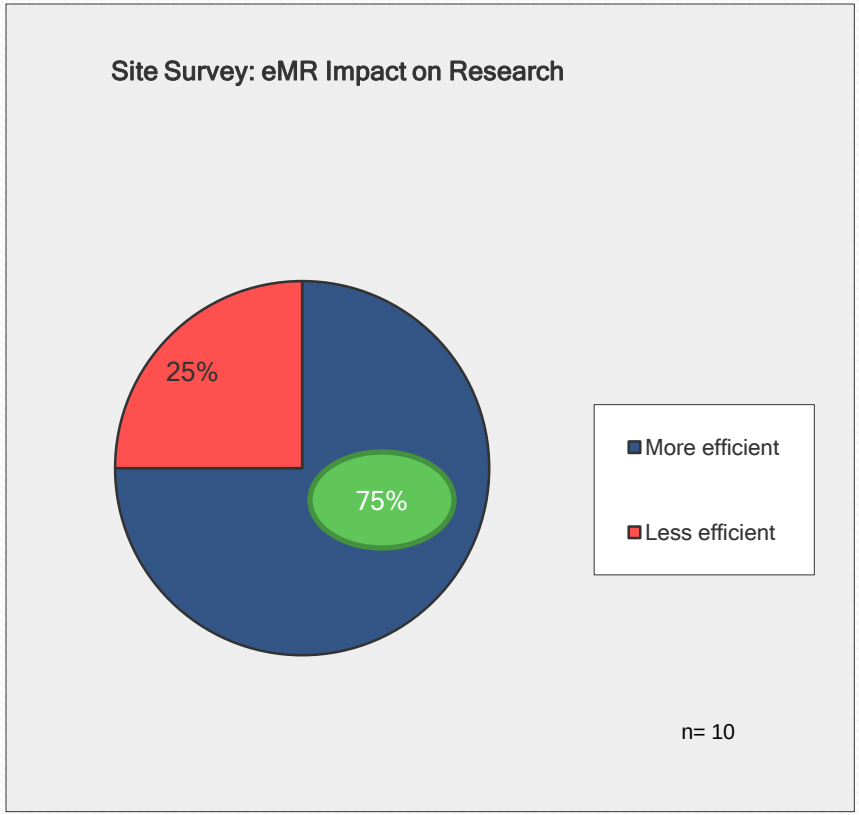
- Examination of approximately 20 industry publications, global regulatory guidance documents, our survey, and recent regulatory actions illustrate the following challenges for reviewers:
  - System access
  - Navigation and training
  - Non-compliance

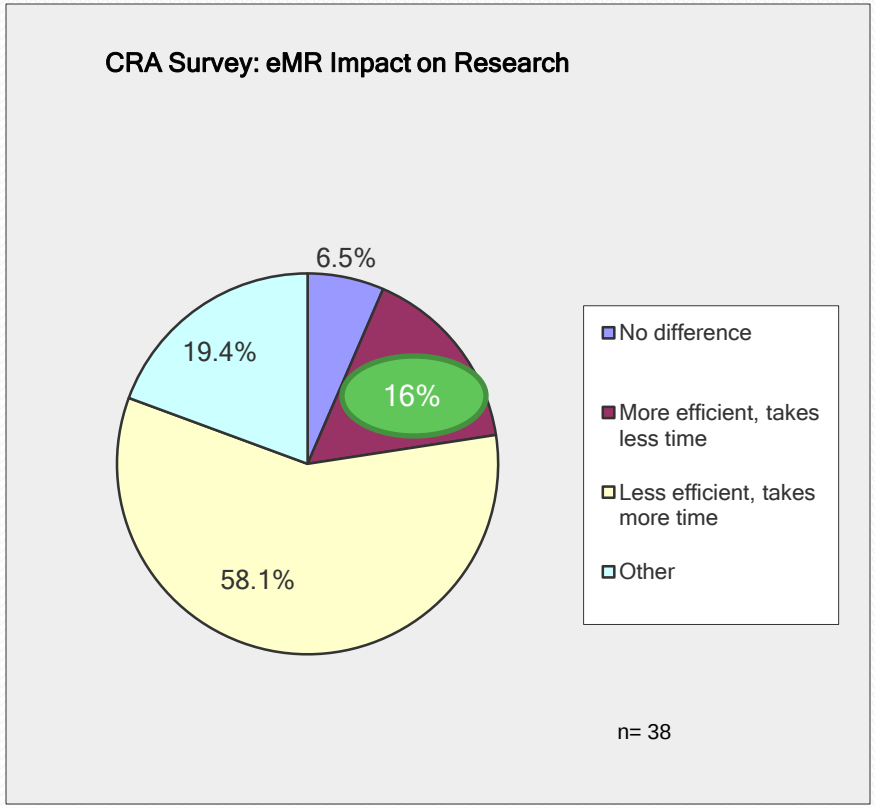
Reviewer Impacts

- CRAs should assess risks associated with site use of eMRs in research
  - Early in the process
    - Site qualification/initiation
    - First contact with the site

Opposing Points of View

Site Survey

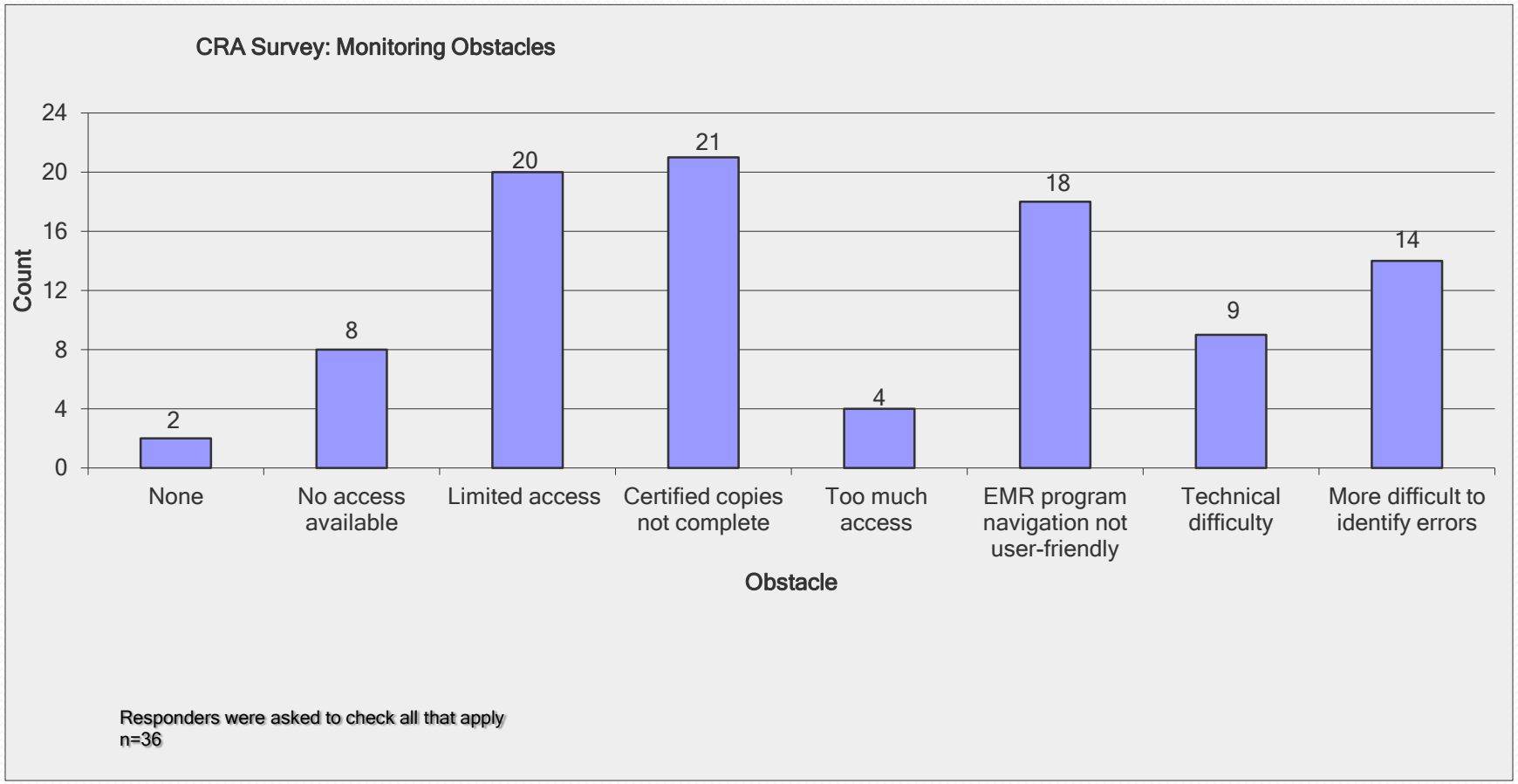




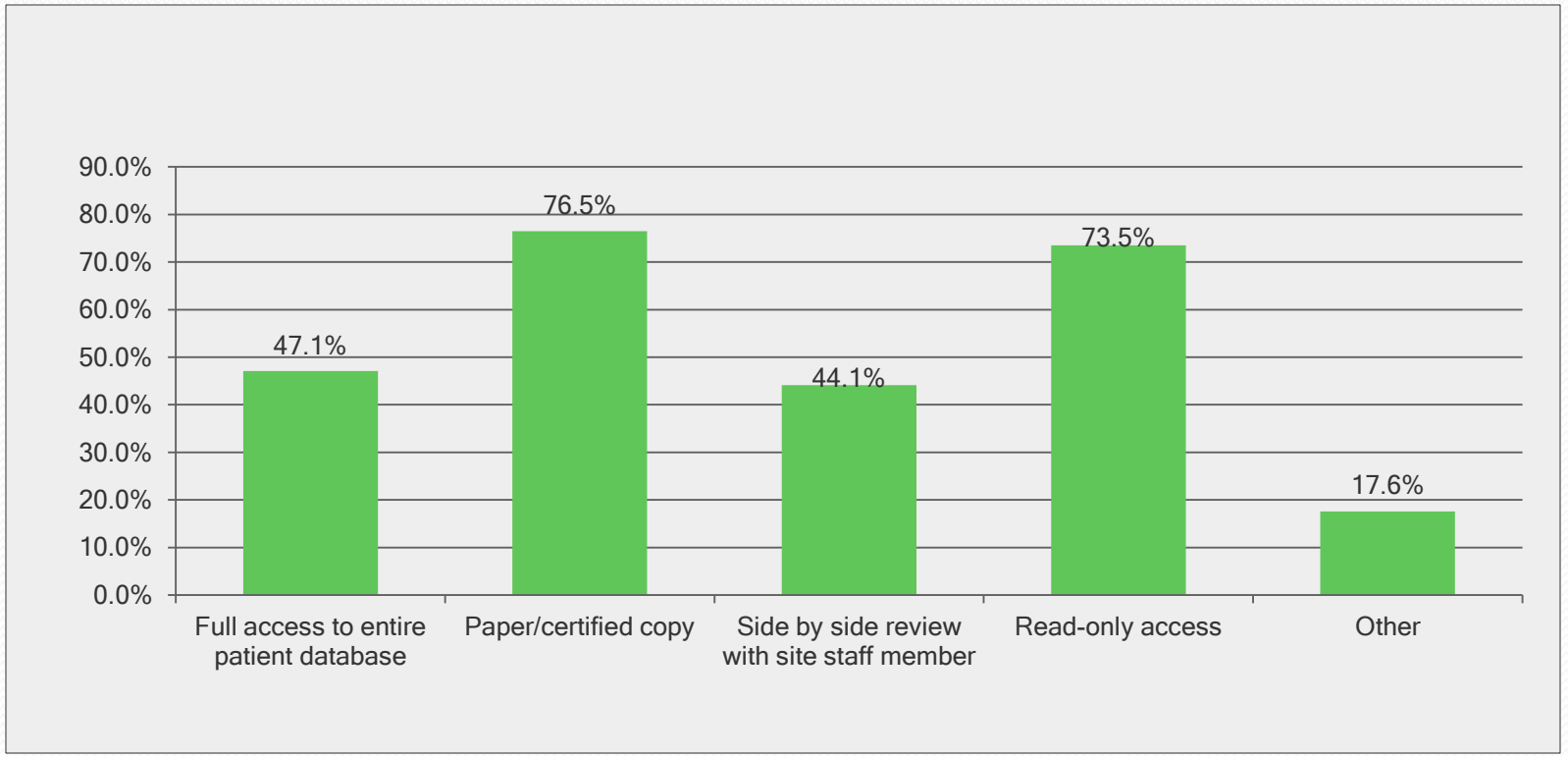
Monitoring Obstacles

- Survey data collected on the monitoring of site eMRs showed:
  - Variety of monitoring approaches are employed
    - Many obstacles reported
  - Data also suggests that monitoring strategies vary drastically by Sponsor

Monitoring Obstacles



External eMR Access Varies by Site



Survey participants were asked to check all that applied
n=36

What access should I have?

- Dr. Toth-Allen, "Monitors and Auditors for a company should have the same access that FDA Investigators do."
  - For compliance reasons, FDA inspectors do not touch eMRs
- FDA and EMA guidance documents state that sites should maintain records of system access authorization with appropriate levels of access clearly documented (e.g., individual user accounts)
  - Level of access not appropriate when reviewers are not restricted to read-only
- When the eMR cannot be accessed, system print outs are used which increases the likelihood for incomplete data

Incomplete Data

- The #1 challenge for reviewers is determining that subject data is complete
  - "Shadow charts" may not include the entire subject source record
- If site uses hybrid eMR-paper systems, reviewers need to review all documentation from the varying systems
  - Device readings
  - Pharmacy system
  - Lab system
- We need to know how long it take/ how often the site enters data
  - Site data entry times often lag 48-72 hours
- We need to know if previously verified data in the system has changed

What if it's incomplete?

- Dr. Toth-Allen of the FDA recommended:
  - Do not use a site if you do not have the ability to look at the electronic record and verify a complete shadow file.
  - You need to have the access to spot check the data.
- Subject records need to be as transparent as possible:
  - Paper vs. eMR
  - Changes should be obvious (trigger for re-review)
  - How often is data generally being entered after a visit/assessment
  - When the data was last entered into the system
    - Timing of subject assessments

Training and Navigation

- Reviewers report difficulty navigating within the eMR as a significant barrier
  - eMRs behave differently
  - CRAs may waste time navigating to records outside of the clinical trial subjects
- Lack of Training
  - Only 22% of the clinical sites surveyed reported providing some level of training to external reviewers.
  - Lack of system security training could result in unauthorized access
  - Lack of training on system could result in wasted time to sort through data
- Training methods vary
  - No training
  - Verbal training, no documentation from site
  - Self training on the User Manual
  - Structured training, with documentation

Non-Compliance

- Certified copies presented do not meet certified copy requirements
  - Same attributes as the original
- Limited protection of Protected Health Information (PHI) as specified in HIPAA and Privacy Directives
  - Access to entire patient database may not be not restricted
  - Display of assessments outside of study requirements
  - Site confidentiality agreements prior to accessing eMRs

How can we ensure compliance?

- Assess the eMR system
- Determine the risks
- Mitigate or manage identified risks

Assess the eMR Use

- Suggest using a checklist to evaluate the system.
  - Does the system meet the regulatory expectations?
  - Does the system provide ALL the source information?
  - If the systems do not meet the requirements then this checklist will assist in determining the mitigating actions that should be taken, as necessary, prior to trial site initiation
- Set the project up for success.

Source Data Checklist

1. Is each eMR user at the site provided a unique username and password to access the system?
2. Is write-access restricted to designated users?
3. What kind of access is granted to CRAs (no access, read-only, etc.)?
4. Does the system use secure, computer-generated, time-stamped audit trails to independently record the date and time the user entered data, modified data or deleted source data?
5. Have the individuals using the eMR had training on the system tasks they perform?
6. Does the system use electronic signatures in the place of hand written signatures?

Sample Tool

Password:	Password is unique and read-only.	Password is public but access is read-only and a site procedure exists to manage password.	Password is non-unique or public but access is read-only.	X	Access is not read-only.
Access Type:	Read-only access to subject population only.	Read-only access to entire population. Site supervised eMR access of study subject.	Read-only access to entire population.	X No direct access (see below).	No read-only access. For consideration, QA/Val review of system requirements prior to site agreement/contract.
Data Access:	Sponsor contract with site with similar agreement or site SDV agreement (with sponsor approval / acknowledgement) for direct access.	Site Agreement or sponsor acknowledgement for use of defined Rho certified copies OR site provides supervised viewing (e.g., someone sits with CRA).	Site or sponsor acknowledgement of no direct access but do agree to a sponsor-specific or other definition of certified copy AND CRA is able to spot check data with assistance.	No site contract/sponsor acknowledgement. Decision in MVR for no direct access but use of Rho defined certified copy. The ability to spot check is not available.	No site contract/sponsor acknowledgement. Decision in MVR for no direct access but use of other definition of certified copy. The ability to spot check is not available.
Access to Data Changes:	Direct Access - changes are accessible for review.	Certified copy of audit trial (entire study) AND the ability to spot check is available.	Certified audit trail change report or a source page listing (if scanned PDF pages) or certified copy of audit trial (since last visit only) AND the ability to spot check is available.	Site attestation for no changes at each visit and end of study. Sponsor acknowledgement prior to agreement/contract. The ability to spot check is not available.	No way to show data changes within system or via print out or no sponsor acknowledgement. The ability to spot check is not available.
Training:	Agreement for site/sponsor to provide training and training is conducted (adequacy determined by site/CRA/sponsor combo).	X	Documentation of lack of training in MVR and sponsor acknowledgement.	X	Documentation of lack of training in MVR and no sponsor acknowledgement.
Data Entry Timeline:	Completed agreement and compliance.	Completed agreement and acceptable.	No agreement but acceptable.	No agreement or non-compliant.	Systematically non-compliant.

Password

Password is unique and read-only.	Password is public but access is read-only and a site procedure exists to manage password.	Password is non-unique or public but access is read-only.	X	Access is not read-only.

Risk: Reviewer can alter records.

Mitigation Options: Request certified paper copies with option to spot check against eMR with site staff.

Access Type

Read-only access to subject population only.	Read-only access to entire population. Site supervised eMR access of study subject.	Read-only access to entire population.	X No direct access	No read-only access. For consideration, QA/Val review of system requirements prior to site agreement/contract.

Risk: Reviewer can see subject data that is not authorized by the patient or reviewer can alter records.

Mitigation Options: Site staff agrees to navigate through system for reviewer.

Data Access

Sponsor contract with site with similar agreement or site SDV agreement (with sponsor approval / acknowledgement) for direct access.	Site Agreement or sponsor acknowledgement for use of defined Rho certified copies OR site provides supervised viewing (e.g., someone sits with CRA).	Site or sponsor acknowledgement of no direct access but do agree to a sponsor-specific or other definition of certified copy AND CRA is able to spot check data with assistance.	No site contract/sponsor acknowledgement. Decision in MVR for no direct access but use of Rho defined certified copy. The ability to spot check is not available.	No site contract/sponsor acknowledgement. Decision in MVR for no direct access but use of other definition of certified copy. The ability to spot check is not available.

Risk: Reviewer cannot access the source record or ensure that all data is present.

Mitigation Options: Site creates a memo documenting direct access not allowed; monitor documents lack of direct access in visit report.

Access to Data Changes

Direct Access - changes are accessible for review.	Certified copy of audit trial (entire study) AND the ability to spot check is available.	Certified audit trail change report or a source page listing (if scanned PDF pages) or certified copy of audit trial (since last visit only) AND the ability to spot check is available.	Site attestation for no changes at each visit and end of study. Sponsor acknowledgement prior to agreement/contract. The ability to spot check is not available.	No way to show data changes within system or via print out or no sponsor acknowledgement. The ability to spot check is not available.

Risk: Reviewer cannot determine if changes have been made.

Mitigation Options: Site agrees to document that all data entries are accurate and complete at each visit. CRA documents in visit report.

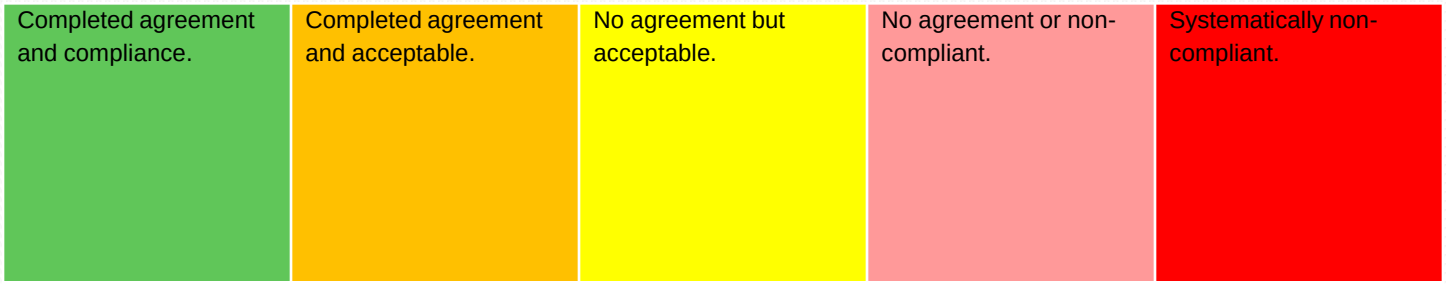
eMR Training

Agreement for site/sponsor to provide training and training is conducted (adequacy determined by site/CRA/sponsor combo).	X	Documentation of lack of training in MVR and sponsor acknowledgement.	X	Documentation of lack of training in MVR and no sponsor acknowledgement.

Risk: Reviewer cannot efficiently function within the system and potentially misses data.

Mitigation Options: Monitor documents lack of training in monitoring report with Sponsor acknowledgement.

Data Entry Timeline



Risk: Data will not be available for review.

Mitigation Options: Site agrees to enter subject data within X hours of completion; Sponsor/CRO acknowledges.

Communicate Risks

- Inform the site of identified risks
- When possible, work with the site to mitigate risks
- Ensure the Site and reviewer understand their responsibilities:
  - Data access agreement between site and sponsor/CRO
    - Site agrees to maintain source data appropriately (e.g., complete certified copies)
    - Site agrees to train reviewers on eMR system (document training)
    - Reviewer agrees to access appropriate records and inform site of inappropriate access

Summary

- Agree on and communicate eMR expectations
- Identify eMR gaps and risks
- Use a risk-based approach to assess risks
- Mitigate risks to an acceptable level
- Document agreements
- Assign resources based on strategies implemented
- Monitor compliance and re-evaluate when needed

References

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