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Configuration Challenges: Implementing Translational Research Policies in Electronic Medical Records

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Abstract

Prospective clinical trials are a key step in translating bench findings into bedside therapies. Electronic medical records (EMRs) are often cited as a significant new tool for advancing clinical trial capabilities into standard clinical practice. However, combining clinical research and clinical care activities into one unified electronic information system requires integrating a substantial body of regulatory requirements and institutional policies. Differing interpretations of external regulations and internal policies need to be reconciled so that the EMR configuration simultaneously conforms to all requirements.

The authors describe how they used a detailed clinical vignette to help focus discussions about their institution's current research policies and how regulations and policies might be implemented in a commercial EMR. The vignette highlighted a number of inconsistencies in the institution's policies and in individual interpretations of regulatory intent.

Attempts to implement potential policies in the EMR system also revealed a number of limitations and inconsistencies in the commercial system. The authors describe a set of compromises that will be implemented at The Children's Hospital until missing functionality is made available from the commercial vendor. Each institution that implements an EMR will need to resolve similar policy and configuration issues at its own facility. The authors highlight these configuration challenges by presenting a list of questions that must be answered unambiguously before implementing translational research capabilities into an operational EMR.

Prospective trials are a powerful tool for assessing the efficacy of medical innovations. New therapeutic treatments and devices must undergo a series of progressively more stringent

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prospective trials to gain regulatory approval.[1,2] Postapproval prospective trials are often used to compare the effectiveness of alternative care strategies. However, there is substantial evidence that the current approach to organizing and conducting these crucial clinical trials is not meeting the needs of patients, clinical investigators, study sponsors, or regulatory agencies.[3,4] Only 7% of eligible patients enroll in clinical trials;[5] for cancer studies, only 3% of eligible patients enroll.[6] Eighty-six percent of clinical trials fail to complete enrollment on time[7]; when a trial must take additional days beyond its initial timetable to complete the trial, 85% to 95% of these additional days are a result of investigators not recruiting subjects on schedule.[8] Low recruitment rates not only delay study completion times; they also threaten study generalizability, because women, minorities, children, and other vulnerable populations are underrepresented in most studies.[9–11] Despite a significant increase in the number of new trials initiated each year, only 3% of all board-certified physicians participate in FDA-approved trials, the number of first-time clinical investigators dropped 11% between 2001 and 2003, and half of all principal investigators never conduct another FDA-regulated clinical trial.[12,13]

Table 1 provides examples of how electronic medical records (EMRs) could accelerate numerous steps in clinical trials, making them more efficient. Further, as EMR pioneers recognized, EMRs have the potential to support clinical care and clinical research simultaneously, streamlining and integrating clinical care and clinical trial systems.[14–17] In the United States, the National Institutes of Health (NIH) Roadmap, the NIH National Center for Research Resources (NCRR) 2004–2008 strategic plan, and the Department of Health and Human Services Office of the National Coordinator for Health Information Technology strategic framework all refer to the government's expectation that the use of health care information technologies will greatly expand the nation's clinical research capacity.[18–21] Numerous private-sector reports also point to the potential of information technology to increase public access to advanced and experimental treatment options available only through clinical trials.[22–25] Well-designed studies are now appearing that demonstrate the ability of EMRs to improve aspects of clinical trials.[26,27]

Configuring an EMR requires an institution to declare explicitly which users in which specific settings have access to certain system functions and patient data. Little has been written about the types of choices that must be made when an institution attempts to configure an EMR to meet regulatory requirements and institutional policies that apply to translational clinical research. In our opinion, institutional leaders interested in developing an EMR would greatly benefit from stories like ours, of institutions that have already configured and implemented an EMR. Although similar questions and issues around clinical care and clinical trials arise in settings that have not adopted integrated EMRs, the stringent requirements for configuring an EMR bring the many competing interpretations of regulatory and institutional policies into much sharper focus.

Using Clinical Vignettes to Review Institutional Research Policies

Policies and procedures may express an institution's intentions, but they do not always reflect actual institutional practice. If configured properly, EMR systems could improve compliance with institutional policies by enabling or suppressing users' access to specific functionalities. However, longstanding institutional policies which may seem acceptable on paper could create impractical or unacceptable workflows when implemented in an EMR. In addition, policy violations could become more visible because of extensive logging and auditing capabilities in EMR systems. Thus, institutional policies and the EMR configuration must be carefully aligned.

In 2003, The Children's Hospital (TCH) in Denver, Colorado, began the implementation of a comprehensive EMR for all ambulatory clinics and inpatient settings. The rollout and configuration of the EMR will be completed by June 2007. At that time, detailed clinical data from all patient encounters throughout the organization will be captured in the EMR. From the initial conception, a key objective of TCH was to merge prospective clinical research and concurrent clinical care activities and requirements within an integrated EMR. Thus, EMR capabilities needed to be configured to conform to additional policy and regulatory requirements specific to prospective clinical research.

To keep policy discussions grounded to real-world issues, we created a detailed clinical vignette that included all of the key steps in a prospective clinical trial (Appendix 1). In this vignette, the EMR records clinical observations, notes, ancillary reports, and test results generated by all caregivers during routine ambulatory, inpatient, or emergency clinical care. The institution's goal is to use the same EMR to find potential study subjects and to record study-specific clinical observations and test results on patients enrolled in IRB-approved prospective observational studies and translational clinical trials. With each question raised in response to the vignette, we enumerated a number of competing interpretations which could be implemented in policy and possibly enforced by the EMR software. Discussing policy issues in light of the clinical vignette revealed a surprisingly wide range of opinions regarding which answer(s) best matched existing (pre-EMR) research policies, practices, and regulations. Different parties have markedly different responsibilities to the institution, investigators, study subjects, sponsoring organizations, and regulatory agencies. Configuring an EMR that meets the needs of all these integral parties requires precise definitions of allowable research practices. Inconsistent policies, procedures, and workflows that have developed over time on an ad hoc or case-by-case basis are cast in a glaring light by this analysis process.

Implementing Institutional Policies via User Roles

Defining and implementing carefully constructed user-based roles and permissions for an EMR is an important technical method for ensuring that the system conforms to regulatory and policy restrictions. Distinct roles are assigned to different users who need access to the same subset of system features to perform their jobs. Role-based security manages user access to system functions and patient information. As illustrated in Chart 1, EMR users may play multiple roles in clinical care and clinical research. In settings where patients receive treatment only in the context of a clinical trial or only in standard care, it may be easy to link each EMR user to a specific role. However, in the setting of mixed care—where some part of a patient's treatment plan is directed by a clinical trial, but other parts of the treatment plan are not—the same user may play different roles for the same patient, even within the same clinical encounter. Thus, it is critical to examine how various functional requirements change the EMR configuration not just for an individual user, but also for a user in a specific role in a specific context.

Defining which access rights to grant to users in specific roles is one of the early steps in configuring an EMR. To accomplish this task, the EMR implementation team needs precise answers to a number of questions:

1. What tasks are required for each identified role (Chart 1) so that individuals in that role can perform their work? For example, screening, consenting, enrolling, and treating study subjects might all be performed by users in one role, whereas setting up case report forms and data-capture screens and entering patient observations into a database might be performed by a user in a different role.

2. What system functions does a user in a specific role require access to in order to perform each task efficiently and in full regulatory compliance?
3. What tasks have dependencies, such as a specific sequence of activities ("Consent form must be signed before any study procedures can be administered")? Dependencies may be "hard" (task cannot proceed until the constraint is satisfied) or "soft" (task can proceed but the user must document the need or resolve the constraint before concluding the task).
4. What tasks can be shared amongst users in multiple roles? What tasks can only be done by a user in a specific role?
5. When are specific tasks performed? When should the system functions that support tasks be made accessible to users?
6. If an individual user can change roles, how is a role change identified so that the correct set of system functions and limitations are made available to that user in the right context? How can these changes in role and system functions occur without disrupting workflow?
7. What patient data should be visible to users in each specific role? Conversely, what patient (or study participant) data should not be available to certain users without a change in role?
8. What special terms, code sets, and allowed values are required to capture specialized clinical data, especially if those data are to be shared or exported to other institutions or databases?
9. What special features (e.g., documentation, billing, security, etc.) are required to meet regulatory requirements?
10. How are exceptions to any of the previous questions invoked, what does the exception change, and when is the exception no longer valid?

In developing configuration specifications, our EMR implementation team used the answers to these questions to link required workflows and tasks to specific system functions for each role.

Aligning and Implementing Institutional Policies in a Commercial EMR

To achieve an EMR that truly integrates clinical care and clinical research, unique user roles, system workflows, and functional capabilities must be combined without impeding clinician productivity. Like other large academic centers, our integrated clinical care/clinical trials system needs to meet the needs of a variety of users: a broad array of clinical care generalists and specialists treating tertiary care patients, an active NIH-sponsored general clinical research center, a large regulatory clinical trials office, a multifacility IRB, and a substantial number of investigator-initiated clinical studies. As we worked on specifying EMR implementation requirements, we identified a set of clinical care and clinical trial roles and identified a set of issues—a mixture of institutional policy and regulatory requirements —that require explicit answers associated with these roles (Table 2). Many of the issues contained in Table 2 appear in the clinical vignette (Appendix 1); the vignette was designed to cast the generalized issues enumerated in Table 2 into a tangible, real-world clinical scenario, making the nature of the questions and alternative answers more accessible to the responsible executives and clinicians.

Reaching institutional consensus on what constitutes acceptable answers to the questions posed in the clinical vignette and in Table 2 has been difficult and sometimes contentious. Clinical care and clinical trials both have complex workflows with substantial regulatory

oversight.[28] The EMR team has had to work closely with clinical, administrative, and regulatory leaders to develop creative approaches to resolving differences while satisfying regulatory demands, workflow requirements, and unique information-management approaches within the capabilities of the commercial EMR system.

As we explored alternative policies, the implementation team described or created test implementations to illustrate the resulting workflows using the functional capabilities in our commercial EMR product. For some alternatives, the current product did not have sufficient functionality to implement a proposed policy. In other instances, a policy could be implemented in the ambulatory care application, but not in the more complicated inpatient application, even though both products were created by the same vendor. In still other cases, a policy could be implemented for clinical laboratory results, but not for pathology results. In a number of examples where a test implementation could be created, the changes in workflow required to craft the solution within the product's existing functionality were clearly onerous and would not be acceptable in actual practice.

In addition to exploring the EMR's capabilities to support new or revised policies, we had to consider long-established policies in terms of the EMR as well. Traditional institutional practice had established that patient safety concerns for potential duplicative radiation exposure overrode strict clinical trial confidentiality policies. Thus, research-related radiology reports historically have been included in the paper medical record. Research-related clinical laboratory tests traditionally have not been part of the paper medical record, but these results are available in the laboratory information system under a unique subject identifier. Both of these historical practices will continue in the EMR. Traditionally, the remaining research-related diagnostic test results, such as cardiology, pulmonary, and pathology reports, have not been part of the paper medical record. Although the current EMR product allows these reports to be labeled as research results, it does not allow research diagnostic test results to be suppressed in electronic displays. Thus, although these reports were not available in our paper medical records, these research-related findings will appear in the EMR. In the past, research-related orders have been written and processed using study-specific order sheets that were not part of the medical record. The current version of computer-based physician order entry (CPOE) system does not support separating research-related orders from standard-care orders in order entry or order review screens. Until new functionality is available, research-related orders will remain paper-based, and standard-care orders will be entered using the CPOE system. In the ambulatory care setting, the EMR allows physicians to mark specific documents as *research notes*, and special access restrictions can be placed on them. Similarly, the EMR's inpatient system allows notes to be marked as research notes, but it does not provide a method for placing special access restrictions on any type of note except for mentalhealth-related notes.

Despite differences in what can or cannot be suppressed from clinical care EMR users in various settings, all orders, reports, and notes that are marked as research will be removed from the legal medical record when it is printed. References to research results or clinical actions based on research findings that appear in the standard-care documentation notes or dictations, however, will be included in the printed legal medical record. Physicians are encouraged to not make standard-care decisions on the basis of research findings, except for those care decisions related to potential study-related adverse events. However, the limited system functionality does not prevent all research results from being suppressed during standard-care encounters.

The EMR vendor has established a clinical research advisory council to provide input into future product developments to incorporate missing functionality. Over time, as new functionality is released, we will revisit our current approach and remove the current

discrepancies so that the research policies and the EMR implementation are consistent across all practice environments.

Moving Forward

Each institution seeking to implement a unified clinical care/clinical research EMR will invest substantial resources in internal discussions, analyses, and compromises to define an *internal* interpretation of a regulatory- and policy-compliant solution. Different interpretations of acceptable solutions will result in different implementation requirements and system configurations at each site. Unfortunately, without consistent requirements across multiple customers, commercial EMR vendors cannot identify missing functionalities that would support the clinical research market's needs. Given the relatively small market size for clinical trial software and the endless list of system-enhancement requests from the clinical care marketplace, commercial EMR providers may not be able to respond to the challenges presented by inconsistent requirements.

To achieve the oft-stated goal of expanding clinical trials and clinical research capacity, existing health care information technology efforts must define the functional characteristics of a regulatory-compliant, integrated EMR–clinical trial/research system. Research-advocacy organizations are calling for similar efforts that would allow organizations to share successful clinical care/clinical research implementation strategies.[29,30] If common implementation models were developed, institutions could more easily leverage their substantial EMR investments to support prospective clinical trials and translational research. A recent symposium sponsored by FasterCures, the NCRR, and the Agency for Health Care Research and Quality has identified the need to include more focus on clinical research needs in the various national health information programs.[31] We urge that one effort within this agenda include the development of vendor-independent model EMR–translational research configuration descriptions that represent “best practices” and meet external regulatory requirements. An organization could then use these model descriptions and tailor them to fit local institutional policies and clinical practices.

If institutional hurdles for executing clinical trials are reduced, the environment for translational clinical trials will improve. But without well-conceived models to guide institutions, the clinical research and clinical care communities will struggle with how best to combine these two worlds. Although each institution may select different answers to issues like those listed in our clinical vignette, having a comprehensive list of questions and alternative responses to consider would accelerate the process significantly.

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Appendix 1

Sample Clinical Vignette Used to Frame Review of Institutional Policies in the Context of Electronic Medical Record (EMR) Functionality. The Comprehensive Vignette Presented Here is Broken into Seven Stages in order to Examine the Policy Questions that Arise with Each Stage

Stage 1: A 15-vear old female patient routinely sees Dr. PCP. On this ambulatory visit, she meets criteria for an IRB-approved pharmaceutical-sponsored prospective trial run by Dr. PI. Dr. PI works for the same institution as Dr. PCP but Dr. PI has no prior clinical relationship with the patient.	
Question 1: Can Dr. PI request an EMR database query using the study's inclusion and exclusion criteria to find patients who might be eligible for her study? If so, can Dr. PI obtain this patient's identifying information so she can ask Dr. PCP to approach the patient to consider entering Dr. PI's study?	**Answer la**: Because Dr. PI has no prior existing clinical relationship with the patient, Dr. PI has no right to perform this query. If Dr. PI obtained an IRB-approved waiver of consent for preparatory research, then she may obtain identifying information for assessing study feasibility, but not to recruit specific study subjects.
	Answer lb: Once the institution's IRB has approved Dr. PI's study. Dr. PI has the right to identify potential subjects. Since Dr. PI will not contact the patient directly but will ask Dr. PCP to first consider the patient for this study, the query is permissible.

Stage 2: The institution implemented an automated clinical trial eligibility screening program within the EMR that generates a message when a patient is seen who meets key trial eligibility criteria. Dr. PCP's patient meets the screening criteria for Dr. PI's study. As the patient's primary care provider, the alert containing patient identifying information is sent directly to Dr. PCP.	
Question 2: Can this alert also be sent to Dr. PI?	**Answer 2a**: No. Knowing that a patient meets the screening criteria effectively provides Dr. PI with confidential information about that patient. Because there is no pre-existing clinical relationship and no consent has been signed, Dr. PI has no right to this patient-identifying data.
	Answer 2b: Yes. Getting a real-time alert is no different than doing a retrospective database query. If Answer lb is allowed, then this answer seems analogous.
	Answer 2c: Maybe. Suppose Dr. PI works in the same clinical department as Dr. PCP and that all physicians collectively take care of all patients seen in that department. It could be asserted that an implied clinical relationship does exist between Dr. PI and the patient, even if Dr. PI has never seen the patient before.

Stage 3: Some of the inclusion/exclusion criteria involve sensitive high-risk sexual practices and drug-use information. Dr. PCP obtained similar information in the past during routine clinical care and appropriately marked this information as confidential in the EMR when it was originally recorded.	
Question 3: Are confidential data available to Dr. PI when she runs a screening inclusion/exclusion query to find potential eligible patients? (Assumes Answer lb holds)	**Answer 3a**: Yes. If Dr. PI's protocol has inclusion/ exclusion criteria that depend on confidential clinical data and if the protocol received IRB approval, then Dr. PI has the right to query the entire medical record without restriction.
	Answer 3b: No. Data marked confidential requires additional permissions before it can be accessed for any research purpose. The IRB must explicitly permit query access to any data element that has been marked as sensitive by any provider.
Question 4: If Dr. PCP rather than Dr. PI requests the same screening inclusion/exclusion query and receives the results, can Dr. PCP's query access confidential data? Because of his status as the patient's primary care provider, can Dr. PCP query all confidential data, even if entered by other providers?	**Answer 4a**: Yes to Dr PCP accessing his confidential data but no to Dr. PCP accessing data marked confidential by other providers.
	Answer 4b: Yes to Dr. PCP accessing all confidential data because he is the patient's primary care provider.
	Answer 4c: No on both counts. Confidential data, irrespective of the originator, requires additional IRB

	oversight/permission before any research-related access (consistent with Answer 3b).
	Answer 4d: Maybe. Rules that apply in standard clinical practice for accessing confidential data across providers would apply in this setting. The answer is based on standard institutional policy, not special regulatory considerations.
Question 5: If Dr. PCP can query confidential information (Answer 4a or 4b), what patient-specific information can Dr. PCP share with Dr. PI prior to obtaining patient consent?	**Answer 5a**: Nothing until the patient signs a study consent.
	Answer 5b: Just the patient's name so that Dr. PI can keep track of "screened but not enrolled" study statistics should the patient decline to participate.
	Answer 5c: Just the clinical data used to perform the screening evaluation. IRB approval does not enable Dr. PCP to share more than just the screening parameters with Dr. PI until the consent form is signed.

Stage 4: Dr. PCP approaches the patient and her parents regarding the clinical trial. She agrees to participate. All required consent forms are signed. The consent forms state that Dr. PI and her research staff members will have access only to the participant's data that relate directly to the study. As part of the pre-trial evaluation, a more extensive sexual and drug-use history is obtained than was documented in the earlier confidential note entered by Dr. PCP. The patient's response to these questions reveals a number of risk behaviors that were not identified in the earlier encounter note.	
Question 6: Assuming Dr. PI was allowed to see Dr. PCP's earlier confidential EMR encounter note, does Dr. PI have a responsibility to inform Dr. PCP regarding previously undocumented risk behaviors of his patient?	**Answer 6a**: Yes, this is a clinical "duty to inform" obligation that trumps other regulatory and policy considerations.
	Answer 6b: Maybe. If the risks are deemed life-threatening and could result in harm to the patient or to others, then Dr. PI must inform Dr. PCP. This permission is based on the existing disclosure policies that apply to suicidal or violent patients.
	Answer 6c: No, unless the informed consent explicitly allows study-related information to be shared with Dr. PCP.

Stage 5: After entering the randomized trial, the patient is seen in the Emergency Department (ED). Due to a concern that the patient's complaints may be related to her experimental treatment, the ED physician uses the EMR's "Break the Glass" security unlocking feature to gain access to trial-specific information, including the study's detailed sexual/drug-use history.	
Question 7: If the ED physician looks at the study information but does not use it for a clinical decision, does that information become part of the legal medical record?	**Answer 7a**: The information retains the same level of protection that existed prior to using the "Break the Glass" feature. The information remains protected by the study consent form's statements regarding data confidentiality.
	Answer 7b: Even though the physician did not use the information for a clinical decision, the information was reviewed and considered during a clinical encounter. Therefore, all clinical trial data obtained prior to the "Break the Glass" event effectively becomes part of the standard clinical record.
Question 8: Does the answer to Question 7 change if the information is used by the ED physician to make a clinical decision?	**Answer 8a**: If the study sponsor pays for all treatment costs, the data retains the confidentiality provisions described in the consent form.
	Answer 8b: Since the information has been used to provide care beyond the protocol guidelines, Answer 7b applies.

Stage 6: The integrated EMR/clinical trials capabilities allow the study coordinator to fill in study case record forms with relevant data that were recorded during standard care clinical encounters that occurred during the clinical trial visit schedule.

Question 9: If the clinical coordinator sees data values from a standard care encounter that are incorrect, can she correct them in the standard-care encounter? If not, how are discrepancies between the	**Answer 9a**: If the clinical coordinator, acting in a different role as a care provider, was the original source of the erroneous data, it can be changed using the usual edit mechanisms evoked when changing any clinical data element.

standard-care encounter data and the study data documented?	**Answer 9b**: If the clinical coordinator, acting in a different role as a care provider, was the original source of the erroneous data, it cannot be changed by this person. There could be an ethical hazard that the change was motivated by the study objectives rather than a true error. Only another care provider, not associated with the study, can alter the original value.
	Answer 9c: If the erroneous data were entered by a care provider not associated with the study, the clinical coordinator can only inform the original provider of the possible error. It is up to the non-study care provider to determine if the value should be changed.
	Answer 9d: The clinical coordinator cannot communicate any concerns about potentially erroneous data. To allow this communication to occur with the clinical care team could raise the ethical risk that the change was motivated by the needs of the study, not due to erroneous data entry.

Stage 7: The clinical laboratory requires a licensed laboratory technologist to review results before they are finalized and released to the EMR. However, for this trial, unique genomic and proteomic assays are run in Dr. PI's lab. These innovative tests are not currently FDA approved. The tests are performed by a trained technician who is not a licensed laboratory technologist.	
Question 10: Can these non-approved laboratory tests be entered into the EMR, even if they are labeled as experimental tests?	**Answer 10a**: No. They are not FDA approved laboratory tests.
	Answer 10b: Yes as long as the tests are never visible to non-study clinical care providers.
	Answer 10c: Yes to study investigators. and yes to non-study emergency providers using the system's “Break the Glass” security
Question 11: Can a third-party payer get access to these experimental test results, which may later prove to be markers for specific diseases?	**Answer 11a**: Never. They are experimental, non-approved tests and were obtained under the confidentiality provided by the Informed Consent.
	Answer l1b: Maybe. These results are no different from other study-specific test results. Whichever answer was selected for Question 7 applies here.
	Answer l1c: Maybe. Existing regulations provide special disclosure protections for genetics data. No special regulations apply to proteomics data. Thus, the two types of experimental data must be considered separately.

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Table 1

Electronic Medical Record (EMR) Functionality in Terms of the System's Potential Roles in Accelerating the Steps of Clinical Trials

Trial step	EMR potential role
Study setup	• Query the EMR database to establish the number of potential study candidates • Incorporate study manual or special instructions into EMR “clinical content” for study encounters
Study enrollment	• Implement study screening parameters into patient registration and scheduling • Query the EMR database to contact/recruit potential candidates and to notify a patient's provider of potential study eligibility
Study execution	• Incorporate study-specific data capture as part of routine clinical care/clinical documentation workflows • Auto-populate study data elements into care report forms from other parts of the EMR database • Embed study-specific data requirements (case record forms) as special tabs/documentation templates using structured data entry • Implement rules/alerts to ensure compliance with study data-collection requirements • Create range checks and structured documentation checks to ensure valid data entry
Submission and reporting	• Provide data-extraction formats that support data-exchange standards • Document and report adverse events
Evidence-based review	• Assess congruence of new findings and existing evidence with current practice and outcomes (incorporate into meta-analyses) • Submit findings to electronic trial banks using published standards
Evidence-based clinical care	• Implement study findings as clinical documentation, orders sets, point-of-care rules/alerts • Monitor changes in care and outcomes in response to evidence-based clinical decision support • Provide easy access to detailed clinical care data for motivating new clinical trial hypotheses

Table 2

Representative Clinical-Trial-Related Functional and Access-Restriction Questions that Affect Electronic Medical Record (EMR) Implementation Decisions

Role	EMR-related configuration questions
Principal investigator (PI) with no prestudy clinical relationship to the patient or study participant	• For a study participant with EMR data obtained before study consent, what part of the preconsent record can an investigator access? • If the PI is allowed to see preconsent eligibility or screening attributes only, how can access to the rest of the record be suppressed? • Can the PI access preconsent data that are marked as confidential or have unique regulatory confidentiality rules? If such preconsent data are screening or eligibility criteria, does access permission change? • Can study consent waive confidentiality or regulatory access restrictions on sensitive preconsent data?
Principal investigator with a prestudy clinical relationship to the patient or study participant	• Is EMR data access changed in a clinical trial?
Local IRB	• Are there any changes to IRB review or oversight requirements if a study is to use the EMR for data collection, management, or extraction? • Are new EMR functional requirements needed to support IRB oversight demands when using the EMR in a study? • Are new consent requirements needed when the EMR is used?
Research subject advocate	• Any unique requirements when using an EMR?
Funding sponsor	• What sponsor-specific data confidentiality restrictions are required as a condition of conducting the study? • What trade-secret requirements are imposed by commercial studies? • Will the confidentiality policy be uniform across funding sponsors, or unique to each? • Can a multicenter study impose unique confidentiality restrictions as a condition of participation?
Study participants	• If clinical-trial-specific data are comingled with standard-care data, are those data discoverable for insurance purposes? For malpractice purposes? What is the “legal medical record” when both clinical trial and standard-care data are commingled? How separable (physically/logically) do these data need to be to maintain legal “firewalls?” • If a person's only contact with the institution is as a study participant, should the patient's identifying demographics be searchable/discoverable in the patient registration system? • When a study participant either completes a study or withdraws study consent, do their research-only data remain part of the permanent EMR database?
Standard-care clinicians	• Are clinical trial data accessible to clinicians who provide standard care only?
Emergency care clinicians	• What are the “break the glass” (treatment unblinding or trial-specific data exposure) requirements when serious adverse events are suspected by nontrial clinicians?
EMR users	• Assuming access to trial-specific data is allowed, can a nontrial clinician change trial data that he or she feels are incorrect? • Can a clinical trial clinician change nonprotocol/standard-care data that he or she feels are incorrect? • Is there a difference in access or update rights between standard-care data that will be included in the research data extract and standard-care data that will not be included in the research data extract?

Role	EMR-related configuration questions
	• Who "owns" data quality for shared (research and nonresearch) data elements?
EMR system managers	• Should research data be separated from standard clinical care data? • How to maintain different user roles and permissions for clinical versus research roles—especially if the same person can play dual roles simultaneously during the same encounter? • Who can create study-specific documentation/case report form screens? If new terms or value sets are required, who controls these additions to the master tables? • Should unusual, unapproved, or study-specific laboratory data be entered into the EMR? Are there any special rules for genomic or proteomic data? If entered manually, what level of clinical training is required for the data entry personnel? Are these data part of the legal medical record? Should these unapproved data elements be visible to nonresearch clinicians?
Clinical trial managers	• What management functions currently managed by external clinical trial management systems (CTMS) can be assumed by the EMR? CTMS functions include recruitment monitoring, data collection completion, study compliance, etc. • Can the EMR manage randomization procedures? Should the EMR track randomization assignments?
Data stewards	• What controls, training, or certifications are required for investigators to access nonprotocol/standard-care data? • What responsibilities should be imposed on data stewards before extracting data from the EMR for study-specific data sets? • Can preconsent data be included as part of a study's data extraction?In a multicentered study where a local EMR is used for study-specific data collection, what data-stewardship responsibilities can the external study data center impose on the study site? • In a multicentered study where a local EMR is used for local study-specific data collection, what data-stewardship responsibilities can the study site impose on the external study data center before releasing data from our institution? • What tracking of extracted data is required?
Institutional support	• Who funds research-related data-management costs such as study-specific data-capture configuration, data extractions, study reports, etc? • How are the incremental additional hardware and software costs from research activities within the operational EMR identified?
Billing and compliance	• What additional information must be captured in the EMR at the time service is rendered so that clinical-trial-specific charges are appropriately identified? • What *mandatory* feature/functions/tasks must be implemented to enable continuous compliance with changing clinical-trial-specific reimbursement rules? • Are there different law-enforcement requirements for revealing clinical-trial-specific data?

Chart 1

Roles for Electronic Medical Record Users Caring for Clinical Trial Participants and Corresponding Roles for Users Caring for "Standard Care" Patients*

Clinical Trail Roles	Non-Clinical Trail Roles
Principal research investigators	Standard care clinicians
Study coordinators	Clinical nurses
Study participants	Patients
Research-only clinicians	N/A
Local IRB	N/A
Research subject advocates	N/A
Funding sponsors	Third-party payers
Research institute/clinical trials office/Office of Sponsored Research	HIPAA compliance office/HIPAA Security Office
N/A	Emergency care/other clinicians
N/A	Non-clinical EMR users
N/A	Clinical administrative user
N/A	Quality improvement personnel
Research database managers	EMR technical managers
Statisticians	N/A

* The same individual user could assume multiple roles, even for a single patient during a single encounter (mixing care scenario).