White Paper

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How Meaningful Use Impacts Healthcare Data Management Professionals

What Healthcare Data Management Professionals Need to Know About Achieving HITECH Meaningful Use and Certification

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Netspective
EXTENDING THE ENTERPRISE

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The Obama Administration's HITECH Act, which is part of the ARRA Stimulus Bill passed in 2009, establishes 25 major "Meaningful Use" (MU) requirements that all electronic medical records systems must implement in order to have their users qualify for billions in government incentive money. This white paper presents an overview of the 25 MU items and how testing and certification will be performed to ensure that they are properly implemented. Healthcare IT professionals need to become experts in MU and how those requirements will change their existing and future healthcare information systems.

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EXECUTIVE SUMMARY

This paper presents an overview of the 25 "Meaningful Use" (MU) items and how testing and certification will be performed to ensure that they are properly implemented. Healthcare IT professionals need to become experts in MU and how those requirements will change their existing and future healthcare information systems.
What you'll learn in this paper:

- What ARRA, HITECH, Meaningful Use (MU), and Certification mean.
- How technical personnel such as data architects, DBAs and developers will be affected by MU.
- The best ways to determine the MU gaps that might be found in existing systems.
- Additional expertise technical personnel may need to meet MU.
- How quickly systems will need to be modified and deployed to meet MU rules.

AMERICAN RECOVERY AND REINVESTMENT ACT

In February 2009 the U. S. Congress passed the American Recovery and Reinvestment Act (ARRA, also known as the "Stimulus Bill" or "Recovery Act"). The stimulus bill provides for about $787 billion across numerous industries; the healthcare-specific provisions of the bill are known as HITECH (The Health Information Technology for Economic and Clinical Health Act) and worth about $19 billion.

With that $19 billion, HITECH offers as little as tens of thousands of dollars for private physician practices to as much as tens of millions of dollars for hospitals and multi-hospital systems that accept Medicare and Medicaid. The money being provided by the bill is not a direct payment to practices and hospitals; instead, the payments will be made as increases in Medicare and Medicaid reimbursements to those care providers that meet the rules and regulations defined in within HITECH.

AN OVERVIEW OF MEANINGFUL USE

HITECH coined the term "meaningful use" and was a game-changer in the healthcare IT industry. In a series of regulations, the Recovery Act specifically required the following:

- Use of *certified* electronic healthcare records (EHRs) in a "*meaningful*" manner.
- Use of *certified* EHRs for electronic exchange of health information
- Use of *certified* EHRs to submit clinical quality and other measures to the government

If they become "meaningful users," the HITECH Act offers Medicare and Medicaid hospitals systems tens of millions of dollars through higher reimbursements.

Unlike older certification requirements that were handed over to organizations such as CCHIT that were left to their own definition of what features and functions should be and shouldn't

be considered for certification, the HITECH Act provisions made a nice separation of concerns where the process of defining what useful features or functions must be present in an EHR was given to independent advisory committees run by the Health and Human Services (HHS) Department. The groups that defined meaningful use, the groups that defined what needs to be certified, and the groups involved in the actual implementation of the certification were cleanly separated so that conflicts of interest would be minimized. While the structure isn't perfect, it's a vast improvement over previous incarnations.

"Meaningful Use" (MU) is a great concept and the approach is designed to lead the industry from:

- Data capture and sharing
- To advanced electronic clinical processes
- And, finally, to improved outcomes

The folks defining MU understand that we will not be able to get to improved health outcomes without a basic amount of information sharing, and important improvements in electronic clinical workflows. How much MU will ultimately affect outcomes is not known but it's a good start.

The government has done a good job defining "meaningful use" to be technology and vendor-agnostic. While some rules are well defined, many rules and the manner in which you'll be judged against the rules are not yet determined so be ready for some confusion.

MU is defined in three stages through rulemaking – Stage 1 in 2011, Stage 2 in 2013, and Stage 3 in 2015. In Stage 1 the National Quality Forum (NQF) wants to focus on the following health outcome priorities:

- Improving quality, safety, and efficiency as well as reducing health disparities.
- Engage patients and families in their health care.
- Improve care coordination. Improve population and public health.
- Ensure adequate privacy and security protections for health information.

Meaningful Use Objectives and Measures

There are 25 objectives and measures that must be met to become a "meaningful user". Keep in mind that meaningful use is not tied to a certified EHR alone; in fact, unless you use the EHR properly and in all the ways the government wants you to, you will not be a "meaningful user".

MU Status

The *Proposed Rule* was published in January 2010 in the Federal Register followed by a 60 day comment period. Over 2000 comments were received and the head of the regulatory body said that the Final Rule should be expected before the end of June (at the time of this writing the rules

In summary, here are the substantive MU objectives that you need to meet:

- Use Computer Provider Order Entry (CPOE).
- Implement drug-drug, drug-allergy, drug-formulary checks.
- Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®.
- Maintain active medication list.
- Maintain active medication allergy list.
- Record demographics.
- Record and chart changes in vital signs.
- Record smoking status for patients 13 years and older.
- Incorporate clinical lab-test results into EHR as structured data.
- Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach. This is a common feature in EHRs.
- Report ambulatory quality measures to CMS or the States.
- Implement 5 clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules.
- Check insurance eligibility electronically from public and private payers.
- Submit claims electronically to public and private payers.
- Provide patients with an electronic copy of their health information upon request.
- Capability to electronically exchange key clinical information among providers of care and patient-authorized entities.
- Perform medication reconciliation at relevant encounters and each transition of care.
- Provide summary care record for each transition of care and referral.
- Capability to submit electronic data to immunization registries and actual submission where required and accepted.
- Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.
- Provide clinical summaries for patients for each office visit.
- Provide patients with timely electronic access to their health information within 96 hours of information being available to the EP.
- Protect electronic health information created or maintained by the certified EHR technology

"CMS' goal is for the definition of meaningful use to be consistent with applicable provisions of Medicare and Medicaid law while continually advancing the contributions certified EHR technology can make to improving health care quality, efficiency, and patient safety."

-HHS Website

through the implementation of appropriate technical capabilities
- Generate and transmit permissible prescriptions electronically.
- Send reminders to patients per patient preference for preventive/follow-up care.

CERTIFICATION

Certification is an official action performed by an organization qualified and duly authorized by the U.S. Health & Human Services (HHS) to perform verification and validation of medical software. The certification criteria and test plans for validating software are defined and maintained by the U.S. National Institute of Standards & Technology (NIST) for HHS. At the time of the preparation of this white paper, there are no officially recognized certification bodies. However, organizations such as CCHIT and The Drummond Group have announced plans to apply to become official HHS certification bodies that will use the NIST test plans and procedures to verify and validate commercial software.

The current certification guidance works well for independent software vendors that can sell to multiple customers; however, it's not as convenient or easy for open source firms or those that build their own in-house medical records systems. HHS and NIST are doing a good job, though, laying out the certification criteria independently so that if you follow the rules appropriately you can become certified at some point.

CERTIFICATION VS. MEANINGFUL USE

Certification is about technology while Meaningful Use is about meeting the healthcare quality and cost reduction goals. It's pretty easy to meet the rules to get your software certified but HHS wanted to make sure that care providers didn't get money for just *buying* software but *using* it to achieve HHS's goals.
Remember that the stimulus bill's money is being offered as increases in reimbursements to Medicare and Medicaid insurance claims – not as cash payments. In order to qualify for the increases in reimbursements you have to use technology in a way to save money for Medicare or improve Medicare patients' health or wellness.

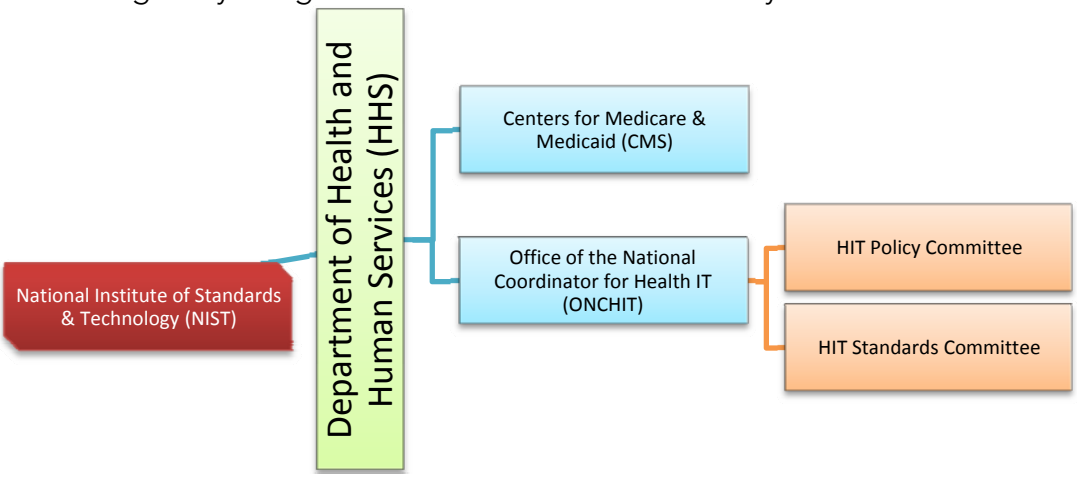
> "Providers and patients must be confident that the electronic health information technology (health IT) products and systems they use are secure, can maintain data confidentially, can work with other systems to share information, and can perform a set of well-defined functions."
>
> -HHS Website

The way the government ensures that you should receive the increased reimbursements is that it forces you to follow the meaningful use rules and do so using a certified medical records system. However, the catch is even if you use a certified system you may accidentally (or on purpose) use the software in a way that HHS does not want you to; in that case, you wouldn't be a meaningful user and would not qualify for the incentive payments. It's quite complicated.

MEANINGFUL USE CONFORMANCE TESTING

GOVERNMENT AGENCIES INVOLVED

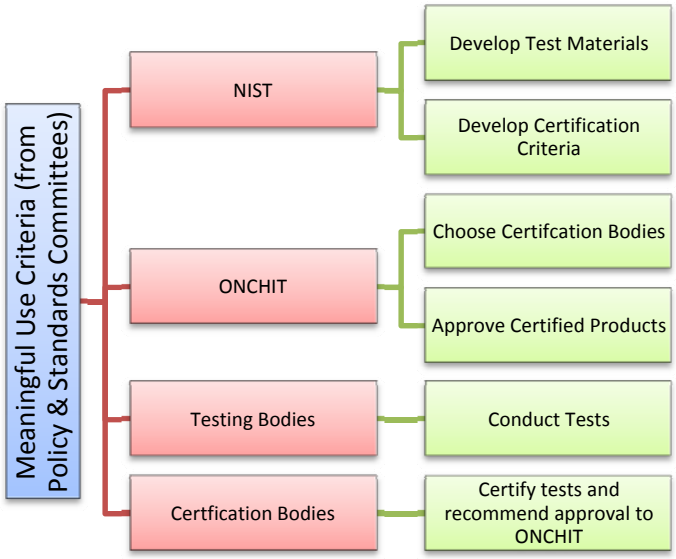
In order to better understand how conformance testing will be done, it's good to take a look at the broad structure of the federal agencies responsible for the work. Unlike past standards such as CCHIT, which had very little government involvement and oversight, MU is fully created and managed by the government and the rules are very strict.



The most important thing to note here is that the ONCHIT or "ONC" has the policy and standards committees but that NIST, which is located in the Department of Commerce and are the foremost experts on standards development are advising HHS on the actual documents and conformance testing for the standards.

CONFORMANCE TESTING RESPONSIBILITIES

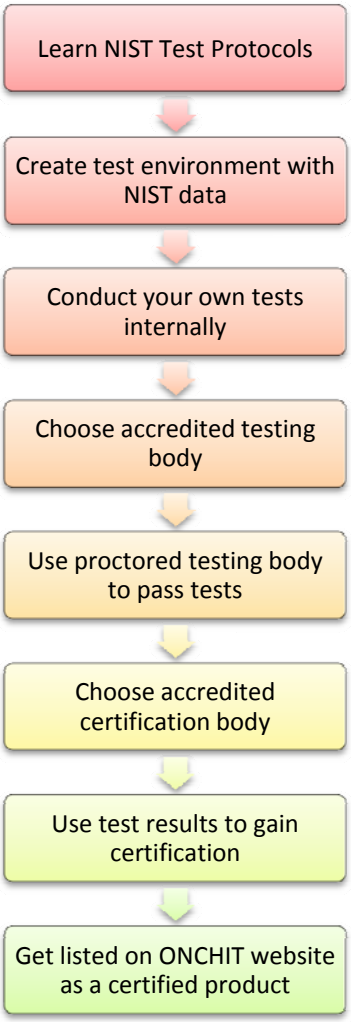
The primary groups involved in conformance testing include the following entities:



- **The Policy and Standards Committees** (they have already done most of their job by creating and finalizing the Meaningful Use Criteria).
- **ONCHIT** will be responsible for selecting independent third party certification bodies.
- **NIST** will be responsible for coming up with the test materials (assertions, procedures, methods, tools, data, etc).
- **Third-party testing bodies** will be responsible for actually performing the tests and validating and verifying conformance to NIST's test plans. Unlike in the CCHIT days, there will be more than one testing body that will be approved for conformance testing.
- **Third-party certification bodies** will be responsible for reviewing output from testing bodies and recommending certification to ONCHIT. Once a certification body recommends approval, the product is "certified" (and not before that time).

PRODUCT TESTING PROCESS

There are three types of products that you and your organization will be familiar with: third-party "vendor" products that you buy and install, open source products that you might buy, install, and tailor, or, your own custom developed products that build from scratch. The process for performing the conformance testing for all three is roughly identical.



All of the products will use the same test materials and certification criteria, developed and maintained by NIST at http://healthcare.nist.gov/use_testing -- the test procedures are available for review at that location. Before you begin your MU journey, make sure you become experts in the rules by reading and understanding the NIST test plans and protocols; if anyone has any question about whether something is really required by the MU criteria, NIST will be the official source because they are responsible for the test plans.

- **Learn NIST Test Protocols**. Start with the protocols and get help from consultants and tools. Focus on the NIST test protocols and not on conjecture on websites and other locations about what is in or out of MU criteria.
- **Create test environment with NIST data**. Instead of using your own test data, create a test environment that uses NIST test data.

- **Conduct your own tests internally**. Don't worry about the certifying and testing bodies initially; try and pass all the tests on your own first.
- **Choose accredited testing body**. Find the least expensive and easiest to use testing body. Because you have a choice, spend some time researching – don't just choose CCHIT as a default but they may be your best choice.
- **Use proctored testing body to pass tests**. Coordinate a time with the testing body to conduct their testing.
- **Choose accredited certification body**. Because testing and certification are two different paths, be sure to choose wisely. In 2010 the certifying and testing bodies are allowed to be the same so depending on when you're conducting your testing you may be able to skip this step.
- **Use test results to gain certification**. You submit your testing body results to the certification body and they approve the test results and recommend certification to ONCHIT.
- **Get listed on ONCHIT website as a certified product**. At this point you can market the certification.

How to Understand the Impacts of Meaningful Use

Meaningful Use will touch dozens if not hundreds of systems and subsystems. This is a general process that should be followed to understand impacts.

Planning

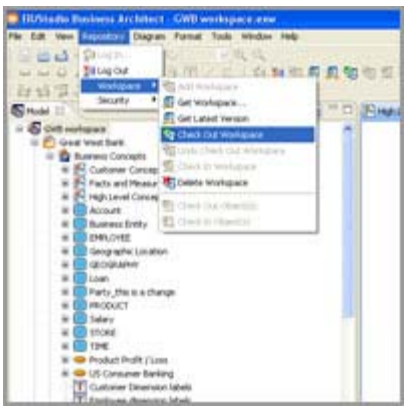
You should start with identifying which areas of MU you will be targeting and define the success criteria. If you can't figure out what success means up front you should not start the process. In most cases, success means that you will be able to pass the NIST Test Plans for MU initially followed by official testing and certification.

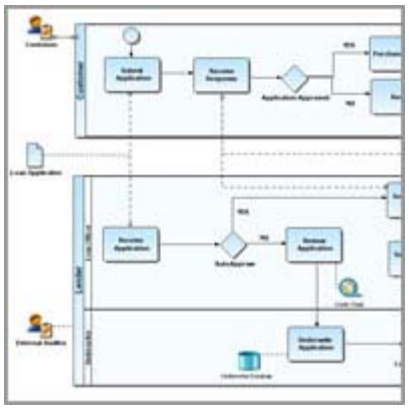
Tools like Embarcadero® ER/Studio® Portal are indispensable for the planning stage. Define the clinical domains that should be targeted. The domains could be your EMR, the lab system, the e-prescribing area, etc. You start off the planning process by pointing ER/Studio to each of your databases and let it extract data definitions and relationships for you. Once you have the relationships you can use the Portal to report on data lineage to understand where definitions are coming from.

You should also use a utility like the Portal to start marking up data elements that will be affected by the MU criteria before actually making any changes – this will foster discussions and allow you to go beyond the requirements of MU while you're making changes. Because Portal can be reviewed and data comments can be provided by end users, business analyst, and DBAs, it allows you to make sure you know the full impacts of all the MU changes.
One of the major new initiatives in both the HIPAA 2009 and MU regulations is improved security and privacy. Embarcadero's line of Database Management and Administration tools provide utilities for managing user roles and access within the database to better control the security and privacy of information. The increased compliance constraints means that understanding your data and how it moves from an application into the database and out to flat files and ETL tools becomes even more important. Visual Data Lineage is one of the key features of Embarcadero's ER/Studio suite that lets you better understand your data assets by giving the task to business personnel instead of forcing DBAs and technical staff to do all the work.

Workflow and Clinical Functionality

Some requirements in MU will cause either minor or complex changes in the workflows and functionality of your applications and systems. You could jump in and start making codes changes immediately but you should really take this opportunity to try and map major clinical business processes in the clinical domains that may be impacted by MU requirements.
You will need to determine whether the business is willing to re-engineer any existing clinical business processes that do not meet the MU guidelines. Embarcadero ER/Studio® Business Architect product will help you combine process and data modeling in one repository – you can immediately see if changing workflow affects data and vice-versa.





Clinical process modeling is difficult but with standard sequences, tasks, and swimlane elements Business Architect will get you started quickly and begin sharing MU conformance requirements faster than trying to explain them in text along. With support for high-level conceptual modeling with subject areas, business entities, relationships and other elements you can get your clinicians fully involved in the documentation and specifications process. As you move to more technical personnel, the modeling tools kick in and allow you to connect real models into the ER/Studio Portal. The objective of all this work is to ensure proper understanding of clinical workflows and getting the functionality right.

> You could jump in and start making codes changes immediately but you should really take this opportunity to try and map major clinical business processes in the clinical domains that may be impacted by MU requirements.

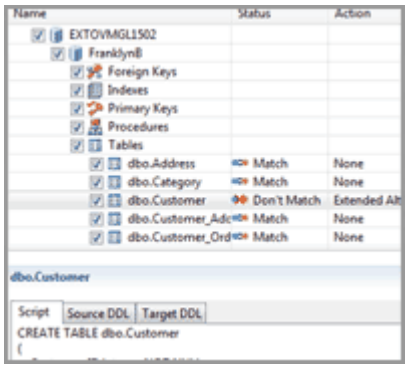
As you're doing your planning and workflow analysis work, be sure your tools support data dictionary standardization with domain inheritance, reusable objects, and automatic updates; it will also be very helpful to have "Where Used" analysis and user-defined mappings features so that you can look up a MU requirement and see if it already is handled somewhere. Be sure the tools support diagramming and visualizations throughout – business users understand pictures and you shouldn't present them with technical terms.

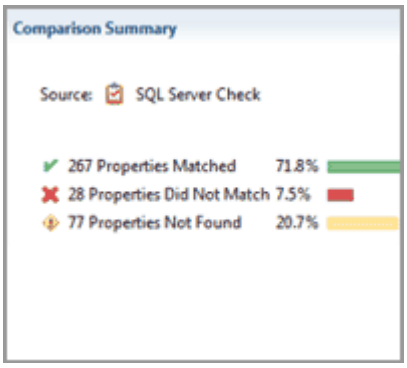
Lowering Coding Risk through Change Management

Before you start your implementation of the code and data model changes needed for MU conformance, you'll want to establish the process for how changes will tracked; tracking changes in code is usually easy: you simply use existing revision control systems (RCS) like CVS, Subversion, Git, or SourceSafe. RCSs do a great job allowing you manage multiple versions of code files and rollback to earlier versions or compare different revisions to understand changes being performed by multiple programmers.

> Be sure you implement a proactive approach to dealing with changes to data model and code before you start your MU journey. Be sure you figure out how to adapt to, control, and effect changes required by MU conformance.

Unfortunately, it's much more difficult to manage data model changes because RCSs don't have the ability to allow rollbacks and comparisons of database schemas. The Embarcadero® DB Change Manager™ package mitigates the risk of change – you don't have to be scared of making changes because Change Manager can protect you from the side effects and unintended consequences of quick database structure changes. Like VCSs for software code, Change Manager can archive the structure (schema) before changes, rollback changes, and compare changes between schema revisions. With features like these you can use junior DBA resources and without having to pull in senior staff for minor and event major changes. A proper change management strategy also allows you to document development, testing, and production promotion scripts and process.





Since you probably have many different databases from various vendors, your change management strategy needs to support all databases from a single interface. Make sure that schema "archive" capture, compare and synchronization along with data compare and synchronization are in your selection criteria for tools. Many tools promise lots of "visual" changes – just make sure that your tools offer alter script generation that handle object dependencies and preserves data while doing the changes.

> Since you probably have many different databases from various vendors, try to be sure you choose data management tools that support multiple databases using the same interface. Don't use different tools for different databases.

Since VCSs are also common in many DBA environments and some of your developers will be involved when making changes, ensure that the change management strategy for data model and structure changes support source code control integration.

Implementation Support

Once you've done your planning work and have started to look at functionality changes you're ready to start supporting the implementation teams – DBAs, programmers, QA, etc. Start with the following:

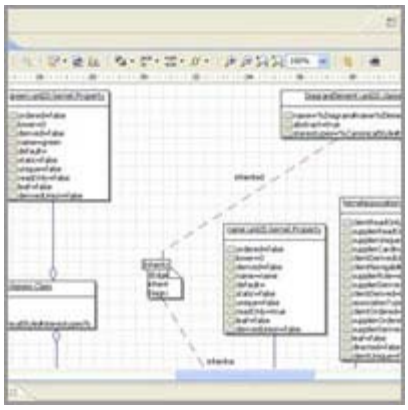
- Identify all data sources and sinks that will should be consumed or published by the MU requirements.
- Identify and catalog all existing applications that may play a role in the MU requirements.
- Identify and catalog all existing services that may play a role in the MU requirements.
- Identify and catalog all external interfaces that may be impacted by the MU requirements.

> Be sure you implement a proactive approach to dealing with changes to data model and code before you start your MU journey. Be sure you figure out how to adapt to, control, and effect changes required by MU conformance.

ER/Studio® Data Architect and ER/Studio® Software Architect components can help you perform all the functions outlined above. The complete UML modeling environment allows you to reverse engineer and manage the class, sequence, use case, and other UML diagrams.

You'll want to be sure your tool includes complete database lifecycle support for forward and reverse engineering because legacy systems won't have existing documents to pull from.

You'll want to be sure your tool includes complete database lifecycle support for forward and reverse engineering because legacy systems won't have existing documents to pull from. You'll also want to be sure you can do bi-directional comparisons and merging for models and database structures because you'll have test and production systems to move schemas into and out of.

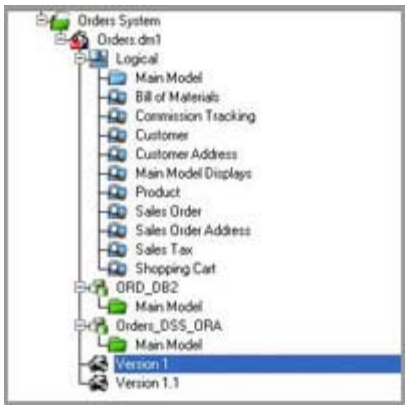


Centralized or Federated Clinical Domain Model

After you've considered the implementation hurdles, this is the time to ascertain whether a central or federated Clinical Domain Model (CDM) makes sense; MU is broad enough that if you don't have a CDM it makes sense to look at this now.
If you think that you can afford the time and effort to put together a CDM, start with the following tasks:

- Identify classes, instances, attributes, and methods needed to represent the relevant knowledge of the clinical data that will be captured.
- Create the hierarchy that will organization the classes, attributes, and methods be organized.
- Identify containment and aggregation strategies.

Embarcadero's ER/Studio® Repository is a tool that you can use to manage your centralized or federated clinical domain models.



You'll want to be sure to use a tool that supports concurrent model and object access for real-time collaboration on data models. Given how fast MU conformance changes will be required you'll want to have real time object status notification to show check-out status of diagrams and objects as code and structural changes are taking place. A pre-defined enterprise data dictionary will eliminate clinical data redundancy and enforce clinical data element standards across your various systems so you'll want to ensure your tools supports sophisticated data dictionaries.

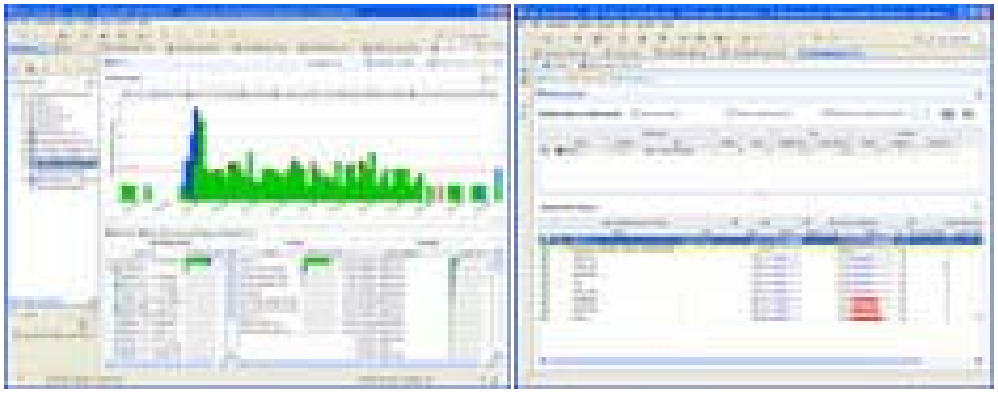
We've already discussed how important change management is so you'll want to have version management features built-into your CDM repository to manage the individual history of models and model objects with the ability to rollback to earlier versions. Auditing requirements will require that your CDM repository security allow binding and associating users to diagrams, objects and dictionaries so that only authorized individuals can affect changes to your clinical models.

Maintain Security, Performance and Reliability Through MU

It takes years to build high-performance and reliable systems. Because MU requires substantial changes to code and data models, you're going to need to have tools that help you measure and maintain performance and reliability so that you can be sure that changes to your systems do not cause unintended consequences. Embarcadero's DBArtisan® and DB Optimizer's cross-platform performance and database administration tools maximize availability, performance and security. The instrumentation and diagnostics it provides help ensure your IT team can proactively pinpoint and manage many database system vulnerabilities that can slow performance and cause downtime. It also provides a SQL profiling and tuning IDE for a graphical visualization of the problems causing poor database performance.

While ad-hoc performance tuning with IDEs and profiling tools are great for development you'll want to be sure that you have automated SQL profiling, tuning, database monitoring

and alert notification solution that allows you to diagnose poor-performing SQL, configure thresholds and proactively notify you across all your critical databases. It helps to decrease response times by enabling users to quickly identify issues and correct potential problems so it's something that's pretty important to consider during your tools selection process.



SERVICE ORIENTATION

One of most innovative models of creating and managing modern information systems, called Service-orientation (SO), is proving that it can handle the needs of other industries (like financials) moving from paper and phone to electronic communications. There are many elements of a successful healthcare enterprise Service-Oriented Architecture (SOA) implementation a unified patient-centric data model, clinical semantics, legacy system integration, patient relationship management, business process and metadata management, thin client user interface, and service orchestration. Where possible you will want to take advantage of the MU conformance requirements to change monolithic applications into services that can be reused across different systems. Instead of immediately jumping into application-specific changes, create a portfolio of potential services that will be needed to be connected to meet the MU data interoperability requirements. For each service provider:

- Identify all potential service consumers.
- Specify business functionality of the new service according to the requirements of all potential service consumers.
- Match business requirements to Clinical Domain Model and implemented services. Refine the Clinical Domain Model to ensure consistency because MU requires longitudinal records (not just event driven).
- Specify all the components that will be needed by the service provider.
    - Data
    - Rules
    - Services (sub-services)
    - Configuration
    - Variations

Embarcadero's DBArtisan® XE solution can help you as you convert monolithic applications into clinical services.

Service orientation requires crossing platform boundaries so you need the ability to be multi-platform capable so your programmers and DBAs can move from one familiar platform to an unfamiliar platform quickly. As you create services you will need to abstracts differences between platforms (so that all databases look similar); you will want to make sure to use wizards to generate scripts –the final result needs to have reusable code that you can use within and across all your services.

Given the complexity of healthcare services, you want tools that help you reduces repetitive tasks through scripting –allowing senior DBAs to focus on business problems and more complex tasks while junior DBAs focus on "triage" tasks. You will be able to get more money from your senior resources with that strategy.

Bottom Line

You're looking at a long and complex MU conformance process filled with many complicated projects and very little time to get your systems up to meaningful use standards. If you start with good planning, move to analyze your workflows and functional requirements, craft an effective change management strategy, and put in good tools and techniques for an effective implementation approach you'll be able to meet the requirements put into place by the government and get better systems for your customers.

About the Author

Shahid N. Shah is an internationally recognized and influential healthcare IT thought leader who is known as "The Healthcare IT Guy" across the Internet. He is a consultant to various federal agencies on IT matters and winner of Federal Computer Week's coveted "Fed 100" award given to IT experts that have made a big impact in the government. Shahid has architected and built multiple clinical solutions over his almost 20 year career. He helped design and deploy the American Red Cross's electronic health record solution across thousands of sites; he's built two web-based EMRs now in use by hundreds of physicians; he's designed large groupware and collaboration sites in use by thousands; and, as an ex-CTO for a billion dollar division of CardinalHealth (now CareFusion) he helped design advanced

clinical interfaces for medical devices and hospitals. Shahid also serves as a senior technology strategy advisor to NIH's SBIR/STTR program helping small businesses commercialize their healthcare applications.

Shahid runs three successful blogs. At http://www.healthcareguy.com he provides valuable insights on how to apply technology in health care, at http://www.hitsphere.com he gives voices of other health IT experts, at http://shahid.shah.org he writes about architecture issues, and at http://www.federalarchitect.com he advises senior federal technologists.

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