

## **Designation of Clinical Research Information Integration as an Objective of “Meaningful Use” of Electronic Health Record Systems**

*Presentation to the HIT Policy Committee  
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### Summary

As the United States undertakes the transformation of health care from an enterprise supported by paper-based transactions to one managed with electronic information technology, an opportunity of fundamental importance exists to create an evidence-based health care delivery system. In order to achieve a high performance health care system, it is necessary for health information technology (HIT) to enable the development and use of evidence at the point of care, a capability that will require modernization of the Nation’s clinical research enterprise. The initial steps in such a transformation can be supported under the “Meaningful Use” approach, which is intended to encourage rapid adoption of Electronic Health Records (EHR) and help steer the design and employment of these tools toward productive, near-term uses while building the foundation to more fully exploit the potential of EHR in the future.

In the next several years, adoption of health information technologies can be employed as a strategy to increase the opportunities for patients and practicing clinicians to take part in research; improve the cost-effectiveness of U.S.-based clinical research; and expand the availability of clinical information for research and discovery. In the longer term, a clinical research enterprise that is configured around electronic information systems will yield more rapid scientific discovery and will provide significant support of related activities including: clinical trials; comparative effectiveness and other outcomes-related research; quality of care measurement; and public health and safety monitoring, including post-marketing surveillance.

The “Meaningful Use” framework as presented by the HIT Policy Committee is well-suited to help initiate the modernization of the Nation’s clinical research enterprise. This is a practical opportunity at the outset of widespread EHR adoption to begin rendering the interface between “bench and bedside” more porous and productive, while providing and indeed improving the required oversight. As applied to clinical research, the “Meaningful Use” approach provides incentives that support immediate benefits for patients, providers and entities that support research investment. Meanwhile, this framework lays a longer-term foundation for accelerated discovery, extensive outcomes research, and ultimately a “learning health system” in which a “bench-to-bedside-to-bench” cycle of information will support continual improvement in knowledge, care and health.

## Background

Clinical research is the lynchpin that connects innovative technologies from basic discovery research to their application as breakthroughs in patient care. The United States has been the world's leader in this area, with \$122 billion annual investment in biomedical research, with half of that sum spent on clinical research (1). It is also noteworthy that it is estimated that approximately one-third of clinical studies in the U.S. are federally-sponsored.

At the heart of clinical research is the immense data collection and analysis that determines the efficacy and safety of medical therapies. Currently, the processes for identifying subjects eligible for research, collecting study parameters, assembling information from multiple study sites, conducting oversight of study protocols, and analyzing results are time consuming, labor intensive, and extremely expensive. Many experts have pointed to the high costs of therapeutic development in the U.S. as attributable to clinical research processes that are in many ways conducted using information management methods from the 1970s.

In many cases, clinical trials supported by U.S. entities are moving abroad or not being done because of the cost and long timeframes needed to complete them in this country. Outsourcing of studies to India, China and South America is expected to grow by 36% between 2007 and 2011. By 2011, it is expected that more than 15% of global clinical trials will be carried out in India (2). If half of the projected outsourcings were kept within the U.S. as a result of improved work processes stemming from improved information management, this would translate to approximately \$300 million annually in studies and jobs retained in the U.S.

Clinical research presents unique requirements that are amenable to solutions supported by EHR systems. But improvements through the use of electronic information exchange have been slow in clinical studies for many reasons, including the lack of informatics infrastructure, exemplified by low EHR adoption, inconsistent data standards and database architecture, and insufficient analytic tools.

Patient recruitment is crucial to the clinical research enterprise. Currently, without the assistance of IT solutions, recruitment is extremely slow, expensive, and low-yield. A national survey in 2009 found that 74 percent of respondents would welcome the opportunity to participate in clinical research, yet few patients are presented this opportunity and researchers have difficulty in finding study participants (3). Likewise, in the absence of IT-enabled data efficiencies, physician participation is constrained by the lack of adequate administrative resources.

The potential efficiencies available through IT solutions are largely untapped. In 2004, studies indicated that over 75 percent of information obtained for support of clinical trials was entered on paper (4). Use of electronic solutions can reduce the cost of data collection by 55% over paper (5). Furthermore, the information once collected is typically entered for various needs from four to seven times by clinicians. Even though

some study data is now collected by electronic systems, an average study site has three separate IT systems; and interconnectivity between institutions is minimal, restricting the useful availability of data (4).

### “Meaningful Use” and Modernization of Clinical Research

The “Meaningful Use” approach affords the opportunity to support significant improvements in the clinical research enterprise in a near-term time frame as EHRs are being broadly adopted. These improvements will positively affect patients, physicians, researchers, entities which invest in clinical research, and ultimately all of us who look to scientific discovery to propel medical advancement. Of special note is the potential to improve participation opportunities for minority and underserved Americans, and to support expanded research in conditions that are especially significant for these populations. Application of the “Meaningful Use” approach will reduce the paper-bound barriers that impede the clinical research enterprise today and will liberate the energy and experience of physicians and the interest and altruism of patients in contributing to research. Three areas of immediate impact are:

1) *Supporting Opportunities for Patient Participation.* A standard set of information in a patient’s EHR could, with consent, be made available for review by research recruitment tools. Provided here are some of the details by which “Meaningful Use” designations can enhance the public good achieved from enhanced participation in clinical research.

- Experience suggests that such an enabled interface could increase patient queries about research participation 10-fold and double clinical study enrollment in three years.(6) Clinical alert systems using EHRs have been shown to increase physician referrals to clinical studies by 10-fold in one community-based study.
- This approach of including meaningful use incentives would help reduce costs and recruitment time for federally-sponsored clinical trials programs. Approximately one-third of all clinical trials in the U.S. are sponsored by federal agencies and many of them have difficulty meeting recruitment thresholds, often because patients are unaware of ongoing studies.
- Innovations in EHR systems will follow incentive development to support connections with patient record information to national clinical studies registries such as [clinicaltrials.gov](http://clinicaltrials.gov) to present opportunities for patient enrollment and determination of eligibility for participation
- Physicians enabling patients to connect with clinical studies through the use of EHRs will be responding to widespread patient interest and supporting more effective clinical research and discovery. “Meaningful Use” incentive payments to compensate clinicians for making these opportunities available represent a good investment for the Nation in the full use of HIT potential.
- An initial consensus set of core patient data elements appropriate for EHR/registry connections has been identified by the EHR Clinical Research Workgroup, under the auspices of the American National Standards Institute (ANSI), the Clinical Data Interchange Standards Consortium (CDISC), and HHS.

The workgroup's recommendations have been accepted by HITSP for development of interoperability specifications by January 2010.

2) *Reducing Barriers for Provider Participation in Clinical Research.* Use of efficiency-improving EHR systems and information standards would enhance clinician opportunities for engaging in clinical research. The business environment of today's health care enterprise has created barriers of time and resources that discourage clinician engagement with patients to discuss or support clinical research opportunities. Incentives through EHR "Meaningful Use" criteria will enhance clinician interest in presenting clinical research options and opening doors for patients to participate in them.

3) *Use of Standards-based EHR Data for Clinical Research.* The IT environment for health professionals and researchers should make possible seamless, secure, and consistent integration of clinical care information from EHRs into clinical research information systems. Such an environment will: reduce time spent on data entry; reduce the need to customize EHR products to support research; increase data accuracy; increase data availability throughout the research community; enable data integration from multiple sources; support longitudinal study as well as re-use of data; facilitate participation by a greater number of clinicians in research; and support more highly targeted research, including specific questions in comparative effectiveness research.

- Use of standards-based data can significantly improve the value proposition for clinical research in the U.S. Recent studies by Gartner demonstrated that improvements in automating clinical trials processes can improve efficiency by 30-50 percent and result in cost savings of \$5.8 to \$6.6 billion. (7)
- Use of EHR systems is anticipated to reduce study start up times by 70-90 percent and reduce overall cycle time for a project by 60 percent. This amounts to an estimated cost savings of about \$6.7 million per study and about 6 months of recruitment time per study. (8)
- These efficiencies will expand the number of clinical studies and accelerate delivery of new medical knowledge and products to clinical care. Reducing clinical studies costs through enhanced patient recruitment and more efficient processes can lead to an increase in numbers of studies and hence increase the pace of development and success in making valuable new products available.
- Harmonized information exchange standards for clinical research and health care is also essential:
  - To aggregate sufficient information across partners such that research findings lead to informed health care decisions
  - For timely safety surveillance on a global scale
  - To link biomarkers (including individual genetic markers) to population characteristics and outcomes
  - To enable clinicians to perform research concurrent with clinical care.

In addition to the direct benefits accrued by "Meaningful Use" designation for support of clinical research through the use of standards-based EHR data, there are potential benefits to improve study oversight and patient protections. The protection of privacy, patient-

asserted choice, security and confidentiality of patient information are important considerations in using personal health information for clinical research. Use of the EHR can provide authentication and role-based access through technology applications to improve patient protections.

### “Meaningful Use” Criteria

The goals of the “Meaningful Use” approach are consistent with the opportunities presented in clinical research:

*Engage patients and families in managing their health and making decisions about their care:* New opportunities for patient participation in clinical research put patients in a more active role. The expanded opportunity is especially important for minority and under-served populations, who are under-represented in clinical research.

*Improve the health of the population:* Significant improvements in clinical research effectiveness would support acceleration of discovery. Standards-based data available from EHRs would also support broader efforts in comparative effectiveness and quality measurement.

*Improve the safety and reliability of America’s health care system:* In addition to supporting more effective discovery research, the development of standards-based data would support efforts including public health and safety monitoring, post-marketing surveillance and outcomes-related research.

*Ensure patients receive well-coordinated care:* The current disconnects between clinical research and patients who wish to participate in research is a conspicuous area of non-coordination in health care.

*Guarantee appropriate and compassionate care for patients with life-limiting illnesses:* Opportunities for participation in research can make cutting-edge research available rapidly to more patients. This application of “Meaningful Use” would be especially important for discovery in rare diseases.

*Eliminate overuse while ensuring the delivery of appropriate care:* This application would support significant new information resources in the nearest time-frame for outcomes research, which is the prime source of useful evidence for appropriate care.

### Conclusion

Adoption of clinical research capabilities as a measure of “Meaningful Use” of EHRs represents a high-yield investment for the Nation. In reducing barriers that impede clinical research today, the changes supported by this application would represent incentives to providers for EHR adoption. In improving efficiency and effectiveness of

information management, the changes would leverage billions of dollars of annual investment. In increasing the availability of clinical information for researchers, the changes would support accelerated discovery and improved health care effectiveness. The changes would have special impact on minority and underserved populations, who have little access to research participation opportunities today, impacting the ability to study conditions of particular importance to them. In seeking to build a foundation for the full potential of EHRs through Medicare and Medicaid Meaningful Use incentives, support for improved clinical research capabilities represents an opportunity to achieve a high performance health care system based on continuous learning and quality improvement.

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