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# Insights

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## FOCUS ON HEALTH CARE



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# Electronic Health Records: The Foundation for the Transformation of Health Care Delivery and Research

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*Health information technology, including electronic health records, represents a significant opportunity to enhance medical treatment through more complete, accurate, and accessible medical information. This discussion summarizes both (1) national plans regarding investment in health information technology and (2) evolving demands for the creation of bio-repositories and data warehouses.*

## INTRODUCTION

In January 2006, President George W. Bush announced a plan designed to ensure that most Americans have electronic health records within ten years. The plan called for (1) the adoption of health information standards, (2) increased funding for health information technology (HIT) demonstration projects, and (3) use of the federal government's clout as one of the largest purchasers of health care in the world to create incentives for health care providers to adopt health information technology. The HIT contemplated by the vision includes electronic medical records, computerized prescribing and ordering of diagnostic tests, clinical decision support tools, and the technology that will enable the interoperability needed to achieve the secure exchange of electronic health information among providers, payors, and others.

President Obama's 2009 economic recovery legislation<sup>1</sup> converted President Bush's HIT vision into the equivalent of a "funded mandate." The Health Information Technology for Economic and Clinical Health Act (HITECH Act)<sup>2</sup> commits approximately \$20 billion of federal support for the establishment of a nationwide health information network and of corresponding standards to assist in that endeavor, including meaningful Medicare and Medicaid reimbursement incentives for physicians and hospitals who move quickly to acquire and implement electronic health record (EHR) technology.<sup>3</sup>

The Office of the National Coordinator for Health Information Technology (ONC) of the Department of Health and Human Services (HHS) is responsible for providing the leadership and coordination for implementation of this HIT vision. The ONC previously articulated four important and interrelated goals: (1) to inform clinical practice with the use of EHRs, (2) to interconnect clinicians so that they can exchange health information using advanced and secure electronic communications, (3) to personalize care with consumer-based health records and better information for consumers, and (4) to improve public health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research.<sup>4</sup>

Together, these goals capture the various dimensions of the current and rapidly growing demand for an electronic health information exchange. That exchange will support uses extending well beyond traditional clinical care delivery, operations, and research. Such uses include as more robust quality and patient safety measurements, pay-for-performance incentive programs, and leading-edge genomic and translational research that explores individualized disease states and treatments and ultimately supports the delivery of personalized medicine.<sup>5</sup>

The need to support such leading edge uses of electronic health information mandates a transformation of today's HIT infrastructure into one that fuels the creation of robust electronic bio-reposito-

ries and standardized information warehouses and networks to facilitate the sharing of vast amounts of reliable clinical care and research information between and among all industry sectors and the patient. The proliferation of the interoperable EHR technology infrastructure contemplated by the ONC's goals and funded by HITECH Act stimulus funds will be the foundation for achieving the HIT transformation. This transformation will move us to a new health care delivery and research paradigm centered around personalized medicine and personalized health care.

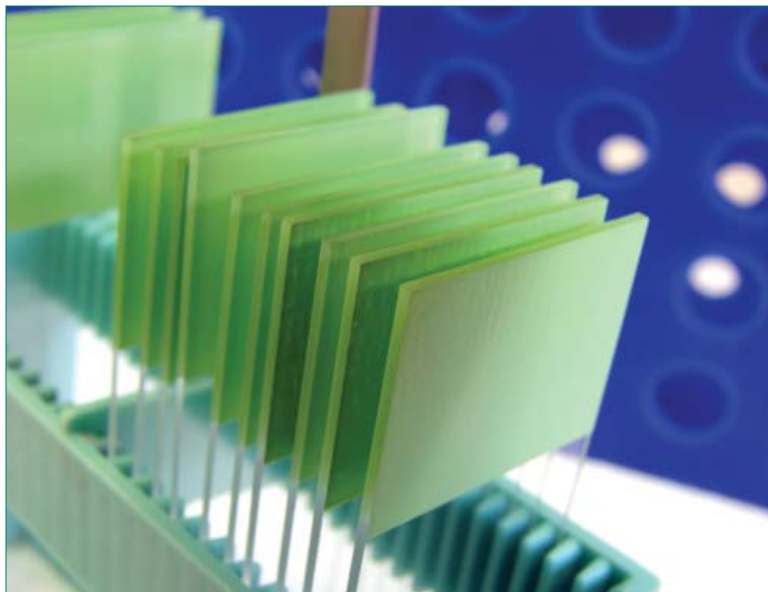
This discussion provides an overview of key recent and evolving demands for the creation of biorepositories and data warehouses for which interoperable EHR will provide a strong and essential foundation. And, this discussion summarizes the key business and legal planning considerations to be addressed at the earliest stages of the repository planning and development effort.

## CATALYSTS AND FUEL FOR THE DEVELOPMENT OF DATA AND TISSUE REPOSITORIES AND REGISTRIES

All institutional and individual providers will need repository resources to respond to the increased focus on improvements in quality and efficiency through comparative effectiveness research and evidence-based medicine. For academic medical centers, universities, and research institutes, in particular, the development of electronic data and tissue warehouses that aggregate and share information on an enterprise-wide basis and in collaboration with other institutions will be essential to qualify for future research funding by the National Institutes of Health (NIH).

Pharmaceutical and device manufacturers need repository resources now to support expanded Food and Drug Administration requirements for post-market surveillance and Risk Evaluation and Management Strategies (REMS) and in the near future to adapt product strategies to respond to the personalized medicine movement. And, clinical research organizations are rapidly realizing how such HIT resources can diversify and enhance the services they make available to the organizations whose research they are in business to support.

The following overview describes various initiatives that have been the catalyst and the fuel for the development of robust, shared data and tissue repositories. These shared data and tissue repositories are an essential and valuable tool for the future of all industry stakeholders.



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## The National Cancer Biomedical Informatics Grid (caBIG™)

caBIG™ is the national cancer biomedical informatics grid initiative launched by the National Institutes of Health (NIH) in March 2008. The purpose of the initiative is to establish an information network enabling all constituencies in the cancer community—researchers, physicians, and patients—to share data and knowledge in order to accelerate the discovery of new approaches for the detection, diagnosis, treatment, and prevention of cancer, ultimately improving patient outcomes.

The specific goals of caBIG™ are (1) to connect scientists and practitioners through a shareable and interoperable infrastructure; (2) to develop standard rules and a common language to more easily share information; and (3) to build or adapt tools for collecting, analyzing, integrating, and disseminating information associated with cancer research and care. caBIG is committed to making the informatics grid available to everyone in the cancer research community, open development of infrastructure and tools, and open source code, while maintaining local control over an institution's own resources and data. The components of caBIG™ are widely applicable beyond cancer.

## Translational Research and NIH Clinical and Translational Science Awards (CTSA)

Translational research involves three areas of translation that generate an on-going, circular flow of input from bench to bedside. The first area is the process of applying discoveries generated during research in the laboratory, and in preclinical

studies, to the development of trials and studies in humans. The second area of translation applies the results of clinical trials into changes in clinical practice—the translation of research into real therapies for real patients. The third area feeds actual clinical care findings back into the research dimensions.<sup>6</sup>

In October 2006, NIH launched the Clinical and Translational Science Awards (CTSA) program to fund the creation of a national consortium of medical research institutions that would work together and share a common vision to: (1) improve the way biomedical research is conducted across the country, (2) reduce the time it takes for laboratory discoveries to become treatments for patients, (3) engage communities in clinical research efforts, and (4) train the next generation of clinical and translational researchers. The CTSA program is led by the NIH National Center for Research Resources and has as one of its principal goals the development of the infrastructure needed to support translational research.

## Personalized Medicine or Personalized Health Care

Personalized medicine is multi-dimensional and is continuing to evolve. HHS views it as a catalyst for a relationship shift between and among, providers, patients, drug manufacturers, drug development regulators and researchers.

Stated in simple and general terms, personalized medicine or personalized health care refers to medical practices that use genetic tests and family history information to develop preventive, diagnostic, and therapeutic interventions that are tailored to individuals on the basis of their specific genetic code. Its goal is to improve health outcomes and the quality of a patient's life.

By way of example, personalized medicine would enable a patient with chronic myelogenous leukemia (CML) to take a diagnostic test that indicates the presence of a mutant gene, called Bcr-Abl, to determine whether he or she can take a drug called Gleevec. Gleevec binds specifically to the faulty gene's product, inhibiting its cancer-causing action. Early studies show a 90 percent initial response rate to this drug in patients with CML and the hope of complete remission.

Similarly, it would provide for a patient to be tested in a doctor's office to discern whether he or she has a particular combination of 31 possible genetic variations in two liver enzymes, known as cytochrome P450, which together are responsible for metabolizing 40-45 percent of all drugs. This information would help physicians fine tune dosages, based on molecular metabolism rather than on previous crude weight estimation.

## Patient Safety Improvements

The Patient Safety and Quality Improvement Act was enacted on July 29, 2005. The Act was developed in response to growing concern about patient safety in the United States and to the Institute of Medicine (IOM) 1999 report, *To Err is Human: Building a Safer Health System*. Its purpose is to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. It creates Patient Safety Organizations (PSOs) to collect, aggregate, and analyze confidential information reported by health care providers.

Currently, patient safety improvement efforts are hampered by the fear of discovery of peer deliberations, resulting in under-reporting of events and an inability to aggregate sufficient patient safety event data for analysis. By analyzing patient safety event information, PSOs will be able to identify patterns of failures and propose measures to eliminate patient safety risks and hazards.

Finally, the Act calls for the establishment of a Network of Patient Safety Databases (NPSD) to provide an interactive, evidence-based management resource for providers, PSOs, and other entities. It will be used to analyze national and regional statistics, including trends and patterns of patient safety events. The NPSD will employ common formats (definitions, data elements, etc.) and will promote interoperability among reporting systems.<sup>7</sup>

## Quality Improvements Through Evidence-Based Medicine

Evidence-based medicine seeks to apply evidence gained from the scientific method (mainly randomized controlled trials) to certain parts of medical practice to predict outcomes. It seeks to assess the quality of evidence relevant to the risks and benefits of treatments (including lack of treatment). According to the Centre for Evidence-Based Medicine, "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."<sup>8</sup>

The Centers for Medicare and Medicaid Services (CMS) is already engaged in the use of data registries. The registries collect outcomes information as evidence regarding whether the effectiveness of certain treatments and products—where clinical information is limited but promising as a basis for registries—is sufficient to support Medicare reimbursement coverage for such treatments and products. The concept is known as "Coverage with Evidence Development."<sup>9</sup>

## Comparative Effectiveness Research

The 2009 federal stimulus legislation<sup>10</sup> also provided \$1.1 billion in funding to support comparative effectiveness research (CER), created a Federal Coordinating Council to oversee use of the funds, and commissioned reports on CER by the Federal Coordinating Council and The Institutes of Medicine (IOM); both reports were issued in June 2009.<sup>11</sup>

The Council's report in particular identifies four categories of investment and activity as part of its strategic framework, including the development of a data infrastructure consisting of distributed practice-based data networks and longitudinally linked administrative or EHR databases or patient registries.

CER involves the "rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients."<sup>12</sup> Traditional health care research, which focuses on whether an item or service is effective and safe in an ideal world rather than in "real world" settings, is difficult to apply to a given patient or population.

In contrast, CER takes a retrospective look at health information from particular patient populations or subpopulations to compare similar products (e.g., competing drugs) or diagnosis or treatment approaches (e.g., surgery versus drug therapy). Both the public and private sectors have been involved in advancing CER for the last couple of years. CER will likely be an essential tool for achieving health care reform, particularly payment reform, regardless of the shape health care reform legislation ultimately takes.<sup>13</sup>

## Expanded FDA Post-Market Authority and Requirements

The Food and Drug Administration Amendments Act of 2007 (FDAAA),<sup>14</sup> created a new section of the Food, Drug and Cosmetic Act which authorizes the FDA to require persons submitting applications for approval to market prescription drugs and biologics to submit a proposed Risk Evaluation and Mitigation Strategies (REMS) as part of the application. The purpose of the REMs is to ensure that the benefits of the drug or biologics outweigh the risks.

## Health Informatics and Medical Informatics

A rapid evolution of health or medical informatics has been occurring on a parallel track with these other significant developments. Health or medical informatics is the intersection of information science, medicine, and health care, which deals with the resources, devices, and methods required to

optimize the acquisition, storage, indexing, retrieval, and use of information in health and biomedicine. Health informatics tools, which will be essential to the implementation of most if not all strategies involved in this current HIT revolution, include not only computers but also clinical guidelines, formal medical terminologies, and information and communication systems.

## GETTING FROM HERE TO THERE

### HIT Development Continuum for Key Stakeholders

Establishing an HIT infrastructure that will support the data and tissue repositories needed to accommodate leading-edge health care reform initiatives will involve various stakeholders, starting points and development continuums. Figure 1 on the following page depicts one possible development continuum. The continuum begins with a single provider's conversion from paper medical records to an EHR system. That provider then integrates its interoperable EHR with the EHRs of other providers, and in some cases implements a clinical trial management system and integrates it with the EHR system. On its own or in collaboration with other stakeholders (such as universities, manufacturers, research institutes, or research support organizations), the provider creates a repository used to meet its operating needs. The provider may make access to the repository available to others on a limited or widespread basis.<sup>15</sup>

The development of data and technical standards to support harmonization of different information systems, networks, software applications, interoperability infrastructures and vocabularies, in both research and clinical care, will be a critical foundational step for any of the collaborative initiatives along the HIT development continuum.

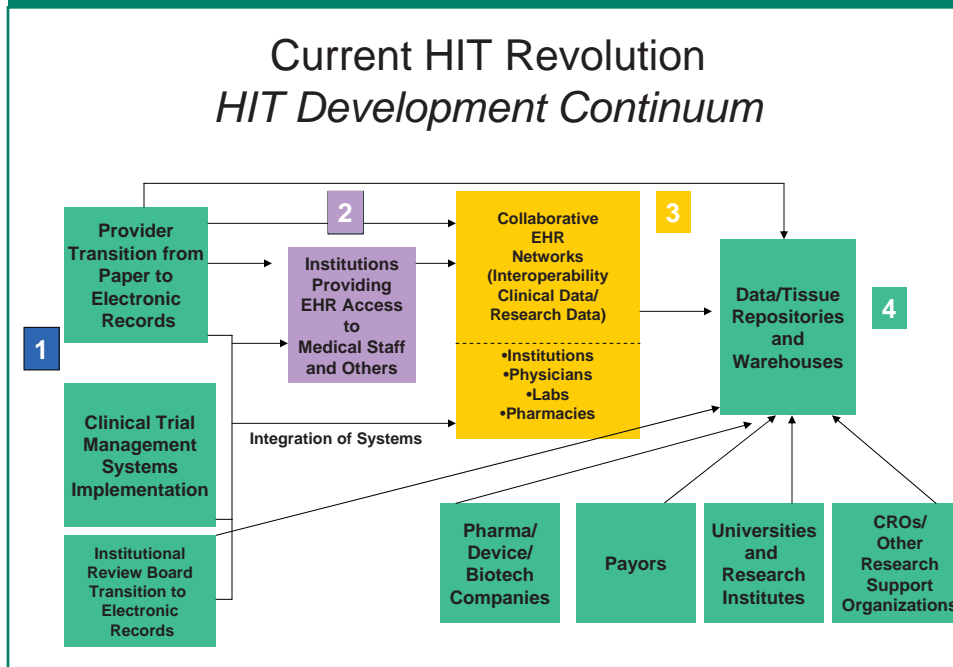
### Key Legal and Regulatory Planning Considerations

If lawfully developed at the front end and lawfully accessed at the back-end, a repository can be a powerful resource and a valuable asset. The following overview summarizes the key legal and regulatory considerations that should be addressed at the beginning of the repository planning and development process.

### Federal Human Subject Protection and Privacy Issues

Individuals provide biological samples and clinical data to a hospital, university or research institution in a variety of ways. For example, individuals

**Figure 1**  
**Current HIT Revolution**  
**HIT Development Continuum**



may give their permission to the inclusion of any incidental, unused/unnecessary, excised tissue following a standard of care surgery; or individuals may give their permission for additional tissue to be excised during surgery (e.g., specifically taking extra bone marrow so that the excess tissue may be included in the repository). Such tissue and associated data included in a repository can also be derived from the thousands of individuals who participate each year in clinical trials for purposes of evaluating the safety and efficacy of medicines and medical devices.

The need for (1) an Informed Consent under the federal Common Rule protecting the safety of human subjects in research,<sup>16</sup> and/or (2) an Authorization or alternative pathway under the Health Insurance Portability and Accountability Act and the corresponding regulations,<sup>17</sup> in order to deposit and withdraw tissue and data into a repository or data warehouse use, is a critical legal feasibility issue.

The applicability of the Common Rule and HIPAA to the establishment of a data and tissue repository or warehouse will depend in large part on the following:

1. the pathway by which data and tissue is collected and stored
2. what information is deposited into the repository originally and what information the researcher extracts from the repository
3. the nature of the intended use

Studies undertaken using a data repository or warehouse for purposes of cost, quality, and safety studies may be considered “health care operations” rather than “research” under HIPAA. Use for such health care operations purposes is not subject to the HIPAA authorization requirement. Careful consideration must nonetheless be given to whether the study is research under the Common Rule.<sup>18</sup>

For research regulated by the FDA, it is also necessary to address whether an informed consent must be obtained. The FDA regulations apply only to clinical research studies that involve an investigational drug, device, or biologic. In most cases, the question of whether a human subject is involved is not an issue because a research study involving a drug, device, or biologic would almost certainly involve a real, live subject on whom the product was tested. Therefore, an Informed Consent would be required. Further, while the FDA has expressed a willingness to lift the consent requirement in certain limited contexts, the FDA research technically does not allow for waiver of the informed consent requirement.<sup>19</sup>

State law may impose additional or more stringent requirements for finding a compliant pathway for depositing and withdrawing data and tissue from an electronic repository. These state laws and the consent requirements associated with them can present meaningful challenges in electronic repository development—particularly with regard to the inclusion of data and tissue collected in the past without adequate consents. For example, some state information privacy laws may present a barrier even to the use of a business associate to create de-identified information or a limited data set.

### Federal and State Tissue Regulations

The FDA has several sets of regulations applicable to the collection and handling of human cells, tissues, and cellular or tissue-based products (HCTPs) for use in various contexts such as (1) use in human transplantation, implantation or infusion in a clinical or research context, and (2) use of any type in research (not limited to research involving transplantation, etc.).

These regulations include the following:

1. Good Tissue Practices (GTPs)<sup>20</sup>
2. Good Manufacturing Practices (GMPs) applicable to drugs<sup>21</sup>

3. regulations applicable to biological products<sup>22</sup>
4. GMPs pertaining to quality system regulations<sup>23</sup>

These regulations will have implications for the collection, processing, transportation, storage, and use of tissue contributed to the repository.

The National Organ Transplant Act of 1984 makes it unlawful “for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation.”<sup>24</sup> Human organs include human (including fetal) kidneys, livers, hearts, lungs, pancreases, bone marrows, corneas, eyes, bones, and skin or any subpart thereof. Valuable consideration excludes “reasonable” payment associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ.

At least nine states have some form of tissue-banking regulation. These regulations will also relate to processing, transportation, and storage of tissue. These regulations must be reviewed to identify the applicable provisions and to resolve any inconsistencies between state law and FDA law.

### Debate Concerning Ownership of Repositories and Their Contents

Widespread disagreement currently exists regarding who owns repositories of biological tissue and data, and the intellectual property rights associated with and derived from them. This ownership question is critical both to use of such repositories for future research and to commercialization of products based on such use.

Recent case law<sup>25</sup> and state laws governing tissue donation will all have implications for the approach that should be taken in individuals’ informed consents. These laws will also affect agreements between and among the parties involved in the repository to establish ownership of the tissue and data—and to the products derived from such data. The law in this regard remains somewhat unsettled.

As the debate continues and key legal and ethical questions are addressed, the participants in the repository should take steps to confirm that (1) the repository complies with applicable law, (2) policies and procedures are in place with respect to necessary consent and authorization for creation and use of tissue and data repositories, and (3) intellectual property ownership expectations are clear and understood by patients, research subjects, clinicians and researchers.



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### Business, Financial and Contracting Considerations in Repository Collaborations

As depicted in Figure 1, a repository initiative may evolve into a collaboration between two or more industry stakeholders, such as an institutional provider, university, research institute, or product manufacturer. Whether the collaboration exists solely by contractual agreement or by a combination of a new entity and a collaboration agreement, the parties should develop a detailed written agreement.

This agreement should address, among others, the following considerations:

1. the purpose, scope and goals of the collaboration
2. governance and management of the relationship
3. the extent of any new or existing HIT infrastructure being created and integrated
4. relative funding (initial and future)
5. relative ownership of, and rights to access and use, all or certain portions of the repository (including any third-party access and use and any exclusive rights of the participants)
6. short and long-term plans, if any, to create an entity and the contemplated design and structure of the entity
7. addition of new participants
8. data content and its integrity
9. managing electronic discovery of records by third parties
10. management and allocation of risk as well as corresponding insurance coverage and indemnification rights
11. development and management of a legal and regulatory compliance plan

12. strategic planning
13. communications and relationships among the participants and with external constituencies (e.g., government, HIT vendors)
14. long-term sustainability of the repository
15. exit rights and strategies

Notes:

1. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).
2. H.R. 1, S.1, American Recovery and Reinvestment Act of 2009, Health Information Technology for Economic and Clinical Health Act (the HITECH Act), § 13001, et seq. (Feb. 17, 2009).
3. See the Daniel Gottlieb discussion on page 43 on the interim and proposed regulations targeted to implementing the HITECH Act reimbursement incentives.
4. “The Decade of Health Information Technology: Delivering Consumer-Centric and Information-Rich Health Care Framework for Strategic Action,” U.S. Department of Health and Human Services (July 1003). <http://www.hhs.gov/news/press/2004pres/20040721.html>. The HITECH Act restates the ONC goals as: (a) ensuring that each patient’s health information is secure and protected; (b) improving health care quality, reducing medical errors, reducing health disparities and advancing the delivery of patient-centered medical care; (c) reducing health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care and incomplete information; and (d) facilitating health and clinical research and health care quality. HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3001(b)).
5. Personalized Medicine or Personalized Health Care is an explicit health reform goal that HHS has addressed in detail in two recent reports: “Personalized Health Care: Opportunities, Pathways, Resources,” <http://www.hhh.gov/myhealthcare/news/personalized-healthcare-9-2007.html>, last visited January 10, 2009; and “Personalized Health Care: Pioneers, Partnerships, Progress,” <http://www.hhh.gov/myhealthcare/news/personalized-healthcare-2008.html>. See also, “HHS Secretary Releases Second Report From Initiative on Personalized Healthcare,” *Life Sciences Law & Industry Report*, 2 LSLR 1004, BNA (November 2008); Michael O. Leavitt and Raju Kucherlapati, “The Great Promise of Personalized Medicine,” *boston.com* at [http://www.boston.com/bostonglobe/editorial\\_opinion/oped/articles/2008/12/26/the\\_great\\_prom...](http://www.boston.com/bostonglobe/editorial_opinion/oped/articles/2008/12/26/the_great_prom...) (December 26, 2008).
6. See [http://en.wikipedia.org/wiki/Translational\\_medicine](http://en.wikipedia.org/wiki/Translational_medicine).
7. <http://www.ahrq.gov/qual/psoact.htm>.
8. [http://en.wikipedia.org/wiki/Evidence-Based\\_Medicine](http://en.wikipedia.org/wiki/Evidence-Based_Medicine)
9. “Coverage with Evidence Development,” is described in a final guidance document CMS

issued on July 12, 2006. “National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development,” [http://www.cms.hhs.gov/mcd/npece\\_view\\_document.asp?id=8](http://www.cms.hhs.gov/mcd/npece_view_document.asp?id=8).

10. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).
11. “Federal Coordinating Council for Comparative Effectiveness Research Report to the President and the Congress,” U.S. Department of Health and Human Services (June 2009). <http://www.hhs.gov/recovery/programscer/ceannualrpt.pdr> and “Initial National Priorities for Comparative Effectiveness Research,” Institute of Medicine (June 2009). <http://www.iom.edu/Reports/2009/ComparativeEffectivenessResearchPriorities.aspx>.
12. Congressional Budget Office Report, “Research on the Comparative Effectiveness of Medical Treatments,” December 2007, <http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf>.
13. See, e.g., “Comparative Effectiveness: Better Value for the Money,” *Alliance for Health Reform* (August 2008), [http://www.allhealthorg/Publications/Quality\\_of\\_care/Comparative-Effectiveness\\_Better\\_Value\\_for\\_the\\_Money\\_84.pdf](http://www.allhealthorg/Publications/Quality_of_care/Comparative-Effectiveness_Better_Value_for_the_Money_84.pdf).
14. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).
15. The 2007 HHS report on Personalized Medicine (cited above) emphasized the collaboration across all stakeholders in both the public and private sectors as being “at the heart of the project.” The 2008 report includes informative descriptions of case studies of collaboration initiations that have emerged since the first report. See also “Moffitt, Merck Join Forces: One of the World’s Largest Drugmakers Forms a Research Venture with the Tampa Institute to Adapt Cancer Treatments to Individuals,” [tampabay.com](http://www.sptimes.com/2006/12/19/Tampabay/Moffitt_Merck_join_f.shtm), [http://www.sptimes.com/2006/12/19/Tampabay/Moffitt\\_Merck\\_join\\_f.shtm](http://www.sptimes.com/2006/12/19/Tampabay/Moffitt_Merck_join_f.shtm) and <http://www.nucats.northwestern.edu/index.html>.
16. 45 C.F.R. Part 46, subparts A through D.
17. 42 C.F.R. Parts 160 and 164 (HIPAA).
18. “OHRP Official Recommends Drawing Lines To Determine Which Activities are Research,” *BNA Medical Research Law and Policy Report*, 7 MRLR 761 (December 3, 2008).
19. <http://www.fda.gov/cdrh/oivd/guidance/1588>.
20. 21 C.F.R. 1270 and 1271.
21. 21 C.F.R. 211.
22. 21 C.F.R. 600.
23. 21 C.F.R. 820.
24. 42 USC Section 274e(a).
25. See, e.g., *The Washington University v. William J. Catalona, et al.*, 552 U.S. 116 (2008).

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