Data Standards: At the Intersection of Sites, Clinical Research Networks, and Standards Development Initiatives

Interactions between the health care and clinical research communities are currently inefficient. The present environment forces unnecessary redundancy, from the capture of patient data in the clinician-patient encounter to multiple uses of that data. Clinical research operations must become more integrated with health care processes to improve efficiencies in both patient care and research. Achieving a single instance of data capture to serve the combined needs of both environments should facilitate translation of knowledge from research into better patient care. A critical first step in achieving true interoperability is to develop formal data standards that are then adopted by the larger health care and research communities. The rewards of interoperability include streamlined subject screening and enrollment procedures, improved reporting, merging and subsequent analysis of clinical data sets, and expansion of knowledge made possible by leveraging research data and results from other domains in the health care community—all of which would increase the quality of patient care. The aggregation of data across multiple sites and the subsequent reuse of that data do face challenges, particularly in ensuring patient privacy; however, these can be overcome by technological innovation and consensus-building among stakeholders.

INTRODUCTION

The need for a more efficient and effective approach to clinical research has been articulated by numerous public (1,2) and private (3,4) organizations over the past several years. Enormous amounts of private and public funds are devoted to the organization of clinical trial groups to test individual drugs, devices, and treatment practices. However, once the research is completed, the groups are disbanded, only to be reconstituted at great expense when the next new project appears on the scene. The creation of a system that translates knowledge acquired during research into clinical practice is thus an important goal for the clinical research system. One of the greatest inefficiencies of the current model of clinical research in the United States is its lack of a sustaining infrastructure that includes streamlined, one-time entry data collection, common data standards and terminology, and cooperative use of data shared among researchers (5).

More importantly, the findings of appropriately conducted clinical research must be integrated into patient care with more efficiency and effectiveness. As stated by M. L. Milleson in 1997, “There is an unsettling, if little known, truth about the practice of medicine. . . . Study after study shows that few physicians systematically apply to everyday treatment the scientific evidence about what works best” (6). Clinical research provides the “evidence” in evidence-based medicine; however, clinical trials are only part of the cycle of therapeutic improvement (Figure 1). This cycle highlights opportunities to integrate quantitative strategies to improve the quality of patient care and has been adapted to focus on the underlying flow and interdependency of data (7). The conduct of research and the application of the knowledge gained must be aligned with the diagnostic process, treatment guidelines, and decision support tools, not only to improve patient care but also to lessen the burden that research places on sites.

Patient care facilities conducting clinical research are central to the interaction between health care and research. Critical to the development of research tools, workflow, and knowl-
edge that enhance research capacity is the recognition of the significance of the clinical site, its research operations in the context of patient care, the role of the investigator in contributing to data standards, and the mission of interoperability.

**INTEROPERABILITY**

The achievement of interoperability is a peak interest in health information technology but is poorly understood in the health care and clinical research arenas. Interoperability is defined as the ability of two or more systems to exchange information and to use the information that has been exchanged (8). The ability to exchange information is called *functional interoperability* and involves hardware, software, operating systems, communications protocols, and all components that serve to move a data item from A to B without customization. *Semantic interoperability* refers to the ability to use the information that has been exchanged. The building blocks of semantic interoperability are common data elements (CDEs). As described by Covitz et al. (9), CDEs are the metadata representing a single concept and its associated permissible values, both of which are drawn from controlled terminology. The interoperability focus in this context is the seamless interaction of research with the clinical and administration processes of health care, supporting the important ability to merge, compare, and leverage clinical findings across initiatives.

Interoperability should be especially important to clinical investigational sites. The clinical investigational site is the bridge and broker between the research sponsor and the patient. Patient care is the investigator’s first priority in a clinical trial. Expectations of a separation of duties between research activities and patient care reinforce this priority; however, this separation of duties has forced patient care and research to operate as two separate worlds.

A typical health care facility uses an information management system to document patient care and to manage the logistics surrounding that care. Often, it must report the same data to multiple organizations (Figure 2). Currently, data are not collected in a way that allows easy reuse, as clinical assessment and data collection occur via independent, parallel processes. For example, a clinician may determine a diagnosis based on a set of test results and then treat the patient, possibly using a computerized physician order entry system (CPOE). In parallel workflows, the treatment and often the test results are then documented in a clinic note; dictated for communication to another individ-
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ual; coded for reimbursement; keyed into multiple Web-based data entry systems for a quality improvement program, Joint Commission reporting, and a clinical trial; and later extracted from the patient records by a nurse for additional reporting requirements. The person entering the overlapping data into all these reporting tools must learn the different data definitions of each reporting requirement and translate data from source documents (10) into the different systems. If uniform data standards existed, these data could be captured once according to consensus clinical definitions and documented in a standard terminology set for seamless transmission to various stakeholders (Figure 3).

From a research site’s perspective, the interoperability of clinical research within existing patient care processes would yield multiple benefits: the rapid incorporation of new evidence to enhance daily treatment decisions and application of new therapies, reuse of data for decision support, improved patient outcomes, efficient dissemination of data to many stakeholders, and availability of ongoing training on best clinical research practices. An important side benefit of reducing the current burden on sites may be an increase in the participation and retention of clinical investigators.

Underpinning the goals of functional and semantic interoperability is the development and application of data standards. In their June 2004 report, the President’s Information Technology Advisory Committee (PITAC) cited lack of standards at the data-element level of specificity as a reason for slow electronic health record (EHR) adoption (11). Formal data standards would directly support key tasks performed by clinical sites, thereby affecting the productivity, quality, and effectiveness of research staff. Replacing manual functions with computerized tools and reusing electronic data produced by patient care processes for clinical research would refocus the attention of research staff on tasks directly related to research objectives. The following sections describe ways in which data standards-driven systems can better support a clinical research project.

SCREENING AND ENROLLMENT

The screening and enrollment process is typically the first target for use of electronic health data to support the research process. The screening and enrollment process often occurs as a by-product of routine interaction between

FIGURE 2

patients and clinical staff—some of whom may have dual clinical and research roles. A study coordinator or study nurse may browse through a list of patients thought likely to meet criteria for study entry, drawn, for example, from admission records from a specific department. When driven by data standards, this process could be changed from manual identification of potential research subjects by clinical staff to automatic computer notification of the study coordinator when a potential candidate meets the specified criteria. In addition, the software application that identifies the potential study candidate and alerts the study nurse could also provide him or her with step-by-step assistance through the clinical screening, consent, and enrollment processes. This integrated approach would provide those managing study operations with the ability to evaluate screening and enrollment metrics, identify frequently failed enrollment criteria, and improve reporting on the patient population in terms of protocol inclusion/exclusion criteria.

**DATA REPORTING**

Reporting clinical data outside of the patient care process poses a greater challenge than using data to facilitate study recruitment; however, it holds enormous value to clinical research and to the health care system as a whole. Clinical sites submit data derived from the patient encounter for many purposes, including assessment, reimbursement, registration of patients in quality improvement initiatives, as well as clinical research studies. The processes for submitting these data are not aligned and require redundant, often manual, workflows that are implemented in accordance with requirements specified by third-party payers. Commonly, clinical staff extract patient data that exist in various paper and computer locations and reenter it onto other paper or computer-based forms to describe the same patient circumstances in required formats. The institutional or office support required for the completion of these duplicative processes is enormous, ever-expanding, and includes the need for ongoing staff training; coordination of timelines, processes, and tools; and support for hardware and software requirements.

Of course, clinical research is only one consumer of the data generated from the patient encounter. In sites that do numerous clinical trials, there may be multiple electronic data capture (EDC) systems in use at any given time, with dedicated computer terminals, Internet ac-
cess, and workstations designated for study-specific staff, each of which occupies premium floor space. The trend toward isolated EDC systems being accessible from one computer via the Internet reduces the dependency on specific computer hardware but has little effect on the overall workflow and, therefore, is only of incremental benefit. Likewise, sites with heavy public health reporting volume may also submit information via fax or even telephone. Vast differences exist in the ability of different kinds of health care sites in different therapeutic areas and with different patient populations to promote interoperability in a wide-area or nationwide network. This limitation underscores the connection between such system-wide inefficiencies and the inability of the health care community to keep up with expectations for quality and productivity.

The reason that reporting requirements are not more aligned is that the data must be selected, interpreted, or coded to meet different requirements, and the current common data standards have been inadequate. Large hospitals with mature data systems may be able to automate some of these processes by manually mapping the reporting criteria to the source. Mapping, however, can change the meaning of the data enough so that two resulting reports from the same source may not be comparable. Mapping to specialized categories can also limit the information’s generalization to the patient care process. Maintaining the ability to use nonreduced, nonmodified data in clinical research enables a much greater ability to produce new analyses not constrained by past uses.

For example, it is common in clinical trials to measure a clinical endpoint that is defined by the occurrence of an event within a certain time window (eg, death at 30 days from an intervention). Rather than collecting data in an aggregated manner specific to trial A (eg, “death at 30 days: yes/no”), the contributing pieces of data (date of intervention, date of death) could be collected so that the planned analysis may evaluate the endpoint of death at the 30-day time point, but the data remain valuable to other analyses as well. A secondary analysis could pool death across similar trials, reporting death as a continuous outcome variable without being constrained by the 30-day mark deemed important in trial A. The value of nonreduced data increases with each reuse as it makes possible the generation of additional knowledge over time.

Obviously, the benefits to clinical sites of using a single source of data for multiple purposes are significant (12). While a clinical research enterprise-wide impact and cost analysis would be useful, reports from the Institute of Medicine (IOM) and the pharmaceutical industry are impressive nonetheless. According to the IOM, use of data standards would reduce the nation’s health care administration expenditures by 20%–30% (13). It could also yield a 35% cost reduction within the pharmaceutical industry for interfaces alone, and it may shorten the time needed to complete clinical trials by as much as a year (14). For example, the manual transcription process required in usual customized workflows would be largely eliminated. The verification and correction processes would be streamlined (15); traditional source document verification would not be necessary because, when a data interchange system is validated, the reported data and the source data would be identical. Field-by-field monitoring efforts could refocus on ensuring that protocol adherence and regulatory requirements are met. Data surveillance at the data center could more readily identify trends and study conduct issues that would help monitors target their efforts.

**STUDY CONDUCT**

The implementation of a research study in a patient population requires faithful adherence to study procedures. While the coordination of study procedures and patient care processes yields the most efficient use of staff resources, there are challenges to using data captured in the clinical environment for research. These challenges, however, are largely attributable to timing of assessments and the belief that nonresearch processes have a significant confounding effect on research results. If one recognizes that the integration of research procedures with health care processes does not limit or change
what data are available, that the raw data describing the clinical condition are similar for research or patient care, that regulatory compliance can be achieved (15), and that the circumstances of data collection can be well controlled and described, the ability to capture the superset of required data within the same user interface to feed both clinical and research databases becomes a viable possibility. This workflow was piloted in the Starbrite project, a single source proof of concept study undertaken by the Duke Clinical Research Institute and the Clinical Data Interchange Standards Consortium (CDISC) (16,17). It is interesting that the converse is also debated; that is, the ability to generalize clinical trial results to mainstream patient care.

The expectation set by Dr. Clement J. McDonald 30 years ago still holds: “Though the individual physician is not perfectible, the system of care is, and that the computer will play a major part in the perfection of future care systems” (18). Although this prediction has not yet been fully realized, quality (19) and efficiency (measured in billions of dollars saved) (20) are improving thanks to the increased use and enhancement of electronic health records with protocol-driven disease management and decision-support capability (21–23). The integration of research and health care processes has not always been successful, but there is reason to expect that implementation of research protocols that are similar to patient care protocols will result in better compliance with prescribed assessments. Today, implementation of these protocols frequently involves both a manual workflow and the use of computers. As both patient-centric decision support tools and research protocols comprise a prescribed set of assessments and procedures, a single workflow interface that merges clinical and research responsibilities of the staff will trigger tasks to be completed without relying on memory of study-specific training or reference materials. For example, when a nurse is interacting with an electronic health record system, both evidence-based treatment guidelines and the research status of the patient can already be defined in the system and trigger orders for blood draws, tests, or other timed assessments. The same user interface could then prompt for study-defined data collection requirements, allowing the study coordinator to capture the data that are not typically collected in routine patient care.

**KNOWLEDGE FROM DATA**

Clinical and administrative data systems have become commonplace in large institutions and are increasingly in use at smaller practices. Much of the needed data are likely already interchanged within an organization’s software applications using Health Level Seven (HL7) messages (24). An obstacle to the implementation of cross-organizational exchange is that software must be customized at each site according to the facility’s unique nomenclature and methodology for the exchange of electronic data. Application interfaces can be built to patch together data systems—although more widely available standards will minimize the customization needed—but the most immediate barrier is that the data elements being transmitted are not standardized.

Maintaining the meaning implied by a clinician capturing data is critical, especially as those data are reorganized and made to conform to reporting conventions. To support this requirement, a shared vocabulary is needed that includes clinical definitions and associations between data elements. Currently, when a clinical site reports data outside of its organization, robust definitions, usually specific to that initiative, must be used to support the integration of that data across sources. Clinicians who use the same terms to describe similar, but not equivalent, concepts may unintentionally introduce ambiguity. Clinicians and investigators, therefore, must subscribe to the same definitions and recognize that differences in analyses reside in the data that are available and not in differing nomenclature.

Operationally, it is easier for a clinical site to report data when custom definitions do not need to be applied between the source data and the reported data. In an informal review of demographic and history data reported on six
Cardiovascular trials, the same data element was collected differently or defined differently about half of the time, with the disease-specific data elements demonstrating the most variation. Furthermore, it is easier for users of aggregated data to leverage data across initiatives without the need for complicated mapping and derivation algorithms. With the use of data standards, findings from one study could be compared with reported results from other research or across the health care realm, proving useful for numerous purposes such as public health reporting, performance measurement, or sample size calculation. Surveillance data collected for public health purposes, for instance, could provide epidemiologic data for studies of disease and aid in the identification of potential study candidates.

**Implementation Issues**

Although differences exist between clinical sites, technology itself is not a limiting factor in the success of using a single source of data for multiple purposes. Methods to transport data within an organization and across institutions are well understood and use existing networks, Internet and Web services, or other tools. Privacy issues do pose a challenge in that they are complicated both by situational definitions of what constitutes protected health information (PHI) and by the diverse strategies for handling patient identification (25,26); however, the requirements for each use can be well described, and identification schemes can often be algorithm driven. Security models exist for the compartmentalization of access to data systems and the encryption of interchanged data. These issues are critically important and are not easily overcome, but strategies do exist (26,27), and collective experience will help to identify the best practices to be used (or inform and generate federal guidance).

**Standards Development**

Interchange standards for data pose a more significant obstacle to interoperability. Standards development organizations, like HL7, have had significant success in finding ways to share data between information technology applications within a health care organization. Similarly, CDISC has made much progress defining standards (some of which are formalized within HL7) used between participants in clinical research studies. Models that are now broadly in use fulfill the implementation needs of those organizations but are limited by the need of the organizations to make local decisions about definitions of standards, which can lead to different organizations implementing the same standards with somewhat different results. Uptake of newly developed standards and business models that address this problem will take time but will increase as the body of experience grows.

Development of a master data elements repository that will further standardize the data collection process is another, more daunting challenge. Production of this master set requires that stakeholder organizations contribute information about the data elements that they currently use. Furthermore, a mechanism for capturing clinical input and promoting consensus building will be needed, along with a sustaining infrastructure for maintenance and an overarching coordination of efforts across therapeutic areas. The National Cancer Institute’s Biomedical Informatics Grid (28), with its established infrastructure, offers a model for this type of work; however, an international, cross-therapeutic solution is necessary.

Historically, data standards have been developed largely from a technical perspective. Use cases are defined, models are derived, and messages are formalized. As these functional standards mature, content standards addressing the semantics must be defined. The responsibility for this work will rest largely with the clinical community that uses the standards. Clinical research leaders—site investigators, coordinating centers, clinical research networks, industry sponsors, and government agencies—need to be aware of standards development and its value to their organizational objectives, and they should contribute to standards development whenever possible. For example, when a study is being developed, existing data standards should be used, or, if they are not available, the require-
ments and products of the new study should be reported and incorporated for future use. Communities of clinicians that organize as research networks or professional societies are in a unique position to leverage a body of clinical leadership and link individual clinicians with the standards development world. Notably, the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards has a history of publishing consensus definitions in specific clinical domains (29–31). Two emerging examples of communities contributing to this process include the Tuberculosis (TB) Trials Network (32) and the Clinical Trials Network: Best Practices organization (33), both funded under the National Institutes of Health Roadmap initiative (34) and coordinated by the Duke Clinical Research Institute (DCRI). The experiences and methodology results of these two organizations contribute to collective experience and should inform the future of the Roadmap initiative and the broader set of stakeholders in clinical research.

The primary objective of the TB Trials Network (TBTN) is to enhance the US public health system’s willingness and capacity to participate in clinical research. The public health system provides care to the majority of TB patients and is a critical resource for identifying TB patients for clinical trials. The TBTN, coordinated at the DCRI, has collaborated with the TB Trials Consortium (TBTC) to develop an adverse event database and a query tracking system to streamline the conduct of an 8,000-patient international trial; created a sustainable TBTC website to promote the sharing of data across the international consortium; and conducted numerous site visits during which nearly 100 public health personnel, study coordinators, and principal investigators were consulted on the barriers and facilitators to conducting clinical research in their respective settings. The TBTN is also evaluating opinion within the human subjects protection community regarding the use of central IRBs and the short form, with the intention of influencing future guidance by the Office of Human Research and Protection (OHRP).

Another key project objective of the TBTN is to address the need for improved interoperability to enhance the public health system’s willingness to participate in clinical research. To that end, TBTN aims to connect with the National Electronic Disease Surveillance System and to develop data standards for TB. Specifically, TBTN plans to standardize the data collected in health care, surveillance, and research as it pertains to the prevention, diagnosis, and treatment of TB and latent TB infection. The effort expects to increase efficiencies and reuse data collected across domestic and international communities devoted to TB. Value and consensus has been built by bringing together global TB stakeholders from organizations such as the World Health Organization (WHO), US Food and Drug Administration, National Institutes of Health, Centers for Disease Control and Prevention, clinical trial groups, and the TB Alliance, along with standards organizations such as HL7 and CDISC, to contribute to the methodology and process of standardizing terminology and data transport mechanisms for the TB therapeutic area.

Significant work has been done by aggregating and reviewing over 2,000 tuberculosis data elements collected across more than 10 international TB databases. A core group of TB experts is actively working to develop the initial set of data elements. This first package comprises the most crucial data elements necessary for the diagnosis and treatment of pulmonary TB. By involving international stakeholders in standards development, the project builds support for and adds value across health care, surveillance, and research communities focused on TB. The working group is an example of cross-functional global interoperability.

Once this TB working group reaches consensus on the standard definitions and permissible value sets for each of the TB terms identified, the data elements will be vetted among the larger TB stakeholder community. This process will produce a standard data element set robust enough to support new clinical trials, allow for the ability to aggregate data across clinical databases that use these standards, provide avenues to share research data with health care and
without modification, and populate the data collection tools used within existing workflows.

This standard data element list will also facilitate the standardization of data transfer between members of the TB community using standards such as HL7. Currently, the TBTN is working with the HL7 Public Health and Emergency Response Special Interest Group to use existing methods and create standard messaging to transport data. Because the Centers for Disease Control has worked with HL7 using version 3 messaging to create a standardized method of transferring surveillance data across the country, the TBTN group may be able to use many of the same messages to expand the circle of stakeholders able to share data.

The Clinical Trials Network (CTN): Best Practices organization was not created with the objective of conducting clinical trials; rather, it was formed as a community of cardiovascular research sites with a shared goal of developing best practices development methodology. The achievement of this goal involves an iterative process by which members of the community contribute expertise and tools to a forum for consensus building, and then the results are shared and vetted in larger research circles and with other networks (forming a “network of networks”) (35). Contributions include study tools, education and training resources, and information technology support and data standards development. These tools are immediately put to use by network members and quickly shared with other similar entities.

A specific aim of the CTN: Best Practices is to develop and pilot the infrastructure supporting cardiovascular data standards development. This initiative has successfully engaged stakeholders from over 30 organizations, including professional societies, pharmaceutical companies, government agencies, and standards development organizations (www.ctnbestpractices.org). Efforts are focused on achieving both semantic and functional interoperability. In an effort that parallels the tuberculosis project, the semantics are being addressed by the creation and vetting of a master set of data elements, with an initial focus on ischemic heart disease. These data elements will be integrated into the National Cancer Institute's Enterprise Vocabulary Server and Cancer Data Standards Repository (http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/vocabulary and http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr), thereby instantiating a public resource for cardiovascular data elements that can be broadly used and enhanced over time.

Efforts undertaken by the new HL7 Cardiology Special Interest Group (www.hl7.org/Special/committees/cardiology), in collaboration with CDISC, seek to develop common data elements and standard methods for representing cardiovascular data in the HL7 and CDISC models. These efforts, currently coordinated by the CTN: Best Practices program, have grown quickly and are intended to become sustained efforts to advance cross-health care cardiovascular data standards. Results as of this writing include aggregation of 10 organizations' contributed data elements, initiation of the review and consensus process, and development of plans for a sustained and coordinated infrastructure in support of cardiovascular data standards (36).

Another significant product of the CTN: Best Practices program will be the lessons learned from a pilot implementation attempting to use the developed standards to meet existing reporting requirements. The pilot will test reporting of electronic data from health care facilities for multiple purposes, such as a clinical trial, quality improvement registry, and clinical performance measures. The results will assess the feasibility of using existing electronic data sources, the utility of standardized data elements and transport standards, and the challenges to staff workflow and adoption.

As groups such as HL7 and CDISC endeavor to support semantic interoperability, they are increasingly reaching out to the clinical community for expert guidance (17,24). In addition, it is important to note that all of these organizations are largely composed of multiple cooperating participants from public and (often
competitive) private organizations, therefore demonstrating that the goal of data standardization can be achieved without compromising an organization’s intellectual property.

The clinical research industry has a history of recognizing and supporting standards-based approaches; in addition, there is an increased need and a variety of ways in which clinical investigators and sites involved in clinical research can participate in standards development. The single most important way is to require usage of standards by default and question the need for custom solutions. Increased awareness and espousal of this approach will help compel organizations involved in the conduct of sponsored research to always consider the use of standards and to provide a strong rationale when they are not used.

**What sites can do to make this happen:**

- Demonstrate an appreciation for the value of data sharing and the willingness and ability to reuse data for multiple purposes by enabling semantic interoperability.
- Recognize the need for adoption of data standards and interoperability practices as a matter of best practice.
- Make sure that research requirements are included in functional specifications for EHR; specify that raw data can be the same for both purposes.
- Engage in the identification of issues that would be aided by data standards.
- Give sponsors feedback when asked to perform redundant work (for example, reporting overlapping information to different parts of the same organization); this will raise collective awareness and recognition of the value that data standards will add.
- Contribute to the identification and definition of standard data elements.
- Pilot implementations of standards-based solutions.
- Participate in standards development organizations, such as clinical special interest groups in HL7 and CDISC project teams.

**BEYOND CLINICAL DATA**

The clinical research community needs more than clinical data standards to reinvent its operations and increase capacity. More effective ways to administer routine processes are needed, including training, tools that facilitate IRB review, standard contract language / master agreements, and site tools for implementing trials. None of these are site-specific issues, and, thus, they should be addressed by the collective research community. There is no reason that information collected by administrative processes and shared across organizations cannot be modeled after clinical data standards in a way that will facilitate exchange. Examples of such modeling include representing the study schedule of assessments from a protocol in a way that can be integrated into applications for budgeting, patient schedules, or data collection systems; co-developing and tracking the progress of study agreements and regulatory documents; and developing an accessible, on-demand, syndicated basic training that can be shared across organizations without compromising intellectual property and the need to maintain organizational identity. This sort of collaboration requires a departure from proprietary thinking and increased confidence that the services and value that an organization offers will differentiate it in the market.

**CONCLUSIONS**

The clinical research community is composed of a significant subset of the larger health care system. However, the interaction between these communities is very inefficient. The current environment forces work initiated by the clinician-patient encounter to take many parallel paths in the service of multiple objectives. Clinical research operations must become more integrated with the patient care environment to improve the efficiency of the research process and to translate knowledge from research into better patient care. It is important to recognize that the clinical encounter is central to all health care communities and should be the focal point for integration. True functional and semantic interoperability is possible only via formal data standards developed and adopted by the larger health care community and not by dissimilar standards developed by any individual group of stakeholders.

Many organizational and national efforts have
been undertaken to study the current environment and to advocate, support, or coordinate specific solutions. As communities of researchers come together, an infrastructure of interoperability will emerge that will include standard nomenclature developed at a data-element level of granularity, shared across therapeutic areas, informed by clinicians, and vetted and maintained in the public forum with methods of interchange approved via formal standards development organizations and processes. The adoption of these standards does face challenges, such as ensuring privacy while sharing data; however, technology is no longer a limitation, and these challenges can be overcome. Stakeholders must abandon the proprietary view of their current workflows and recognize the benefits that interoperability will yield for their organizations and health care in general.

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