ORIGINAL INVESTIGATION

Current Status of Integrating Information Technologies into the Clinical Research Enterprise within US Academic Health Centers: Strategic Value and Opportunities for Investment

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ABSTRACT

Little information exists about the incorporation of information technologies (ITs) into clinical research processes within US academic health centers (AHCs). Therefore, we queried a group of 37 leading AHCs regarding their current status and future plans in clinical research IT. The survey specifically inquired about the presence or absence of basic infrastructure and IT support requirements; individual applications needed to support study preparation, study conduct, and its administrative support; and integration of data from basic research, clinical trials, and the clinical information systems increasingly used in health care delivery. Of the 37 AHCs, 78% responded. All strongly agreed that a "state-of-the-art" clinical research IT program would be ideal today and will be essential tomorrow. Nonetheless, no AHC currently has an IT solution that even approached this ideal. No AHC reported having all of the essential management foundations (ie, a coherent vision, an overall strategy, a governance structure, and a dedicated budget) necessary to launch and sustain a truly successful implementation of a cohesive clinical research IT platform. Many had achieved breakthroughs in individual aspects of clinical research IT, for example, adverse event reporting systems or consent form templates. However, overall implementation of IT to support clinical research is uneven and insufficient.

These data document a substantial gap in clinical research IT investments in leading US AHCs. Linking the clinical research IT enterprise with its clinical operations in a meaningful fashion remains a crucial strategic goal of AHCs. If they are to continue to serve as the "translational research engines" that our society expects, AHCs must recognize this gap and allocate substantial resource deployment to remedying this situation.

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To accelerate the discovery of new therapies, the National Clinical Research Enterprise in general and academic health centers (AHCs) in particular need to place a high priority on using information technology (IT) to integrate their clinical research efforts with their clinical missions.[1] However logical and desirable this goal is, implementation of IT applications to streamline and improve the safety, efficiency, and effectiveness of these human investigational processes is costly to develop, time consuming to install, and labor intensive to maintain. Currently, these applications are not in the critical pathway of patient care or within the proximal scope of the intense operational mandates that frame the realities of the AHCs. Therefore, they are often simply not being developed or are being delayed in their implementation.

To obtain objective data on the status of AHCs using IT to support standardizing, streamlining, and improving the safety of their clinical research processes, we undertook a comprehensive survey of leading academic health centers that were members of the AHCs' Clinical Research Forum. The Clinical Research Forum, as it is now known, was formed more than 9 years ago to provide a venue for AHCs to discuss their policies and best practices in clinical research (for a description of the Clinical Research Forum and a list of participating members, see the Appendix). Its membership accounts for over half of the National Institutes of Health extramural research funds.[2]

METHODS

A subcommittee of Clinical Research Forum members composed of knowledgeable IT managers developed a formal survey tool to learn

- Where members are in setting the IT vision for clinical research
- What progress has already been made
- Where collaborations and sharing of best practices can advance progress

The survey occurred in two phases. The first was the dissemination of the survey tool developed and beta-

tested by several clinical researchers and IT staff for accuracy and completeness. Following their suggested modifications, the survey was sent to the then 37 member organizations (see the Appendix), along with a letter explaining the purpose of the survey. In this letter, members were asked to respond if they wanted to participate and, if so, to identify the person responsible for clinical research IT within their institution for the interview. Each organization was asked to review the survey questions, collect all needed documentation, and invite any additional people to the interview.

The person identified as the official responsible for clinical research IT in the respondent institution was then interviewed by one of two authors (F.T. or D.K.). Using the survey tool to ensure that the same questions were asked in the same manner, these extensive interviews lasted from 1 to 2 hours each. During this time, considerable detail was obtained about the granularity of the current operational status of that center. The topics addressed in the verbal interview were as follows:

- Suites of IT applications and progress toward implementation
- Specific clinical research applications to support education, regulatory compliance, study preparation, study conduct, and administrative processes
- The most pressing IT priorities for the upcoming 2 years
- The current status of clinical research IT vision, governance structure, and budget
- A discussion of best-in-class IT applications developed or customized by the organization (best-in-class applications have the most desired functionality and typically are the most advanced)

Completed surveys were then reviewed by both interviewers and the staff of the Clinical Research Forum to ensure consistency of responses. The findings were then tabulated, reviewed by the same group to identify key findings and outcomes, and presented to the Forum's annual meeting in March 2005.

RESULTS

Content of the Survey Tool: Matching Clinical Research Processes with IT

The survey tool was designed to associate IT applications with the major processes and data flows within clinical research. Clinical research processes are both complex and variable, depending on the type of study, sponsor, patients, and research departments involved. Figure 1 pro-

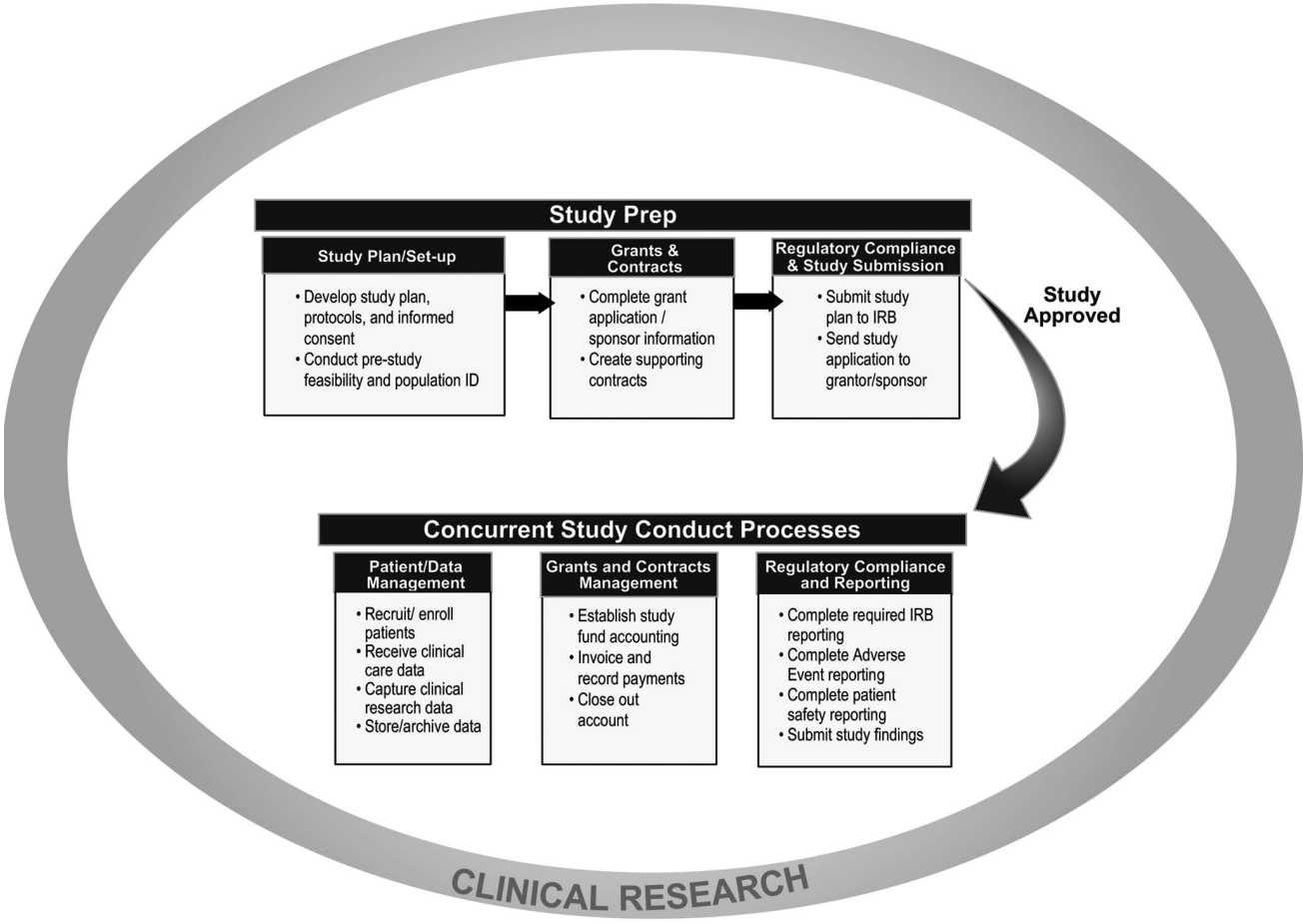

FIGURE 1 Core clinical research processes. ID = identification; IRB = Internal Review Board.

vides a simplified summary of the processes involved in preparing for and conducting clinical research studies. This was the framework for the initial flow of questions asked during the survey process.

Study preparation typically includes obtaining information to assess the feasibility of the research, building protocols, establishing a workflow, writing the consent forms, working with a grant and contracts office to identify and establish funding, and obtaining Internal Review Board (IRB) approval.

The subsequent conduct of human studies then adds processes. These include identifying patients and subjects for recruitment, enrolling them as study subjects, scheduling their visits and procedures, capturing and managing the resulting data to ensure safety and measuring outcomes, working with the grants and contracts office to monitor expenses and sponsor payments, and supporting ongoing regulatory communications with the IRB or US Food and Drug Administration, for example, to fulfill adverse event and other regulatory reporting requirements.

In creating the survey tool, it became apparent that many IT applications were used in both preparing and conducting studies but for different purposes and data requirements. We also identified applications that were specific to one phase, such as electronic data capture, as well as those that cross the clinical research department boundaries.

Overall, when viewed from an IT perspective, clinical research can be conceptualized in several tiers, each with specific IT applications and data needs. The first tier is composed of niche applications that are often used to support specific processes, for example, an application to support informed consent or patient enrolment.

In the center of Figure 2 are three major individual suites of clinical research applications: patient data management, grant and contracts interactions, and IRB submission and study reporting (the second tier). These IT functions are essential for both study preparation and conduct and thus represent a focus for several of the queries during the interviews.

Finally, not all of the necessary systems are confined to the clinical research domain, as shown by those crossing the ring around clinical research in Figure 2. These IT applications (and their interfaces with the clinical research IT) represent a third tier of IT applications that were the final target of queries of the respondents. For example, clinical data are needed from the hospital's clinical infor-

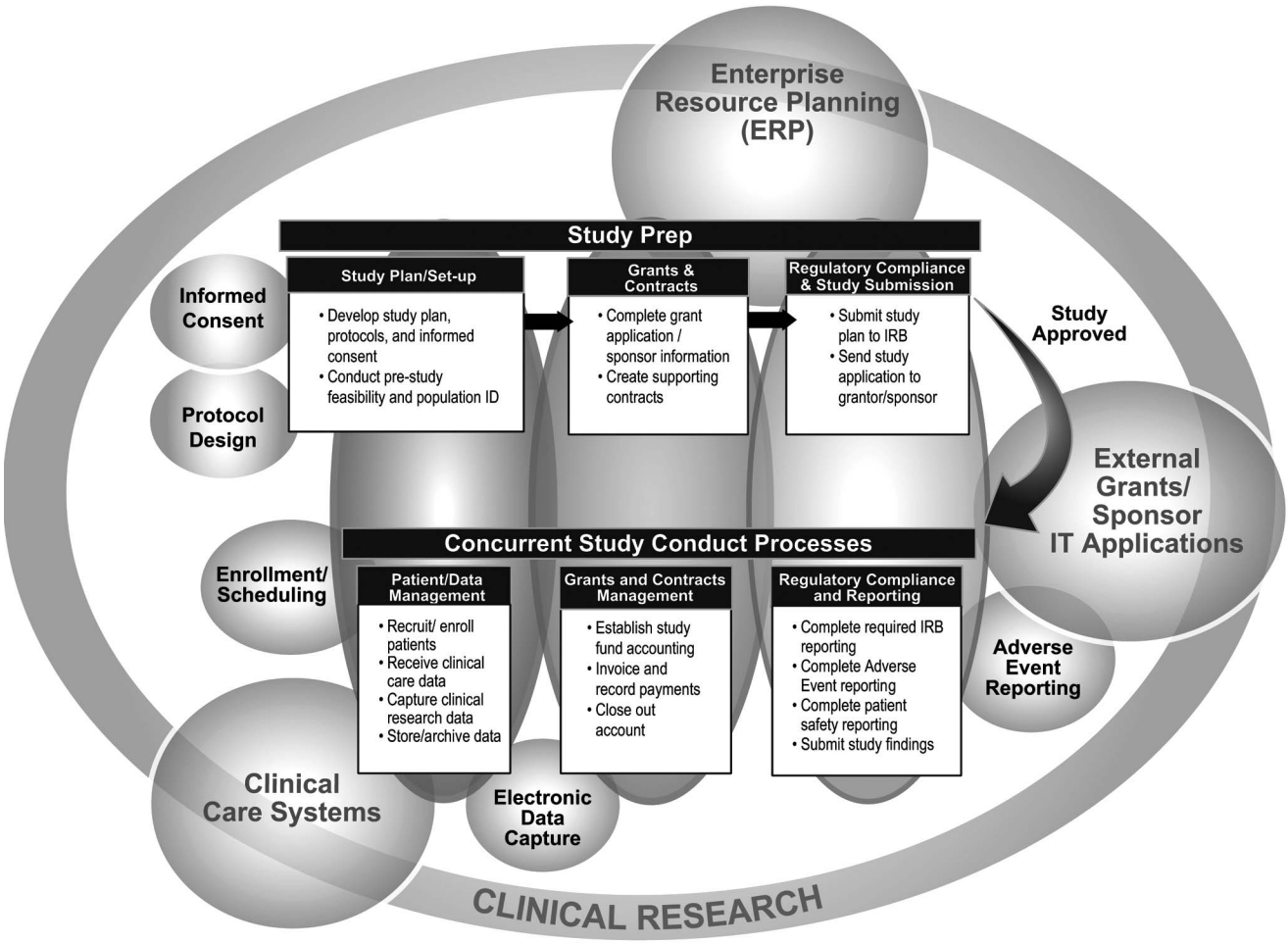

FIGURE 2 Addition of supporting information technology applications to the clinical research workflow. ID = identification; IRB = Internal Review Board.

mation system, such as results, diagnosis, and patient demographic data. The grant management applications for many organizations are a part of larger Enterprise Resource Planning (ERP) application suites that include materials management, general financial applications, and personnel and payroll systems. Electronic IRB submissions and reporting to outside agencies are becoming more commonplace and require connectivity and data transfer capabilities to other departments both within the organization and to outside agencies. These IT applications were then investigated by another series of specific questions targeting their existence and integration with the first two tiers of more clinical research–specific IT applications.

Study Participation

Twenty-nine of the 37 members approached (78% response rate) participated in the survey, resulting in 27 completed surveys because two sets of members share common systems. This high participation by these busy IT leaders derived from a desire to share what they know and to learn from others' experience. The survey respondents included leaders from IT services, clinical research, research computing, and senior AHC executives, sometimes in multirespondent telephone calls.

Overview of Clinical Research IT Solutions

The single most striking finding of the survey (Figure 3 and Tables 1 and 2) was that *none* of the responding AHCs had completed strategic planning for clinical research IT, assembled or written a compelling specific clinical research IT vision, developed an appropriate governance system to execute this strategy, and committed a stable funding source to clinical research IT. Several had undertaken individual elements of these processes or were planning to initiate them, but none had assembled all of these elements.

In terms of the adoption of individual IT solutions to components of the landscape, the general percentages of implementation were low and are summarized in Figure 3. It is apparent that only a minority of institutions have started to fully embrace and invest in clinical research IT. However, some organizations have implemented an integrated suite of clinical research administrative, reporting, and data capture applications for a single area of clinical

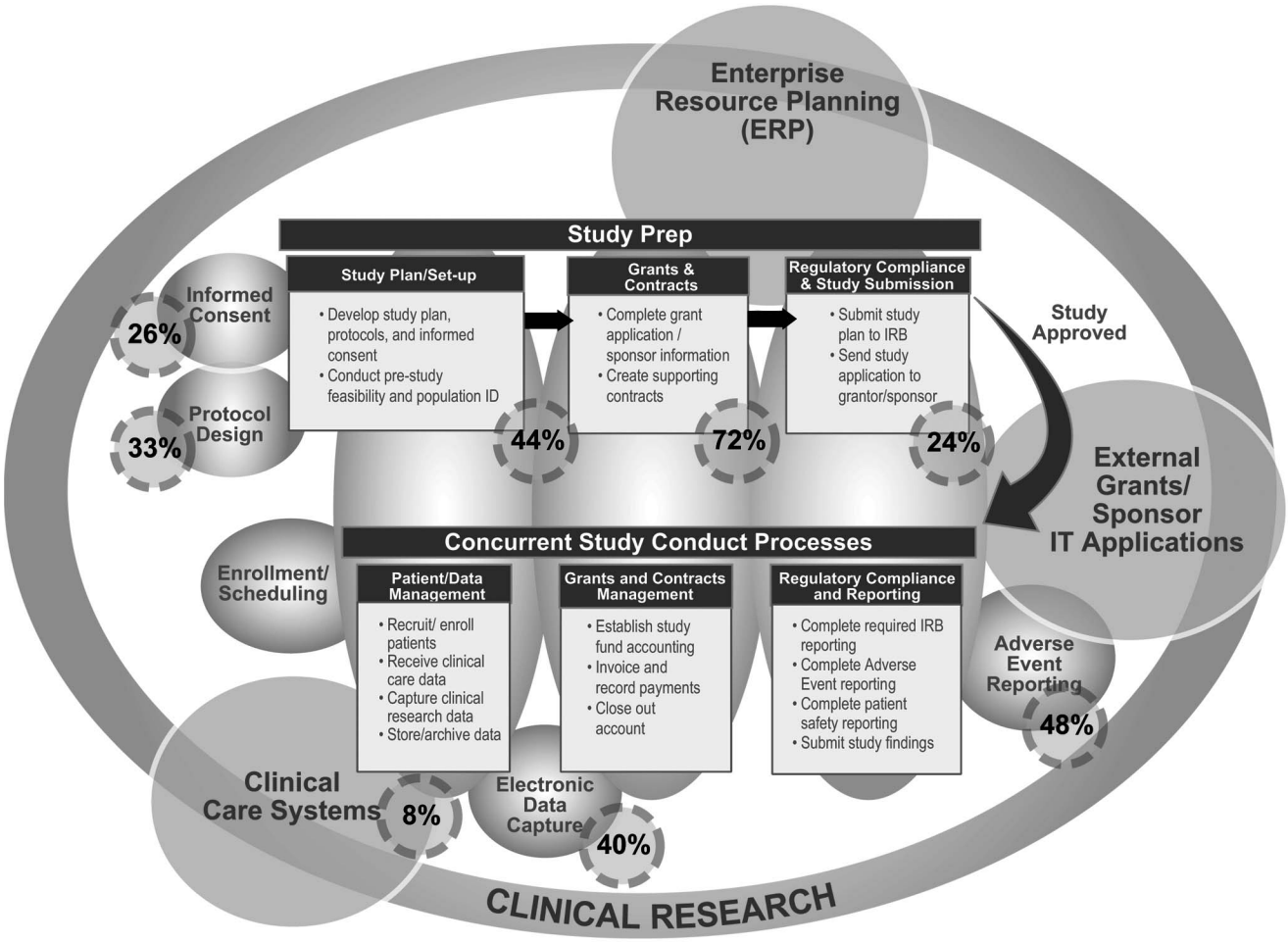

FIGURE 3 Rates of adoption of supporting clinical research information technology (IT) applications across leading academic health centers. ID = identification; IRB = Internal Review Board.

research. This type of success typically occurred in the areas of cancer research or acquired immune deficiency syndrome (AIDS), where more resources were available. These specific IT applications may be capable of being expanded to other research specialties.

Administrative Applications

The extent of implementation of core administrative applications that support clinical research is highly variable, as shown in Table 1. Although the majority of respondents have implemented a grants management system, the implementation of other applications was low or the applications automate only basic administrative functions.

Of particular interest to study participants were template-based applications for protocol design and consent form development—two important applications that help mitigate risk and improve workflow efficiency. Our survey revealed a high level of adoption of protocol design and consent form template applications, although about half of the responding AHCs were merely using Microsoft *Word* templates, not IT applications called "smart template" systems, which eliminate repetitive reentry of data. Even at the basic *Word* template level, having these forms available electronically significantly improves patient safety, information accuracy, and completeness.

An electronic Internal Review Board (eIRB) submission application clearly has the potential to automate a currently paper-intensive process and error-prone process and improve workflow and productivity. The current low rate of adoption of this application (see Table 1) is expected to rise quickly. This application had the highest number of AHCs with this implementation in progress (44%).

The University of Texas Southwestern's CIRCUIT, Northwestern University's ARIA, and the University of Pennsylvania's IRB/educational system are three examples of homegrown IRB solutions that have been successfully implemented. The leading commercial vendor product, Click Commerce, has been implemented within several AHCs, including Johns Hopkins University School of Medicine. In all of these cases, eIRB submission is envisioned as but one module of a larger clinical research application suite.

For administrative applications, eIRB was listed as the top administrative application priority, with the electronic submission and tracking of grant applications being the second highest priority (see Table 2).

TABLE 1 Administrative Application Implementation Progress

Application	*% Installed*	*% in Progress*	*% with No Application Installed*
Electronic IRB submission	24	44	32
Adverse event reporting	48	24	28
Grants management	72	8	20
Protocol design templates	55 (33 are smart applications, 22 are Microsoft *Word* templates)	4	41
Consent form templates	48 (26 are smart applications, 22 are Microsoft *Word* templates	26	26

IRB = Internal Review Board.

TABLE 2 Top Administrative Information Technology Application Priorities

Top Priorities for the Next 2 Years	*Number of Responses*	*% of Total*
IRB applications: submission, tracking	6	
Electronic grant management applications: submission and tracking applications	4	
Clinical trials management applications	3	
Finance related: billing compliance	3	
User-friendly "smart" consent forms	2	
Enrolment tracking	2	
Education tools	1	
Total responses	**21***	**41**

IRB = Internal Review Board.
*Not all respondents identified an administrative application as a top priority.

Clinical Data Applications

The implementation of clinical data applications is limited (Table 3). Only 44% of respondents have a patient data warehouse to support clinical research. Many of these

TABLE 3 Clinical Data–Related Application Implementation Progress

Application	*% Installed*	*% in Progress*	*% with No Application*
Patient data warehouse	44	4	52
Electronic data capture	40	4	56
Integration with clinical care systems	8	0	92

warehouses support a large research center rather than the entire AHC.

Only 40% of AHCs surveyed currently have electronic data capture applications for clinical trials, and only 4% had the implementation of this application in progress. Similarly, only 8% of respondents can integrate clinical research data with patient clinical data from hospital information systems. Commonly cited obstacles to achieving combined patient care and clinical research databases include (1) a lack of common data vocabulary, data standards, and coding schemes; (2) multiple clinical care information systems within the health delivery system requiring separate interfaces, data reformatting, and resolution of data inconsistencies; (3) out-of-date clinical care information systems that are in the process of being replaced; (4) each research department and study having its own research database requiring an untenable number of interfaces to other clinical care information systems to create a single source; and (5) a decentralized organizational structure and culture within the clinical research community.

Even with the above-mentioned obstacles, the survey showed some progress in the area of centralized clinical research data warehouse development, including data mining tools, cohort identification capabilities, and the ability to drill down to obtain additional information on patient results. Partners HealthCare is an example of a delivery system in which all of their hospitals send patient results to the Research Patient Data Repository, which covers more than 2 million patients. Clinical investigators can search for deidentified patient information for grant proposals. On IRB approval, they can then receive additional detailed patient information. The Mayo Clinic has a similar warehouse and data mining system called the Life Sciences System, developed in collaboration with IBM, which will eventually include patient tissue information. The University of Pittsburgh's Medical Archival System is a text-based archive of clinical, billing, and financial documents with tools to assist the researcher in finding relevant information.

Implementing clinical data–related IT applications was cited by 41% of the survey responses as being a top priority in the next 2 years (Table 4). This priority list includes data in clinical data warehouses with mining tools, bidirectional interfaces with hospital clinical information systems, and automated data capture systems for clinical trials.

Build or Buy Single versus Multiple Application Suites

The survey also analyzed whether the existing clinical research IT applications within AHCs were bought or developed in-house. In addition, the survey determined if these applications are part of a larger suite of applications from a single source (vendor or in-house developed) or an ensemble of systems from multiple sources (a combination of different vendor and/or in-house developed applications):

- Fifty-nine percent of the organizations still follow a "best-in-class" strategy that generally results in assembling a collection of applications from different sources.
- Those with application suites (26%) were generally using a homegrown approach, the exception being two respondents using a commercial vendor.
- Fifteen percent of organizations were migrating from best of breed to single suite, and all of these respondents had selected the vendor.

No organization was moving in the direction of developing its own best-in-class approach. The fact that organizations are moving to vendor solutions is early evidence of the progress some vendors have made in offering viable alternatives to homegrown application suites. Areas of largest penetration for vendor products are summarized in Table 5.

TABLE 4 Clinical Data–Related Information Technology Application Priorities

Top Priorities for the Next 2 Years	*Number of Responses*	*% of Total*
Clinical research data warehouse with mining tools, cohort ID, study results, recruitment registries	7	
Clinical care systems related: access to, extract from, bidirectional interfaces with clinical research databases, installing clinical care systems at hospital sites	6	
Electronic data capture for clinical trials	6	
Access to and integration with Laboratory Information Management Systems	2	
Total responses	21*	41

ID = identification; IT = information technology.
*Not all respondents listed a clinical data–related application as a top priority.

TABLE 5 Vendor Applications Implementations at Member Sites

Clinical Research Area	*Vendor Applications Implemented at Member Sites*
Regulatory compliance	Click Commerce IRBWise IRB Manager
Grant management	Oracle Clinicals COEUS (MIT developed)
Study preparation	Click Commerce Oracle Clinicals
Study conduct	Phase Forward Study Manager

Besides clinical research application vendors, hospital clinical information systems vendors have expressed interest in working with members of the Clinical Research Forum to embed data capture requirements for clinical research into their application products. This is an important step toward creating real-time data exchanges between research and care delivery activities in support of translational research.

Infrastructure Support

The survey also documented a lack of basic IT services across clinical research communities. These communities are rarely organized as individual departments. Separate e-mail systems and networks for each research discipline or division or schools within the organization of each AHC are the rule rather than the exception. These multiple, separate components of essential infrastructure (and the related fragmentation of IT support staff across the entire research community) add to the "silo mentality" of the current clinical research enterprise and thus become future barriers to the success and development of subsequent cohesive institutional solutions to these problems.

The resulting inability to share data and communicate effectively, the pain of surviving or not surviving a major IT failure (unrecoverable data server crashes) or near-misses (virus invasions), and the need to comply with Health Insurance Portability and Accountability Act (HIPAA) security requirements all make a compelling case for clinical researchers to move toward IT centralization and compliance with common IT standards. In fact, the need for a centralized IT network and data management had the highest number of votes for the most pressing IT future needs as listed in Table 6 (tied with installing a clinical research data warehouse). Thus, despite all of these existing pressures, the movement of AHCs from "islands" of research to "enterprise-wide" requirements is slow.

Management

The survey indicates a striking absence of core management mechanisms needed to guide and manage IT use.

TABLE 6 Basic Information Technology Services Priorities

Top Priorities for the Next 2 Years	*Number of Responses*	*% of Total*
IT Services department related: centralize support, data management, data storage/backups and archiving	7	
Improved network infrastructure and communication	2	
Total responses	**9***	**18**

IT = information technology.
*Not all respondents listed an IT services project as a top priority.

Fifty-six percent of the organizations have not established an institutional vision for IT and clinical research. Only 26% have a written vision; the remaining 18% have a "vision," but it is currently not documented. The reasons for this lack of a compelling central institutional vision center on two overriding themes: (1) poor communication, both formal and informal, between clinical researchers and the IT department organization and (2) decentralized clinical research centers of excellence, which may have developed distrust of central research administration, which is often viewed as basic or regulatory in its research orientation.

Most organizations surveyed (60%) do not have a clear picture of how much is spent on IT for clinical research (Table 7). In fact, some respondents could provide only rough estimates (often guesses) of research IT spending as a percentage of total research spending or total IT spending.

Governance models lined the full spectrum from no formal governance to central research and IT governance. Governance includes budgetary responsibility and a central forum to review requests for IT, approve projects, and monitor progress. The results (Table 8) indicate that effective governance of clinical research and IT does exist, but more than 40% have separate IT and research governance and 30% are even further decentralized. Discussion about best practices in governance failed to yield a single solution that fits each situation. These results generally indicate that many AHCs may not be ready to undertake such discussions and make such decisions.

TABLE 7 Information Technology Spending for Clinical Research

	Respondents		
IT Budgeting	*%*	n	*Responses*
IT budget for research as a percentage of the total IT operating budget	19	5	2–25% of total IT budget
IT budget for research as a percentage of the total research budget	11	3	5–10% of total research budget
IT-related spending for specific clinical research projects	11	3	Capital spending ranging from hundreds of thousands to millions
IT spending for research is unknown	60	16	Responses ranged from "No idea" to "No idea, but very small"

IT = information technology.

TABLE 8 Governance Models for Clinical Research Information Technology within US Academic Health Centers

Governance Model	*Description*	*Respondents* %	n
Central research and IT governance	Central research steering committee control IT-related planning and projects; may have subcommittees	30	8
IT services department centric governance	IT services department directors/managers with specific responsibility for clinical research but no IT services department representation on the central research committee	19	5
Independent governance	Separate IT and research governance organizations and IT has no specific focus for research	22	6
Ad hoc committees	Committees that include IT and research expertise formed to address a specific project, eg, grant management	7	2
No formal governance	Separate and decentralized governance for IT and research with little communication or coordination	22	6

IT = information technology.

The lack of a central governance structure for clinical research is one of the major barriers to creating and sustaining a vision and achieving common IT services and data sharing between research and care delivery.

DISCUSSION

The current landscape of clinical research within AHCs in the United States is a complex and fragmented tapestry involving patients, clinical investigators, basic scientists, scientific experiments, regulatory infrastructure, and diverse support personnel. All of these elements interact in a loosely interwoven series of work processes cast against a typically sketchy institutional infrastructure for information technologies. Most AHCs have invested heavily in their regulatory infrastructure. Investments in the day-to-day research and administrative infrastructures to support these processes have been more sparing. Workflow and regulatory requirements are as variable as the patient populations involved, the nature of the experiments planned, the funding sources, and whether drugs or devices are involved. This highly variable landscape makes the currently paper-based processes extremely cumbersome and highly susceptible to errors. Therefore, it is logical that AHCs should place a high priority on leveraging IT to support the management of these functions.

However, based on the 78% response rate of these leading AHCs within the United States, the journey of instituting IT solutions to their clinical research processes is just beginning. Overall, these organizations have made some progress, but it is particularly noteworthy that not one has achieved the ultimate solution or has assembled the fundamental management mechanisms, for example, governance and budgets, to initiate this journey. For example, no single center yet had in place the vision, strategy, governance, and funding model that are essential for a successful outcome. Most could not even supply an approximation of their clinical research IT budget, even as an estimate of their total IT expenditures. Thus, except for grant management, a process primarily addressing the needs of the research administrator and not clinical investigators, IT adoption in most AHCs is both limited and decentralized.

At a time when research teams increasingly collaborate across state and national boundaries, one of the most significant findings from the study was the lack of basic IT services, such as central e-mail systems and networks across clinical research communities within single systems. This lack of common infrastructure and services diminishes the overall capability of clinical researchers to share information and communicate effectively. Each entity ends up inventing its own solution to address universal issues, such as HIPAA security compliance. A timely move to common standards and IT centralization could increase the efficiency of IT resources and help break down the silos that exist today.

These findings strongly imply that effective representation from the clinical research enterprise is absent from the table when these resources are being allocated within AHCs. Furthermore, it appears that their infrastructure and governance are highly fragmented and simply not able to compete with the more pressing clinical operational needs within the AHC, despite the fact that the future of our AHCs and the innovations that they need to bring to our nation's health are intimately tied.

To achieve an IT-enabled clinical research enterprise, AHCs can learn from the few respondents who had developed a coherent clinical research vision. Those AHCs had the following commonalities. Each was using IT to promote interdisciplinary collaborations of disparate groups. Each had also directly incorporated its IT organizations

into its clinical research business plan and its workflow processes from education to study preparation to trials. Perhaps most importantly, each had a top-level understanding, leadership, and unwavering support for data standardization and aggregation from all sources.

However, having a vision is clearly just the start. Impediments to implementing this vision, cited by respondents, include foremost a lack of funding, process, and governance issues. In addition, there is a clear tension between the clinical research and care delivery missions of AHCs, as signaled by the absence of a single leader charged with the responsibility for all components of the clinical research–IT spectrum of activities within the organization. Finally, issues around data and application ownership and control were evident.

Building the optimal IT solution for clinical research as described above is a multiyear journey and even then one that is possible only with senior-level institutional commitment and guidance (backed up by financial support), a central clinical research and IT governance, and a clearly defined vision of the end result desired. However, since AHCs in the United States are really the nation's "translational research engines," wedding their well-categorized patient populations and longitudinal medical experiences (all valuable phenotypic information) with their powerful basic research engines must be high on the agenda of their leadership. Understanding the magnitude of the problem, placing clinical research IT functions higher on the long-term priority list of AHCs, and funding IT appropriately emerge as the most important messages of this survey. One element of the tacit contract of AHCs with societies is to provide new therapies for disease. This cannot occur without improved integration of IT into the clinical research process.

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APPENDIX

The Clinical Research Forum is a consortium formed in 1996 to focus exclusively on the complex agenda of clinical research. Its fundamental goals are to sustain and expand a group of well-trained clinical investigators and promote environments that support comprehensive research capabilities within academic institutions. Forty leading academic health centers are Forum members. As a group, they identify a limited number of key issues affecting the climate for clinical research and work to foster improvements, both within member organizations and at the national level.

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University of Virginia School of Medicine
Vanderbilt University School of Medicine
Washington University School of Medicine
Yale University School of Medicine

* Joined after the completion of the survey. Wake Forest University School of Medicine Health Sciences participated in the survey but is not currently a member.