

## Letting Investigators Lead

Perspectives on adoption of technology at U.S. Academic Medical Centers and how sponsors will be impacted.

Over the past several years there has been increasing recognition at Academic Medical Centers (AMCs) in the United States of the important role of software and systems technology in the management and execution of clinical trials. We have worked with more than 15 centers that have made significant investments in new system initiatives within the past three years.

This article will examine the drivers and strategy behind current initiatives for clinical trial systems at AMCs, their near-term impact, and the possible future evolution based on scientific, financial, and operational changes. In doing so, we consider what this means to both sponsors and the industry as a whole.

### Issues at hand

For the past 40 years there has been a significant decline in the global share of clinical trials conducted at U.S. AMCs. The last decade has seen significant changes in the milieu for clinical trials at these centers. They include environmental changes (macro) and investigator level changes (micro). At the macro level, AMCs have seen:

- Increasing risk and cost for compliance in terms of conduct and billing
- An erosion of competitiveness from an operational perspective
- An increasing cost disadvantage, as many industry trials have moved offshore
- Increasing competition for government funding
- A desire to collaborate that's driven by overarching change in funding, like the NIH's Clinical and Translational Science Award (CTSA)

- A need to control multiple system proliferation and to standardize information
- Increasing complexity of trials and recruitment in clinical research with a genomic basis.  
At the micro level, investigators have seen:
  - An increased interest in their thought leadership despite declining trial numbers at AMCs; this is in great measure due to interest in genomics and translational science impacting clinical research, and it increases sensitivity to operational deficiencies within the investigator's institutions
  - Increases in investigator-initiated trials
  - Need for multicentric electronic data collection
  - Increasing control by institutional managers from a regulatory (ethical and privacy/legal) and financial perspective
  - Increasing implementation of top-down measures that are perceived as additional overhead
  - Cost pressures in study grants aimed at decreasing the cost of information infrastructure and management
  - Frustration with management and systems.

A quick review of these factors speaks to the lack of alignment between investigators and their institutional managers. This malalignment contributes significantly to the current state at even those institutions where infrastructure systems efforts are already underway. It follows that trial sponsors are not yet receiving the benefits of these technology implementations.

### The current state

Almost all the change this author has seen is reactive to one or more of the component issues listed, with only a few institutions taking a proactive approach. Those that took the proactive road include some institutions that were early winners of the CTSA awards, as well as some institutions with a global perspective.

Within the large reactive group of institutions, changes are being wrought almost exclusively as a response to macro factors at the institutional and



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environmental level. Very few infrastructure deployments have been driven by the needs of individual investigators.

Of the macro factors, the most significant drivers have been billing and compliance. While these are necessities, investigators and researchers are driven by their need for the collection and management of data, and not quite as much by management issues. Indeed, sponsors share the same priorities with the investigator.

This discrepancy in priorities has led to a clear division of interest in systems infrastructure, and a resulting clear division of duties within institutions. Harmonious implementation and maximal impact have been best obtained when investigators have been allowed to control systems implementation from their perspective, while management functions have been seamlessly implemented through a back-office approach. In instances where the investigator leads, teams have been able to rapidly roll out EDC at a national and international level, while billing, compliance, and control functions have been overseen by specialist teams.

### Impact of systems architectures

In a classic double whammy from a legacy perspective, systems architects have focused on functional approaches, breaking up most systems in the research domain into EDC, Clinical Trial Management, or Institutional Review Board (IRB) systems. Very little thought has been given to creating a complete model of the clinical research space or to making specific views and flows around this model available to different departments for different functions.

Thus, instead of a holistic view of the world of clinical research, most systems have offered a view that promotes deployment in functional silos. In this environment, systems developers are in turn reacting to departmental needs and budgets for systems development or purchase.

The sequel to this systems development legacy has been a fractured environment at AMCs, often with a variety of systems not communicating with each other as well as strategic change that has been held hostage by historically developed systems. A consequence is that crucial data are not getting to sponsors in a timely fashion (see Figure 1).

### Successful deployment strategies

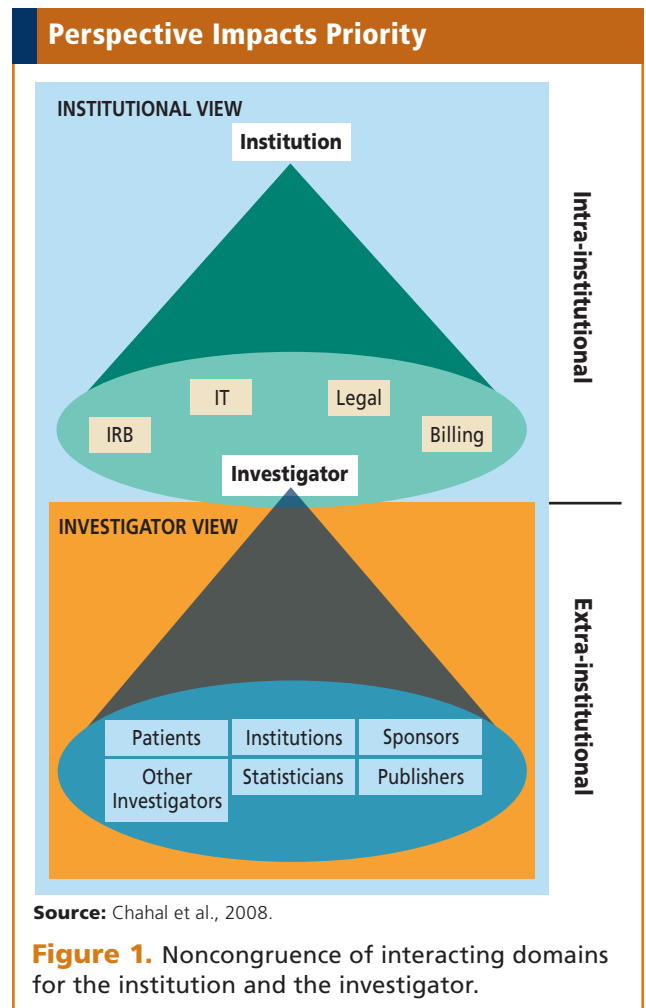
Despite the handicaps, many AMCs have made significant progress with systems infrastructure for clinical research. In our experience, two approaches have met with the best success: the Wide and Light, and the Heavy but Narrow.

An approach we have seen at some institutions has been to select systems for deep functionality but deploy them Wide and Light at the beginning. This approach may see all departments and researchers brought on board for one issue or function (registration or budgeting). Once this one thing is achieved, plans are made and the second function or feature is implemented across the whole organization.

## In instances where the investigator leads, teams have been able to rapidly roll out EDC.

This approach allows demarcated successes at an institutional level, clarity of objectives, and easier planning with a clear focus on personnel required. The Wide and Light approach has been done best when the primary, near-term objectives are related to management, control, or money.

In the Heavy but Narrow approach, institutions have looked to deploy intensive system functionality to support specific, narrowly focused departments or studies. These involve one or more of the following factors: a high internal or external profile in research, high throughput, diverse geographic involvement, and high costs. While this deployment is more intensive in effort, it is also more constrained in the need for numbers of staff involved and the need to overcome cultural/organizational barriers to change.



The Heavy but Narrow approach has seen the best returns when investigators are institutionally enabled and supported and when they are looking for early and high returns from technology investments in the research and clinical domain. The commitment to provide the best possible internal support to the investigator creates significant returns for technology investment in clinical trials.

### Future needs and strategies

Significant effort will be required by AMCs to create a rich environment for clinical research that improves the return on invest-

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ment to sponsors as well as to their own institutions. Early steps toward that goal have been taken by many AMCs in addressing the current drivers for change described earlier. However, even as the current environmental issues are met by systems deployment, there are new issues cropping up that will impact future strategy significantly.

Important among these are: the need for collaboration at several levels; projections of leadership and operations across geographic and national boundaries; and the use of standards, openness, and efficiency to obtain the highest possible levels of safety. Lastly, there are systems today already anticipating a free market where the investigator is not tethered to his or her parent institution.

Current efforts at collaboration focus largely on the ability to transmit and share data. Future efforts are likely to see greater attention paid to collaboration with and among patients, collaboration on specific services within trials, collaboration in the social dimension, and, for sponsors, collaboration and transparency through direct data capture.

The need to project institutions and researchers across boundaries will mean accelerated technology development in an area where AMCs should theoretically excel: the publishing, sharing, and management of trial-related content (standard procedures, specific issue management and resolution approaches, recruitment). This content is often available today in individual centers and departments but is not valued or managed in line with its likely future importance.

### Safety management

Safety in trials is another priority at AMCs and with sponsors. The sponsor for each study dictates one system or another for reporting (with up to  $n$  systems for  $n$  ongoing studies), the government in each country or jurisdiction may dictate yet another. The internal IRB dictates one more. External safety events (which are related to ongoing entities being studied but occurring at

separate institutions) may be reported differently. Apart from inefficiencies in the system, the logistics applied create an environment that is far from optimal for the best delivery of safety-related information. Over the next few years, information and operations strategies to counter this problem are likely to become relevant.

### Harnessing the net

Investigators today are limited to their own institutions by older organizational structures that do not mirror or exploit the changes wrought by the Internet and systems that take appropriate advantage of it.

Sponsors and grantors, insurance mechanisms, and employment contracts often limit the investigator's reach in terms of outsourcing or cosourcing study-related processes, patients, and analyses. Systems infrastructure and services are lifting these barriers. We are seeing increasing numbers of investigators turning to external services to increase both efficiency and speed of execution of trials.

We believe this may become a future trend for AMCs, where investigators are no longer tied to or defined by their institution. This mirrors the way information technology and consultants operate, with a wider reach thanks to email and the Internet. The tools for these groups are ubiquitous and collaboration ready. The tools for investigators and researchers are awaiting use to engender a similar change in reach and relevance across organizational boundaries.

### Conclusion

Technology infrastructure investments in AMCs must address a wide variety of needs. An AMC may have well over a thousand open studies at any given time. The institutional challenges in managing such a vast enterprise-within-an-enterprise should not be underestimated.

The time taken for a large AMC to adapt, change internal processes and controls, and take advantage of new technology can be long. Clear, targeted approaches have been successful in deploying systems to achieve strategic goals at AMCs. From our experience, success is best achieved by supporting investigators, and it is important that such support come front and center in managerial thinking. From the sponsor's perspective, the improved operational support for investigators has both a direct and indirect impact—in execution time, safety, recruitment, tracking, compliance, data management, and many other aspects of a clinical trial.

Changes being implemented at AMCs today are set to bring them and their investigators to a level of technology leadership that is much better suited to serve the strategic objectives of sponsors. It is safe to say that AMCs are increasingly competing for sponsor business with systems as a core part of their offerings. Efforts to showcase and exploit these new abilities in wider strategic partnerships are already under way.

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