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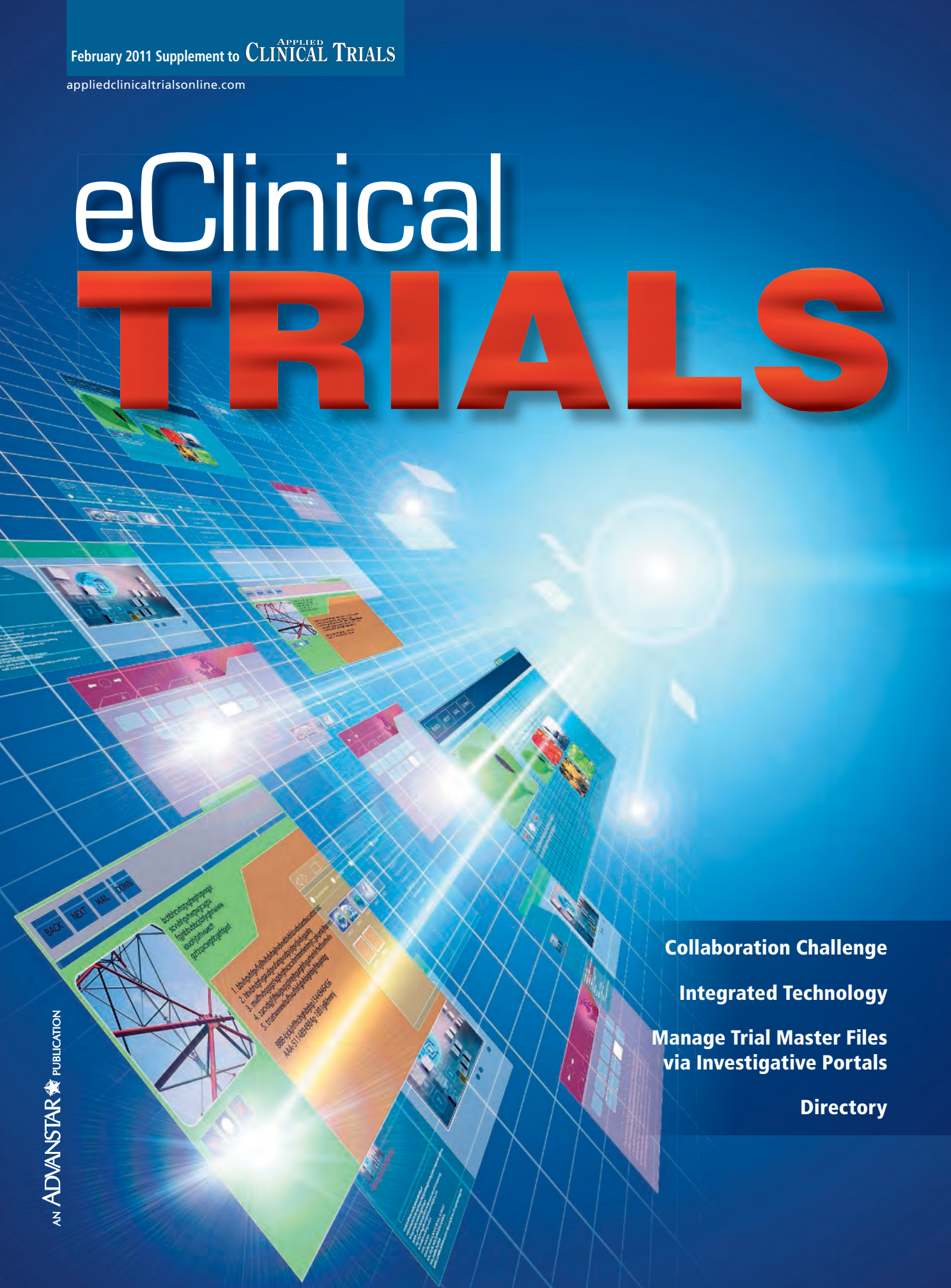

Collaboration Challenge

Integrated Technology

Manage Trial Master Files via Investigative Portals

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From the Publisher

Recently, considerable advancements have been made in the eClinical trials area, especially regarding integrated technology and eTMF solutions via investigative portals.

The eClinical Trials supplement features articles on various aspects of clinical trials technology, as well as our eClinical Trials Directory, where you can find up-to-date contact information on the industry's vendors.

Kind regards,

Wayne K. Blow
Publisher, *Applied Clinical Trials*

APPLIED CLINICAL TRIALS

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CHET SHEMANSKI

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Collaboration Challenge

The seven elements of an integrated clinical collaboration platform.

The estimated cost of running a clinical trial in the United States ranges from $20 million for a Phase I trial, to $100 million for a Phase III trial. Sponsors can invest significant dollars to improve the efficiency and reduce the costs associated with running trials. Site efficiency and productivity can be improved by centralizing information, providing recruitment and screening tools, automating scheduling, managing finances, and providing accurate reporting and metrics. Historically, suppliers of electronic data capture (EDC) and clinical trial management systems (CTMS) have focused explicitly and exclusively on managing the data involved in clinical trials. The problem is, however, that the data is only part of the equation. Equally important are the documents, dates, notifications, and other elements of collaboration.

Management of essential trial documentation is, indisputably, one of the most time consuming and costly activities associated with conducting a clinical trial. ICH E6 guidance on Good Clinical Practice (GCP) specifies an inventory of over 200 discrete documents that must be managed before, during, and after the trial. Any or all of these documents must be available for audit by the sponsor and for inspection by the regulatory authorities, and considering the massive volumes of documentation involved in the process, the effective management and exchange of study documentation can have a significant impact on the cost and time to complete a clinical trial.

Yet despite the costs in time, effort, and money, the trial master file (TMF) is often still managed through a combination of paper and simple shared folders, scattered across many locations in various countries. Management of a paper TMF can be resource intensive–documents are handled by multiple people from collection at the investigational site to placement in regulatory binders. TMF documents are tracked manually using spreadsheets or checklists that provide little visibility into what has been collected to date and what is missing. Often, duplicate copies are collected and filed unnecessarily while others expire or go uncollected. The result is decreased operational efficiency, higher costs, and the risk of regulatory non-compliance, and possibly approval delays.

Need for collaboration

Collaboration is defined as the ability for individuals and teams to work together in an effective and efficient manner. There are many barriers to collaborative management of clinical trial documentation including: the lack of a centralized, globally accessible platform to manage and store essential study documentation; inconsistent document management processes across

the organization and between organizations; inconsistent or incomplete work assignments; inefficient notification of key events requiring follow-on action; and incomplete, missing, expired, or redundant documentation,

Removing these barriers is an important part of establishing an environment that fosters collaboration among all constituencies involved in managing clinical trial documentation—keeping them connected, informed, and on task by providing access to everyone at any time, from anywhere. Internet portals that allow stakeholders to access trial information and monitor overall trial progress are often viewed as a solution to the collaboration challenge—and are often accompanied by claims of increased productivity and decreased trial costs. However, portal solutions can fall short because they present information from diverse sources in a unified way and may not be well integrated with the underlying processes that create, manage, and disseminate that information. This is addressed in the model of an integrated clinical collaboration platform.

The integrated clinical collaboration platform

An integrated collaboration platform is a unified collection of seven discrete components that, in combination, can provide an environment where diverse constituents can participate in the creation and management of clinical trial documentation in real time. Each component, by itself, has intrinsic value—but the combination of the seven components in an integrated platform creates a system that connects trial participants and supports collaborative document creation, review, approval, and ongoing management.

Element 1: workspace provisioning

At any given time, a pharmaceutical company can be actively engaged in hundreds of clinical trials. Imagine the effort and overhead involved with provisioning collaboration websites to support that volume of work using traditional web development methods. Considerations include ensuring consistent adherence to established corporate branding standards; corporate and regulatory standards; a process that is repeatable; and computer system validation tasks associated with regulated systems. These considerations can be streamlined for the use of workspace templates.

Workspace templates quickly create collaboration websites and basic content. Any number of new websites (or workspaces) can be generated from a template, which is a set of content pages and schemas (which are themselves stored on the web server as a set of HTML and XML files). A workspace template contains specific design information about a website, including the lists that are part of that website, web parts used in the website, the website's themes and borders, and navigation, as well as some content (such as document libraries). Different workspace templates can be defined for different types of trials—drug vs. vaccine, oncology vs. CNS, Phase I vs. Phase III, etc. Once the characteristics of a trial are defined and the appropriate template selected, the provisioning of the workspace is automated using an electronic workflow.

Globalization, specialization, and outsourcing are changing the way clinical trials are conducted.

Element 2: self registration

Factors such as globalization, specialization, and outsourcing are changing the way clinical trials are conducted. The industry is moving from a purely transactional environment to one where collaboration is much more important. In order to support this transformation, corporate IT is being asked to open up the network firewall to support extranet collaboration (i.e., collaboration with individuals outside the organization). The administrative workload of maintaining external user accounts, in addition to internal user accounts, prohibits many organizations from establishing this type of collaborative environment.

Extranet access poses a unique set of challenges that must be addressed in the integrated collaboration platform:

- How can I automate and manage the process of external user account requests and account provisioning?
- How can I keep external user account information (e.g., username and password) segregated from internal user account information?
- How can I relate external user account provisioning to key prerequisite tasks such as accepting a privacy statement or signing a confidentiality agreement?
- How can external users perform their own password changes?

Automating the user account provisioning process eliminates the need for corporate IT intervention and improves the efficiency of opening the clinical collaboration environment to extranet users. This automation is accomplished through a workflow that routes extranet user self-registration requests to the Clinical Program Manager for review, credential verification, and approval. Once the request is approved, the workflow sends an e-mail to the registrant containing a link to the collaboration workspace, a system generated username, and a temporary password. When the extranet user logs in for the first time, they are re-directed to an area of the workspace where they must first complete the prerequisite tasks and change their password before gaining complete access. Through automation, the administrative burden typically associated with workspace creation and external user account provisioning by corporate IT is eliminated and another barrier to effective clinical trial collaboration is removed.

An eTMF collects essential trial documents and makes them available to disparate constituencies.

Element 3: the electronic trial master file

All companies in the pharmaceutical industry must maintain a TMF for each clinical trial they sponsor. Even though regulatory guidance (such as ICH E6) exists, there is no comprehensive common model for managing those documents. Typically, a company is left to interpret the guidance and develop a unique TMF management strategy—one based on institutional knowledge, past experience, and opinion. This is a highly inefficient way for an industry to operate for many reasons:

- All drug development companies and contract research organizations (CROs) spend considerable resources defining and redefining the content of the trial master file for each clinical trial.
- The relative burden on smaller companies that have limited TMF management expertise and limited financial resources is very high.
- Records and information exchange between collaborating companies can be cumbersome and at times may inhibit or prevent cross-licensing or joint ventures.
- Inconsistent terminology and file structure from sponsor to sponsor wastes time and makes sponsor audits less efficient.

In 2009, the Drug Information Association (DIA) embarked upon an effort to define a standard taxonomy for clinical trial master files for use by the industry. This collaborative effort involved over 120 representatives from 87 biopharmaceutical companies, contract research organizations, consultancies, technical vendors, and regulatory agencies and resulted in the definition of the DIA TMF Reference Model.

An electronic trial master file (eTMF) collects essential trial documents electronically in a central location and makes them available to disparate constituencies, via the Internet, from any location at any time. As the industry moves toward larger, more complex, global clinical trials, an eTMF becomes even more important. The benefits of using an eTMF include streamlined processes, increased transparency, simplified tracking, and enhanced security. To get the maximum return on an eTMF, including significant cost savings, it has to be considered as a management tool rather than just an electronic document repository. With that said, a good eTMF is based on industry guidance (such as the DIA Reference Model), includes a comprehensive document inventory, provides metadata requirements, organizes content logically, uses standard nomenclature, may be used "as-is" or adapted to meet specific needs, and is more than a just an electronic filing cabinet.

Element 4: managing clinical content

Many drug sponsors rely solely on shared drives and e-mail as the primary mechanisms for storing and sharing essential trial documentation. While these solutions can work somewhat effectively when dealing with moderate volumes of documents, they cannot scale to meet the complexity of large global clinical trials. In today's world, the volume of clinical trial documentation is growing, not shrinking—resulting in increased management costs and the need to disseminate important information both quickly and efficiently.

Enterprise document management systems (EDMS) can provide significant advantages in managing the eTMF as they address every stage of the document lifecycle—from initial creation through review and approval. Although many commercial document management solutions provide comprehensive lifecycle management, few companies may be able to take full advantage of that function because the lifecycle management process requires collaboration to extend document management solutions outside the firewall. These solutions can be viewed as being complex, clumsy, and not well integrated with common productivity tools such as e-mail, task lists, and calendars. In many organizations, the electronic management of a document only occurs once it becomes final and is marked as record—rendering the EDMS as nothing more than a very expensive shared drive.

The clinical collaboration workspace simplifies the management of essential trial documentation by effectively integrating document management processes with the way people work on a daily basis. Workflows, not people, drive the creation of many documents. For example, at the start of a trial, when a principal investigator is granted access to the workspace, the system automatically generates an FDA 1572 Statement of Investigator form, pre-populated with the investigator's demographic information, and e-mails a link to the investigator for final completion and sign-off. Once this is complete, a work item is sent to a Clinical Research Associate (CRA) for a final QC check of the submitted form and electronic approval. If the investigator fails to complete the task within a specified amount of time, the system can send them a reminder e-mail as well as a notification to the CRA that a follow-up telephone call might be in order.

Element 5: workflows—managing clinical tasks

Getting work done on a day-to-day basis frequently requires information from or tasks to be performed by other people. Options to communicate these needs include e-mail, phone calls, and in-person discussions, but often it's difficult to get people to respond to these communications or directives in a timely manner (or at all). Many work

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items are dependent on the completion of preceding work items and failure to complete them on time hinders productivity and decreases efficiency. Within the context of a collaborative clinical trial, a standard work item inventory defines what work needs to be done, when the work needs to be done, and who is responsible for completing the work. It also facilitates the tracking and reporting of what is expected and what is missing from the project. Often, a completed work item or a group of completed work items may trigger other events (e.g., send a notification to ship product) which eliminates unnecessary delays.

All work items in the inventory should be standard, meaning no "ad hoc" activities exist. Work items can be planned or spontaneous. For example, the creation of the FDA 1572 form is a planned item while the creation of a Serious Adverse Event report is a spontaneous item. In either case, once these documents are created, the management of the remaining lifecycle stages is automated using electronic workflows. These workflows implement standard business processes and enforce consistency by assigning tasks to the appropriate people at the appropriate time. By allowing people to concentrate on performing the work at hand, and not "what happens next," variability is removed from the process, which leads to improved operational efficiency and enhanced productivity.

Besides standardizing business processes, workflows also provide several other benefits including real-time visibility into the process, delegation of work items, assignment of work items to members of a group instead of an individual, escalation of incomplete work items, automation of rote tasks, and notifying stakeholders of completed work and key events.

Element 6: alerts and notifications

The ability to communicate critical clinical information to global collaborators in a timely way can reduce operational costs and delays through the elimination of postal delivery, overnight couriers, and fax machines. As mentioned previously, the integrated collaborative clinical platform makes extensive use of electronic workflows for things like workspace creation, user account provisioning, document creation, and document lifecycle management. A key aspect of electronic workflow is the inclusion of automated alerts and notifications. Both alerts and notifications are used to keep those involved with the collaborative process abreast of what is happening on the trial. Both typically leverage e-mail or SMS technology to communicate with the recipient. Alerts however, require the recipient to complete a reciprocal action while notifications are usually informational in nature.

For example, when the clinical protocol is amended, an alert is automatically sent out to all active principal investigators working on the trial to inform them of the new amended protocol. The alert includes a link to a work item that requires the investigator to open the document and then acknowledge that the document was read—the electronic equivalent of a protocol signature page. In a similar situation, when an expedited safety report is created by the pharmacovigilance group, a notification is automatically sent to all of the principal investigators that are participating in clinical trials for the drug(s) referenced in the report. However, since there is no regulatory requirement for the investigator to acknowledge reading the report, the notification e-mail only includes a link to the document and not the electronic acknowledgement task.

Notifications can also be used to inform people of upcoming events, of key milestones that have been reached, or as reminders for upcoming or past due obligations. They can also be used as escalation vehicles on the same past due obligations. The alerts and notifications that are sent should contain standard text and formatting and should include visual clues regarding the subject and importance level of the communication. Depending on local privacy laws, it may be necessary to include an "opt out" for certain types of communications.

Communicating critical information to global collaborators in a timely way reduces operational costs and delays.

Element 7: the study portal

Look up the definition of the word portal and you will find some very interesting results. In architecture, a portal is defined as a gate, doorway, or tunnel. In fiction, it is defined as a magical or technological doorway that connects two different locations in time or space. And finally, in technology, it is defined as a website that functions as a single point of access to information on the Internet. If you further refine the search and look up the term Internet portal, the picture becomes pretty clear—an Internet portal presents information from diverse sources in a unified way; providing a way for enterprises to present a consistent look and feel with access control and procedures for multiple applications and databases, which otherwise would have been different entities altogether.

Internet portals have been used in the life sciences industry for most of the past decade, however the widespread adoption of the investigator portal concept has been slow. Like most new, transformational technologies used in clinical trials (such as electronic data capture), investigator portals are plagued with the reputation of being unintuitive, cumbersome, and difficult to master. Clinical investigators and their supporting site personnel are usually quite comfortable with their existing processes and manual workflows—regardless of how inefficient or

error-prone they might be. It is a simple case of the "devil that you know."

When designing an investigator portal to support key activities such as study start-up and document exchange, there are many things to consider. First and foremost, keep the design simple. It is critical that the portal is visually attractive and easy to use. A simple and streamlined user interface that requires one or two mouse clicks to navigate is much easier to learn (and remember) than one that is overly complex and appears busy. The investigator should be presented with a dashboard-like overview of key trial metrics, current work items, and important communications upon log in. Less frequently accessed information can be presented on subsequent pages that can be accessed quickly and easily.

Next, it is very important to provide a comprehensive training session on the use of the portal. This usually can be accomplished in a few-hours during the study start-up meeting. Alternatively a link to an online training video can be included in the portal so that it can be viewed again if a refresher is needed. Once training is completed it is important to provide the users with the ability to access a frequently asked questions (FAQ) page—this is especially important for casual users of the portal.

Summary

It is clear and widely accepted that the cost of clinical trials continues to escalate and increased operational efficiency is a key component of cost control/reduction and the speed of the trials. Most software investments focus on managing the data involved in clinical trials, but ignore the documents, despite the massive costs and time involved in creating and managing that content. Even today, most clinical trials continue to be paper-based and are supported by manual document management processes. The eTMF is at the heart of a clinical collaboration portal. When combined with the other six elements—standard work item inventories; self registration; complete and compliant document management; automated workflows; alerts and notifications; and a portal that connects the collaborators—the result is an integrated platform that can dramatically reduce the time and effort involved in creating and managing documents. The result is a similarly dramatic reduction in costs and complexity.

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TOM GRILL/GETTY IMAGES

Bill Byrom

Integrated Technology

Building a technology foundation to support clinical development efficiency.

It is clear that standalone systems to facilitate trials do not interoperate sufficiently to maximally leverage technology. The challenge then is to achieve an integrated solution with the next generation of technologies that are aligned to accelerate development. This article considers the eClinical technology foundation required to bring greater efficiency and productivity to clinical development. To explore this, we need to agree upon a definition of what eClinical is. eClinical means more than simply a clinical trial technology, such as an electronic data capture (EDC) system, but a combination of technologies that form an integrated solution. This integration should focus not simply on sharing data, but around simplifying the way individual applications operate together to smooth the workflow and access to information for the key technology end users: site personnel, study managers, study monitors, clinical supplies teams, senior management, regulatory, and pharmacovigilance teams. This changes our attention from purely data integration, to explore how end user workflow and processes can be operated seamlessly when multiple technology solutions such as EDC, clinical trial management systems (CTMS), and randomization and trial supply management (RTSM)—typically delivered using IVR/IWR technology—systems are in use together. Five objectives underpin the effective delivery of this definition of eClinical:

Data integration. Ensuring that key data are shared by appropriate applications—eliminating duplication of tasks and associated data reconciliation activities.

Convergence of technologies. Blurring the boundaries between applications by making functions contained within one technology product efficiently accessed via another. Convergence goes beyond data integration to making workflow simpler and more efficient and intuitive for users.

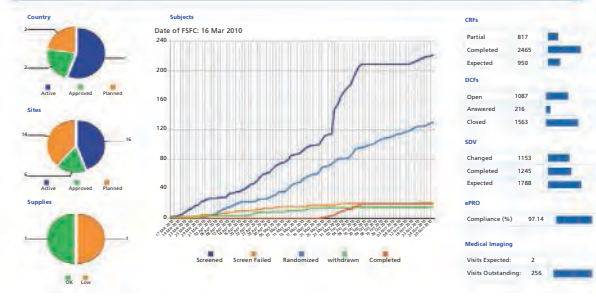
Data consolidation for decision making. Enabling users to access data that is extracted from multiple technology solutions and presented together to aid their ability to understand trial progress and data.

A common technology suite. Having a common navigation and look-and-feel for a collection of technologies to simplify training and usability.

Integrated service delivery. Providing integrated project management and support when an integrated combination of technologies is deployed.

This article will explore some of the key components of the technology platform that are required to deliver this vision of eClinical: a clinical technology integration platform (CTIP), identity management solution and portal technology, and an enterprise reporting application with associated information architecture. This platform

eClinical Portal: Dashboard Component



Source: Perceptive Informatics.

Figure 1: The portal provides a single view of high level study performance metrics with consolidated data from multiple clinical trial technologies.

must be capable of efficiently managing the complexity of interactions and data between systems within a defined suite of technologies, but must also be capable of interacting with the potentially more complex combination of solutions operated by other parties within the clinical trial network.

Clinical technology integration platform

Until recently, most integration efforts in the clinical trials environment involved point-to-point solutions that require the creation of customized links between each application. These point-to-point connections between trial technologies provide significant benefits in removal of duplication of activities and data, and eliminate the need to reconcile common data between systems. However, there are inefficiencies and limitations inherent in this approach. Typically, point-to-point integration requires custom links to be built between each set of applications, and these usually require rebuilding for each study. In addition, because of the number of connections often in play, it is complex to support and maintain full visibility of all the moving parts in a single study—not to mention multiple studies. The number of point-to-point connections often required also means more complex testing and validation activities are required and potentially repeated should one solution be modified or upgraded mid-study.

The objective of the clinical technology integration platform (CTIP) is to provide the same data integration benefits in a more robust, repeatable, and supportable way. The CTIP is a software platform or hub that sits in the "middle" of other applications—serving as a central platform that facilitates and manages all interactions between multiple technology systems. Each application is connected via a single connection to the CTIP only, providing scalibility and increased supportability—these connections can be made in such a way as they do not require re-building for each study, but simply configuration. The CTIP controls the interactions between the systems, catalogs the data each system contains, and keeps track of what information each systems "needs" from the others. With a full audit trail and an activity monitor, this component of the eClinical platform provides full visibility of all the integrations and processes through a single interface, increasing the ability to support a high number of integrated technologies across a large number of studies.

In its simplest form, this approach achieves the same data integration as point-to-point integrations but does so in a more scalable and supportable manner. However, data integration does not need to be a synchronous exchange of data files, but some integrations have value when implemented in a synchronous manner using web services so that one application performs a live call of another system, inputting data, executing commands, and returning a response directly. This is one of the routes to product convergence and a way for the increased benefit of simplifying the workflow for the end user can be realized. To achieve convergence, however, may require adjustment to individual products to ensure the function can be delivered effectively and appropriately. Let's consider two examples of product convergence:

Enabling site users to utilize EDC to perform randomization and dispensing activities. Rather than create a monolithic application supporting full EDC and RTSM functionality, it is possible to use synchronous integration between EDC and RTSM to achieve seamless workflow. The user requirement is to action randomization, dispensing, and pack replacement events from within the subject records held by EDC, without having to exit the EDC application or log into another application. To achieve this, the CTIP must manage web service interactions between the EDC and RTSM applications to ensure that when a randomization event is actioned, for example, the appropriate subject data from EDC is transmitted to RTSM and the randomization number and medication pack numbers allocated are returned and presented through the EDC interface. To operate seamlessly, a number of modifications to the EDC application are required. First, during the EDC study design phase, the designer requires the capability to define visits that map to certain RTSM events and identify specific data points within specific eCRFs. These need to be provided to identify the subject and operate the randomization. Second, the EDC interface needs modifications to enable RTSM actions to be accessed simply, and the capability to report web-service status, display returned information appropriately, and alert the user to error details if a subject event cannot be performed for some reason—for example, the subject is not eligible. Behind the scenes, the application needs to be enabled for web-service operations. The end result, a converged product combining EDC and RTSM functionality, provides a single application for the end user to perform their workflow efficiently.

Enabling sponsor users to action user accounts for clinical trial applications directly from their CTMS application. CTMS applications contain the names, addresses, and contact details of many of those involved in operating a clinical trial—in particular, study site personnel. These provide the vital user details required when creating and managing user accounts for the required trial technology applications such as EDC and RTSM. Enabling CTMS to write these details into these applications and action automatic creation and distribution of user accounts would assist sponsor workflow and ensure that all applications contain the most up-to-date information when user details change. Again, implementing this concept requires changes to the individual applications. For example, CTMS may not contain all the user types and details required by the receiving applications, and changes to the user account creation and management processes may need to be implemented in the receiving application. This is just one example of convergence that could utilize CTMS to trigger actions in other systems.

Portal software provides a framework for web-based access to a broad range of data and applications.

This approach to simplifying workflow through appropriate product convergence can be brought further forward through the effective use of portal and identity management applications.

Portal and identity management applications

In its broadest definition, the Oxford English Dictionary defines a portal to be "a doorway, gate, or other entrance..." That in mind, portal software is an essential component of the eClinical-enabling platform as it can provide a framework through which to provide web-based access to a broad range of data and applications, consolidated through a single entry point. For example, entering the portal could give a user access to information (study protocols and documents, study news and announcements), data (study metrics and data reports consolidated from multiple applications, for example CTMS, EDC, RTSM, and others), and study applications they have rights to access, such as EDC. This is a critical component of further product convergence in providing a single framework from which all applications and activities can be accessed via a single log-on. Achieving this also requires an identity management application to ensure that users can be granted access to multiple applications via a single user ID, and ultimately that active sessions can be recognized between applications so that additional sign-on is not required.

As we consider how multiple applications can be presented effectively together through a common framework it is helpful to look at the example of the Apple iPhone. The utility and popularity of the iPhone are a result of three things: value—the convenience and usability that is achieved by the presentation of multiple applications through a single unit; design—great look and feel, intuitive navigation and (some would say) coolness; and quality—function underpinned by robust and reliable performance. Examining these in the context of portal and identity management software helps to focus on some key principles that should be aimed to achieve in bringing together data, information, and applications through a portal framework.

Value. We've stopped expecting to carry multiple devices to perform the things we like to do—phone, music player, camera, GPS—yet we have this precise expectation of our study sites and study teams whom we require to utilize more and more independent technology applications to perform their clinical trial activities. Portal software provides an opportunity to develop a framework within which all trial applications and data can be accessed with the appropriate rights and security. The portal, however, is only of value if it does not add to the burden of specific users but helps them to work efficiently. Site-sponsor collaboration portals, for example, can only be effective if they help sites to complete their work and activities and don't simply create additional tasks to perform for the benefit of the sponsor or CRO. Bringing applications together within a single framework provides value greater than the sum individual components when:

- Users have a single point of authentication providing access to all their applications without multiple log-ons, achieved through effective use of identity management applications.
- Data and metrics are consolidated from multiple databases such as CTMS, EDC, ePRO, and RTSM, and displayed in a user-role-specific manner that helps the specific user type understand their progress and manage their work, achieved through data integration and effective information architecture to enable data to be consolidated and reported effectively (Figure 1).
- Functions that live in specific applications can be exposed in a way that guides the workflow of the user. For example, the portal might bring together all queries from EDC, ePRO, imaging and safety systems and present them together as outstanding tasks to the site user.
- Additional application portlets can be included that broaden the activities and information users can access, such as collaboration, news, and discussion areas.
- The framework permits access to multiple studies, programs, and portfolios through a single entry point dependent upon the access rights of the user.

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In creating iPhone, Apple has also created a framework standard enabling others to design and publish "apps." This is a value add for iPhone and the same holds true for a portal—additional value comes from a standard framework that makes it easy to construct new compatible portlets that can be applied in combination with others to comprise a specific portal application.

Design. Usability is a key requirement for any trial technology. Intuitive to use, simple navigation should enable the user to rapidly access the data, information, or function they require to perform their activities. Combined with an understanding of user-specific workflow, portal applications can present activities and data in a way that is able to guide the user to their most critical tasks and help them complete their work efficiently. The applications and data presented with most prominence may change depending on the stage of the study, making it easy for users to get to where they need to rapidly. Application of design principles and user interface standards will ensure that users do not have steep learning curves when utilizing new functions exposed through the portal. When providing or exposing access to other applications through the portal, common interface and navigation rules and standards make the use of a product suite more effective. Microsoft achieved this in the creation of their Office suite where diverse products can be used with a familiar and common navigation and interface.

Quality. All the above are great conceptually, but without a powerful enabling platform and well considered architecture and infrastructure it is unlikely to be successful. Users seek reliable and robust solutions that improve and aid the completion of their required activities.

As an industry we may have some way to go to deliver the vision described above, but knowing the vision enables us to determine the steps toward achieving that end game.

Enterprise reporting application

Each technology used in clinical trials contains data from which valuable reports can be delivered. One problem is that a user, such as a trial director, may have to visit the reports contained in multiple applications to obtain the information they need. These reports display the data in different styles and formats—meaning that if you were to compile these into a summary report the result would be a mismatch of styles and formats. This makes it difficult for the reviewer to easily interpret the contents due to having to reorientate when viewing data presented using a variety of approaches. For example, bar charts created by two applications may present country totals using an alternate color key and differing axis scales. Studies have shown that the use of color can be used to make quick association; conversely, inconsistent color schemes can confuse. Utilizing a common reporting technology and applying consistent reporting standards facilitates this.

Devising an architecture that enables data from across multiple applications to be consolidated in a warehouse or mart means that all essential data from multiple technologies can be accessed and reported alongside each other through a single interface. More importantly, pulling together data from disparate applications can provide more valuable metrics and insights. An example is measurement of the data visibility gap. An RTSM system contains real-time data on patient visits, as randomization and dispensing actions within RTSM are performed while the patient is in clinic. This data provides insight into the progress of other activities—for example, how long does it take the site to begin the data entry activities on the EDC application, or to ship a medical image to the core laboratory. Consolidating the data from these applications in near real time facilitates such measurements. In turn, a CTIP technology readily enables consolidation, ensuring that the data warehouse or mart is fed with up-to-date data from each solution.

An important consideration around implementation is data security. In the individual technology solutions, access rights within the application controls access to data (or subsets of the data). For example, within RTSM certain users such as those managing clinical supplies may require access to unblinded data to monitor the usage of medication units within each treatment group. Access to this data is controlled through the rights management of the RTSM application. When you remove the data from the RTSM application, you need to apply the same security rules to ensure users are only exposed to data their role type allows. This is one of the methodologies that can be applied by an identity management solution.

Conclusion

Achieving this vision for the future requires a powerful enabling platform composed of the right building blocks to enable the delivery of fully integrated and interoperable systems to support comprehensive data access, streamlined workflow, and overall greater efficiency improvements in clinical development. This vision is focused not simply on providing advanced and tighter integration between a defined suite of products, but also on providing a framework to enable effective interaction with a complex collection of applications hosted remotely by other organizations. Only then will there be effective information flow across various functions and organizations involved in executing clinical studies. A key goal is to enable greater visibility into trials and improve data access for faster, better decision making.

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Vito Anthony Losito and Rodd Schlerf

Manage Trial Master Files via Investigative Portals

Automated eTMF solutions reduce costs, improve productivity, and enhance data management.

As pharmaceutical companies face intense pressures from looming patent expirations, weak drug pipelines, and heightened competition, they are implementing new technologies to improve operational efficiencies in clinical trials and speed drugs to market. Document workflows in a clinical trial environment require coordination of tasks and people from multiple organizations including the study sponsors, CROs, investigator sites, academic institutions, and research ethics boards. During study start-up and throughout the course of a trial, a number of essential regulatory documents have to be processed in a short period of time. Most recently, CTMS and investigator portals have automated trial master files (TMF) and regulatory workflows and played a central role in enabling companies to expedite study start-up while significantly reducing costs, improving collaboration and data management, and speeding site/study initiation.

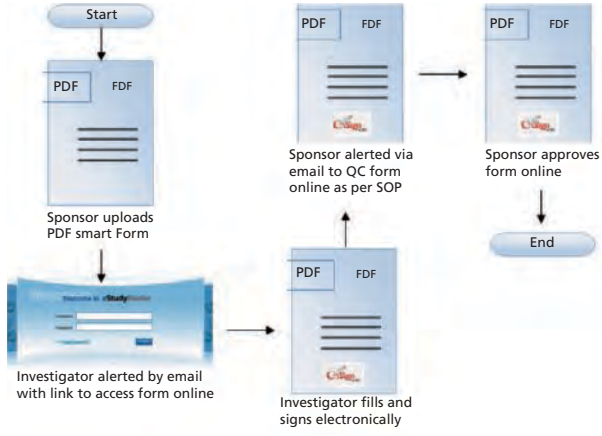
A TMF consists of thousands of pages, and includes everything from regulatory documents, correspondence, and data to documentation that supports compliance with local regulations. With paper-based TMF systems, managing documentation is a time-consuming and cumbersome task that often involves eliminating duplicates (generated in multi-center clinical trial environments where documents reside in various organizations and/or across geographical regions), replacing lost documents, scanning, indexing, and filing. Ensuring that all required documents are included in the final TMF, with required approvals, and managing metadata also become arduous tasks when using a paper-based system. With an eTMF solution, however, all documentation—including documents from sponsors, subsidiaries, CROs, and field-based personnel—is located in a centralized place, making it readily available for viewing and tracking by trial personnel from any geographic location. eTMF solutions also allow assembly of the TMF to occur gradually during the course of the study. As such, eTMFs accelerate the production, review, approval, and submission stages in addition to eliminating time-consuming and costly processes that diminish clinical trial efficiency.

EntraLogix, a site management organization that developed an investigator portal solution for its own needs, which is now commercialized, reports cutting study site initiation time from an average of 102 days to an average of 49 days through the use of its investigator portal system. By automating the clinical development process and cutting down the days to site initiation, CROs and sponsors can potentially gain valuable time to market their approved compounds under patent protection.

Evolution of the investigator portal

Second generation investigator portals are web-based collaboration platforms designed to aid in TMF management. The TMF consists of regulatory documents as well as artifacts related to the clinical trial that permit the evaluation of the trial conduct and quality of the data produced. The latest portal technologies leverage enterprise-level collaboration, document management, electronic forms, and digital signature technology to integrate the TMF with investigator site files (ISF), data, and metadata. These new clinical trial applications handle documents electronically throughout the entire document lifecycle, and cover all steps from site selection to study close out. Third generation investigator portals are designed and developed specifically for TMF requirements.

Investigator Portal Workflow



Source: Entralogix and ARX.

Figure 1. Investigator portal process broken down into five steps.

Using enterprise level portal/application technology such as Websphere or Weblogic, the clinical trial web applications offer a full set of features for online collaboration, regulatory document processing, and data integration. Through document workflow and task management capabilities combined with electronic forms and digital signatures, organizations are using these investigator portals to streamline operations while significantly shortening timelines, reducing costs, and speeding development.

With investigator portals, life science companies are also meeting the desire of regulatory authorities to have clinical documents submitted electronically. One of the key initiatives of investigator portals is referred to by the FDA as "Leaving the Paper-Based World Behind—Creating an All-Electronic Environment for Managing Data on FDA-Regulated Products."[1] The Agency has been developing standards and systems that will enable the electronic receipt, management, and storage of FDA-regulated product information. The FDA will use the Janus data warehouse to store and manage study data about the products it regulates, as well as clinical study information. Further, data exchange standards are being developed to provide a consistent way for information across organizations to be handled and to ensure that sending and receiving systems both understand what information is being exchanged. This is a significant leap forward as it demonstrates direct exchange of data from the systems of life science companies to the FDA's system. Whereas transmission of scanned PDF documents provides information that is static, difficult to query, and non-relational, electronic forms allow end users to enter, retrieve, and display data, while digital signatures are used to authorize it.

Study start-up time

In the past 12 months, EntraLogix has been using an eTMF system built on enterprise level portal web application technology, electronic forms, and digital signatures. The company started eight new clinical trials and reduced its average study start-up from 102 days to 49 days from initial site contact to site initiation. EntraLogix's regulatory documents remain in electronic format from conception to archiving. Digital signatures are a key part of the solution because investigators sign documents from their computers, regardless of their geographic location. Equally important, digital signatures allow maintenance of an eTMF without the need to digitize documents. Figure 1 uses a financial disclosure form to demonstrate how documents are processed electronically.

Evaluating automated eTMF solutions

Investigator portals have evolved from information gateways to web-based automated eTMF applications that allow online collaboration, centralization of documents, and control over the regulatory process. These systems are built on business process automation, and the integration of disparate applications, workflows, and data.

Portal technology. Possibly the most important factor to consider when evaluating an eTMF solution is the portal's adherence to standards. An eTMF solution must be able to easily integrate with disparate applications. To be able to integrate, the portal technology used needs to comply with Java Portlet Specification (JSR) 168. This enables interoperability among portlets and portals by defining a set of APIs for portlets and addresses standardization for preferences, user information, portlet requests, responses, deployment packaging, and security. Examples of compliant portal technologies are: BEA Weblogic, IBM Websphere Portal, and Oracle Portal.

Electronic forms. Instrumental to business process automation is the electronic form. Aside from eliminating the hassle and cost associated with printing, distributing, and archiving paper forms, electronic forms can be completed more quickly because they can automatically format, calculate, look up, and validate information for the user. Further, with digital authorization and routing via secure web server, review and approval cycle times can be significantly reduced.

Electronic forms initially emerged as a means to replicate a paper document on a computer screen. Today, electronic forms provide a richer, interactive environment for end users. For instance, an investigator attempting to complete a financial disclosure form can be guided through the process of completing the form. After investigators have completed the electronic form they simply submit it online. The next person in the business process, such as the sponsor's document reviewer, is then automatically notified to review and approve the form online.

Digital signatures

Digital signatures allow source documents to be signed and maintained electronically without ever introducing paper into the process. They eliminate the cumbersome processes of printing, routing, scanning, and archiving paper documents solely for the purpose of obtaining signature authorizations. Further, digitally-signed electronic records are compliant with worldwide regulations including the FDA 21 CFR, Part 11. As a result, they provide legally enforceable electronic records that are recognized by sponsor organizations and regulatory authorities. Organizations that implement automated eTMF solutions with digital signatures benefit from expedited business processes and significant cost reduction, while maintaining legal and regulatory compliance.

It is essential to understand the difference between "digital signatures" and "electronic signatures." Digital signatures are a sub-category of electronic signatures that provide heightened levels of integrity and non-repudiation. Whereas proprietary (closed-system) electronic signatures can only be trusted and verified within a specific application, standard digital signatures allow any party to verify the signature for signer identity and intent, and content integrity, regardless of the system(s) they are using. In eTMF solutions, digital signatures have various advantages, including: open system trust, where signed electronic records are portable, sustainable, and completely self-contained; security, where non-repudiation is ensured and indication of tampering is always provided; and compliance with the strictest industry regulations.

Investigator portals with integrated digital signature capabilities enable the various participants in a clinical trial, including sponsors, CROs, investigators, and IRBs, to sign the documents that constitute TMFs. These documents include NDAs, financial disclosures, 1572s, CVs, protocols, IRB approvals, informed consents, trial agreements, contracts, certifications, safety letters, drug shipment and handling forms, delegation of duties forms, and others. Digital signatures are also being used to authorize project plans, internal audit reports, archiving forms and expense reports, as well as in other clinical activities such as site monitoring reporting and site close out reports. By enabling the participants in a clinical trial to digitally sign off on these electronic documents, delays, costs and low-level security associated with paper-based documentation are eliminated. In addition, since the documents are being created, signed, and distributed electronically using standard digital signatures, any party with access to the documents can verify the signer's identity and document content integrity—inside or outside of the investigator portal.

When evaluating the digital signature solution in use with an automated eTMF system, it's important to ensure that the signature solution is intuitive for site personnel. A digital signature solution that requires extensive training will not be adopted as easily or quickly as one that is intuitive and simple for end users to adopt. This carries the risk of reintroduction of paper into the regulatory workflow for signature authorization purposes, which would consequently delay site initiation and other processes in addition to incurring added costs. It is also important for the digital signature system to allow for easy system administration including the ability to quickly add signing permissions to remote personnel, and also remove signing capabilities once the signing requirements and/or study are completed.

Practical considerations

The use of eTMF is well underway, and certainly beyond the early adoption stage. Well-designed eTMF solutions that make it easier for organizations to manage the investigator site file and related documents have been well-received and easily implemented across hundreds of sites.

The bigger challenge to adoption of eTMF solutions are the life science companies. With workflows and processes that span many disparate systems, hundreds to thousands of users, various departments, different geographic locations, and well-established standard operating procedures, implementing an eTMF solution naturally seems daunting. Thankfully, experience with eTMF solutions has shown that there is a golden path for successful implementation within life sciences organizations.

The first step is to develop a vision for your organization. Implementing a good eTMF solution is a gated process that takes between two to five years. The eTMF solution should be a transactional system that includes electronic forms and digital signatures, and captures data in a relational database system. The system should be a robust, external-facing portal web application with functions for all clinical service providers including investigators, site personnel, IRBs, auditors, and third-party vendors. Further, it should include integration with existing internal-facing document management systems and data exchange with organizations such as the FDA.

With a vision in place, it is possible to start developing the requirements that your organization needs to achieve the end goal. List, in no specific order, all the functions your eTMF solution must be able to do. In addition to a functional requirements list, you also need to consider the technical requirements. There are a number of important technical items to consider when looking at purchasing or developing an eTMF solution that are consistent with the industry's migration to paperless clinical trials. First, the future of clinical trials will depend heavily on data interchange; as such, your eTMF solution must be designed and built for data interchange. The solution must have electronic forms that produce pure XML. Also, the

electronic forms must be able to capture data in a relational database. The electronic forms must be compliant with ODM and HL7 standards. Lastly, the electronic forms must be integrated with a compliant digital signature solution. Second, your solution should be J2EE compliant as there are a number of important advantages to this architecture. With J2EE servlets and portlets, the solution can use server-side to process all requests such that the client only needs a web browser. Also, J2EE is a services oriented architecture with compliance with a number of important standards, making integration with back-end document management systems and data interchange much simpler.

With functional and technical requirements in place, it is now time to investigate the eTMF solutions available on the market. If you can find a commercial eTMF solution that meets the top 80 percent of your requirements out of the box, the chances of successfully implementing the system are very high. With your solution selected, it is time to plan the implementation gates for key functions. When it comes time to start implementing your eTMF solution, start with the most fundamental piece: a portal for all the TMF documents. Documents that must be printed for signatures are digitized during the study and placed in the eTMF. The first stage of implementation should include functions for all the clinical service providers to track and manage their documents electronically. The second stage of implementation should include the implementation of electronic forms and digital signatures. This will significantly reduce the need to digitize, index and file documents. Document, workflow, and task management is now completely electronic and spans the entire spectrum of clinical service providers regardless of organization or time zone. This is when significant gains are made in productivity and study start-up times are significantly shortened. The final stage of eTMF implementation is integration with existing internal document management systems and data exchange.

References

1. Food and Drug Administration, *Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products* (FDA, Rockville, MD 2004).

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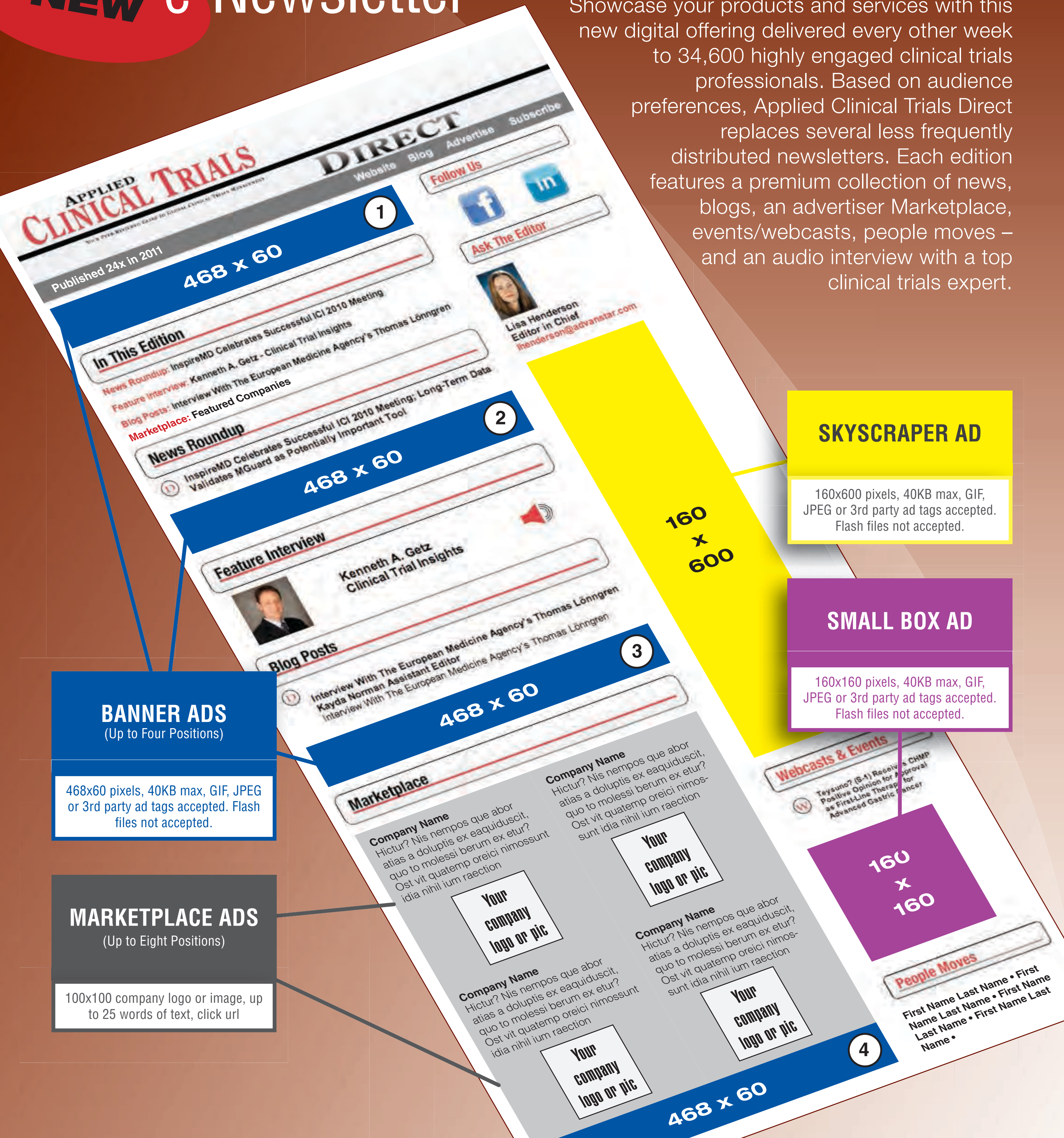

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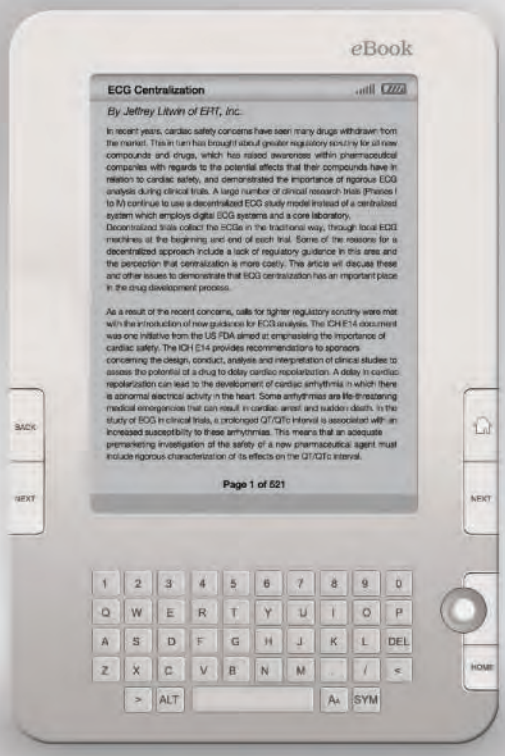

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