Part Two: From Convergence Vision to Reality

Perceptive Informatics MyTrials Technology

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“Effective use of converged eClinical technology to deliver scientific and business objectives is the cornerstone on which Perceptive’s MyTrials eClinical platform is built. All other choices – underlying IT architecture, vendor selection, optimizing the user experience – were informed by this central premise.”

– Bill Byrom, Ph.D., Senior Director of Product Strategy, Perceptive Informatics.

It’s become quite clear that convergence is the engine for the next generation of eClinical platforms. Simply assembling point tools (RTSM, CTMS, EDC, etc.) and enabling them to share data – albeit an important earlier advance – isn’t sufficient. What’s needed is a unifying architecture that blurs lines between ‘functionalities’, leverages an integrated data structure, enriches the user experience, and, importantly, plays nicely with external tools and partners’ (see Part One: Taming Technology Chaos - Perceptive Informatics’ Vision of eClinical’s Future).

Delivering this ambitious vision isn’t a trivial exercise. Consider the clinical data management challenge associated with just one study handled by Perceptive MyTrials: it had three arms, 1,236 subjects, 2,066 disposition events, 679 adverse events, 92,603 concomitant medication doses, 73,723 exposure interventions, 10,605 drug accountability issues, 11,080 medical comments, 265,687 ECG tests, and overall 1,015, 684 medical measurements. That’s just the clinical data.

To cope with trials’ increasingly complicated workload, the MyTrials environment was carefully built using robust technology from industry-leading vendors such as IBM, Informatica, Information Builders, and TIBCO. “A key point is the confidence we have in the technology and vendors used in MyTrials and that clients can also share that confidence. Our approach is to seek out best-of-breed, proven vendors and form long-term partnerships. Everything is for the long term; nothing is short term. Picking our technology is a safe bet as well as being advanced,” says Andrew Harrod, Senior Director Enterprise Architect, Perceptive Informatics.

A detailed discussion of the technology used in Perceptive MyTrials is beyond the reach of a short paper, but a substantive overview is instructive. MyTrials is SaaS delivered and based on a federated architecture that emphasizes standards (XML, SAML, BRIDG, etc.) where practical, openness for third-party integration, data virtualization techniques that minimize data movement and speed performance, and agile development techniques to accommodate rapid change.

The core MyTrials infrastructure elements include:
- Clinical Technology Integration Platform
- Enterprise Portal Technology
- Enterprise Reporting Capability
- Identity Management
- Perceptive eClinical Applications (including CTMS, EDC, RTSM, ePRO, Medical Imaging)

These building blocks form the basis for the MyTrials environment. SaaS delivery dramatically reduces deployment and support issues and permits users to leverage the full capability of MyTrials core components. The unified architecture also delivers a common look and feel for users and smooth transition between workflows for different roles.

1Part One: Taming Technology Chaos Perceptive Informatics’ Vision of eClinical’s Future; Perceptive Informatics White Paper
2InformaticaWorld 2013 presentation, Perceptive Informatics
THE CTIP IS FOUNDATIONAL

Think of the Clinical Technology Integration Platform (CTIP) as a software hub that sits between other applications, serving as a central platform that facilitates and manages all interactions between multiple technology systems. Developed using industry-leading integration and Extract Transform Load (ETL) software, CTIP delivers integration services necessary to ensure easy, robust integration across Perceptive’s product suite as well as the ability to integrate effectively with external applications.

Besides acting as an overall controller, the CTIP catalogs the data each systems contains, keeps track of data each system needs, and maintains a full audit trail and an activity monitor. Unlike other solutions in which vertical tools have multiple connections to other systems, in MyTrials individual applications have just one connection to the CTIP. This approach achieves the same data integration as point-to-point integrations, but does so in a more scalable and supportable manner.

“We’ve taken base products from leading vendors and extended the pallets within them with re-usable software assemblies; this allows us to deliver configurable interfaces in many cases as opposed to having to build new every time,” says Steve Quigley, Associate Director, Enterprise Architecture, Perceptive Informatics. Understanding technology tradeoffs and vendor strengths also informed the CTIP development process.

“While TIBCO and Informatica technically overlap and duplicate some features, they have different backgrounds. TIBCO’s heritage is from real-time event driven integration and Informatica is from ETL. We use the best of each. Overall they give us a very flexible technical toolkit that enables us to integrate anything,” says Quigley. Notably, Perceptive was named Informatica’s 2012 OEM Partner of the Year for Perceptive’s expertise and effective use of Informatica data integration technology in building MyTrials.

Data flow and data models were key considerations in designing the CTIP. “We value not copying the data as a principle; it should be moved only when meaningful to do so,” says Steve Chartier, Director of Engineering, Perceptive Informatics. “Data are always in the authoritative system and additionally data is combined into our clinical data metrics mart for reporting and visualization purposes.”

To a considerable extent, minimizing data movement – thus reducing associated overhead and versioning problems – is accomplished using data virtualization and semantically defined datamarts. Overall, a Publish & Subscribe dataflow (built with TIBCO technology) is deployed.

“Our ETL is quite clever,” says Chartier. “We have developed an extensibility model with interfaces based upon our information model and depending upon the genre of services that feed the information model. For example, we have the notion of a CTMS (Clinical Trials Management System) defined as a semantic interface within our ETL. This idea of having an interface at the level of common clinical services allows us to plumb in multiple kinds of CTMS systems very rapidly.”

Among other things, the information model/ETL strategy produces higher performing systems. Consequently, Perceptive is able to deliver high SLA adherence, data freshness and data agility. “This is unique to Perceptive. We can take data from transactional systems, from hundreds of clinical trials, and combine that data and bring it into a presentation format in an hour or less. That’s different from traditional efforts, which usually go into data warehouses and rely on overnight processes,” notes Chartier.

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*Perceptive Informatics Named 2012 “OEM Partner of the Year” by Informatica; view here*
A use case helps illustrate data flow. In the process of a patient visit, a site worker might log into the EDC (Electronic Data Capture) system to input data, perhaps the patient’s blood pressure. That data, now in the EDC, is immediately available to other clinical systems. The RTSM (Randomization and Trial Supply Management) system might, for example, request the data and decide that based on the new blood pressure the patient’s medication dosage should be titrated up. The system might indicate medication pack A7 instead of A8 (to maintain required clinical blinding) should therefore be administered at the visit.

The key takeaway: Trial activities (patient visit, medication dispensing, etc.) occur at the site. The data input, data management, and system response are via web services. A decisive enabler is that the data put into the EDC is immediately available to other clinical systems.

Next, data is going to be extracted from the EDC system and brought into the Clinical Metrics Data Mart – this happens within an hour of data input to the EDC as scheduled workflows query the EDC system and bring the data first into a staging area, the Operational Data Mart (ODM). Hourly the data in ODM are combined and brought into the Clinical Metrics Data Mart (CMDM).

An important point is the ODM is separate from the CMDM and the data it contains can be transformed into standard or client specific extracts. This process enables Perceptive to provide comprehensive clinical data generated by best-of-breed transactional systems and flowing through b2b interfaces to clients. They in turn bring that data into their internal data hubs and feed downstream analytic systems that they’ve chosen to host themselves; this critical capability reflects the reality of installed systems at clients and the need to integrate with clients’ systems.

“We understand people need data in different consumption formats and to the extent the data can stay within MyTrials we will present new semantic definition to the data. That happens today where the customer might interact with the data in their EDC systems through a semantic interface we’ve designed. But we can also supply data in their preferred formats. We would never tell a client he must get rid of one of his systems," says Chartier.

Given the inevitable changes in trial requirements and the steady advance of clinical technology, Perceptive has embraced Agile Software Development to rapidly capture change. Datamarts and their associated ETL are updated quarterly in accordance with Perceptive’s MyTrials extensive product roadmap. It’s worth noting that every time a new clinical fact needs to be created, the data model must be enhanced from getting the data from its source system, to updating technical specs, and generating ETL definitions.

The whole process is lean. “In any particular sprint, which for us is a two-week cycle, we might add 8 or 10 facts, and there might be 10 or 20 data elements within each fact. So we might add 100 or 200 elements of clinical information within a two-week cycle. That includes conceiving it, implementing it, and testing it. So our embracing of agile allows us to enrich our clinical model with information in the transactional systems incredibly quickly," says Chartier.
ROBUST IDENTITY MANAGEMENT IS INDISPENSIBLE

Multiple logon identities and associated passwords – long the bane of solutions in which diverse eClinical applications are simply strung together – have always been difficult to manage and cumbersome to use. Perceptive MyTrials overcomes this challenge with an identity management capability built using IBM Technology (IBM Security Identity Manager).

“The idea is to identify an individual uniquely across all of our systems and to have one identity per person within our systems; everything is linked off that one identity,” says Amit Amte, Associate Director, EA, Portal Platform, Perceptive Informatics. “Users have one account, one set of credentials, and that provides access to the different systems.” Accounts are established in one of two ways; either the user can create an account directly or an account can be set up for him or her by MyTrials administrators on behalf of the client. Use of a federated architecture is an important enabler here.

“Once the account is created we manage the identity centrally,” says Amte. Users are given access and privileges based on their roles, and administrators are able to modify or revoke access at anytime. “This was harder to do when in the age when all of these systems maintained their own user names, accounts, and passwords. “If a user were to become blacklisted by the FDA, for example, we are able at anytime to go into our identity management system and suspend that user. Previously doing that was a substantially longer process.”

This sophisticated identity management permits much tighter control over user activities and also enables single sign on, a significant productivity booster.

The MyTrials Identity Management infrastructure also enables federation, trusting identity authentication on third-party IT systems. “We see a growing need amongst some of our sponsor customers to provide access to our MyTrials environment directly from their IT systems without the need for their intended staff to sign on. Effectively we are able to trust the authentication managed by the sponsor’s Identity Management system.” said Amte.

This is becoming increasingly important for customers who want to embed our products with their processes as if they were software solutions that they had installed in-house.

PORTAL TECHNOLOGY – MORE THAN JUST A WINDOW

Few parts of the Perceptive MyTrials solution are more important than the user experience platform. It is the primary point of contact, the conduit to other applications, and in many instances it’s the workspace for MyTrials users. Developed using IBM WebSphere technology– IBM calls this ‘on the glass integration’ – the portal is an integration space where users come in and 1) are able to see everything they have access to, 2) able to navigate to seek more information, and 3) able to enter specific systems to perform tasks.

In a typical use case, an investigator at a site would log on, request access to a particular trial, be granted access, and from that point forward be able to navigate to any area of the portal that provides more detail about the trial. “All this information is customized for you,” says Amte. “We have your bookmarks for the specific site resources and trials you have and documents that you can access that are specific for that trial.”

The investigator would see some data about the study but only for his or her site. “The investigator might say, ‘Oh, I have ten patients, nine of them waiting to be seen for the next visit, etc. The portal is a gateway to the information and for the user to go and take some action,” says Amte.

This rich integration between the MyTrials portal interface and back-end applications is a competitive differentiator. What’s more, the MyTrials Experience has been designed to evolve and accommodate both internal and external integration needs. “For example, the IBM product allows us to expose and consume portlets using the WSRP standard. That allows us to effectively internalize other services as well as being able to expose services from our system over to other portals,” says Amte.

The MyTrials portal interface has already evolved, transforming from what was initially a mostly static window on trial activities into a dynamic space; this enhancement process is ongoing.

“Users will see more customized and actionable content being captured and presented from the portfolio of product and services. For example, we’re already looking at a Facebook-like interface where you could look at a specific trial or a study and see all the notifications or postings the way you can on Facebook now. It’s like the wall of things going on and you’ll be able to subscribe to one or another stream of information, specifying what’s important to you and what’s on your periphery. You’ll see those kinds of collaboration capabilities come out more.”
REPORTING CAPABILITIES—DELIVERING TIMELY INSIGHT

Because Perceptive MyTrials is a converged solution, mining the data for insight can be done more deeply, widely, and quickly. “We aggregate important information from the source systems—the applications that are used to capture data on the trial as well as the applications used to manage the trial. All that information is put into the Clinical Metrics Data Mart (CMDM) where necessary transformations and computations are performed to produce metrics for use by decision makers,” says Nikki Dowlman, Ph.D., Product Director, Perceptive Informatics.

Broadly speaking, MyTrials reporting was designed for multiple user types and trial roles (e.g. sites, monitors, study managers etc.). Based on their familiarity or skill set with handling data they can either extract the data and further manipulate it or they use MyTrials’ interpretations presented in standardized tables and graphs. “You have users who are comfortable with numbers, very familiar with the databases, Excel, and want to manipulate data themselves. At the other end of the spectrum are users who would run screaming from the room if you presented them with an Excel spreadsheet. We were very conscious of those extremes and kept that mind when examining the various technology vendors,” says Dowlman.

Data is aggregated from MyTrials various components using Informatica and Oracle technology. “We can pull all that information out and present it in a single place in the MyTrials environment to provide a full picture of the trial,” notes Dowlman. There’s a dashboard and standard template reports as well as ‘self-service’ data extracting capability.

Data are generally reported in a way that represents the trial life cycle. So for whatever the stage you are in the study, we have relevant reports; if you are bringing sites onboard, recruiting subjects, in a maintenance phase, or a closeout phase, etc. Depending on the trial phase, there are data visualizations that are meaningful for that moment in time.

The information captured from the various eClinical applications, such as RTSM, CTMS, Medical Imaging and EDC, provides a powerful planning tool. If for example, the RTSM system reports a visit, you know to expect a forthcoming CRF. If after a week no CRF has arrived, the system can flag that. You can start to monitor and manage the process more effectively because you have a fuller picture of related trial activities. “The sum of the data becomes greater than the sum of its parts,” says Dowlman.

This comprehensive reporting is not restricted to a single study. Development is progressing to expand MyTrials reporting to encompass a client’s entire portfolio. A first release in fall 2013 introduces the capability to look at metrics for an entire geography such as Germany or the U.K., and assess how that region is performing and if the region is performing well or if there is a wider problem.

“We’re continuing to work up the hierarchy, from operational type data for a single study to strategic data with strategic level reporting programs,” says Dowlman.
CONCLUSION

Fulfilling convergence’s promise to deliver the full benefits of eClinical technology is an ongoing process. Efforts to extend the scope of eClinical platforms beyond management of single studies to entire clinical trials programs are proceeding. The rush to effectively use mobile technology for eClinical activities is underway. Embrace of social media mechanisms a la Facebook is an emerging imperative. Better and expanded use of predictive analytics has already started.

The technologies required to deliver these eClinical functionalities can be intimidating and fast advancing. Perceptive Informatics has both the clinical domain and technology expertise to effectively assess the changing technology landscape, select leading edge tools from leading vendors, and deliver a best-of-breed eClinical technology. Perceptive MyTrials represents a major step forward in leveraging converged technologies. Whether used completely on its own or in a mixed environment with a client’s internal tools, MyTrials delivers many of the benefits of convergence today.

For more information about the Perceptive Informatics’ eClinical portfolio, including its comprehensive MyTrials solution, visit http://www.perceptive.com