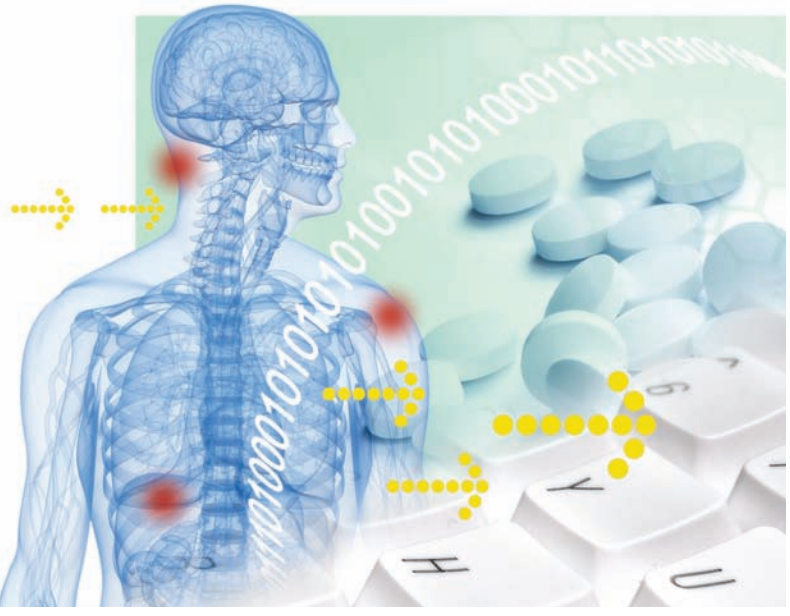
Bio·IT World Signature Series eClinical Technology 2011

# eClinical Trials Technology 2011 – The Next Decade



There is no doubt that new software and technologies are poised to bring about significant improvements to the way in which clinical trials data are organized, collected and managed in the coming years. As detailed elsewhere in this issue, the need for such enhancement has never been greater.

In this Signature Series supplement, the first of 2011, *Bio·IT World* is pleased to allow vendors to detail their unique solutions and competitive advantages as we seize upon technological insights and innovations to enhance the clinical trial process.

Good clinical trial management begins with an accurate model, but trial simulations are only as good as the models that generate them. **Archimedes** specializes in using a large-scale simulation model of human physiology to run a virtual clinical trial with a million people, spanning 30 years, in three hours. The company says it has validated its technology in dozens of trials in recent years,

**ClearTrial** says that its latest software is enabling clients to compress the clinical study planning cycle times from months to weeks, produce accurate forecasts of staff and project costs and milestone dates, and accelerate the delivery of accurate and achievable budgets.

**DecisionView**'s Study Optimizer is a web-based tool for modeling, planning and tracking patient enrollment. With many clinical trials costing their sponsors millions of dollars in unplanned overruns, the investment in such technology can quickly pay for itself many times over.

According to **Perceptive Informatics**, the proliferation of bespoke technologies has resulted in biopharmaceutical companies looking for ways to further improve efficiencies and streamline supplies management at investigative sites around the world. To that end, a configurable randomization and trial supply management (RTSM) technology can simplify clinical trial logistics and reduce the required amount of medication stock, as well as offering useful real-time access to the data.

**Clinical Ink** has developed the first electronic source record to comply with a host of FDA and EMEA standards to replace paper source documents with electronic forms. The company insists that "electronic source is the best option to fundamentally alter the business model of clinical development."

The increasing complexity and globalization of clinical trials provides a tailor-made opportunity for vendors such as **Almac**, helping sponsors gain access to real-time data. "The challenge of the upcoming decade for clinical trial sponsors," they write, "will not only be how to cost effectively integrate data, but also how to apply multiple data collection modes internationally to enhance study workflows and improve overall trial management."

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## CLEARTRIAL

# New Planning Software Improves Clinical Development Efficiency

Under the current global operating environment biopharmaceutical and medical device companies face far more limited financial resources, while time-to-market pressures are intensifying and worldwide clinical research activity is rising steadily. In response, companies are becoming more demanding of their planning and forecasting capabilities and setting lower tolerances for variance between planned and actual performance.

Historically, the life sciences industry has relied on a mix of spreadsheets, databases of previously contracted prices, and ballpark estimates from CROs as budgeting and planning tools. Often, each functional area has its own separate planning tools and methodology, augmented by "back of the napkin" calculations.

Recent research from the Tufts Center for the Study of Drug Development confirms the drawbacks of these approaches: "Most companies acknowledge that capacity planning and forecasting techniques are neither sophisticated nor scientific. Many report relying on institutional knowledge, politics, experience, and "gut feeling" in their planning decisions. Nearly all companies state that there is wide variability and inconsistency in capacity planning and forecasting practices across various departments and areas within clinical development."[1]

## ClearTrial: A New Type of Clinical Software

ClearTrial software leverages embedded industry intelligence and clinical knowledge to provide visibility to the operational and financial plan for a study, and the ability to quickly model new scenarios as clinical assumptions or business requirements change. The result is more efficient and accurate clinical study planning, budgeting, and execution.

ClearTrial delivers a comprehensive set of features to help you meet your clinical study planning goals.

- **Embedded global clinical intelligence:** ClearTrial offers industry-proven algorithms for over 150 therapeutic indications and specific clinical development data from 80 countries, simplifying study planning.
- **Activity-based planning methodology:** By building study plans "bottom-up" from more than 140 documented study assumptions, you can ensure that study plans reflect your development goals.
- **Centralized repository for operational data:** With ClearTrial, your clinical plans are kept in a secure database, accessible via a secure web connection. Your institutional knowledge is thus highly secure, while the system is scalable to any number of users in any part of the globe.
- **Fast "what-if" scenario planning:** The software's Rapid Scenario Planning™ capability lets you assess multiple clinical development strategies in minutes, and then select the one that best meets your business goals — whether driven by cost, timelines, resources, or a combination.
- **Rapid time to value:** Thanks to its Software-as-a-Service delivery model and easy-to-use interface designed by clinical operations professionals, ClearTrial software can be operational in less than a week, quickly delivering business value to your organization.

### Milestone Dates Comparison

| Milestone | Clarity baseline v2 | Clarity baseline v3 | Difference |
|---|---|---|---|
| Project Activity Start Date | 14-Oct-2010 | 14-Oct-2010 | 0 days |
| First Site Approved | 25-Nov-2010 | 20-Jan-2011 | 56 days |
| Last SIte Approved | 04-May-2011 | 18-May-2011 | 14 days |
| Investigator Meeting | 07-Apr-2011 | 21-Jan-2011 | -76 days |
| Drug Available to First Site | 09-Apr-2011 | 23-Jan-2011 | -76 days |
| First Subject/Patient In (FSI/FPI) | 14-Apr-2011 | 28-Jan-2011 | -76 days |
| Agreement on Statistical Analysis | 02-Jun-2011 | 11-Mar-2011 | -83 days |
| Last Subject/Patient In (LSI/LPI) | 07-Mar-2012 | 06-Oct-2011 | -153 days |
| Last Subject/Patient Observation | 14-Jun-2012 | 30-Dec-2011 | -166 days |
| Last Data Query Resolved | 24-Jun-2012 | 09-Jan-2012 | -166 days |
| Database Lock | 28-Jun-2012 | 13-Jan-2012 | -166 days |
| Final Report | 12-Oct-2012 | 28-Apr-2012 | -167 days |
| Study Duration (approx months) | 23.9 | 18.4 | -5.5 |

**ClearTrial software enables rapid "what-if" scenario planning based on your clinical assumptions. Compare multiple scenarios by assumptions, cost, resource demand, and timelines.**

## Key Benefits

*Clinical Development*

With visibility to the operational and financial plan for a study, ClearTrial customers are compressing clinical study planning cycle-times from months to weeks while reducing study costs.

*Clinical Operations*

By providing fast and accurate forecasts of costs, FTE demand, milestone dates and more, ClearTrial software accelerates delivery of accurate, defensible, and achievable study budgets.

*Clinical Outsourcing*

With visibility into industry-standard study hours, costs, and resources, ClearTrial customers are reducing outsourcing cycle-times while increasing their negotiating leverage.

**For more information, visit: www.cleartrial.com**

(1) "Assessing Biopharmaceutical Company Practices in Measuring Capacity and Cost," Tufts Center for the Study of Drug Development, September 2010


# Compress study timelines. Reduce study costs. Improve study feasibility.

It's not a dream. It's a reality for biopharmaceutical and medical device companies around the globe using ClearTrial software.

How? By leveraging the software's embedded industry intelligence and clinical knowledge to quickly and easily optimize the operational design of a clinical study—no matter how complex.

The result is that ClearTrial customers:

- Compress study timelines while reducing study costs
- Accelerate delivery of accurate, defensible, and achievable study budgets
- Reduce outsourcing cycle-times while increasing negotiation leverage

…while improving study feasibility.

**Looking for greater efficiency in clinical development? Contact us today.**

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CLEAR TRIAL®

Advanced visibility to your clinical trials®

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CLINICAL INK

# Electronic Source Records (ESR) — What EDC Should Have Been

The single biggest cost driver of late-stage clinical development is the on-site monitoring of paper source documents at the site. Capturing source data on paper, while initially easy, ultimately is costly, error-prone, and time consuming for both sites and sponsors. Eliminating paper source documents will reduce monitoring and data query resolution costs by HALF — while lowering compliance risks.

Nonetheless, paper remains prevalent at sites, even in EDC studies, because of familiarity and a lack of viable alternatives. Clinical Ink has developed the first electronic source record (ESR) to meet FDA, EMEA, HL7, and CDISC standards and guidelines to replace paper source documents with electronic forms — particularly the requirements relating to electronic source *documents* versus source *data*.

## How Does Suresource Work?

Clinical Ink's SureSource™ solution maintains the natural workflow, ease of use, and mobility of a paper chart — everything from "pulling a chart", capturing handwritten notes & drawings, flexible navigation, and the freedom to work without regard to connectivity — while allowing fast, secure transmission of source documents and data electronically.

***SureSource Tablet*** — Investigators and Study Coordinators use a tablet PC instead of paper forms to record patient visit details. The information on the form is converted to data and auto-populates the study database — all the time, effort, and error associated with re-entering data into a CRF is eliminated. Additionally, real-time data validation and "intelligent" forms ensure information is captured completely, accurately, and in exact compliance with the protocol while the patient is still in the room.

***SureSource Portal*** — Monitors, sponsors, and site users access a web portal to review electronic source documents remotely as the visits happen in real-time. Source Data Verification (SDV), the most time consuming and least valuable monitoring activity, is eliminated; there are no discrepancies between the electronic source document and the database. As a consequence, monitors can apply their expertise to review source documents for relevant medical context, safety trends, and protocol compliance rather than wasting effort to identify simple data errors and omissions.

## Benefits

In addition to relieving the work burden on sites, directly quantifiable benefits to sponsors include:

- Eliminate SDV cost and time; up to 50% of monitoring effort is SDV; partial SDV increases risks
- Dramatically reduce queries; 65% of data queries are due to discrepancies with source documents
- Remote real-time site monitoring; more frequent/focused interactions with less on-site travel
- Audit trail of source; dramatically reduce risk of fraud and increase protocol compliance
- Site recruitment enhanced; sites are paid within days for fully validated/reviewed data and use a tool that actually reduces their workload

Patient care also improves as details of clinical research visits can be included as part of the patients' medical record either as an HL7 data export or printed paper copy — all without added work by the site.

Electronic source is the best option to fundamentally alter the business model of clinical development.

**ARCHIMEDES, INC.**

# Clinical Trial Simulations: Creating Evidence and Proving Value

More and more, mathematical models are used to simulate clinical trials in order to learn about drug effectiveness and safety, optimize trial design, lower the risk of failure, and select drug candidates for advancement. Considering the complexity of clinical trials, it makes sense to rely on comprehensive models that have been validated against available evidence.

Archimedes is a healthcare modeling company that has built a large-scale simulation model of human physiology, diseases, interventions, and healthcare systems. The Archimedes Model can run a virtual clinical trial with a million people, spanning 30 years, in three hours.

The Archimedes Model has been in development since 1993. It is an integrated model that contains pathways relating to more than ten medical conditions, including diabetes, obesity, myocardial infarction, asthma, congestive heart failure, and several cancers.

**More than 50 landmark clinical trials have been used to validate the Archimedes Model**

Written at a high level of detail using object-oriented programming, the Model runs on a distributed computing network. At its core are hundreds of ordinary and differential equations that represent human physiology and the effects of diseases. Coupled with this is a realistic representation of healthcare systems including all key components such as physician behavior, patient compliance, and costs.

Archimedes scientists continually calibrate and validate the Model by simulating real-world clinical trials and comparing the simulated results against the results of the original trial. To date, more than 50 landmark clinical trials have been used to validate the Model.

The Model is used by health and economic outcomes researchers, as well as clinical researchers in life sciences, managed care, government agencies, and academia. These diverse users turn to the Model to find answers to their questions about efficacy, costs, target markets, and much more.

For example, in a study for Kaiser Permanente, the Model predicted that the use of a bundled drug combination would lead to significant improvements in health outcomes and reductions in healthcare costs. These results were confirmed by KP when the program was implemented. (http://bit.ly/i2bWpf)

Clinical trial simulations are an invaluable tool, but they are only as good as the models that generate them. With so much at stake, you need a model you can count on. The Archimedes Model—highly detailed, carefully validated—is the most comprehensive, accurate model of health and healthcare available. Contact us for more information.

**Visit www.archimedesmodel.com for more information.**

ARCHIMEDES

## The Role of Mathematical Models

The quality and cost of healthcare are determined by the decisions we make about which people get which interventions, and how we deliver those interventions.

Ideally we would base all our choices on clinical trials. For every important question we should implement different options, observe the outcomes, and choose the option whose outcomes best meet our objectives.

Unfortunately, this approach is not feasible. Answering just one question with empirical research can be expensive, difficult, and time consuming. Trying to answer all questions and study all options is utterly impossible.

Mathematical models can be used to bridge the gaps in empirical research. For example, imagine that there is a trial comparing Drug A to no treatment, and another trial comparing Surgical Treatment B to no treatment. If a model can accurately simulate the two existing trials of A and B, as well as other studies of the outcomes of interest in the populations and settings of interest, then that model can help decision makers choose between A and B. I believe that the use of models will be indispensible to the comparative effectiveness initiative; a budget of $1 billion can only support a handful of new trials whereas there are hundreds of important comparative effectiveness questions.

David Eddy, MD PhD
Founder Archimedes

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## DECISIONVIEW, INC.

# Driving Innovation in Clinical Trial Enrollment

## StudyOptimizer™— Patient Enrollment Modeling, Planning and Tracking

Biopharma companies focus tremendous energy on developing drugs that target unmet medical needs. Delivering these therapies quickly and cost effectively is important to the patients who wait for these medicines, and the businesses that develop them.

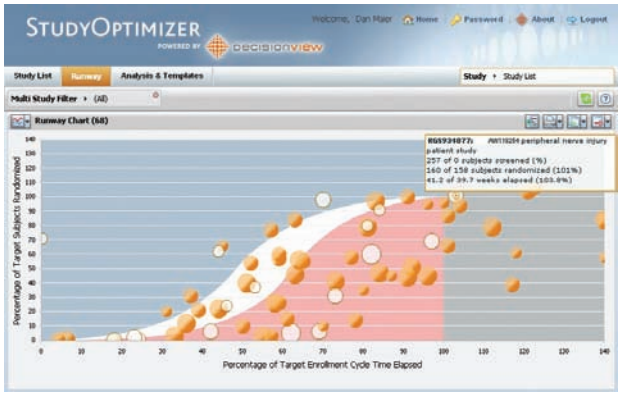
Unfortunately, while global clinical trials have gotten significantly more complex over the past two decades, the majority are still planned and budgeted the same way they were 20 years ago — on spreadsheets. So it shouldn't be surprising that 70% of all trials finish more than a month late, at an incremental cost of $35,000 per day.

The industry cannot continue to operate the same way it has for the past decade and expect better results. Instead, clinical operations organizations need to think differently, re-examine core business processes, and leverage innovative technologies that will allow them to dramatically change the cost and productivity equation.

### Driving Enrollment Innovation

StudyOptimizer from DecisionView Inc. is one such innovative technology, providing an enrollment modeling and planning platform that enables global clinical trial organizations to drive significant time and cost improvements through their patient enrollment process, and more broadly, throughout their clinical operations. StudyOptimizer enables organizations to:

- **Create Feasible Enrollment Plans**
  Users leverage historical enrollment data to create plans and forecasts that are realistic and reflect real-world metrics. For larger global trials, regional and country teams can work collaboratively, to capture and validate assumptions and enrollment behaviors specific to their geographies.
- **Track Enrollment By Trial, and Across the Portfolio**
  For each trial, StudyOptimizer forecasts the trial end-date based on real-time data, displayed in intuitive visuals, allowing for timely decision-making. For clinical operations executives, StudyOptimizer also provides a consolidated dashboard showing enrollment performance across all trials in the portfolio, alerting users to delayed trials at a glance.
- **Diagnose Causes of Trial Delays**
  Intuitive, data-rich visualizations allow users to pinpoint sources of delay and drill down into specific performance areas, countries, and sites to identify plan assumptions that are being violated, and determine the impact on forecasted end dates.
- **Rescue and Optimize "Problem" Trials**
  Once delays are diagnosed, users model intervention scenarios and optimization strategies, creating different options for adjustments to the plan, and comparing the impact of these scenarios before taking action. And once plan changes are approved, StudyOptimizer tracks actuals against the adjusted plan, while still retaining the original plan that was the baseline for the study.



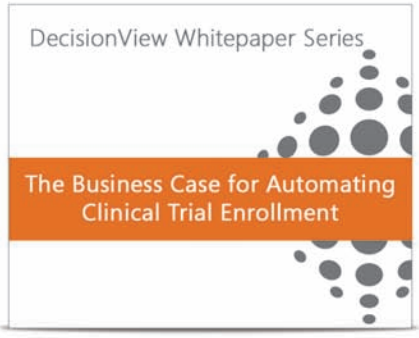

### Leveraging The Cloud

StudyOptimizer is a web-based solution that can be leveraged by Study Managers and other users around the world. The application is delivered via a Software-as-a-Service (SaaS) model, and can be deployed on a study-by-study basis, or across all of an organization's trials. This flexible approach drives significant cost and time-to-market advantages by delivering a proven, production-ready solution to your enterprise quickly.

DECISIONVIEW
Bring the Future into Focus


**StudyOptimizer™** has been selected by 7 of the top 10 global pharmaceutical companies to drive significant time and cost improvements in their clinical operations.

Bring the future of patient enrollment planning, tracking and forecasting into focus in your organization. Find out more at www.decisionview.com.



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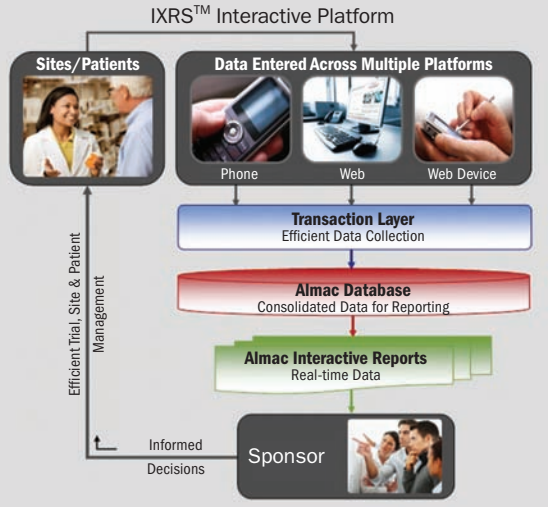
**ALMAC**

# Making Clinical Trials Work Better: IXRS™ Technology and the Future of Clinical Trials

Sponsors of R&D continue to increase their use of clinical technologies in response to the challenges of managing clinical trials globally and satisfying regulatory mandates for product efficacy and safety. Clinical technologies offer the promise to streamline arduous manual processes and speed the drug development cycle. Moreover, as trials have become increasingly sophisticated in design (e.g., adaptive trials), sponsors require access to real-time data in order to make decisions throughout the course of particular studies. Thus, having flexible and multiple technologies to collect clinical trial data has become a pressing need for biopharmaceutical companies.




Interactive Voice and Web Response Systems (IVR/IWR) are among the most utilized, flexible, and proven technologies available to trial sponsors. Early pioneers in this segment of the technologies market, such as Almac Clinical Technologies, were formed in the mid 1990s and continue to play pivotal roles in the management of patients, sites, and drug supplies for clinical trials. Sponsors use IVR/IWR to recruit, screen, enroll, and randomize patients into clinical trials, and then to assign the investigational drug and placebo (in double-blind studies) in a blinded manner. IVR/IWR systems, such as Almac's integrated phone and web platform (IXRS™) are also used to manage drug ordering and inventory, schedule and track patient visits, collect electronic Patient Reported Outcomes (ePRO), and improve patient compliance through the use of reminders and alerts.

IXRS™ systems have been developed in approximately 60 languages and are in use in over 80 countries. Data collected via telephone, the Web, and handheld devices is stored in a single database. This data is available in real-time for sponsors through Almac Interactive Reporting, a new reporting platform that provides "dashboard" views of summarized trial metrics and key performance indicators (KPIs). Dashboards are populated with data from a suite of reports to provide a holistic view of the study at a glance. Given this integrated stream of data, sponsors can make informed decisions during the course of the study as well as improve the management of patients, sites, and drug supplies – three key elements that must be coordinated for the success of any trial.

Research conducted by Almac with clinical trial sites and sponsors indicates that there are regional differences in user preferences for phone vs. Web to conduct transactions in IXRS™. User preferences are often a result of varying technology infrastructures in regions of the globe as well as particular users' familiarity and access to technologies. Given these differences, IXRS™ users prefer to have the flexibility of using the phone and/or the Web. That trend will proliferate as the use of mobile phone and Web technologies increase. Therefore, the challenge of the upcoming decade for clinical trial sponsors will not only be how to cost-effectively integrate data, but also how to apply multiple technologies (land-based and mobile) internationally to enhance study workflows and improve overall trial management.

ALMAC

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PERCEPTIVE INFORMATICS

# Cutting-Edge Configurability

## Accelerating global clinical trial programs: Achieving greater data collection efficiencies and more streamlined supplies management by maximizing the use of cutting-edge Randomization and Trial Supply Management technologies

Over the last two decades, randomization and trial supply management (RTSM) technologies, commonly delivered using IVR/IWR systems, have played an important role in simplifying clinical trial logistics and reducing the quantity of medication overage required to conduct studies globally. RTSM technologies allow Sponsors to track subjects, maintain randomization balance, and manage medication stock: minimizing wastage throughout the duration of the clinical trial. They also provide Sponsors with the all-important ability to access this data in real-time.

Against the backdrop of ever-growing complexity and global nature of today's trials, the common trend has been to increase the level of customization in the design of RTSM technologies. Whilst flexibility is required to enable systems to apply effectively to the requirements of different Sponsors and trials, within a Sponsor organization a more standardized approach is possible and can provide significant benefits. Biopharmaceutical companies are looking for ways to further improve efficiencies and streamline their supplies management capabilities and many are now looking to technology vendors to assist in implementing next generation configurable RTSM systems to achieve significant reductions in study build timelines and cost per study.

### Configurable system reality

Next generation configurable systems utilize a set of pre-validated modules that are designed to take account of a Sponsor's specific patient, site and supplies management needs. The modules are constructed to be employed across multiple trials, and individual trial requirements are incorporated through switchable options, thereby providing flexibility within an efficient and secure pre-validated framework.

There are numerous potential benefits of this new approach for customers (figure 1). Ultimately, it allows Sponsors to deploy repeatedly usable technology across many trials, thereby streamlining the entire study build process. Enough flexibility is built in to these systems to enable their use across diverse protocols and therapeutic areas. In this way, Sponsors can maximize the benefits across their portfolio of trials. Importantly, this approach ensures that all study teams utilizing an RTSM application benefit from a best-practice standard approach that fits with the Sponsors processes and procedures, meaning each team does not need to re-invent this along with the help of the vendor.

### Working with the right vendor partner

Developing a configurable system requires agreement of standard processes and approaches, and required options around these. It is also going to be an evolution of a system through a number of version releases. Success requires an empowered and experienced governance team within the

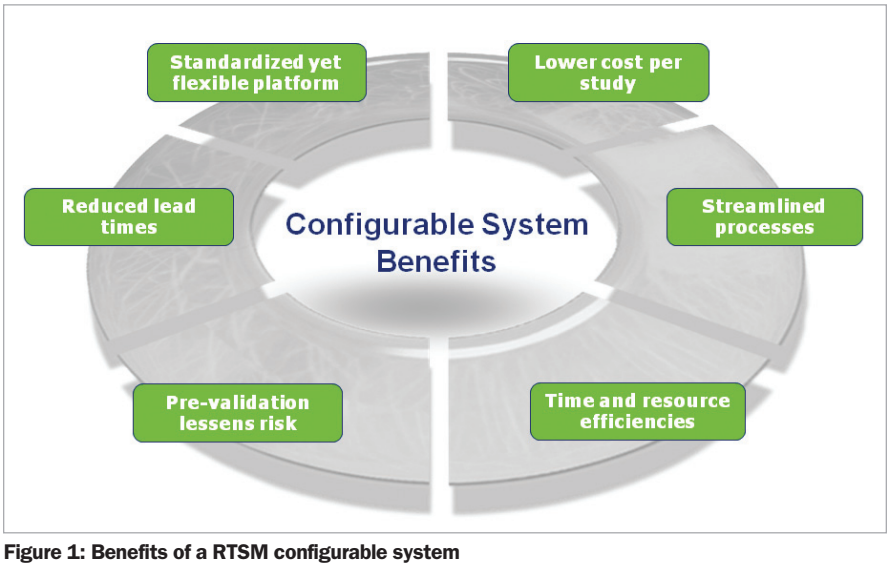
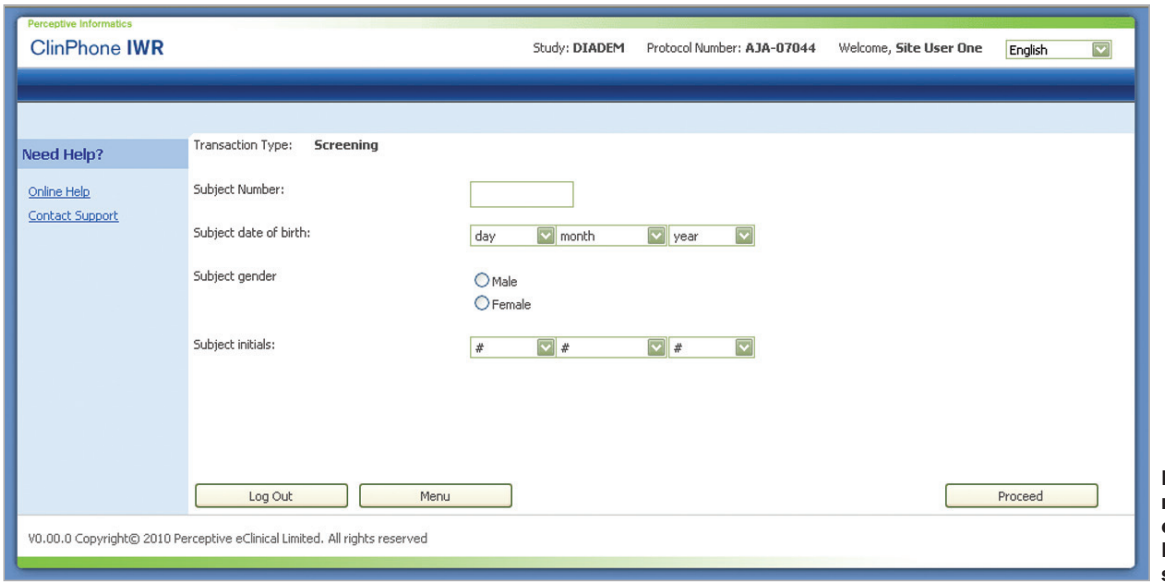



**Figure 1: Benefits of a RTSM configurable system**




**Example of a next generation configurable RTSM web solution.**

Sponsor organization and an experienced vendor partner. Attributes to look for when selecting the right vendor include:

- **A proven track record of delivering configurable systems with an experienced consulting approach to their development.** An experienced vendor will be able to advise on Sponsor system requirements through analysis of study protocols, previous RTSM applications utilised, Sponsor processes and other frequently utilised technologies such as EDC and CTMS. This will enable development of a system that will meet the needs of the majority of studies performed by the Sponsor.
- **Fully flexible RTSM platform.** Enabling a truly client-specific configurable standard to be developed requires a highly flexible system as a starting point. This flexibility should also be expressed in the ability to utilise components of the configurable system alongside custom components for trial designs that do not follow the standards developed.
- **Robust IT enabling infrastructure.** Ensuring the infrastructure to support and maintain study applications using phone and web interfaces is robust, reliable and resilient; and that additional platform infrastructure will facilitate, for example, integration with key Sponsor systems as required.

## The results

The next generation configurable system delivery approach to RTSM helps customers achieve significant reductions in study build timelines: typically by several weeks over traditional approaches. These savings are not simply in vendor timelines to build and test an application, but also result in simplification of the specification process reducing the time and resource required by the Sponsor's study team during the study start up phase. The reduced study start-up timeline, in addition to a reduction in cost per study for the RTSM technology itself, means customers can potentially make huge time and money savings per trial.

Darren Wells
*RTSM Product Director, Perceptive Informatics*

**For more information visit us on the web at: www.perceptive.com**

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## Case Study

Perceptive Informatics has experience of developing next generation configurable RTSM systems for major pharmaceutical companies. In one recent case the client has saved several million dollars in the year since the system was put live and achieved a return on their investment in 2-3 months. Studies of varying complexity, including many with integrations to other clinical systems, are being delivered significantly quicker and more smoothly than was the case prior to the system's implementation, providing yet further unquantified benefits to the client.