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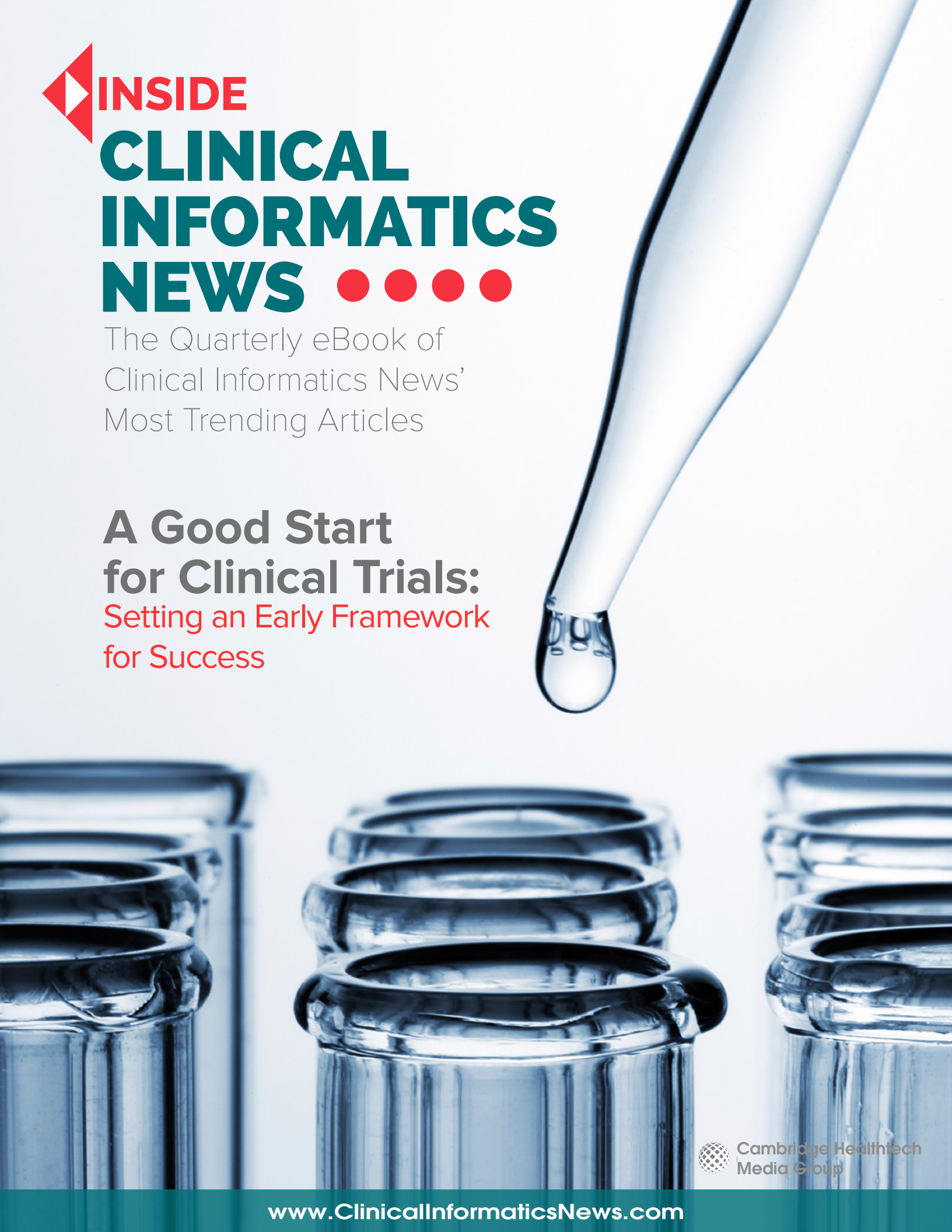
A Good Start for Clinical Trials:

Setting an Early Framework for Success



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A Good Start for Clinical Trials:
Setting an Early Framework for Success

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Clinical Informatics News reports on innovative technologies from clinical trials to medical informatics. Technology continues to permeate all aspects of clinical trials and the patient experience, and the tools to support these efforts are maturing rapidly. ClinicalInformaticsNews.com and the Clinical Informatics News email newsletter provide authoritative news, views, and insights on the vast landscape of innovation between clinical trial management and delivery of care.

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Clinical Trials to the Clinic

EDITORIAL DIRECTOR
Allison Proffitt (617) 233-8280
aproffitt@healthtech.com

SCIENCE WRITER
Aaron Krol (781) 972-1341
akrol@healthtech.com

PUBLISHER
Lisa Scimemi (781) 972-5446
lscimemi@healthtech.com

MARKETING ASSOCIATE
Lisa Hecht (781) 972-1351
lhecht@healthtech.com

MANAGER, BUSINESS DEVELOPMENT
Jay Mulhern (781) 972-1359
Digital advertising
jmulhern@healthtech.com

MANAGER, BUSINESS DEVELOPMENT
Katelin Fitzgerald (781) 972-5458
Lead Gen Companies A-K
kfitzgerald@healthtech.com

MANAGER, BUSINESS DEVELOPMENT
Elizabeth Lemelin (781) 972-1342
Lead Gen Companies L-Z
elemelin@healthtech.com

Contributing Editors
John Russell
Ann Neuer

Cambridge Healthtech Institute
PRESIDENT
Phillips Kuhl

Contact Information
editor@healthtech.com
250 First Avenue, Suite 300
Needham, MA 02494

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Allison Proffitt

A Good Start For Clinical Trials

In the clinical trials marathon, getting out of the starting gate can seem like more than half the battle. Trial design, set up, and enrollment are time consuming and challenging—all before the first data points are collected.

But there are efforts underway and products being developed to ease these pain points.

A site network, ACRES, hopes to mimic the global airline system and link sites for smooth collaboration. The network hopes to enable secure data exchange, be a central location for investigator profiles, and eliminate redundancies in site selection.

Infinata, maker of BioPharm Clinical, is also taking on site surveys and feasibility questionnaires. They convened a group of industry players to give feedback on the challenges and present their wish lists. One of the biggest requests from SPRI Clinical Trials-Global: integrate site survey tools so that teams are comfortable with them, and happy to use them.

> "...we can't forget the most crucial component to a clinical trial: the patients."

Fresh from a name change, trial software provider eClinical Insights is taking a technology focus. Putting aside consulting services, eClinical Insights is focusing on technologies for a "post-EDC world".

But we can't forget the most crucial component to a clinical trial: the patients. The International Society for Pharmaceutical Engineering (ISPE) surveyed trial participants on the views of their materials. The survey found a shift from a pharma focus, to one more inclusive of sites and patients. The patients' requests were simple: better communication, some control over communication method, and some convenience factors, like having their medications delivered to their homes.

Mytrus and Consent Solutions are doing their best to enable convenience. The companies are equipping patients with electronic informed consent options, including iPad –based forms that are interactive.

In order to keep abreast of this changing landscape, we're presenting some of the most interesting stories from the last quarter as Inside Clinical Informatics News. It's our hope that this will serve as an update on some of the newest players in the market and insight into some of the emerging trends.

Allison Proffitt
Editorial Director

TrialShare Brings Much Needed Transparency to Clinical Trials Data

BY ANN NEUER | JULY 15, 2013

Making sense of the millions of data points that characterize a clinical trials database is a tough challenge for sponsors in pursuit of new therapies. For therapeutic areas such as autoimmune disease, allergy and asthma, and transplantation, the Immune Tolerance Network (ITN), an international clinical research consortium, can help. Through TrialShare, a simple-to-use clinical trials research web portal developed at ITN, investigators and study management teams can better interpret data throughout the clinical trials process.

TrialShare is part of ITN, a non-profit sponsored largely by the National Institute of Allergy and Infectious Diseases (NIAID) and funded by the National Institutes of Health. ITN has a mission to accelerate the clinical development of immune tolerance therapies through an interactive process with established investigators in academia and industry. Built using the open source LabKey Server framework, TrialShare provides open access to ITN's clinical studies, its datasets, and bio-repository to the scientific community.

Adam Asare, Senior Director of Bioinformatics and the visionary behind TrialShare, explains ITN's open access policy, "Being publicly funded, there is a big push to be transparent and provide public access to the datasets from our clinical trials. But clinical trial data can be very complex, so making them transparent to the public can be difficult. Through methodologies made available in TrialShare, this goal can be met. As part of this process, TrialShare allows researchers to reproduce and possibly expand our findings."

The process works by ITN soliciting proposals to answer the best scientific questions within its areas of focus. ITN collaborates mostly with the academic community across the globe, but also from the biopharmaceutical industry to co-sponsor clinical trials, most of which are Phase II. ITN then publishes the clinical data results in scholarly journals. "Through TrialShare, data and analysis code used in the manuscripts become interactive as users can click on links and see detailed descriptions of how the datasets were analyzed so they can re-run clinical analyses," Asare says.

This ability to make data and analyses reproducible is one of the most significant values of TrialShare. According to research presented in Nature Genetics in 2009, reproducibility of gene signature biomarker data in published literature is iffy at best. Almost half the data cannot be reproduced for reasons such as data are not available, software is not available, or the methods are unclear.

In the ten years since the launch of ITN, more than 1,000 clinical datasets have been released, with statistical code from six of its publications. Many of ITN's clinical trials originate from solicited proposals utilizing specimens from ITN's extensive biorepository of more than 270,000 de-identified samples maintained by ITN. These samples are linked to extensive laboratory assay results using flow cytometry, gene expression, and immunohistochemistry. Users can access assay and other clinical information about these samples through download. TrialShare also includes visualization tools that allow users to see the original analysis and then further interpret that information through user-defined filters.

Accessing ITN TrialShare is simple. Interested users can visit www.itntrialshare.org and click on "Create an Account."

"We had more than 30,000 page hits within the first few months of the launch of TrialShare. It's proven successful because we understand how researchers would like to look at their data and make the best use of it," Asare notes.

For this work, ITN was awarded an Honorable Mention prize at the at the recent Bio-IT World Best Practices Awards held at the Bio-IT World Conference & Expo in Boston. Of the 34 projects evaluated, ITN received one of two honorable mentions for outstanding innovations and excellence in the use of technologies and novel business strategies that will advance biomedical and translational research, drug development, and/or clinical trials.

> "It's proven successful because we understand how researchers would like to look at their data and make the best use of it..."

ADAM ASARE, SENIOR DIRECTOR OF BIOINFORMATICS, TRIALSHARE

Informed Consent Goes Digital

BY ANN NEUER | AUGUST 29, 2013

Electronic solutions have become a mainstay in clinical trials, yet one critical aspect, the informed consent process, has stubbornly remained paper-based. And that's about to change.

In an industry-wide effort to make clinical trials more patient-centric, sponsors are beginning to look at the informed consent process as more than a dry but mandatory paper document that describes the study protocol in all its complexities to potential study volunteers. Driven by a desire to streamline clinical trials, meet strict timelines, and embrace suggestions from an Institute of Medicine report on improving clinical trial quality through a more patient-centric view, sponsors are poised for meaningful change.

At the same time, input from the Food and Drug Administration is spurring interest in a better informed consent process. In August 2013, a new FDA guidance on risk-based monitoring was released, which states that use of electronic informed consent may facilitate sponsor oversight of human subject protection.

"Pharma seems to be committed to moving toward patient-centricity, patient engagement, patient interaction in earnest. What could be more patient-centric than making sure patients understand informed consent?" says Anthony Costello, CEO of Mytrus, a California-based clinical technology and services company.

Costello explains that understanding the details of a clinical trial is critical to patient engagement, as patients who do not understand a trial are more likely to drop out, a factor that wreaks havoc on tight budgets and enrollment deadlines. He adds, "We know from past experience that patients often do not understand consent. For example, they may not realize that a study will require multiple visits or multiple blood draws. Almost every company we talk to has an initiative to make their informed consent more understandable."

> "Pharma seems to be committed to moving toward patient-centricity, patient engagement, patient interaction in earnest. What could be more patient-centric than making sure patients understand informed consent?"

ANTHONY COSTELLO, CEO, MYTRUS

Similarly, Dr. Susan Brink, CEO of Consent Solutions, an internet-based system for informed consent, concurs that pharma is seeking to put the patient in the center of the clinical trial experience, starting with the informed consent form (ICF). And with the rise of the tablet, namely the iPad or the Android tablet, it is possible to complete the process at the site with SecureConsent, an interactive e-consent system that uses multi-media and collects a digital handwritten signature.

According to Dr. Brink, "As part of the informed consent process, we engage people with video and audio. As they see and hear the information, instead of reading a paper form, they begin to understand what the trial will entail. For example, if there will be three visits a week for several months, we put in a link to a calendar that actually displays when the visits will take place."

She explains further that an interactive medical terminology library is included, so if a potential subject does not know what an MRI is, there would be a picture of the machine and a link that describes it.

To gauge the patient's understanding of the consent information, a series of screens are set up along with two statements at the bottom of each screen, either "I understand", or "I have a question." To advance to the next screen, the patient must select one of the two options. If the patient selects "question", someone at the site is notified electronically, who then comes in to review the information with the patient and provide a response. All questions must be answered before the patient can sign electronically.

Enroll, the Mytrus solution, also uses an iPad, videos, and other multi-media tools to engage patients and boost their level of comprehension. In addition, there are quiz questions throughout the process, and patients can flag words or paragraphs they don't understand so site staff can address those issues.

To determine the value of this effort, both SecureConsent and Enroll collect metrics as to how long a patient spent looking at each of the consent screens on the tablet and where they have problems understanding terminology or concepts. Sponsors are able to see which paragraphs are problematic in terms of confusing patients or causing them to decide against participation in the study.

Costello says, "None of this information has existed before, so we are creating a treasure trove of data for sponsors. In the dollars and cents analysis of implementing new clinical technology, these data help sponsors determine their ROI. We have modernized all the pieces of the clinical trial data chain, such as the case report form, EDC, ePRO, and IVRS, but the ICF remains a pile of paper. It's the last piece of the data chain to go digital, and it's ready to happen."

DR. SUSAN BRING
CEO, CONSENT SOLUTIONS

> "...we engage people with video and audio. As they see and hear the information, instead of reading a paper form, they begin to understand what the trial will entail."

Building a Global Clinical Trials Network

BY ALLISON PROFFITT | OCTOBER 29, 2013

The idea came to Greg Koski while sitting in an airplane. "The entire world has come to recognize that the process that we've evolved for trying to get a new medical product—whether it's a drug, a device, or biologic—actually properly tested and reviewed, marketed, is fraught with enormous problems," Koski says, "not the least of which, is the enormous inefficiency, redundancy in the process."

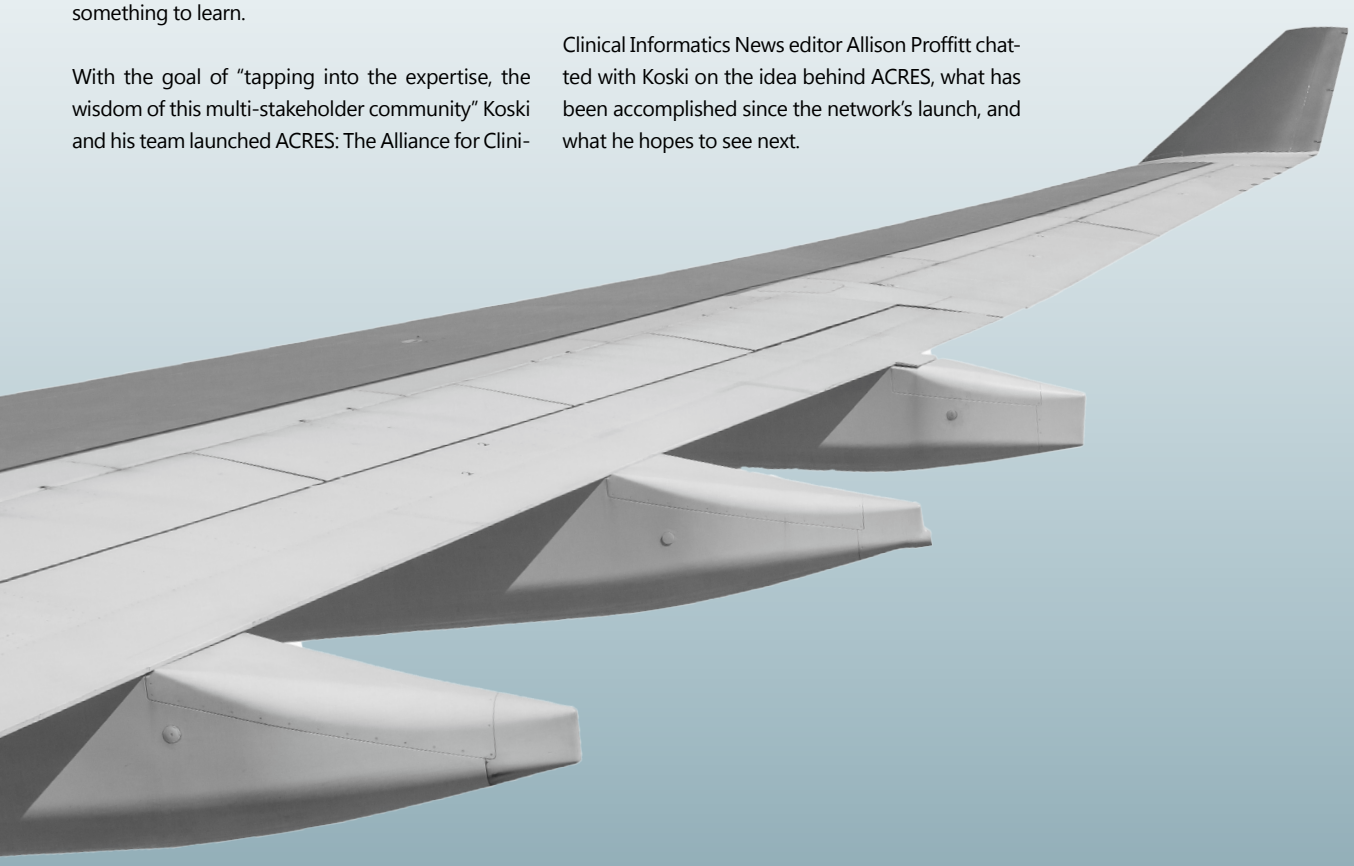
Koski knows a bit about the process. He served as Director of Human Research Affairs at Massachusetts General Hospital and the Partners Healthcare System in Boston. He left New England to go to Washington and set up the Office for Human Research Protections, where he began introducing systems thinking into the realm of human research, and worked with National Cancer Institute to build systems for clinical research.

But it was at an airport that he realized that other industries have tackled logistical challenges before—and maybe the clinical trials industry had something to learn.

With the goal of "tapping into the expertise, the wisdom of this multi-stakeholder community" Koski and his team launched ACRES: The Alliance for Clinical Research Excellence and Safety. ACRES hopes to combine strategic technologies to build an open, global system for clinical research.

One of their first technology partners is ViS (see, Insightful Site Selection: Tools of the Trade). "We are proud to support ACRES. The ACRES network will enable sites to share their capabilities and efficiently communicate with sponsors and international peers," said ViS CEO, Fabio Thiers. "It provides the foundation for a more efficient and sustainable clinical research enterprise, resulting in faster patient access to better and safer medical treatments."

Clinical Informatics News editor Allison Proffitt chatted with Koski on the idea behind ACRES, what has been accomplished since the network's launch, and what he hopes to see next.



Clinical Informatics News: Greg, how did the idea for ACRES come about?

Greg Koski: For about ten years I have been writing about and talking about the need to properly align good ethical principles with good business practices in order to basically have this entire industry and the process of clinical research remember what it's really there for, which is to bring new products to the people of the world in order to improve health, productivity and quality of life. We seem to have lost that sense of direction and it's time to be restored.

If we can redesign—truly innovate—the way we've been doing things and effectively apply systems thinking to these processes, we can achieve enormous gains in safety, efficiency and quality in a way that actually benefits not only the people of the world but also the companies that are doing these things, their shareholders and everyone else.

And so, about a year and a half ago, after writing and talking about this kind of stuff for a long time, with the encouragement from a number of people in the industry, academia, regulatory affairs, the ethics community, we launched a non-profit organization called the Alliance for Clinical Research Excellence and Safety, ACRES for short. And the goal of ACRES is to achieve these kinds of integrated improvements and efficiencies through systems thinking, while being driven by the desire to do clinical research in a much more effective way that aligns ethical principles with the business practice.

CLN: How do airplanes factor into this?

Koski: I was actually flying into San Diego [to speak at a BIO] meeting and as we were landing in San Diego, I was still thinking about the remarks that I would be making at this meeting. And as we were landing in San Diego, I looked out the window and I saw all of these planes lined up in the pattern in order to land. And San Diego's a tricky airport to land in because you have to come in over the mountains and drop down into the city and try not to go into the ocean. And I said, "Isn't that remarkable that you have all of these planes coming in from all over the world, they're all speaking the same language, they all know how to use the air traffic control system, the ground control systems, and the baggage systems to work together." I said, "What if we apply that same kind of thinking to the clinical trials process?"

We set out to basically build a global system for clinical research that in many ways is inspired by the global air transportation system. More than half a century ago the airlines realized that they couldn't run a global endeavor like air transportation without actually having a truly global system with appropriate standards that ensured interoperability, appropriate safety and so on.

We said, "Look, if they can do that for an airline, for an industry that's as complex and competitive as the airlines, what would happen if we tried to do this for clinical research?"

If we think about a global system for clinical research, it basically translates into not a collection of internationally-accredited airports around the world but an entire network of accredited clinical research sites around the world, all of which are connected through a shared information technology infrastructure that is designed to use standards to acquire information at the source from the ongoing processes at each of these sites and to acquire and aggregate that information effectively in an appropriately-secured data warehouse so that, again, with appropriate protections for privacy, for proprietary information and so on, that those data can be actually analyzed for a variety of purposes. The benefits are absolutely enormous.

CLN: What's the progress so far?

Koski: We're about a year and a half into a process of actually building this global system. And at the core of that is what we call the ACRES Global Network, which is this amalgamation or alliance of clinical research sites all of which are committed to safety, to excellence in their performance, and quality in all of the data that they produce. They should be properly interconnected so that the information that is derived from the process will not only be the data that support the actual clinical trials themselves but data that can help to improve operations, to improve safety, and to drive integration and simplification in such processes as monitoring, regulatory oversight and so on.

Our hope is to be able to register an initial group of 10,000 affiliated sites by the end of the year so that we can engage those sites in the several processes that we have underway, what we call our foundation initiatives, to build the additional components of the network so that in a sense the initial 10,000 sites would be a group of beta test sites where we can use this interface to reach out to them to get their feedback on things such as the development of the site accreditation standards that we're working on, get their feedback, evaluation of new pieces of the information technology platform as they are developed and rolled out, as well as, again, an avenue to be able to provide additional goods and services to support them. Ultimately, if we were as successful as the airlines, if we were able to have, say, 80% of all of the sites globally that are committed to safety, quality and excellence in performance as part of this network, that network could be used by all of the pharmaceutical companies, device companies, biotech companies, as well as academic institutions, public health entities and all to do research in a very efficient and safe way all over the world.

CLN: Who is involved so far?

Koski: The interface that we rolled out last week was developed through a collaboration with ViS and another organization called HealthCarePoint, HCP. They are only two of several organizations that we have been in discussions with as part of an effort to use a consortium of development models, a best-of-breed approach that takes existing technologies that are already established, like ViS

> "...driven by the desire to do clinical research in a much more effective way that aligns ethical principles with the business practice."
>
> –GREG KOSKI

and HCP. Three other IT collaborators have recently joined as well: ii4sm, Research Dataware and Forte Research Systems.

Two other organizations that are allies with ACRES are CDISC and SAFE-Biopharma. CDISC, of course, has been around for more than a decade. They're the world's leader in developing standards for the acquisition and interchange of clinical trials data. CDISC standards are used globally and we believe that ACRES will provide an opportunity to have even further acceptance and application of those standards.

We're working to also incorporate the SAFE-Biopharma Association standards for secure information exchange. It's currently the system that supports most of the exchanges of data among all the big pharmaceutical companies. We believe that using those standards and the technologies that support them, such as digital certificates that can provide not only secure transfer of information, but also non-repudiation and other capabilities that are essential, this will be an extremely valuable contribution to the entire process as a whole.

Our goal at ACRES is to basically be a catalyst and an implementation engine for achieving these enhancements in safety, quality and efficiency that are not only possible but are fully anticipated from this global systems approach.

CLN: The efficiencies that you're explaining sound great for sponsors. But why does a site sign up?

Koski: Even with this very, very early phase rollout of the demographic information system that ViS has developed that allows their information to be shared with sponsors who are doing feasibility studies to identify sites where they will be able to conduct studies in a quality and efficient way. At the same time, sites that register with ACRES are provided with an HR management package through the HealthCarePoint, through a system they call the PET-ABC HR Management system.

At a very simple level if a company were going to do a trial it would need to ensure that each of the investigators, members of the research teams had certification of their training in GCP. The PET management systems are a way for sites to enter those kinds of data, not only about GCP but training for other critically important scale such as the Rankin Stroke Scale or other kinds of scales that would be for which specific training and certification is required if you're going to use them in a clinical trial.

By having that secure place where this information can be archived and then shared securely with sponsors, with IRBs, with regulatory agencies, it provides a very great value to sites.

We anticipate there will be many, again, early adopters and they will participate in the ongoing ACRES foundation initiatives, actually help build this system. And then we'll continue. We're actually launching an effort now to begin the registration of sites globally through a number of different initiatives.

CLN: What's the business model? Do sites pay to be registered? Do sponsors pay to access the bank of information?

Koski: For a one-time investment of about $50 million we can build and implement the entire ACRES Global Network and have it become self-supporting in probably three and a half years. We're looking at this as a five year development effort.

At the present time, the funding for ACRES has been provided through contributions from individuals and from companies in order to support the initial development. We've just launched a development campaign that's a multi-pronged approach that will reach out to private foundations as well as industry sponsors, governments also, and this is an initiative that's very appealing to venture capitalists strangely enough.

Ultimately as the network is actually implemented, we anticipate that there would be a variety of revenue streams that would come in part from the sites that would pay some form of a registration fee. They currently are not asked to at all. We're providing more to them then we're asking from them. That's a good place to start.

We anticipate that a combination of user fees or/and registration fees. And there are also several potential models for generating fees from the providers of goods and services that would want to use the network in order to make their products available to the clinical research sites.

Currently, there are no fees being charged to any of the sites for registration or sponsors. We are in fact reaching out to a number of major players in the pharmaceutical industry as well as the medical device industry, the CROs and private foundations in order to fund the initial building of the network.

CLN: How are you building membership?

Koski: The approach that we're using is to send directed invitations to a number of organizations that have multiple sites. These are organizations that have been allies of ACRES since its inception. And we expect that many of these sites will bring large groups of sites into the network all at once. We are establishing regional bases in Asia, Latin America and Europe, likely in the Middle East and in Africa as well so that through these regional bases we will reach out to establish connections with sites on either a regional or a national basis in order to bring them into the network.

ACRES
Alliance for Clinical Research Excellence and Safety

CLN: Who comprises the ACRES team?

Koski: We have about 75 individuals who are really senior leadership individuals from around the world that bring their expertise in multiple sectors to the development activities that are underway. In the executive office, we have myself as President and CEO and I also serve as Chairman of the Board of Directors at the request of the Board of Directors. Andy Olmsted and Beat Widler are the co-founders. Andy is our Vice President for Information Technology and Beat is the Vice President for Quality Management. And then we have Matt Whalen, our Chief Operating Officer; Brian Edwards is the Vice President for Safety and Pharmaco Vigilance; and Johan Karlberg, Managing Director of Clinical Trials Magnifier is VP for Site Development and support.

We also have within the executive office, Diana Howard, our Director of Finance and Administration; Dennis LaCroix, who is our General Counsel; Mary Tobin, who is basically a jack of all trades, who works as a special advisor to myself and Matt as well as anybody else on the team who needs it. We have recently brought on board also Kate Madigan, who formerly was the, I believe the Executive Vice President or Senior Vice President actually of ACRO, the Association of Clinical Research Organizations, a CRO-based organization. Kate will be working with us also on a number of activities around, particularly around communications and the ACRES Alliance.

This is the team that is basically coordinating what we call the matrix development of our foundation initiatives. When you're building a system you have to ensure that all of the components are actually developed in parallel and that they will all work together when they're finally completed. Each of our project steering committees is cross-fertilized with the other ongoing initiatives so that we have a high fidelity link to ensure that each group knows what the other is doing so that it all comes out to be compatible in the end.

Infinata Hosts Roundtable to Plan New Site Survey Product

BY ALLISON PROFFITT | NOVEMBER 22, 2013

Of the pain points in clinical operations, Infinata believes site surveys are one of the worst: a crucial step to study start up that is often painful and slow. The company invited representatives from the sponsor, CRO, and site communities to Boston last month to discuss needs, ideas, and solutions to the challenge. The company plans to use the results of the discussion to fine tune their forthcoming site survey product that they expect to launch in February.

Dan Diaz, VP of Global Business Development for SPRI Clinical Trials- Global, was part of the conversation. Diaz has been in the CRO industry for 19 years, and before that worked in pharma. During his stint with Marion Merrell Dow (now part of Sanofi), Diaz was involved in grassroots efforts to get patients involved in clinical trials.

The ideas he used then are now back in play, Diaz says.

"Only 1% of patients with cancer in the United States are enrolling in clinical trials," he says, quoting Tufts University research. "That is very disturbing. It's not that the industry is saying that it's cheaper and it's for cost, only, that we go outside of the United States. It's really because we've had a hard time getting patients with cancers involved in these new treatments."

It's time for a change in the industry, Diaz believes. Site selection and patient recruitment must improve. He quotes his mantra: "You can't do things they way your mother did them."

At SPRI Clinical Trials, Diaz has been using BioPharm Clinical, an Infinata offering, and feasibility tools for about five years, and has been pleased. Tools like Infinata's help us identify where these patients are, where these interested physicians are, and where the successfully-enrolled studies have been conducted, he said. Diaz says he's seen evidence time and again that analytics tools out-perform more traditional methods of site survey.

But there is always room for improvement, and Infinata encouraged the roundtable members to give granular feedback.

One of Diaz's major concerns is that even the best tools for feasibility and site survey aren't really incorporated into workflows and used. "Many times as a company we have access to these tools but our clinical teams have been hesitant to use them," Diaz said. "They're not used to them; it's not the way their mother did it."

Diaz said that tools must be designed to be implemented in both top-down and bottom-up ways: "such that the CRAs at the site level can utilize this to validate and to verify the information that they're getting from their study coordinators at the site. The management teams within these CROs and pharma companies are supporting the utilization and purchasing of these tools even though it may not be a revenue generator."

Diaz also stressed that tools need to be offered as corporate licenses, not charged on a study-by-study basis. "If you're going to spend $30,000, $50,000, $100,000 on a tool, no project manager can spend that kind of money. Directors don't usually have the ability to spend that kind of money. It's got to come down from the top." But the users are at the study team level: the study managers, the project managers. "You almost have to force people who do startup to use this as part of every project," Diaz said, so that tools are fully integrated and capabilities are fully exploited.

> "YOU CAN'T DO THINGS THE WAY YOUR MOTHER DID THEM."
>
> –DAN DIAZ

Other attendees called for a product that "can help with integration issues currently in the marketplace for the site survey process." And another pointed out: "People do not like having to answer the same questions over and over again. We need a survey tool that pre-populates answers."

The conversation was an opportunity for Diaz to give feedback, but also for him to get insights and work with others at the table. "I'm always looking at what we can do differently from the site level," Diaz said.

"From a global CRO level, how is Quintiles adjusting and utilizing these tools?... A mid-sized pharma company like Shire… how are they able to bring these new tools to the study level?"

Diaz said the experience was a chance to share experiences with colleagues and learn much.

From Infinata's perspective, the conversation was equally as rich.

Right now, Infinata clients use BioPharm Clinical to access lists of potential investigators and sites. When it's time to send out feasibility questionnaires, though, CROs and biopharmas have to transfer their findings to a third party system and start with blank feasibility surveys. Amanda Murphy, head of product development for BioPharm, said the company is hoping to change that.

"We've been toying with the idea of a new product, and there are three different industries that are directly impacted by this issue: CROs, biopharmas, and actual sites," Murphy said. "We had this roundtable to get the three different perspectives into one room and see what everyone's pay points were, learn more about their workflows, and see how that could be incorporated into a solution."

The roundtable approach is a new one for Infinata, who in the past has beta tested products with clients, but Murphy said that gathering of varied stakeholders was very valuable.

"At Infinata we really learned a lot and gained a lot of insight into this problem that everyone is experiencing," she said.

Patients Weigh in on Clinical Trial Materials

BY MAXINE BOOKBINDER | DECEMBER 6, 2013

In the first survey of its kind, a collective of large pharmaceutical firms, under the auspices of the International Society for Pharmaceutical Engineering (ISPE), conducted an international study investigating patient feedback on their clinical trial materials.

The purpose of The ISPE Patient Initiative: Survey on Patient Experiences with Clinical Trial Materials, conducted by ISPE's Investigational Products Community of Practice with support from 11 underwriting companies, was to collect patient responses regarding how their clinical trial materials impacted satisfaction, compliance, and completion. Investigators also gathered patient recommendations for future trials.

"We wanted to understand what patients think. This is an opportunity to better meet the needs of the patients," said Dr. Christine Milligan, Global Director of Strategic Development Solutions at Catalent Pharma Solutions and Team Leader of the project. "We want to know patients are informed about their clinical materials. What is the patient's feedback? How does this feedback improve our performance? The primary challenge for the investigational product professional is to get the right product to the right patient at the right time, every time. We now want to challenge ourselves to ensure the right product is in the right format to meet the needs of the patient."

Approximately 100,000 surveys were sent to former and current trial patients in North America, South America, Africa, Asia, and Europe; 1,425, 97% from the U.S., were evaluated. (The remaining surveys were either not returned or did not meet study criteria.) The study focused solely on packaging and materials and how the industry can increase patient compliance by being more flexible, cost-effective, and more user-friendly while still adhering to strict regulations.

Milligan said participating agencies no longer want to produce clinical materials "from the perspectives of only the pharmaceutical industry; going forward, we want to ask the patients and the investigative sites. Our industry has reached the tipping point at which information will flow both ways."

The project goals were simple but important: 1) to understand what patients experience while dealing with medicinal instructions and packaging; 2) to determine how suitable these materials are; 3) to produce improvement ideas for future packaging; 4) to increase collaboration between industry and regulatory bodies under the scope of ISPE; and 5) to construct and publish 21st century global guidelines.

Some of the results were encouraging to the task team. For example, 90% of participants said that packaging and instructions were either "very easy" or "somewhat easy" to use. A majority (82%) reported taking all medicine as directed; 60% said the packaging and/or instructional design and layout of the medicine kit helped them take their medicine on schedule. In fact, 52% reported that no packaging changes were needed. Participants stated they wanted the medicine to work, they wanted to follow instructions, and they wanted their trials to succeed.

More study is needed. All patients rely on getting detailed information, but those who don't understand what to do or how to use their medicine want additional reinforcement.

Project investigators are honing in on weak areas. For example, 78% of patients replied that it would be "very helpful" or "somewhat helpful" if prescriptions and refills could be delivered to their homes, rather than patients travelling, sometimes long distances, to pick up resupply medications in person. A majority also said they wanted increased communication with clinical staff. However, this could be done electronically; patients prefer to select the method of communication, whether through email, text messages, smartphone app, a website, telephone, regular mail, or in person. The key is having the option to choose.

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"Patients want reassurance they are taking their medication correctly," says Milligan. "They want to be valued and they want to comply." According to the study results, many patients said they wanted to feel they can ask questions, to know their questions will be answered, to repeat instructions back to staff for clarity, and to check in with staff when necessary. At focus groups, patients discussed feeling that protocol was more important than their physical symptoms. When staff increases involvement with patients in the clinical process, patients feel more important, resulting in higher compliance.

One critical issue involves improving the process of returning unused medicine. Some patients claimed they didn't know they had to return it; others chose to keep it. It is imperative that clinical staff clearly explain at the beginning of trials, before any medical kits are dispensed, that unused medicine must be returned and why.

"We need to eliminate the 'one size fits all' approach," says Milligan. "Of course, scientific inquiry must maintain consistency. There are other ways to accommodate patients without jeopardizing integrity. This includes labels, reminders, and staff communication."

Patients also want more pictograms to help explain instructions. Still in development, these will need to be understood by patients worldwide.

Improving the appearance of packaging instructions is a small change with a potentially big impact. Instead of having all text in the same font, size, and color, important text can be in larger, bold print, which draws attention and is easier to read.

The project, which took almost a year to complete, is entering a new phase. Team members met again in December 2013 to "dig deeper into the data, talk to regulators, and present findings," says Milligan. The team will present its findings internationally, including China, Japan, and Europe. "We will take suggestions from specific regions. We want to know, 'What do you see as really unexpected? What do you see as really expected?' " ISPE will eventually publish a best practices guide based on expert recommendations and patient input.

The ISPE Patient Survey Project Team includes members from ISPE, Almac, Novo Nordisk, Pfizer, Catalent Pharma Solutions, Takeda, and CISCRP.

New Name, Focus for PharmaPros

BY ALLISON PROFFITT | DECEMBER 3, 2013

After 17 years in clinical operations, PharmaPros is shifting their focus and changing their name. The company unveiled its new identity – eClinical Insights, Inc. – last week, and a new product today.

The changes in direction have been a long time coming, Brion Regan, Head of Strategic Development & Partnerships, told Clinical Informatics News on the day of the announcement. Regan, son of PharmaPros founder and CEO Peg Regan, says that the company has a history of evolving as the market has changed.

"In the mid-2000s we started to service the smaller to mid-sized companies... Ultimately what we saw was that when EDC [electronic data capture] hit the market, that was no longer going to be a model that was going to be successful for us. We had really taken on a lot of CRO-type services that [were] outside of our mission."

In the past several years the clinical trials landscape has shifted to outsourcing and global trials. The technology landscape has become fragmented, said Regan, and the company realized that the technologies it was using internally fit a need in the industry.

In 2009, PharmaPros launched DataFlow Manager. Regan said it was soon clear that technology offerings would be the future for the company. PharmaPros leveraged their existing relationships with CROs and sponsors and began building a portfolio of technology solutions. As consulting projects came to an end, agreements weren't renewed and new contracts weren't signed.

The name change, Regan said, signifies the end of a metamorphosis that began with the DataFlow Manager launch.

eClinical Insights is a software company, Regan stressed, not technology enabled by a back-end "army" of busy consultants. There are no custom development services; no bespoke applications.

What the industry needs, Regan said, is a holistic view, technology that's easy to implement and rapid to configure: operational intelligence, not point solutions.

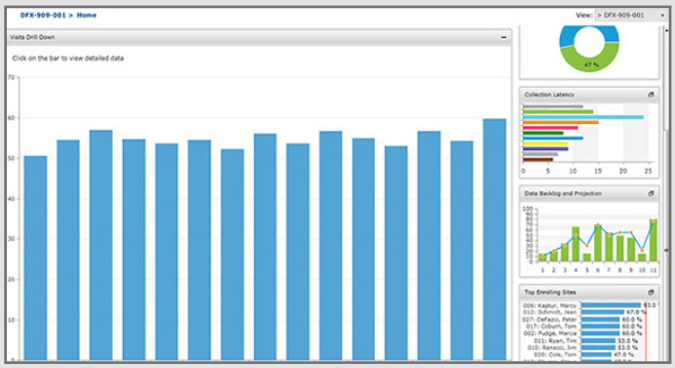
With the shift in vision comes changes in the company structure and the client portfolio. Regan says that the headcount at eClinical Insights is down by about 40%, though he maintained that many of the company's employees "converted" and still represent a depth of experience in the industry.

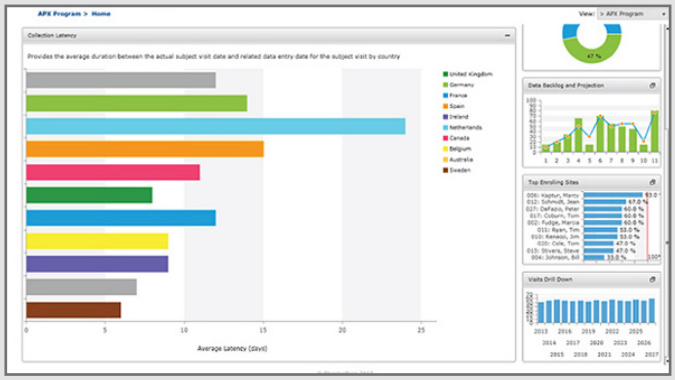
It's a point that distinguishes eClinical Insights from its new competition, he believes.

"People in our company are not just software developers. We wanted to retain the value of people who have run clinical trials before and who are proficient in technology," he said. "When software gets developed in a vacuum it can look pretty on the surface, but implementing it in a real clinical trial is a little bit more complex. Having people who have that perspective, who understand what this is really going to look like on the ground... is valuable."

As for clients, Regan said 30-40% of the company's services customers have turned into technology customers. He said eClinical Insights is finding the most traction with CROs.

"CROs are probably the companies most affected by the challenges in the industry today... A lot of them might have their own ECD systems or their own technology, but in fact they're only using their technology at best 25% of the time. The rest of the time the sponsor is dictating which systems they want the CROs to use. It's a very challenging business model," Regan said.





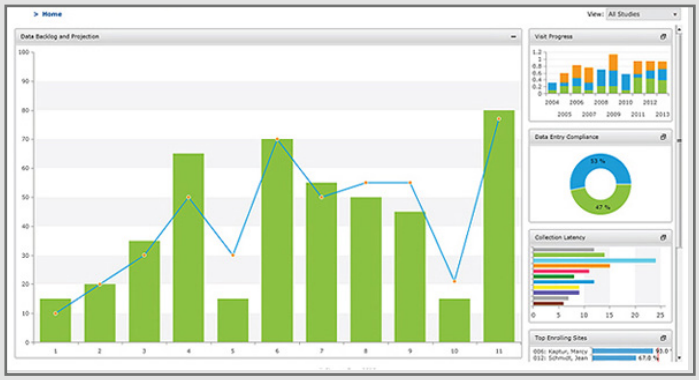


IMAGE CREDIT: ECLINICAL INSIGHTS

> "Our goal is to be able to extract away the complexity of the underlying systems and provide a holistic view in a scalable way."

A SCREENSHOT OF THE ECLINICAL INTELLIGENCE PLATFORM IN USE.

"There's not a lot of predictability in what systems they're going to be using in different trials and different programs. They needed a scalable way to bring data together regardless of what the underlying system is. Our goal is to be able to extract away the complexity of the underlying systems and provide a holistic view in a scalable way."

Products for a Post-EDC World

The backbone of eClinical Insights is a platform of tools, all leveraging integrated data. In addition to Dataflow Manager, the company has recently added TrialOps Director. Users will likely start with one product and choose to add on others, Regan said.

"Users aren't entering a lot of information into our system," Regan says. Instead, "it's being automatically derived from source data that's being integrated and aggregated up into our analytics engine… We're positive there's nothing else in the industry that can do this."

He calls it "post-EDC technology, a step above that transactional, data management technology."

This week, eClinical Insights added another product: EndPoint Reviewer, an endpoint adjudication system. "For instance," said Regan, "if it's a medical device trial or a cardiac trial, there are often medical experts or key opinion leaders who are asked to come in and adjudicate potential safety events in the trial."

The exercise, Regan said, can be arduous. "It's very manual; there are a lot of source documents that are required." Adjudication typically happens in one room at one time, but EndPoint Reviewer can automate that.

The tool mines clinical data in real time, and users can set "triggers" that identify events. "Then the doctors can go online at their leisure and participate in the adjudication. It's set up so they don't have to be in the same room to do it."

The automation is a concept that underpins the whole eClinical Insights platform.

"If there's information that resides in another system, it's not going to be entered into our system. It's going to be leveraged automatically," Regan said.

The company has built interfaces to all of the leading ECD technologies. Using commercial APIs, eClinical Insights has built a platform that is a "superset of every flavor we've ever seen." The platform is accessing ECD technologies in real time, "and incrementally aggregating and integrating that information."

"Our philosophy has always been automation," Regan said. "Even back in the old days when we were developing custom technology, the mantra was, 'Never repeat the same task twice. Always automate.'"

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