Volume 22 Number 12 December 2013/January 2014

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Volume 22 Number 12 December 2013/January 2014

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APPLIED CLINICAL TRIALS (Print ISSN: 1064-8542, Digital ISSN: 2150-623X) is published monthly except July/Aug and Dec/Jan combined, by Advanstar Communications Inc., 131 West 1st Street, Duluth, MN 55802-2065. Subscription rates: $70 for 1 year (12 issues), $120 for 2 years (24 issues) in the United States and possessions; $90 for 1 year, $140 for 2 years in Canada and Mexico; all other countries $130 for 1 year, $235 for 2 years. Single copies (prepaid only): $9 in the United States and possessions; $11 in all other countries. Add $6.50 per order for shipping and handling. **Periodicals postage paid** at Duluth, MN 55806 and additional mailing offices. **POSTMASTER:** Please send address changes to *APPLIED CLINICAL TRIALS*, P.O. Box 6115, Duluth, MN 55806-6115. PUBLICATIONS MAIL AGREEMENT NO. 40612608, Return Undeliverable Canadian Addresses to: IMEX Global Solutions, P. O. Box 25542, London, ON N6C 6B2, CANADA. Canadian G.S.T. number: R-124213133RT001. Printed in the U.S.A.

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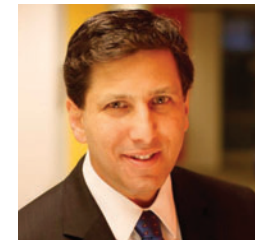

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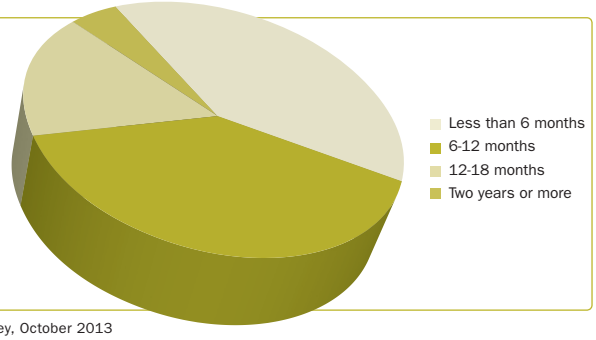

Source: Applied Clinical Trials Clinical Technologies Survey, October 2013

eLearning

Risk-Based Monitoring: Models, Myths, and Momentum

This webcast will look at the current state of clinical monitoring through recent surveys, discuss the various models under the umbrella term of "risk-based monitoring," and highlight many of the challenges and barriers to changing monitoring models, www.appliedclinicaltrialsonline.com/monitoring.

Applying Pharmacogenomics to Real-Time Drug Development Decisions

Pharmacogenetic sample collection and profiling of clinical populations can enable understanding of drug response and efficacy. This webinar presents a case study from Merck demonstrating the model, www.appliedclinicaltrialsonline.com/applying.

Science of Biobanking

Several institutions have provided their investigators access to an extensive repository of biological samples. Indiana University, Purdue University, and the University Of Notre Dame are such institutions, and have formed a statewide collaboration, the Indiana Clinical and Translational Institute (CTSI). CTSI maintains and operates the specimen storage facility. The facility provides the infrastructure for the storage of biological samples in dedicated freezers and liquid nitrogen facilities. The facility operates under formal standard operating procedures for controlled access, facility and equipment monitoring, alarming, and quality and administrative oversight in compliance with International Society of Biologic and Environmental Repository and the NCI Best Practices.

"Through CTSI's one stop shop, we assist investigators who need access to specialized biospecimen collections and biobanking services relating to sample collection, sample processing, and DNA isolation," states Colleen Mitchell, Joint Biorepository Operations Manager for Indiana University Melvin and Bren Simon Cancer Center Tissue Procurement and Distribution Core and the Indiana University Genetics Biobank. "The IUSCC Tissue Procurement and Distribution Core provides shared facilities and infrastructure support for tissue procurement and distribution," states Mitchell. "Within this distribution core, the IUSCC Tissue Bank is a tissue procurement resource for solid cancer tissue. Solid specimens with confirmed histology and diagnosis are available from surgical patients following excision from a large variety of cancers."

Lina Genovisi, PhD, JD, *is a contributing writer to Applied Clinical Trials*

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Applied Clinical Trials

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GLOBAL NEWS

Jury's Still Out on How Best to Handle Trial Data

The EMA is currently reviewing and analyzing more than 1,000 comments received during the public consultation on its draft policy on trial data, which ran from June to end of September 2013. The Agency has warned that the need to study so many submissions may delay the issuing of a final policy, which was initially planned for the end of 2013.

"The public consultation on the policy has generated input from an unprecedented range of stakeholders. Patients, healthcare professionals, pharmaceutical industry representatives, researchers, transparency campaigners, academic and public institutions, health technology assessment bodies, and a range of others sent their comments to the Agency," noted a statement released on November 13. "Many of the contributors provided detailed in-depth comments, some of them substantial, some of them technical, including suggestions relating to methodological and technical aspects of the implementation of the policy."

As part of its collaborative approach to developing a methodology for the release of clinical trial data with its stakeholders, the Agency is currently devoting attention to all comments received and reaffirms its commitment to transparency and the principles of publication and access to clinical trial data, EMA added. To conduct the appropriate in-depth analysis required, the Agency will spend additional time in this reviewing phase.

"The Agency has embarked on the development of a policy on publication and access to clinical trial data because it believes that the release of data is about establishing trust and confidence in the system," continued the statement. "The Agency is also firmly of the opinion that availability of data broadens the scientific knowledge base, fosters innovation, and encourages investment in the development of medicines, and ultimately benefits public health."

—*Philip Ward*

VIEW FROM WASHINGTON

Clinical Supply Issues Challenge Sponsors and Patients

The International Society for Pharmaceutical Engineers (ISPE) examined issues involving supply and production of investigational medical products. at its annual meeting in November.

A new ISPE survey (www.ispe.org) on patient experiences with clinical trial materials examines how upstream decisions on the packaging and labeling of clinical supplies can influence the success of a clinical study. Clinical supplies that are easy to use, have clear labeling and directions can improve patient satisfaction with participating in a study and enhance compliance, according to responses from 1,400 study participants. Also, there's strong interest in direct-to-patient refill and resupply options, especially when clinic visits are difficult.

One concern, noted Ken Getz, Director of the Center for Information and Study on Clinical Research Participation, which conducted the study for ISPE, is that a strong minority of patients say they keep unused clinical trial medicines for later use. Analysts cited the need for clearer policies and instructions on unused medicines, for investigators and patients.

Clinical supply delivery also is important for direct-to-patient studies, which have gained more attention as an option for remote trials. While such studies may reduce burdens on clinical sites, they raise logistical challenges for sponsors in maintaining blinding, scheduling timely delivery of test products, and ensuring that patients understand directions.

ISPE members noted tensions within pharmaceutical companies about providing comparators to other firms, particularly for newly approved therapies. More streamlined drug manufacturing systems that reduce excess production have tightened up supplies available for comparators, driving up prices. This has created "a perfect storm for counterfeits" to enter the clinical supply system and compromise patient safety, observed Terry Walsh of GlaxoSmithKline.

Walsh and others have established the Clinical Trial Comparator Network under the TransCelerate BioPharma initiative to support reliable and efficient distribution of comparator drugs to clinical sites. The aim is to replace two-company comparator supply arrangements, which can take months to negotiate, with a network that adopts standard legal agreements for participating manufacturers to supply other network members with products needed for legitimate research purposes. Price negotiation will be left to individual companies.—*Jill Wechsler*

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LETTER FROM THE EDITOR

Exciting Changes for Applied Clinical Trials in 2014

In various internal and external surveys this year, *Applied Clinical Trials* has evaluated its print magazine, digital products, and web site to determine what our readers want and how they are consuming information.

Digital product adoption among our readers is growing at a faster rate than what we would normally anticipate. That includes our eBooks, use of the magazine's digital edition, webinar attendance, and web site access for news and articles.

To address these needs, in 2014 we will be offering six print issues of *Applied Clinical Trials*, down from the 10 issues we published in 2013. In no way will this affect the authoritative quality of our content. We will continue to accept and publish the peer-review articles that we are known for, which are externally reviewed by our experts on the editorial advisory board. These articles will appear online first and will be identified as peer-reviewed.

The six printed issues will be highly-targeted and focused on those areas that our audience have rated highly over the past two years. These are: global trials; clinical technologies (ClinTech); oncology drug development; clinical trial management; clinical trial innovations; and drug safety and testing.

Another interesting growth area for *Applied Clinical Trials* is in conferences. In a recent Industry Standard Research survey, it showed in the next 12 months conferences would be a major source of information. Because of our relationship with CBI, a producer of clinical trials-related conferences in the United States, we will increase our involvement in the 2014 roster of CBI clinical conferences.

Additionally, we are increasing our coverage and frequency of online information. We are fortunate to have over 140,000 dedicated and loyal professionals worldwide as readers of *Applied Clinical Trials*. Thank you for your opinions and comments in the annual survey. We will continue to work with you to remain the leader in bringing you the trusted information you need, when you need it, and how you need it.

Remember, we are still only an e-mail away, or contact us through our LinkedIn Group, Facebook, and Twitter.

—*Lisa Henderson*.

DATA ANALYSIS

Reasons for Clinical Failures by Phase

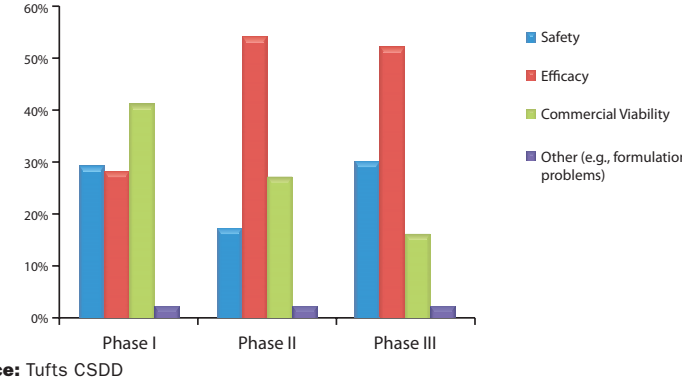
The Tufts Center for the Study of Drug Development (Tufts CSDD) recently analyzed the reasons for clinical failures for 410 drugs that entered human testing between 2000 and 2009.

The results of this analysis show that commercial viability—as opposed to safety—is the leading cause of Phase I failures. Commercial viability played a diminishing role in the reasons for drugs failing in later clinical phases. Safety issues accounted for one-third of all drugs that failed in Phase I and Phase III studies; and for 17% of all Phase II failures.

Efficacy issues dominated both Phase II and III accounting for more than half of the total drugs that failed (54% and 52% respectively). Tufts CSDD researchers conclude that the ever-changing commercial landscape combined with insights gleaned from later-stage studies conducted among larger patient populations present ongoing drug development risk-dynamics that are difficult for sponsors to anticipate and manage.

—*Tufts Center for the Study of Drug Development, https://csdd.tufts.edu.*

Reasons for Clinical Failures by Phase



Source: Tufts CSDD

Figure 1. Commercial viability—as opposed to safety—is the leading cause of Phase I failures.

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On Trial—Europe's Response to Antibiotic Research Gap

Global action and collaboration is needed to tackle the threat of antibiotic-resistant diseases.

Dealing with antibiotic resistance is important—and the subject received lots of attention in November, during different manifestations of the annual antibiotic resistance event around the world. But just as important—and probably more so—is the related question of how to stimulate development of new antibiotics. A workshop at the European Medicines Agency witnessed Andrzej Rys, a senior European Commission official, urge "further action" at policy level in Europe, including making the best use of medicines legislation to bring new antibiotics to patients. In order to do so, it was necessary, he suggested, to bring greater clarity, flexibility and speed to the authorization procedures for the approval of new products, and to look again at the way that the risk-benefit equation is calculated.

At the same meeting, Barry Eisenstein, now head of scientific affairs at Cubist, and a former Lilly research boss, underlined the need for "greater trial feasibility and regulatory predictability." Speaking on behalf of the European drug industry at the EMA meeting, he urged adoption of a tiered approach to authorization that would allow earlier approval for antibiotics.

He pleaded for using the totality of evidence for antibiotic approval and for setting interpretive breakpoints. Suggesting that pharmacodynamics can provide a valuable guide, he contended that if safety is good in Phase I and II, "you probably have a drug." He also called for measures to facilitate small research programs.

Sally Davies, the UK's Chief Medical Officer, has been one of the most vigorous advocates of stimulating antibiotic research, issuing apocalyptic warnings about the need for action. Earlier this year she highlighted a "discovery void" with few new antibiotics developed in the past two decades, leaving the "armory nearly empty as diseases evolve and become resistant to existing drugs."

Davies told this columnist during November that governments around Europe should be more energetic in pushing academia into action, and in promoting collaboration with industry. "Academia on its own doesn't know enough about development paths, so tie-ups with industry are vital," she said. Companies at present do not get engaged because of the lack of incentives, and this has to be dealt with, she insisted. In her view, the public-private partnerships such as the European Innovative Medicines Initiative (IMI) are "a good start." But she also urged examination of other approaches, such as the use of transferable patent vouchers, or even paying more for antibiotics. Within Europe, she said that Sweden and Norway are proving strong allies in the bid to boost research—but that not every European country shares the enthusiasm. "We have work still to do to educate the countries in Eastern Europe," she added.

Peter O'Donnell
is a freelance journalist who specializes in European health affairs and is based in Brussels, Belgium.

Meanwhile, the Swedish government allocated nearly $40 million for research on infection and antibiotics over the next four years. Roche said in November that it would resume the development of antimicrobial drugs, while taking over an experimental drug, developed with EU funding, by Polyphor. And IMI has announced plans to conduct clinical trials with innovative anti-infectious agents, using new trial designs, across a new network it has set up of nearly 300 clinical sites across 34 countries.

A broad coalition of national research institutions has put the development of novel antibiotics at the head of the agenda it is now finalizing under a "Joint Program Initiative on Antimicrobial Resistance," which brings together the larger EU member states, along with Canada, Israel, Turkey, and Norway.

In the initiative's scientific advisory board foreward to the draft research agenda, it stresses combining the efforts of the industry, public health bodies, and academic bodies.

In addition to the scientific dimension, "it is essential that regulatory processes are streamlined and economic barriers are lifted to allow the rapid and successful introduction of novel antibiotics and antimicrobials to the market."

Marco Cavaleri, head of anti-infectives and vaccines at the EMA, accepts that regulators could offer advice and liaison "to maximize the chances of regulatory success" for public-private partnerships projects. even though "due to conflict of interest it is not appropriate to take an active part in this kind of initiative."

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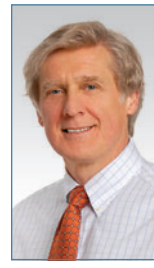
Clinical research processes need to be simplified before new technology can be properly utilized.

I recently acquired one of those neat new fitness bands that keeps track of my daily activity and sleep patterns, warning me when I haven't run far enough this week and praising me when I have. One of the newer versions also tracks my food and drink intake, will buzz me when I'm spending too much time as a couch potato, and even keeps track of my mood (grumpy meter alert). It doesn't directly link with my GPS watch and heart rate monitor—yet—but I'm sure the upgrade's coming for a nominal additional cost. All this real-time data about me is safely (allegedly) stored in the cloud where I can view it on my phone, tablet, or laptop.

My neighbor across the street has recently wired his house (the "connected home") with learning thermostats programmable by phone, and with smoke detectors that can send alerts—either for smoke or when its batteries need replacing, instead of that infernal beeping. He may next buy one of those refrigerators that can notify Peapod when you're running out of milk. *Time* recently described the Motorola pill that is swallowed and emits a password that can be read by a computer. This is not sci-fi—an ABI Research study estimates that 10 billion wireless devices are already connecting to the Internet today—with many more to come. Many commonly refer to this as the "Internet of things," a term used to describe the wired world where our devices track and monitor themselves, keep us informed, and cry for help when they need replacing, refilling or repairing.

Some 15 years ago, I wrote a paper in the *DIA Journal* titled "The Elegant Machine," which discussed how to introduce the concept of elegance into what had become a very busy, overly-complex, and ridiculously inefficient clinical data management process. The guiding principles of my machine—plan before you do, standardize data, push data capture upstream using best fit tools, provide online access to information, and let technology drive the process—are surprisingly still relevant, and, in a broad sense, not incompatible with the Internet of things. But, alas, many of the shortcomings of our research processes I criticized then are sadly still with us.

In 1998, mobile telephones were clunky and far from ubiquitous. Data connectivity was primarily by telephone modem. Fifteen years later, smartphones can be found in the farthest corners of the world, and everyone is connected through the Internet. Yet, in clinical research, we're still generating queries, overcompensating with monitoring and documentation, and manipulating and transforming data over and over again as we move it through the research loop.



Wayne R. Kubick
is Chief Technology Officer for the Clinical Data Interchange Standards Consortium (CDISC). He resides near Chicago, IL, and can be reached at wkubick@cdisc.org.

Our research machine is much closer to Rube Goldberg than elegance. For you youngsters who haven't heard of Rube Goldberg cartoons, try Wikipedia. Webster's dictionary describes Rube Goldberg as an adjective for "accomplishing something simple through complex means." Yep, that sounds like exactly what we do with many of our research processes, though hardly with the amusing creativity of a Rube Goldberg machine.

Now, like others my age, I regularly look for opportunities to simplify my life. I steer clear of garage and estate sales, try to avoid paper and ruthlessly purge my e-mail inbox. I even try to spend time now and then digging through drawers, closets, and garages to fill a trash bag or two. While I'm not quite so thrifty about my wine collection, I at least try to avoid creating new collections of other things I'll eventually have to shed.

But in the world of research, we embrace clutter. SOPs enforce complex documentation requirements with red tape workflows, measured in volume rather than quality and necessity. Take our approach to computer system validation. Processes around validation are typically medieval—analysts and testers generate reams of printed paper with wet signatures, and paper clipped attachments of screenshots and reports. This mountain of detailed documentation is meticulously scrutinized by the regulatory and quality assurance police—painstakingly combing for non-conforming corrections or missing dates on every trivial typo. If the documentation trail can't be measured in feet, it's generally assumed to be inadequate.

And what exactly does this accom-

plish? The basic premise of validation—documented evidence that a computer system meets requirements—is inherently simple. We simply need to describe our key needs, and provide just enough evidence that the system we used has been shown to meet them. The rest of the mess is created by us. Surely we would all prosper if we simplified—describing the most crucial functions in plain, simple terms, and providing spare, clear evidence that we actually tried the functions, maybe by using the tracking tools that computer systems already offer. Some overworked auditors might actually thank us for making the review so much easier.

The ingrained habits of excessive validation expectations—a practice that's ironically sustained by extending job security for both IT staff and auditors—is further encumbered by the timeworn tradition of sponsors conducting technology vendor audits of that validation. For some reason, each company feels it has to audit each technology vendor separately in person, sifting through those documentation haystacks over and over again. The process is often punitive—there's a small cottage industry of contract auditors for hire who feel they can only earn their pay by finding deficiencies that are often trivial or irrelevant and demanding immediate corrective action.

This costly, time consuming, and unnecessary practice still comes in an age where different pharmaceutical sponsors are working together to solve other common pre-competitive problems in partnerships like TransCelerate Biopharma and the Innovative Medicines Initiative. TransCelerate Biopharma, in addition to helping define therapeutic area data standards with CFAST, is already supporting multiple projects to share information about the qualification of sites.

It's not a stretch to set up a similar industry initiative to subscribe to an independent registry of audit information about other suppliers, such as technology vendors, CROs, and labs. We simplify when we do something once, and use it many times.

You can't really blame the regulators anymore either, even though perceived regulatory risk inhibits so many companies from trying anything even remotely different. FDA has opened the door to improved efficiency with guidance documents endorsing risk-based monitoring and use of electronic source documents. And regulators are working more closely with industry in many cases to address many of our long-standing problems. Some long-held sacred cow beliefs—such as the impression that CRAs had to review every data point on-site—are not really prescribed in the predicate rules. Much of the bureaucracy of research has just evolved over time and become firmly embedded in our culture.

Elsewhere, global demand for increased data transparency is making research data more available, yet its usefulness is still severely handicapped. It's not just that published data often do not conform to public industry standards, which makes it difficult to fully understand, much less roll up and compare data from study to study. In many cases, the published data lack sufficient context to allow thorough understanding—being able to view the data through the lens of the study protocol and analysis plan. Use of a standardized, structured protocol definition—which should accompany each posting of study data—would be an enormous leap forward.

But just making computer-readable protocol documents available would help as well. In the same way that Google Images indexes graphics found on the web with keywords—by looking at the textual content on the page the image was found, as well as the page title, filename, etc.—we already have technology available that would allow us to extract much useful contextual information about protocols that provide useful metadata to associate with these postings of data for shared use by the research community. Instead of waiting for an order to dig back and unearth such artifacts later, the industry can simplify by just making such behavior a habit for every study.

Which brings us back to the Internet of things. We should be using direct monitoring devices on study subjects already. We already have bottles that can track when pills have been dispensed. Companies are developing lab on a chip devices that can be used directly by patients and report back to a database. Not to mention microscopic streaming cameras that can be swallowed and stream video as with the Motorola password pill.

But we're never going to be able to use the new technologies of everyday life in research with our feet shod in the cement of antiquated processes. So, time to get back to basics. We need to focus on the core elements of the predicate rules, such as ensuring patient safety, maintaining good science, and ensuring traceability and reproducibility of results.

Of course, people say it's too risky, too difficult to take the first step, and too overwhelming a problem to address anyway. Which brings up the familiar anecdote of the little boy, painstakingly tossing beached starfish one by one back into the sea, who is warned that with so many thousands in the sand he can't possibly make a difference. "Well," he says tossing another, "I made a difference to that one."

Maybe some of us can make a difference on the next study we start. Simplifying our lives in research can make a huge difference in providing better treatments and cures to patients, even if they only happen one at a time.

Clinical Technologies

Lisa Henderson

As we move towards cloud-based technologies, lingering questions and concerns remain.

From ePRO, to eCRFs, eTMFs, trial management in the form of CTMS, to sophisticated analytics for forecasting, modeling and trending everything from site feasibility to recruitment and budgets…there are not many areas of clinical trials that technology does not touch. But technology brings with it its own set of complications, especially in our current world of outsourcing where sponsors and CROs share data to leverage decision-making and benchmarking.

With this in mind, *Applied Clinical Trials* and our conference company CBI, producers of ClinTech 2014, surveyed where our audiences are in regard to clinical technologies. We focused on how purchasing decisions are made; integration and maintenance issues; and views of technology providers.

The short history of clinical technologies is that it took EDC approximately 10 years to reach a 70% adoption rate. Even now, EDC may not be the primary data collection source, many trials still use paper—more likely in emerging regions, small trials, and Phase I trials. In the early adoption years, technology providers began adding on those aforementioned "e" technologies, or eClinical, that added to the chain of software services for the clinical research enterprise. Along the way, it became clear that suites from one company weren't as important to industry as best of breed solutions, which led to integration issues coming to the fore.

But also in that time frame, there has been one significant change in the landscape that impacts technology choices—cloud-based solutions or cloud computing. At last year's ClinTech 2013, it was clear that the cloud was the inevitable choice for sponsors making technology decisions, but there was much trepidation in that choice. What about security? What about legacy data? What would the cloud look like in five years?

We asked survey respondents to describe their feelings about cloud-based solutions (Figure 1). Thirty-four percent believe the cloud is a cost-effective solution. But a slightly greater number also find the cloud confusing or not secure.

This opinion piece, http://bit.ly/194UXiW, written by Rick Morrison, founder of a cloud-based analytics and data collaboration company, appeared on our blog. It provides a simple and understandable outline of the benefits of cloud computing—these include:

- Lower ongoing cost
- No capital expense
- Pay only for what you use
- More secure
- Focus on core competencies
- Scalable
- Quick deployment

Wayne Kubick, technology columnist for *Applied Clinical Trials*, wrote about the cloud two years ago, which can be accessed here http://bit.ly/HJwutp. Two years later, Kubick observes, "As we approach the end of 2013 the external world in general is certainly flying into the cloud, but much of the world of regulated clinical research is still frequently chained to the ground." He believes that the majority of us access and use cloud applications everyday on smartphones and pads, but there still exists a

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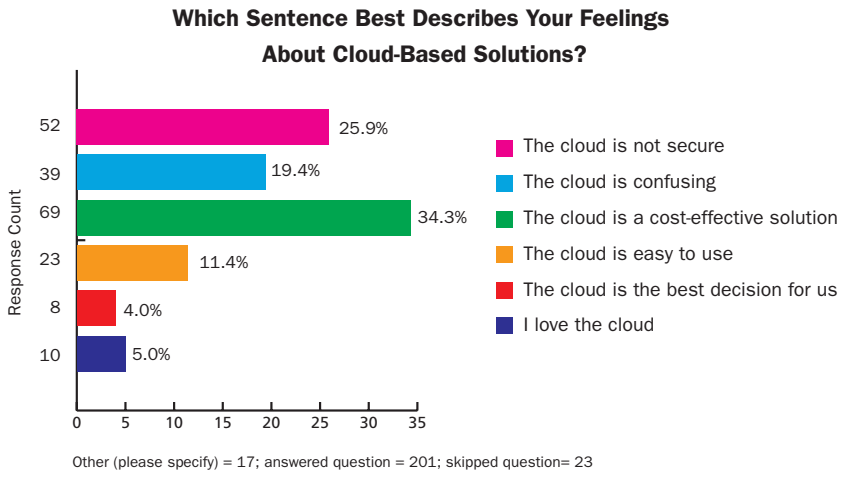
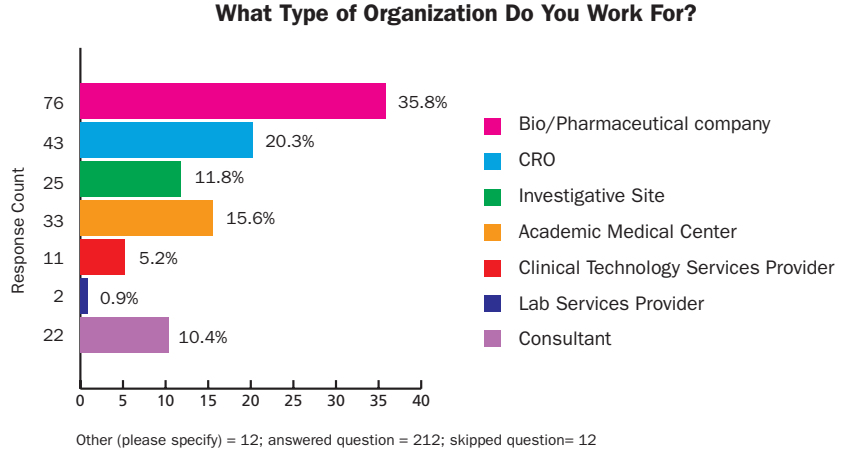


Source: Applied Clinical Trials, Clinical Technology Survey, October 2013

Figure 1. The cost-effectiveness of the cloud is the best description of respondents' feelings about cloud-based solutions.



Source: Applied Clinical Trials, Clinical Technology Survey, October 2013

Figure 2. Most survey repondents work for a bio/pharmaceutical company, followed by a CRO.

level of risk aversion, and adherence to legacy regulatory and IT attitudes and that hold industry back. "While these constraints persist within these enterprises, we're seeing the cloud as the platform of choice for collaborative initiatives such as IMI (with its eTRKS translational medicine system) and TransCelerate Biopharma and others. Smaller companies are more likely to make the transition sooner for their internal systems. And there are a number of technology start-ups gambling that the cloud will be the only platform of choice before long. Though old habits die hard, I do foresee the balance tipping within the next three years—it will simply be too difficult to ignore."

And a note on security, both Kubick and Morrison believe that cloud suppliers are more capable of preserving security. Kubick notes that security is absolutely fundamental to their survival and Morrison says they have more experience with computer infrastructure than sponsors, and by virtue of their working with more systems and data, they become security experts more easily than sponsors.

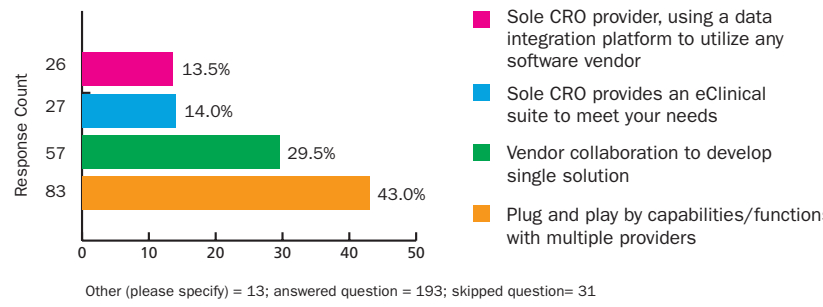
Diving deeper into the cloud, we wanted to look at the profile of those 5% who responded "I Love the Cloud." If you love the cloud, you are 66% more likely to be buying workflow management or document management solution in the next two years. And you are evenly distributed between a purchasing a solution to help with risk-based monitoring, recruitment or study start up at 22.2%. If you love the cloud, cost is very important to you, and ease of integration with existing solutions, potential solutions, and external providers is very important. And your primary resource for finding new solutions is Google search at 40%.

CROs and technology

There are varying thoughts on how clinical technologies vendors can impact the industry. In this column from early this year, http://bit.ly/1864axQ, Ken Getz reflected on how CROs could be moving the industry forward in innovation and efficiency. From a technological standpoint, he noted, "Leading CROs are aggressively pursuing new and innovative initiatives to facilitate sustainably higher levels of speed and efficiency. They have introduced a number of eClinical solutions designed to simplify and optimize data and project management and to coordinate disparate technologies." Perceptive Informatic's (Parexel) launch of the MyTRIALS platform and ICON's launch of ICONIK are two such examples.

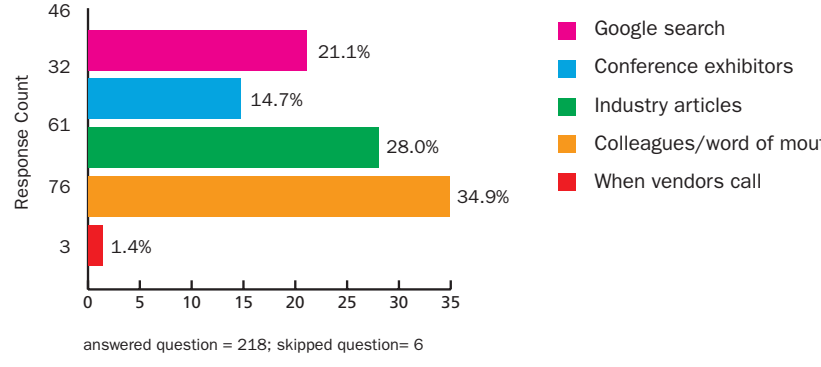
Other initiatives Getz described use technology solutions to optimize investigative site performance include Covance's Xcellerate methodology and ICON's Firecrest Clinical.

In this piece, http://bit.ly/I1prg6, published in April of this year, Graham Bunn, PhD, Vice President, Partnerships at Perceptive Informatics, takes the position that as sponsor and CRO partnerships increase and sponsors leave more of the management of trials to their outsourced partners, they should also leave the technology decisions to the CROs. By giving up the requirements for multiple technologies, CROs can gain their own efficiencies in the process. "This change in approach by sponsors has changed the way technology vendors work with their CRO customers. Some large technology vendors have developed a CRO partner program to better serve this segment of the industry, and in the process provided benefits to both the CRO as well as the sponsor. Vendors have implemented strictly controlled, high quality training and testing programs along with user testing (certification), company accreditation and associated branding to recognize high quality CRO partners who are familiar with their technology. This not only enables the CRO to differentiate themselves in the marketplace, but also allows sponsors to feel confident that their strategic CRO partner is correctly qualified and supported throughout the contract duration."



Source: Applied Clinical Trials, Clinical Technology Survey, October 2013

Figure 3. Plug and play by capabilities/functions with multiple providers is the most popular current model.



Source: Applied Clinical Trials, Clinical Technology Survey, October 2013

Figure 4. Most survey respondents hear about new solutions from colleagues/word of mouth.

In our survey, 35.8% of the respondents work for a biopharmaceutical company and 20.3% CROs (Figure 2). We asked: "What is your current model with external partners?" (Figure 3) the majority of the respondents said "plug and play by capabilities/functions with multiple providers." This was followed by vendor collaboration to develop a single solution; and a close tie between sole CRO provides an eClinical suite to meet your needs and sole CRO provider, using a data integration platform to utilize any software vendor.

The second choice refers to reports that pharma companies are asking different vendors to collaborate with each other to come up with one solution that meets their needs. In that way, the pharma company doesn't end up using both services that don't completely meet all their needs or they end up paying for portions that they don't want or need.

Criteria for Solutions

When choosing a technology solutions provider, what criteria was most important? Responsiveness to business needs and cost were closely rated as Very Important by our respondents at 69.4% and 63.8% respectively. Reputation in the market was rated Important by 48.9% of the majority.

How respondents discover new solutions is mostly through colleagues and word of mouth, at 34.9% (Figure 4). But the criteria for choosing the vendor—not the solution—is more closely aligned. Respondents list cost, ease of use and ease of integration with existing solutions as very important, all hovering around 60% (respondents were allowed to choose three criteria). Under Important, best of breed solutions won out, followed by ease of integration for potential solutions. A word

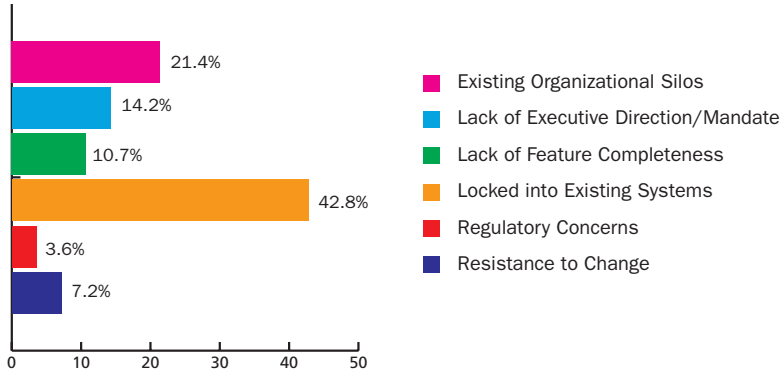
How Would Rate the Importance of the Following Criteria When Considering the Technology Solution?

	Very important	important	Somewhat important	Not Important	Rating Count
Cost	61.4% (132)	33.5% (72)	51% (11)	0.0% (0)	215
Best-of-breed solution	23.7% (51)	60.5% (130)	14.9% (32)	0.9% (2)	215
Ease of use	60.1% (131)	35.8% (78)	4.1% (9)	0.0% (0)	218
Ease of integration with existing solutions	59.9% (130)	34.6% (75)	5.5% (12)	0.0% (0)	217
Ease of integration for potential solutions	39.2% (85)	44.2% (96)	15.7% (34)	0.9% (2)	217
Ease of integration with external providers	30.2% (65)	39.5% (85)	25.1% (54)	5.1% (11)	215
				Other (please specify)	3
				answered question	219
				Skipped question	5

Source: Applied Clinical Trials, Clinical Technology Survey, October 2013

Figure 5. A majority of respondents ranked cost, ease of use, and ease of integration as "Very Important."

What is the Primary Challenge in Adopting a Unified Solution? (choose one)



Source: Medidata webinar, IRT & EDC: A Unified Experience, May 2013

Figure 6. Being locked into existing systems is the primary challenge to adopting a unified solution.

or two about integration. In our survey, 39% of the respondents noted that technology integration was their biggest challenge (Figure 5). At two recent CBI conferences, integration issues did come into discussion. And not that there is an "integration" backlash, however, some caution that not every solution need be integrated. Much like metrics, thought around what truly will add value by being integrated should be assessed. In addition, even if, for example, a CRO and sponsor enter into a partnership, which will inadvertently call for some level of data sharing, just because two entities may use the same vendor solution doesn't ensure an easier integration. Johann Proeve, Head Global Data Management at Bayer Healthcare, discussed its data management partnership with Covance at CBI's Sponsor and CRO Business Process Systems and Integration conference. He noted that even though both companies use Medidata's Rave as their EDC, these systems are highly configurable—and customized to their needs—so integration is not necessarily a seamless activity.

And there are other challenges to integration or solutions unification, which came up during a webinar about Medidata's IRT and EDC solution (Figure 6). These challenges resonate with Kubick's overall cloud challenges above.

But it is true that the respondents to our survey think that integration is important—either with existing solutions, potential future solutions or with their external providers.

Our respondents said top areas they are planning to purchase solutions in the next two years are risk-based monitoring, workflow management/document management, and study start up. For trends, respondents rate mobile technologies as the only "must-have" technology—other choices were big data, EHR integration, investigator portals and clinical trial supply management.

If we are to agree with Wayne Kubick, that the tipping point into cloud computing is only three years away, then more and more companies will need information on these technologies. *Applied Clinical Trials* will be the lead media partner on CBI's ClinTech 2014 conference, which will address these topics, and we will continue to feature articles, news and more about clinical technologies in our ClinTech section on our website at www.appliedclinicaltrialsonline.com/ClinTech.

Clinical Trial Design Automation

Srini Dagalur, PhD

Incorporating CDISC-based libraries to store study components for study design and building eCRF pages.

There have been significant changes in the way clinical trials are executed today—with a move towards eClinical where technology-based solutions are being widely used to drive automation and overall efficiency into the clinical trial end-to-end process. The majority of these current approaches are more siloed around systems such as CTMS, EDC/CDMS, IVR and submissions management (i.e., trial master file, CSR, etc.). There still exists certain phases such as study design and study build within the clinical trial process that can have a significant impact based on reduction in overall time for getting trials ready for study execution across the clinical sites.

This article provides a framework called clinical trial design automation that helps establish a recommended approach to manage the study design and study build phase of the overall clinical trial process. The approach includes process and technology to aid in speeding up critical elements of a clinical trial lifecycle—elements covered are from study design (protocol design) to study build. This article highlights how this recommended approach will drive efficiencies by reducing overall timelines for building eCRF-based clinical trials including the drive towards reusing protocol elements and eCRF page elements using standards-based libraries. The conceptual architecture provided describes the components of the architecture and the process upon which this recommended approach for clinical trial design is founded on. Most of the components necessary for the proposed approach can be configured based on pre-existing solutions in the marketplace, while the core component termed clinical design interchange doesn't exist and will need to be designed and built. The use of industry data standards and CDISC-based messaging format for storing and communicating is proposed. The key mechanism in the proposed approach is the creation and maintenance of study components which are constantly being built in a clinical library resulting in reusable components that enables flexibility and adaptability to changing needs/regulatory requirements and support for global clinical trial execution.

This recommended approach has significant value for key clinical trial stakeholders—sponsors, CROs, and eClinical vendors, each with the potential for driving efficiencies in the study design and study build phases of clinical trials resulting in the overall cost reduction of clinical trial execution while enabling flexibility to meet new regulations and clinical trial trends.

Current state of clinical trial design

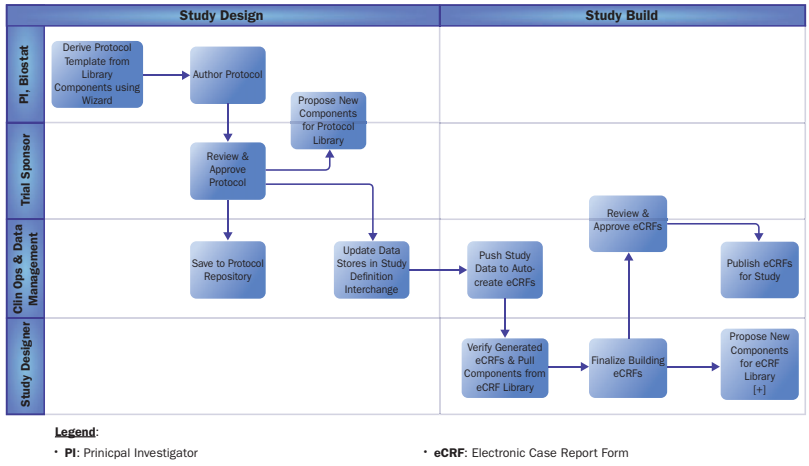
Life science organizations are facing challenges with escalating costs emanating from increased operational complexities and ever-changing regulatory requirements within the United States and across the globe. In many cases, primary increases in costs for bringing products to market are around planning and execution of clinical trials. Further, the clinical trial market place is experiencing the following key trends as a result of increased cost of drug development, reduced probability of drug success, and failure to meet trial deadlines due to trial operational complexities.

Current Clinical Trial Design Challenges	
Study design—protocol development	• No systematic reuse of standards and templates, ad-hoc development leading to delays in authoring and review. • Inefficient collaboration and limited visibility between/within therapeutic areas without cross-program harmonization.
Study design—clinical data capture build (eCRF)	• Studies designed and built from scratch each time, manual design and programming of eCRF's. • Use of ad-hoc design for each protocol resulting in inefficiencies (repeat process for each protocol) and delays in developing eCRFs. • Limited leverage of industry best practices.
Trial document management	• End-to-end management of protocol documents from authoring to electronic definition present challenges for regulatory document tracking and submissions. • Protocol amendments issues and the need to review documents by multiple owners adds to the complexity of trial document management.
Access to data and information	• Limited ability to use data as an asset, data exchanged as documents. • Disparate clinical trial metadata repositories in proprietary formats.

Source: Srini Dagalur

Table 1. The current design and review process has many inherent challenges that span the clinical trial process.

Proposed Study Design and Study Build Process



Source: Srini Dagalur

Figure 1. The intent of the proposed approach is to enable the reduction in cycle times based on process improvements including reuse of clinical trial design content.

- **Maturity of CRO's, emergence of boutique CROs, and other support organizations.** Studies show that CROs[1] complete drug development faster than the drug companies themselves, without sacrificing data quality. Boutique CROs are focusing on specific therapeutic areas and provide expertise such as protocol design, patient/investigator recruitment, etc.
- **Globalization impact has increased clinical trials being conducted outside of United States and Europe.** It has been driven by reduction in costs, increased patient recruitment across varying demographics, and less bureaucracy.
- **Drive toward adaptive trial design.** Eighty-nine percent of all drug candidates from the initiation of Phase I through FDA approval fail in the clinic. Adaptive trials offer the potential to enable more levels of doses to be studied using maximum tolerated dosage over a select patient population.[2] Adaptive trials improves the decision making in the identification of drugs with reduced probability of success.[3]
- **Implications of EHR/EMR.** Aiding in patient recruitment[4, 5] by identifying patients that meet clinical protocol criteria. Clinical data captured via these methods are helping answer questions about the safety, effectiveness, and costs of new treatments.

Clinical trial design automation

The proposed approach is based on building clinical studies centered on the following steps:

- Developing study/protocol based on individual protocol components that are stored in a reusable CDISC-based repository.
- Designing individual eCRF page elements that are stored in a eCRF library.
- Leveraging study maps which define eCRF pages based on linking eCRF page elements to study/protocol components.
- Building entire eClinical studies based on study maps.

The intent of the proposed approach is to enable the reduction in cycle times based on process improvements including reuse of clinical trial design content (study design and study build) while providing for a flexible framework that adapts to meet clinical protocol needs (Figure 1).

Each of the key components of proposed solution architecture is described in detail below:

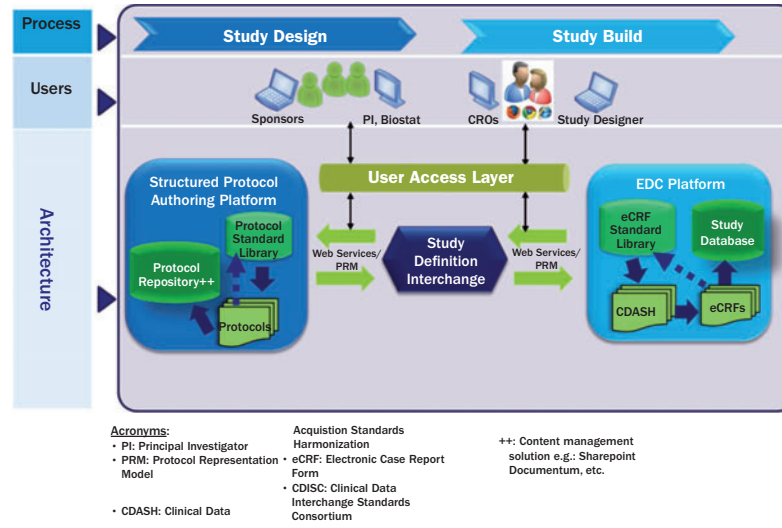
Structured protocol authoring platform. This component is based on document management solutions that provide structured authoring,[6] wherein complex documents are broken down into

smaller components and then assembled together via document maps to create final published documents in multiple formats. In the case of clinical trial protocols, it is based on decomposing clinical trial protocols (includes protocol amendments) into components and building protocol components independently and then assembling these components into protocol documents using pre-defined protocol document maps. All these components are stored in a document store called the protocol repository that serves as the primary content storage mechanism for managing protocol components. The protocol repository is based on the protocol representation model (PRM)—a CDISC standard that supports the planning and design of a clinical trial protocol including protocol amendments. Further, the submission data tabulation model (SDTM)—trial design model (TDM) datasets are used as a source of elements for PRM.

As this approach to protocol authoring takes effect, the protocol repository becomes richer in content and further drives speed of authoring protocols. This approach results in reduced overall time to approve studies/protocols based on:

- Minimizing document hold-ups with different authoring groups.
- Using a component library that brings speed to content creation by reusing elements and also developing standard components that do not change across protocols.
- Enhancing support for regional/local/country specific protocol changes by targeting specific protocol components that are impacted due to regional regulatory needs, which also speeds up overall approval times compared to traditional approaches.

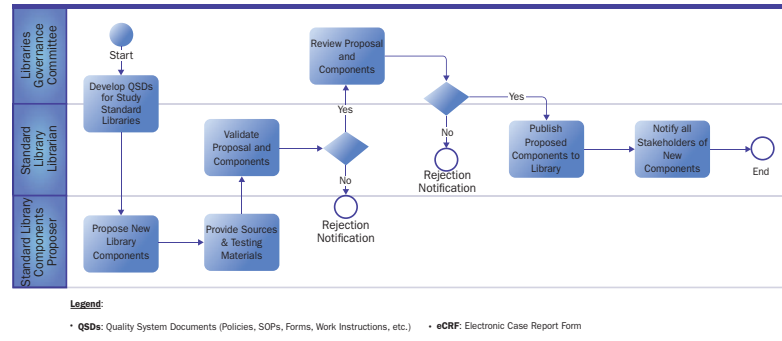
Design Automation



Source: Srini Dagalur

Figure 2. The key components of proposed solution architecture.

Proposed Process Diagram



Source: Srini Dagalur

Figure 3. Outlines of how standard libraries are managed and maintained to help create re-usable protocol elements during study design and build.

The implementation of this part of the proposed architecture can be based on configuration of pre-existing structured/component authoring solutions that meets this proposed approach.

EDC platform. The EDC platform[7] manages the design and build of the eCRF pages including the underlying clinical database that support these eCRF pages, all during the study build phase. This architecture component provides this feature and also includes the eCRF design tool that enables the layout and creation of eCRF pages. The study definition interchange provides a standard-based CDISC integration layer that describes the protocol structure defined during the study design via a map. This map links pre-existing elements across protocol and eCRF page elements. During the study build phase (i.e., eCRF build) the EDC platform processes the map information to link each of all protocol component elements to its corresponding eCRF page elements based on these maps. The eCRF pages are then generated including the database to store eCRF results. Within this component as eCRF pages are generated, for those protocol components for which eCRF page elements do not still exist in the eCRF library, new eCRF pages including maps will be created and maintained.

Study definition interchange. This is the core component of the proposed architecture and functions as the connectivity layer between protocol authoring (study design) and eCRF build (study build). The study definition interchange component manages all mapping and any transformations that are necessary between protocol elements and eCRF page elements. It provides integration services that are based on CDISC standards linking protocol authoring platform to the EDC platform. The rules, transformations, and maps linking study/protocols to eCRF pages are also stored within this component. Maintaining all these elements requires a simple user-interface to create, update, and manage components throughout the lifecycle. On the study design (protocol authoring) side, all elements in the protocol repository are exposed in the form of PRM elements within the study definition interchange layer in order to be transformed into specific eCRF page elements based on pre-existing protocol maps and transformation rules. On the study build (eCRF page creation) side, the study definition interchange component takes each protocol component exposed as PRM components and maps it to eCRF page elements based on clinical data acquisition standards harmonization (CDASH) standard, a subset of CDISC.

Since the study definition Interchange component of the proposed solution architecture has to be designed and built, below are some key design considerations for this component:

- Store all study definition metadata in this component.
- Leverage dictionaries and CDISC standards to provide interoperability between clinical systems across study design and build (e.g., WHO Drug, PRM/SDTM/TDM/ODM/CDASH, etc.).
- Align on standards naming/metadata across all areas (global, therapeutic area, study, etc.).
- Maintain version control, data traceability, and audit trails for regulatory compliance.
- Leverage an ETL engine that supports transformation and store maps for study metadata across standard libraries.

The study definition interchange is a new component that does not exist in the market and will need to be developed or extended based on some pre-existing solutions.

For the clinical trial design automation approach to be effective it is integral for the maintenance of both the standard libraries—protocol and eCRF—both of which manage and store protocol components across all clinical trials (Figure 3).

Proposed maintenance process

Key groups for proposed process are described in detail below:

- The governance committee is responsible for managing and approving overall content within study standard libraries: protocol and eCRF. They also approve QSD (quality system documents) that describe the process and policies to help manage study standard libraries.
- The standard libraries librarian helps manage, track and get documentation ready to governance committees for approval. Based on approval status help notify users of standard libraries in terms of components that are ready to be published and made available for clinical studies within the organization.
- The component proposer group is primary authors of components that exist in the standard libraries. This group is responsible for preparing documentation on new components including updates to pre-existing library components. Works with the librarian group in getting documentation ready for approvals via the governance committee.

These three groups in concert with the proposed process help maintain the study standard libraries and enable the proposed approach in driving efficiencies into study design and study build process.

Conclusion

This proposed approach has significant value and benefits for the clinical trial stakeholders: sponsors, CROs, site users, eClinical vendors, and others (regulatory, IRBs) based on driving efficiencies and flexibility into clinical trials process, reduction in cost and time across study design and study build phases.

See additional charts for stakeholder steps and benefits of clinical trial design automation online.

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Developing a Successful Peer-to-Peer Mentoring Program

Ivana Furimsky, Karen Arts, and Sarah Lampson

Clinical research organizations should look to peer-to-peer mentoring for professional development.

Clinical research professionals, such as coordinators and administrators, play a key role in the success of clinical research projects. In order to meet global standards, clinical research professionals conducting clinical research involving human subjects are required to take training in guidelines for good clinical practice (GCP), which describes the responsibilities and expectations of all participants in the conduct of clinical trials, including investigators, monitors, sponsors, research ethics boards, and clinical research staff.[1,2] Another standard which is being accepted increasingly by organizations conducting clinical research involving human subjects is training in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS).[3]

Clinical research training practices vary across the globe and likely rely on available resources to provide such training. Most of the clinical research training offered in GCP and the TCPS is offered through classroom or online tutorials. These formats provide the required subject matter, a quiz, and a certificate of completion as formal recognition that the training has been completed. However, this format for training often lacks the practical aspects of transferring this newly acquired information into practice.

Frequently, training of new clinical research professionals is left to the principal investigator, who is ultimately responsible for ensuring compliance of the project with the applicable regulations. In many situations, clinical research training may be delegated to other members of the research team, or left up to the individual themselves. Inconsistent work practices, questionable data quality, and protocol execution issues may be encountered if learning the day-to-day operations of clinical research is done informally and/or on the job.[4]

Peer-to-peer mentoring can be described as a form of mentorship that takes place between a person who has an expertise in a particular skill and a person who wants to learn that skill, where both the mentor and mentee may be at the same level in an organization.[5] Peer mentoring can offer a valuable source of support and information to less seasoned staff that work within similar work environments, and can offer an organization or research team a low-cost method of training new research staff.[6]

In response to the need for clinical research mentoring within an environment of limited resources, the Network of Networks (N2)[7] developed a peer-to-peer mentoring program to provide mentoring opportunities to research professionals across Canada. By developing a system where seasoned clinical research mentors are paired with less seasoned mentees, the goal was to offer guidance to clinical research staff who have little formal training, as well as support staff in the acquisition of new practice skills.

The N2 Mentoring Program is coordinated by a committee of voluntary research professionals, which is responsible for communication about the program to N2 members, reviewing applications, pairing mentors with mentees, and evaluation of the program. Mentors participate on a

voluntary basis and the program is available to all N2 members at no cost.

The network of networks

N2 is a not-for-profit collaboration of healthcare organizations and other stakeholders, in Canada, that conduct clinical research involving human subjects. N2 is a national initiative that aims to enhance Canada's research capability and capacity, whose membership includes over 200 clinical research sites across Canada.

Development of the peer-to-peer mentoring program

The overall goal of the N2 Mentoring Program is to pair mentors, who have expertise in conducting clinical research, with mentees, who are in need of developing new skills in conducting clinical research. As part of the planning process, the N2 community was consulted through surveys, for suggestions on topics such as mentor criteria, determining the length of the mentor and mentee relationship, and mentoring formats. By having the mentoring program under the auspices of the N2, all mentors had access to the most up-to-date research tools, standard operating procedures, information about best practices in clinical research, and access to more formal training in the regulatory requirements of conducting clinical research. The goals of the mentoring program are:

- To facilitate a national, institutional mentoring program by pairing volunteer mentors with more junior colleagues for a four month period
- To develop a roster of mentors along with their areas of expertise
- To develop a process by which mentees will be paired with appropriate mentors
- To obtain feedback from both the mentor and mentee about their experience.

The mentoring formats are decided upon by the mentor and mentee and can be person-to-person, via telephone, e-mentoring, or a combination of all three.

Pairing a mentor with a mentee

Both mentor and mentee participants are required to complete an application form before they are considered for pairing. The form asks for demographic and contact information, area of research expertise, therapeutic area, and number of years of experience in research. Mentor applicants are asked to check a list of areas of expertise in which they can provide mentoring. Mentors are chosen based on the following criteria:

- Research professionals who have at least five years experience in clinical research
- An expertise in a particular area of clinical research
- Interested and available to provide mentoring to less seasoned clinical research staff

Mentee applicants are asked to check a list of areas in which they would like to receive mentoring. All participants are asked to provide consent to have their name and contact information shared once a potential match is found.

The mentoring committee reviews all applications within five days and a response to applicants indicating their application has been received is sent. The information in the application forms is inputted into an Excel database, which is stored on a secure network. This information is the source for the mentor and mentee pairing and makes up the mentor roster for future pairings.

When an application form is received from a mentee, a member of the committee reviews the areas in which they want to receive mentoring. The mentor roster is then reviewed for a mentor who has an expertise in the area of expertise being requested. The mentor is then contacted to determine their availability for mentoring. If a suitable pairing can be made, the mentor and mentee are contacted by a member of the mentoring committee and their contact information is exchanged.

The mentoring formats are decided upon by the mentor and mentee and can be person-to-person, via telephone, e-mentoring, or a combination.

The mentoring committee recommended a period of three-to-four months for the mentoring relationship, with the belief that having a clear endpoint would make the mentor/mentee pair more productive. Mentors and mentees are invited to contact the committee at any point in the relationship to request assistance or another match as needed. At the three-month mark the committee makes a point of checking in with the pair to see how the mentoring relationship is progressing. The committee contacts both the mentor and mentee to obtain feedback through an anonymous online survey once it is determined that the pair has reached their goal.

Spreading the word

In August 2011, information about the N2 mentoring program was sent electronically to all research organizations that are members of N2. Each organization has a N2 member representative responsible for distributing research information in accordance with its own organizational process or guidelines. Interested individuals were encouraged to complete the mentor and/or mentee application forms and send them to the N2 mentoring committee.

Six months after the initial communication, a newsletter was sent through the same process to all N2 members with an update regarding the mentoring program. The newsletter provided a description of the mentoring program and progress to date. Interested individuals were encouraged to forward completed application forms to the mentoring committee.

Evaluation of the mentoring program

On an annual basis, the N2 community provides input on the need to continue with the N2 mentoring program. In 2012, the N2 community indicated that the need for a clinical research mentoring program continued to exist.

Through an anonymous survey, participants of the N2 mentoring program also provide input on their experiences and are offered the opportunity to provide input on how the N2 mentoring program can be improved. In the paragraphs to follow, we offer results of our N2 mentoring program evaluation.

Mentor/Mentee demographics

Currently the mentoring program has 14 research professionals who have volunteered to be mentors. Mentor applications were received from Alberta, British Columbia, and Ontario. All mentors have at least five years of experience (range five to 25 years). The mentors come from a variety of clinical areas, such as: acquired brain injury, cardiovascular, hematology, mental health, oncology, pediatrics, and eye research. Many mentors have expertise in monitoring, auditing, training, clinical trial coordination, budget, and contract negotiation. The mentors used a checklist on the application form to indicate the areas in which they were comfortable in providing mentoring. The most common areas of expertise were consenting research subjects, clinical trial applications, education and career development, and SOP development.

Currently the mentoring program has 14 research professionals who have requested mentoring in particular areas of clinical research. Mentee applications were received from British Columbia, Ontario, and Saskatchewan. Mentees have varying years of experience ranging from less than one year to 16 years. The mentees come from a variety of clinical backgrounds such as brain injury, cardiovascular, eye research, kidney disease, and orthopedics. Many mentees have roles in clinical research coordination, or research administration and management. The mentees used a checklist on the application form in order to identify areas in which they wanted mentoring. The most common areas were grant preparation and regulatory requirements.

All individuals who sent applications for the mentoring program received an acknowledgement e-mail within 10 days of receiving their application. If a pairing was suitable, contact information was provided to both mentor and mentee. It was up to the mentor and mentee to make the connection and establish the goals of their relationship, the most suitable method of communication, and to determine the length of the mentor/mentee relationship. Whereas no timelines were set for the relationship, a committee member contacted the pair after three months to enquire about progress.

As of August 2012, the mentoring program successfully paired nine mentors with mentees. In seven out of nine cases, the mentors and mentees worked in different cities. There were five mentees that had not yet been paired. One reason was that a mentor was not available to provide mentoring in the expertise being requested. In these cases the mentees were notified of the situation, and told they would be contacted once a mentor became available.

Post pairing survey

The goals of most mentor/mentee pairings had been achieved by three months. A survey link was sent via e-mail to the 18 participants, both mentors and mentees that had completed the mentoring program. Seven participants responded to the survey, which gave a response rate of 39%. Four of the respondents were mentees and three were mentors. The mentoring committee reviewed the feedback provided by the respondents.

The survey asked participants the following four questions:

- Please share the best part of your experience.
- Overall how valuable did you find your mentoring experience?
- What suggestions do you have about how we could improve the program?
- Do you agree to us sharing your name and best part of your experience in the N2 newsletter?

To the final question, all respondents agreed to having the best part of their experience shared in the N2 newsletter. However some did not want to have their name identified. Some common responses that emerged from the mentees were:

- An appreciation of the time their mentor spent with them
- The mentoring program was easy to accommodate into their busy schedule
- Mentors were able to provide support through shared experience
- Mentors provided valuable tools and information which helped in developing skills

Common responses from the mentors included:

- Being able to share their knowledge with a peer
- Meeting a peer in their field
- Knowing they could help someone in their field

The survey asked participants to rate their overall experience on a scale of 1 to 10 (10 being excellent). The average rating was 8.8 with a range of 8 to 10.

Suggestions for improvement revolved around providing more structure to the mentoring relationship. The mentors' responses suggested that mentees have some defined goals or learning objectives. One mentor suggested providing a list of topics to discuss with the mentor in the beginning as a way to help develop the relationship. The mentees' responses also suggested a need for defined goals or plan for the mentoring relationship and a final feedback or assessment of their learning. One

mentee also found that being paired with a mentor from a different city was difficult, since she preferred face-to-face communication.

Future directions

The N2 mentoring committee continues to provide research mentoring opportunities to its members and is looking at more effective strategies to communicate information about the N2 mentoring program to its members. Evaluating the outcomes of these different communication strategies will be important.

An improved communication strategy will play an important role in enhancing and gradually expanding the mentoring committee database. Through expansion of the mentor roster, mentees will be paired with with suitable mentors fairly quickly and avoid a wait list.

Quantifying the mentor-mentee interaction, in terms of the number of hours during the mentor relationship, may also be important. Of interest would be the number of hours the mentor and mentee spent on activities aimed at attaining their goals within the three-to-four month period.

The committee recognized that there may be some individuals who do not want to provide mentoring for an extended period of time, but who may be interested in conducting a one-hour webinar on a research topic geared to a wider audience. Also, individuals may not want to be mentored for an extended period of time; however they may be willing to participate in a webinar on a research topic of interest to them.

The N2 mentoring program introduced the first webinar in May 2012, titled: "Conversations for Power and Possibility: How to Transform Your Life and Change the World." It was lead by author and coach Darlene Chrissley. The number of participants was high; there were 55 phone lines reserved for individuals and groups, at 18 different sites. The webinars were free to all N2 members. The high number of individuals enrolled in the webinar led the committee to believe that there may be individuals who want to be involved in furthering their research knowledge, but may not want to be mentored through pairing for an extended period of time.

Conclusion

The N2 mentoring program continues to operate on a voluntary basis. An annual N2 membership survey indicated that 79% of members found the program to be of relevance to their organization and important to continue with the program. There has been little cost with operating the mentoring program other than the time that committee members, mentors, and mentees devoted to the program.

The N2 mentoring program aims to fill a gap between formal research education and the application of this formal education into daily practice. There is a need for a cost-effective mentoring program that can pair seasoned research professionals with those who are less seasoned and in need of developing skills. Within the context of N2, mentors and mentees are fortunate to have access to up-to-date resources, best practice guidelines, and research tools developed by the wider N2 community at little to no cost.

It is possible for an organization to develop such a program for its research professionals. The success of this program is dependent on individuals who volunteer their time to ensure the operations run smoothly and who regularly evaluate the feedback from participants and needs of the research community.

> **Survey participants rated their overall experience of the mentoring program, on average, 8.8 out of 10.**

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Our Corporate Profiles section provides readers with the essential, up-to-date information about the companies that provide services to the clinical trials community. We compile this section to give readers the opportunity to gain a deeper understanding about the products, services, and capabilities of key vendors in the industry by profiling each company and highlighting their histories, present, and future.

Please contact the *Applied Clinical Trials* staff with your questions and comments. We look forward to hearing from you.

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NUMBER OF EMPLOYEES
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inVentiv Health Clinical

Corporate Description

inVentiv Health Clinical is a leading provider of global product development services for pharmaceutical, biotechnology, generic drug, and medical device companies. Our services include Phase I-IV clinical development, bioanalyses, and clinical resourcing solutions of any scope—from a single professional to an entire functional team. Our competitive advantage is highlighted through the following capabilities:

- Best-in-class clinical, commercial, and consulting disciplines across the product development lifecycle in our Convergent Services Solution
- inVentiv Health Clinical, with 6,500 professionals providing clinical development support in more than 70 countries
- Dedicated project teams by therapeutic area with more than 320 MDs and PhDs
- Customizable strategic resourcing solutions from contingent staffing to functional models and staff lift-outs
- Data-driven and research-informed communications strategies to maximize effective patient recruitment and retention, including exclusive access to United Health Care claims data on more than 90,000 patients

Major Products/Markets Served

Phase I-IIa: For proof-of-concept, First in Human (FIH), or bioequivalency studies, our extensive database of study participants and relationships with leading hospitals ensure rapid recruitment for clinical studies. In addition to a dedicated project manager for each study, we deploy a team of experts and specialists in quality assurance, and scientific and regulatory affairs to custom-fit a program to clients' needs.

Phase IIb-III: We combine extensive therapeutic knowledge with a commitment to quality and proven operational expertise to meet our clients' product development goals. We offer a full range of clinical trial services, including biostatistics, clinical monitoring, data management, global safety and pharmacovigilance, regulatory consulting, medical writing, project management, and full-service patient recruitment and retention.

Late Stage: We guide clients through the post-approval environment with a dedicated team of experts in strategic and operational planning, observational studies and patient registries, health economics and outcomes research, safety/risk management and epidemiology, and traditional interventional studies.

Strategic Resourcing: Our broad capabilities and worldwide resources allow us to tailor resourcing solutions on a global scale. We deliver the right resources, customized to our clients' needs, and continually look for ways to reduce costs, enhance quality, and deliver timely results.

Bioanalytical: With two North American laboratories and over 40 years of experience in offering bioanalytical service excellence, inVentiv Health Clinical delivers the best turnaround times in the business. We have the highest capacity for small molecule analysis and the largest suite of Mass Specs in the industry. We provide comprehensive analytical support of preclinical and clinical studies for small or large molecules.

Technology: We provide comprehensive support services for a variety of clinical trial data management and EDC systems. Our technology services are built on fully validated business continuity plans, redundant data storage, and timely backup procedures to ensure the integrity of clients' data. We offer a complete IVRS/IWRS and eDiary solution that is easy to deploy, scalable, and compliant with 21 CFR Part 11.

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WWW
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NUMBER OF EMPLOYEES
6,500

DATE FOUNDED
1995

Advancing Clinical Innovation

inVentiv Health Clinical combines state-of-the-art clinics and bioanalytical labs, leading therapeutic expertise in Phase II-IV, and customizable strategic resourcing approaches to provide a full range of clinical development services to accelerate drug development.

- Global Footprint: A top 5 CRO operating in more than 70 countries
- Therapeutic Excellence: Leading therapeutic expertise aligned to all stages of development
- Patient Recruitment and Retention: Data-driven and research-informed communication strategies to maximize effective patient recruitment and retention
- Late Stage Expertise: Effectively generating and persuasively communicating evidence of real-world safety and value
- Strategic Resourcing: Adaptive, cost effective solutions from contingent staffing to functional models and staff lift-outs

inVentiv Health clinical

www.inVentivHealthclinical.com/innovation.act

LabConnect

Specialized Testing | Biostorage | Clinical Kits | Global Network | SciOps | Sample Tracking

Corporate Description

LabConnect provides global central laboratory services including routine and esoteric laboratory testing, kit building, sample management and tracking, biostorage, and scientific support services for its biopharmaceutical and CRO clients. LabConnect currently has over 25 locations worldwide and central laboratory capabilities on six continents.

Services

Specialized testing. With more than 4,000 validated tests across its network, LabConnect can handle everything from general safety testing to the most complex molecular diagnostics and biomarker analyses. LabConnect's extensive test menu includes a broad range of validated assays and diagnostic platforms as well as method development and validation services.

Specimen tracking. LabConnect's real-time specimen tracking service, SampleGISTICS™, follows the clients' specimen samples from collection through logistics to receipt at any lab or storage location in the world. LabConnect provides enhanced visibility of each individual sample and our advanced virtual accessioning process enables immediate query resolution, thereby improving efficiencies for our clients.

Scientific operations support. LabConnect provides dedicated contract scientific professionals based upon the specific functional expertise our clients require. Our SciOps services give clients management control without the time and cost strains of managing internal headcount, payroll, and human resource issues. These personnel have the scientific knowledge to handle intricate clinical protocols and the management of our clients' internal and external research and development projects.

Biostorage solutions. LabConnect offers a comprehensive suite of biostorage solutions for multiple sample types. LabConnect ensures our clients' specimens are accessible for prompt retrieval and shipment, while maintaining the correct temperatures according to our clients' protocol.

Clinical kits. LabConnect custom designs, builds, and distributes visit-specific collection kits with pre-labeled tubes to minimize errors. Our kits are consistently rated as some of the best in the industry by investigator sites. Our clients can easily order kits and check inventory online using our innovative KitREACH system.

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DATE FOUNDED
2002

PRA

Corporate Description

As the world's fourth largest CRO, PRA is transforming clinical trials through our people, innovation, and transparency. We combine therapeutic and operational expertise with local knowledge to serve clients across all phases of drug development. Our successful history of helping to bring new drugs to market demonstrates our successful approach to clinical research.

With operations in 80+ countries, we seamlessly deliver comprehensive clinical trial and Strategic/Embedded staffing services through advanced technological tools and finely tuned systems. Our strategic growth, operational transparency, and forward-thinking approach have positioned us to meet the demands of a diverse marketplace.

Major Products/Markets Served

PRA performs studies globally across all therapeutic and phases (I-IV) of drug development. Over the last 30+ years, we have amassed a level of expertise that enables us to work on a variety of compounds, ranging from niche treatments and therapies to blockbuster drugs. PRA clients further benefit from our strategic investment in key therapeutic programs and research areas, including neurology/psychiatry, oncology/hematology, biosimilar products and rare diseases.

Major Services

PRA's core services:

- Phase I-IV study management
- Phase I clinic and bioanalytical lab "pairings" in the United States and Europe
- Bioanalysis (both large and small molecules)
- Therapeutic expertise (feasibility studies, protocol design, and scientific support)
- Post-approval study/registry management
- Safety and risk management/pharmacovigilance
- Embedded Staffing Solutions

Services that Differentiate

- **An evidence-based strategy** for country/site selection in clinical trials, employing public and private data-mining and medical informatics to enhance recruitment
- **World-class therapeutic expertise** including our own drug development experts, regional key opinion leaders and robust investigator network
- **Industry-leading Early Development Services** group that features state-of-the-art clinics in Europe and the US, with bioanalytical laboratories in close proximity to each
- **Early patient pharmacology services** in Europe and the US, specializing in renal/hepatic impairment, and CNS studies including Human Abuse Liability (HAL)
- **A newly formed Strategic Solutions Division** that provides Phase I-IV full service and innovative embedded staffing services

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NUMBER OF EMPLOYEES
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DATE FOUNDED
1976

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NUMBER OF EMPLOYEES
2,200

DATE FOUNDED
1967

Corporate Description

The pharmaceutical industry trusts PCI for the packaging solutions that increase products' speed to market and opportunities for success. Only PCI brings the proven experience that comes with more than 50 successful product launches a year and over four decades in the healthcare business. Leading technology and continued investment enables us to address packaging needs throughout the product life cycle—from Phase I clinical trials through commercialization and ongoing supply. Our clients view us as an extension of their business and a collaborative partner, with the shared goal of improving patients' lives.

Major Products/Market Served

We offer global packaging and distribution services, supporting programs in over 100 countries worldwide through our global distribution network. Project management and support services are offered across two continents, ensuring seamless trial support for your program.

Major Services

Packaging Services

- Blister packaging
- Pouch/sachet filling
- Bottling
- Kit assembly
- Tube filling
- Vial/syringe labeling
- Custom device assembly
- Compliance prompting packaging
- Walleting
- Expiry date extension
- Sch II-V controlled substances
- Refrigerated storage and cold chain distribution
- Penicillin products
- Cytotoxins and potent compounds
- Storage
- Distribution
- Returns management and destruction

Program Support

- Project management
- Package design and development
- Cross-continent CT services
- Labeling services including randomization, code breaks, and multi-language capabilities
- On-site laboratory services including analytical, microbiological, method development, import, ICH stability testing, and EU product release
- Child resistant/senior friendly packaging
- Comparator product procurement
- Over-encapsulation and placebo capsule manufacture
- Cold Chain including 2 to 8 C, -20 C, and -80 C
- QP services
- Web-based connectivity
- Fourteen global facilities audited by regulatory agencies including FDA, MHRA, DEA, Home Office, and ISO

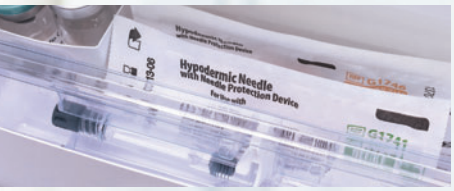
Recent Developments

In May 2013 Frazier Healthcare and Packaging Coordinators, Inc. completed the acquisition of AndersonBrecon, Inc. from AmerisourceBergen Corporation. The combined PCI provides unparalleled expertise in a range of proprietary pharmaceutical and biotechnology packaging innovations for healthcare clients across the globe.

Packaging Coordinators, Inc.

Our Commitment

To Deliver an Exceptional Customer Experience.



Successful Clinical Trials Start Here.

We believe our customers deserve nothing less than exceptional service, at every stage of their product's development, from each phase of clinical development to successful commercialization. Our experienced team offers expertise in all aspects of clinical packaging, storage, and distribution services. We are with our clients every step of the way, providing scalable solutions to support the earliest Phase I studies to the largest global Phase III/IV studies.

The ultimate measure of success is commercialization of your product, and PCI helps navigate the clinical phases in launching over 50 new products a year. Our expertise helps clients bring products to market efficiently and effectively, with keen insights to enable launch and commercial success. With an expert team focused on your investigational product, PCI is uniquely positioned to support your product throughout its life cycle.

Exceptional customer support for the success of your clinical trial.

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- Global Storage & Distribution
- Life Cycle Support

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www.pciservices.com

Packaging Coordinators, Inc.

Spectra Clinical Research

Nicholas Brownlee, PhD, President

We pride ourselves in working side-by-side with our customers to understand their specific needs and move their trial toward success.

Corporate Description

Spectra Clinical Research provides central laboratory services to pharmaceutical companies, academic institutions, and other medical organizations conducting Phase I–IV clinical trials. Backed by over a decade of clinical trial expertise and 30 years of central laboratory services to the dialysis community, we are able to support diverse clinical trials of all sizes.

Spectra Clinical Research acts as a unique resource for organizations conducting clinical trials. As a division of Spectra Laboratories, we leverage the capacity and technology of a large organization while maintaining the flexibility and responsiveness of a small specialty laboratory. We continually review and streamline our processes to ensure timely, accurate results. Furthermore, our advanced testing platforms, specimen management, online data management application, and dedicated team of service specialists help move each trial toward a successful outcome.

Markets Served

Spectra Clinical Research provides central laboratory services to pharmaceutical, biotechnology, research, government, and academic organizations. We have participated in trials spanning a wide range of therapeutic areas including nephrology, gastroenterology, oncology, women's health, and central nervous system (CNS) disorders. Our global support network ensures continuous, reliable service for clinical trials in locations worldwide including North America, Israel, South America, Europe, Australia, South Africa, Asia, and India.

Products and Services

- A dedicated project manager prepares all study-specific documents, coordinates activities with partner laboratories, and attends investigator meetings.
- Specially trained personnel shepherd each sample through the laboratory.
- Designated customer service representatives assigned to each study ensure personalized assistance throughout the trial.
- Support for numerous esoteric tests includes soluble transferrin receptor, aluminum, zinc, I-PTH, and others.
- Microbiology department offers 24/7 testing services for bacteriology.
- Pediatric testing services.
- ELISA and EIA tests can be set up and validated.
- Advanced web-based reporting and data management.

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How high?

At Spectra Clinical Research, we believe you deserve more than clinical expertise from your **central laboratory** partner. You deserve responsiveness and flexibility. That's why our dedicated project managers and customer service specialists make it a point to understand your unique needs and deliver unmatched support every step of the way. It's also why we're always updating our state-of-the-art facilities and streamlining our processes to deliver accurate results—on time, every time.

Give us a call today, and see how high we'll jump for you.
1-800-517-7157 or visit www.spectraclinicalresearch.com

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Myoderm

Corporate Description

Myoderm is a world leader in the sourcing, distribution, and management of pharmaceutical products and supplies for clinical trials, including biosimilar trials. Our clients span the globe and include biotech companies, CROs, clinical trial packagers, and a majority of the world's top 10 pharmaceutical companies.

At Myoderm, we pride ourselves on our proven ability to secure the products and supplies our clients require with superior speed, efficiency, and economy. Through our deep expertise, innovative approach, and commitment to personalized service we offer two unique sourcing solutions to meet our clients' needs.

Services and Capabilities

GlobalSource—GlobalSource uses our international network of manufacturers and suppliers to access any quantity and type of drug you need for clinical trials. This includes branded, generic, and OTC products in all therapeutic classes and dosage forms, as well as hard-to-find medications.

GlobalSource Benefits

- Access to restricted/hard-to-find drugs through our relationships.
- Transparent pricing.
- Consultative guidance to analyze individual challenges and pinpoint customized solutions.
- Product integrity maintained with our secure GMP facilities.
- In-depth knowledge of global markets.

CentralSource—CentralSource is a revolutionary turnkey service that centralizes the sourcing, distribution, and inventory management of rescue, concomitant, and standard-of-care therapies for clinical trials. With CentralSource, all drugs and supplies are consolidated at our distribution facility, which then directly supplies each trial site on an ongoing, as-needed basis.

CentralSource Benefits

- Volume cost savings from consolidated sourcing.
- Standardized products ensure trial integrity.
- Drug pooling across multiple protocols minimizes waste.
- Detailed reporting and established resupply levels ensure accountability.
- Recall monitoring and lot traceability protect trial integrity and patient safety.
- Invoice consolidation and detailed reporting streamline administration.

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DATE FOUNDED
1987

SynteractHCR

Boutique Experience on a Global Scale
As a dedicated full-service multinational CRO, SynteractHCR has more than two decades of experience supporting biotechnology, medical device and pharmaceutical companies in all phases of clinical development, across multiple therapeutic areas. We have managed over 3,500 projects across all phases of clinical development, and have contributed to more than 200 product approvals.

We work closely with you to customize programs, using our Intelligent Clinical Development (ICD+) approach to deliver timely, high-quality data to help you get to decision points faster.

Our Services
- Project Management
- Clinical Operations
- Data Management
- Interactive Response Services
- Medical Monitoring
- Medical & Regulatory Affairs
- Medical Writing
- Biostatistics
- Safety

Therapeutic Expertise
Our breadth of experience guiding companies in the clinical trial process extends across indications and offers notable expertise in oncology, CNS, infectious disease, endocrinology, cardiovascular, respiratory, and ophthalmology.

Shared Work—Shared Vision
This is the way we do business, a promised standard that includes ongoing support from a specialized team dedicated to meeting or exceeding your expectations. It is our longstanding philosophy, developed to convey our collaborative, customized approach tailored to your needs.

Geographic Footprint
SynteractHCR operates in 16 countries, offering our clients strong international and regional clinical trial support throughout the world. Our geographic footprint extends from North America to Europe, into Israel, and includes an emerging presence in South America.

Longstanding experience and talent
With longstanding therapeutic experience and deep clinical trial know-how, our experts can help you in making smarter decisions with confidence.

Accessible team of experts
Any time, any level, anyone. SynteractHCR offers you direct access to our executive, senior management and project teams.

To learn more please call us at 1-760-268-8200 or visit www.syneracthcr.com

Check out our online resources to download detailed case studies, articles, and videos. www.syneracthcr.com/NewsEvents/Resources

SynteractHCR

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NUMBER OF EMPLOYEES
800

DATE FOUNDED
1988

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Virtual CRA Meetings: Promoting Discussion, not Silence

Virtual CRA meetings hold a lot of potential, but work still needs to be done to ensure effectiveness.

Luizinha Monteiro, CCRP
Lead CRA, Quintiles
Contributor, ClinOps Toolkit Blog
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Ineffective meetings are frustrating for everyone. Due to lack of participation, important information is often repeated which results in lost interest and decreased attendance. The purpose of virtual meetings is to communicate study information and decisions. It's a forum in which ideas are shared and resolutions brainstormed. These meetings, as currently conducted, are unproductive.

CRAs need information for their job performance and outlet to communicate issues. Recently, I completed some online "effective meeting" trainings. While the information was interesting, its relevance was limited since it was regarding face-to-face meetings, not virtual meetings. The question still remains how to create a more effective virtual meeting.

I came up with the following ideas:

- Be clear on the purpose of the meeting. The team needs to understand the purpose and the value of attendance and participation.
- Decrease distractions. The Lead should communicate participation and attention expectations beyond placing phones on mute. The CRAs should listen, take notes, ask questions, and offer suggestions.
- Start and end meetings on time. Don't devalue the time of those that are punctual by having them wait for those that are tardy.
- Record the meetings and emphasize attendance. Attending the CRA meeting is not suggested but mandatory. If they are unable to attend, CRAs should review the recording and the Lead should follow-up with the CRA to ensure understanding. This extra step will reduce the risk of important information being missed and decrease the necessity to repeat information.
- Involve CRAs in the meeting agenda/purpose. Generally, Lead CRAs create an agenda, detail, and presentation. The Lead CRAs aren't dealing with the day-to-day issues, therefore, shouldn't be the sole contributors of the meeting topics. CRAs should be encouraged to contribute toward agenda topics to improve the meetings' relevance and create a collaborative environment.
- Follow-up on action items. If an issue was escalated and resolution ideas suggested, follow-up with the CRAs during the next meeting. This improves CRA accountability and demonstrates the Lead CRA's interest in the CRA's success, as well as emphasizes the importance of timely resolution to the team.
- Ask specific questions. To ensure understanding of new processes, call on people and ask specific questions. "Jane, if a discrepancy is noted, who should you contact?" is much more effective than "any questions?" Use of direct questions should be limited to curb feelings of being picked on or tested. The purpose isn't to isolate but to engage the CRAs.
- Limit discussion to agenda topics. While we want to encourage participation, we need to ensure that the agenda items are fully addressed and the meeting ends on time. Ad hoc items can be tabled to the end of the meeting if time is available, off-line, or added to the next meeting agenda.
- Detailed meeting minutes, not a general overview. Recordings are only available for a limited time, so once the recording is gone, discussions and decisions are lost.

With change there may be other unforeseen challenges, the meetings need to be focused and collaborative and the above are some simple ideas that can be implemented for a successful team environment. What are some things that you are doing to engage your virtual study team and have effective and productive meetings? Visit www.clinopstoolkit.com for discussions.

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