CPC Quarterly

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CPC provides an unbiased forum where biopharmaceutical companies and clinical service providers can collaborate to improve the clinical development process.

Principal Reason for Losing Investigators and How to Remedy

Michael O. Regentz, CSI, CeBSA,
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Some Principal Investigators participating in clinical trials complain that they are not being paid on time and/or the right amounts according to their contract! According to those PIs, poor payment processing is the major reason for choosing to not participate in more trials for a given sponsor. One PI said, "I did my part, on time, and properly, but, I had a devil of a time getting the sponsor to pay me on time for the correct amounts."

Clinical data and project information volumes grow exponentially when a sponsor or CRO expands from conducting Phase II to larger Phase III trials. A component of this growth is the number and degree of complexity of investigator contracts in conjunction with the amount of paperwork necessary to properly pay the investigators.

In an effort to increase the rate of retention of good investigators who have proved competent, sponsors, CROs, and SMOs have expanded the scope of Clinical Trial Management Systems (CTMS) to help manage payment processing. One result has been improved relationships with investigators. An additional and directly measurable benefit is lowered cash reserves in banks which are often required when the CRO is managing payments for sponsors.

However, it is short-sighted to deploy a CTMS without incorporating investigator payment processing into the overall "processing architecture" of the CTMS. Payment events must always map directly to measured clinical trial events in order to reap potential benefits. By using one system to manage clinical and payment events, the time required to reconcile payments to clinical events is greatly reduced.

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Clinical Providers Consortium's First Annual Meeting

The Clinical Providers Consortium will be holding its first annual meeting on **Wednesday, September 14, 2005 from 1:00-4:00 PM** following the conclusion of the IBC Biopharma Life Sciences Conference being held September 12-14, 2005 at the Hilton Boston Logan Airport Hotel.

The meeting will be open to member and non-member companies with a dedicated session to companies interested in joining. As a Consortium member, you will be an active participant in developing industry standards, establishing best practices, providing a common forum for information sharing, and innovating our industry.

The objectives of the meeting will be as follows:

- Goals for FY 2006
- Committee Formation
- National Perspective
- International Perspective
- Membership Drive for 2006
- Introduction of the Officers

We look forward to seeing you in September!

Accelerated and Improved Site Feasibility, Training and Activation

Basic building blocks for a successful trial

Lance Converse, CEO, ePharmaLearning

The keys to improving a clinical trial's operational success include selecting the best sites for the study, ensuring those sites clearly understand the protocol and study procedures, and are activated efficiently. By focusing on these three fundamental building blocks of study launch, Pharmaceutical companies and CROs can improve site performance and quality while reducing cycle-times and cost.

BETTER SITE PROFILING AND SELECTION

Selecting the best sites for a study begins with ensuring they have the right patients, experience and capacity to be successful in your trial. Although there are no guarantees that patient population profiling will always result in overenrolled studies, one could improve those odds substantially by using de-identified insurance claims data to help make better site selection decisions from the onset… kind of like selecting the hitters with the best batting averages.

The use of de-identified decision support data such as insurance claims and prescriptions used to estimate a sites' patient population has risen in popularity over the last few years. By combining clinical experience data (1572s), claims data (ICD-9s) and prescription data, with a study-specific online screening/ feasibility process conducted by a trained

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Founder's Corner

We would like to start out by thanking Winchester Business Systems and ePharma Learning for their contributed articles to this issue of the CPC Newsletter. We invite you all to submit articles for our upcoming newsletters. We recommend that you keep the article in the range of 500-1000 words in length and select a topic that covers a pressing issue or emerging trend in your segment of the market. Email your articles to us at info@clinicalproviders.org.

In future editions of the newsletter, we are going to create a new section titled "Industry Feedback Corner". We want to gather your feedback on the industry: whether it's a reaction to a previous article or topic of the newsletter, a hot question you'd like to pose to the industry, a reaction to or summary of emerging trends, a suggestion for the consortium, or a general statement about the state of our industry. Your feedback can be in the form of a sentence or paragraph, whatever the length, we will look to publish it in upcoming newsletters. **To submit your feedback, simply email us at info@clinicalproviders.org** and let us know that your feedback is for inclusion in the "Industry Feedback Corner". As we receive your feedback, we will include it in upcoming issues of CPC Quarterly.

We hope you enjoy this issue of CPC Quarterly and encourage you to share it with your colleagues. We look forward to seeing many of you at the first annual meeting in Boston.

Principal Reason for Losing Investigators and How to Remedy (continued from page 1)

To illustrate:

- If you wish to compensate the investigator for all subject screening visits, you must count, track, and reconcile the visits in the CTMS with the event payment details;
- If you wish to compensate the investigator for IRB or lab pass-thru payments, there must be a way to specify these payment events within an investigator contract and to track the actual event occurrences within the CTMS; and
- If you wish to compensate an investigator for completing specific trial milestones, there must be a mechanism for recording the completion of the milestones and generating a payment event.

It is important to note that you have made a good first step in deciding on a single-system approach to project management and relationship management in your CTMS. In addition to that first step, here are the critical factors and common steps which have produced results for companies who are successfully managing investigator payments using a CTMS:

1. Accounting works closely together with Clinical Operations to define the elements that comprise proper payments to investigators.
2. Design the Accounting System, Chart of Accounts, and the CTMS to work alike even if not directly connected to each other.
3. Design a "Master Investigator Contract" that includes all of the items applicable for a particular trial – use this model for all future trials.
4. Ensure that there is a reasonable way to measure all contract items and milestones for payments.
5. Do not expect investigators to send invoices that are consistent and payable.
6. Plan for pass-thru payments for IRB's, ad agencies, travel, and others.
7. Allow for unplanned events to occur during a trial that may require an investigator payment.
8. Link payment events to actually measured events within the CTMS.
9. Establish investigator milestones that have truly measurable points.
10. Derive the individual Investigator Contracts from the Master Investigator Contract – do not define measurement or payment events that are not part of the Master Investigator Contract.
11. Assign responsibility for processing investigator payments to essentially one person in Clinical Operations as well as one person in Accounting (Accounts Payable).
12. Establish a "fixed schedule" for processing investigator payments – once a week, every two weeks, once a month, or once a quarter.
13. Ensure that there is "feed back" between the accounting process/system and the clinical process/system to indicate when a check has actually been sent to the investigator including the payment event detail.
14. Create Investigator Payment Progress Reports that illustrate Investigator Progress in trial and financial terms simultaneously.

Sponsors and CROs spend a significant percentage of their budgets recruiting, developing relationships with investigators, and training clinical sites to run trials for them. Being paid on time is certainly incentive for investigators to continue participating in your clinical trials. Although inaccurate payments may not be the only reason given by the investigator for severing a partnership, it should definitely not be the major roadblock to continuing to conduct trials for you. And that is, because it is preventable.

It has proven fruitful for companies to move from a disorganized, multi-system approach to an approach where everyone involved in the trial – including marketing and finance - is working from the same database. Of course, the data in the database is sensitive and it is necessary to have an integrated, centralized security model that provides access to the kernels of information in a granular way – by role (administrator, clinical operations, finance, etc) and type of access (deposit/read, edit, approve, etc). ■

Accelerated and Improved Site Feasibility, Training and Activation (continued from page 1)

enrollment specialist, will generally result in improved enrollment rates.

Starting with a database that includes the universe of experienced investigators, ranked by their patient populations, trial experience, and responses to effectively designed online feasibility tools, will increase your pool of potential investigators, improve your chances for meeting enrollment goals, and accelerate site selection timelines.

ADULT-LEARNING ENRICHED STUDY TRAINING

Improving the protocol and study procedure training process could arguably yield the best return from a cost saving and site performance perspective. Major pharmaceutical companies pay more than $350,000 for a 75 site in-person Investigators meeting without any verification the sites understand the protocol, study procedures, or technology required to conduct the trial. In an effort to reduce cost, many pharmaceutical companies are turning to webcasts in lieu of the expensive in-person meetings.

This can be a dangerous proposition if the right process and tools are not in place. In today's technology-driven clinical trials environment, site must be provided with effective live and "on-demand" online training that incorporates adult learning theory with interactive exercises and assessments to certify completion and verify content comprehension.

The result of a well-designed online protocol and study procedure training program will result in 60% improvements in protocol comprehension and 40-50% improvements in site data quality at more than 70% cost saving to traditional in-person Investigators' Meetings.

IMPROVED ACTIVATION & COMMUNICATION

The increase of technology-enhanced clinical trials in addition to the complexity of protocols and study procedures is straining an already over-worked workforce of Investigators and Study Coordinators – future customers of the pharmaceutical industry. Using portal technology to help provide sites a single online place to go for all of their study needs certainly helps accelerate and improve the study launch process for Sponsors while streamlining and systematizing study launch for site staff. In fact, a recent survey of more than 1500 sites revealed that the most appealing (out of 20 possible things a sponsor could provide) was "a single place to go online for all my study needs"… patient recruitment assistance was number 18 of 20.

The Investigator Portal allow sites to log-on to one secure workspace to complete feasibility surveys, online study documents, online protocol/procedure training, and link to clinical trial applications such as EDC and trial management technologies. The system time-stamps and tracks all user and training activity for study and site progress reporting. Further more, portals will track this information across protocols, to auto-populate forms, track completion of didactic training, etc. shortening study start up for site staff – something critically important in today's environment.

In order to improve clinical cycle-times and site quality, pharmaceutical companies can improve the three important tasks associated with site activation while achieving significant cost saving. Converting 100 studies to online site activation can result in cost savings of more than $40 million dollars per year. ■

ePharmaLearning is a global leader in improving and accelerating site feasibility, study education, and project launch.

CPC VOLUNTEERS NEEDED!

The Clinical Providers Consortium is currently looking for individuals to participate on the following committees:

- Communications Committee
- Events Committee
- Finance Committee
- Industry Liaisons
- Purchasing Committee
- Regional Committees
- Steering Committee

If you are interested in joining one or more of the above, please email us at info@clinicalproviders.org.

Are You a Sponsor Company?

We Want Your Feedback

The CPC invites you to participate in our quarterly newsletter. We invite you to use our newsletter as a forum to voice your perspective on the industry.

We would like the opportunity to hear your vendor relationship experiences. Perhaps you have a great success story or maybe there is a hot topic you want to address, we even want to hear your complaints! As vendors, we want to know what we need to improve on to better serve your company.

If you would like to submit your comments and suggestions, please email the CPC at **info@clinicalproviders.org** and note that your feedback is from a Sponsor companies perspective. We look forward to hearing and learning from you!

CPC Welcomes Its First Charter Members: Winchester Business Systems & MEDTOX Scientific, Inc.

The Clinical Providers Consortium is pleased to announce Winchester Business Systems and MEDTOX Scientific, Inc. as the first charter members of the Consortium. We are excited to have these two companies join us and we look forward to collaborating with them in the future.

Winchester Business Systems, Inc. is a leader in providing software and implementation services to Life Sciences companies worldwide. Winchester's software solutions include applications for the Life Sciences, Health Care, Government, Financial and Manufacturing sectors as well as security and other compliance solutions across all industries. Winchester's Professional Services Division works collaboratively with the client to ensure the success of each implementation or engagement.

MEDTOX® Scientific, Inc. is a company committed to technology, quality and service. The company has two operating divisions - MEDTOX Laboratories and MEDTOX Diagnostics. MEDTOX Laboratories, located in St. Paul, Minnesota, includes our SAMHSA-certified drug testing laboratory, esoteric clinical laboratory, Clinical Trials Services division and Consolidated Medical Services group. MEDTOX Diagnostics, located in Burlington, NC, operates a manufacturing plant for diagnostic drug screening devices.

Clinical Providers Consortium's First Annual Meeting-Boston, MA

September 14, 2005
1:00-4:00pm
Hilton Boston
Logan Airport Hotel

For more information, please visit www.clinicalproviders.org

Are YOU a CPC Member?

The Clinical Providers Consortium is open to all vendors and service providers that work with pharmaceutical, biotechnology and medical device companies.

We encourage you to join CPC to take advantage of the following member benefits:

- Listing on the CPC Website with link to your company home page
- Networking with service providers throughout the industry
- Committee participation
- Publications including the CPC Quarterly Newsletter
- Industry conferences, meetings and seminars
- Discounts with product and service providers (car rentals, office sup plies, insurance providers, etc)

Membership fees are due on a yearly basis and are based on number of company employees.

The Consortium invoices based on a fiscal year of September 1 - August 31. The Consortium is designated as a 501(c)(6) trade association. Membership dues may constitute a business expense but not a charitable donation.

Please visit our website at **http://www.clinicalproviders.org/howtojoin.htm** for more information and to download a copy of the membership application.

Contact Us

For more information about the Clinical Providers Consortium or if you would like to submit an article or topic suggestion for future issues, please email us at **info@clinicalproviders.org**

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