Letter from the Chair

Nimita Limaye, PhD, CCDM

Dear Members,

Welcome to the Winter Issue of Data Basics!

Despite Hepatitis C being one of the most important causes of chronic liver disease, the current standard of care (SOC) works for less than 50% of the patient population. Diagnostic FDA approved PCR tests have demonstrated that HCV protease inhibitors such as Telaprevir and Boceprevir, when used in combination with peginterferon and ribavirin, result in a dramatic decrease in the viral load. This issue of Data Basics focuses not only on hot topics such as this, but it also reflects upon the much discussed ‘eSource draft guidance’ released by the FDA. It dwells upon the art of designing CRFs par excellence and stresses upon the difference that effective edit checks can make to the quality of data.

This has been a year well spent, with nine webinars conducted on key topics such as adaptive trial design, biostatistics, data integration, lean six sigma, CDISC standards, device trial strategies and metrics. Eight online courses on hands-on topics including query processing and tracking database updates, SAE reconciliation, data management plans, safety review and coding, 21 CFR Part 11, data trending, processing lab data and project management were also conducted. Task forces worked hard to review and provide valuable feedback to the FDA on the ‘eSource’ and the ‘Risk Based Monitoring’ guidances, endorsing SCDM’s stature as a thought leader and key contributor on global rulings. We have exceeded last year’s numbers, with a total membership of over 2700, with over 700 new members joining SCDM this year. Fifteen percent of our new members represent student members and no less than 30% of the new membership is global, primarily from India and the UK. The global recognition of the CCDM certification is apparent, with 30% of the over 550 CCDMs this year, representing global CCDMs, with almost 45% of these out of India. Our partnership with MCI, our new AMC with a global presence in the US, Europe and in India, complements SCDM’s global vision.

Personally, this has been an enriching experience for me. The steady warmth, acceptance and support of a board representing top global thought leadership, the prompt and able support received earlier from EDI and now from MCI, and the amazing encouragement and support that I have received from the membership all across the globe, has been overwhelming. To each one of you, for the confidence that you have placed in me and in SCDM, my sincere gratitude. We will work hard to live up to the trust that you have placed in us and do seek your support in endorsing SCDM’s position as the global leader in the field of data management!

Thank you and wishing you all a wonderful holiday season!

Dr. Nimita Limaye
2011 Chair
SCDM Board of Trustees
Letter from the Editors

Dear Readers,

The virology therapeutic area is deeply challenging, requiring innovation and commitment. As we have assembled the articles for this Winter’s Data Basics issue, we were struck by the complexity of virologic illnesses themselves (consider HCV or HIV/AIDS) as well as the complexities faced when developing treatments for them.

As is usual in Data Basics, we approach our topic from a variety of perspectives, with articles touching on different aspects of virology treatment development as well as more general issues. We open with Victoria Johnson's survey of the barriers that prevent diagnosis and treatment of the most well-known virologic disease, HIV/AIDS; we include an opinion piece regarding the FDA’s new draft guidance on electronic source data; and wrap up with an article outlining an HCV RNA monitoring system designed to make viral load data available quickly to assist in proper dosing.

In between, Kit Howard applies the latest research on forms design to CRF development, resulting in some fresh recommendations. And there is much more!

We hope this issue will give you a deeper look into the virology therapeutic area and with it new perspective and energy for your own important work.

Data Basics Co-Editors,
Derek C. Perrin and Janet Welsh

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2012 SCDM E-Learning

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Enabling Pharma companies to achieve their objectives with clinical efficiency.

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Multinational multicentric trials as well as technological changes in Clinical Data Management (CDM) have increased complexities and costs. Furthermore, the data coming in from multiple sites, coupled with the language barriers therein, have made the need for high-quality, cost-effective, end-to-end data management imperative.

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Background

During a summer session at Northeastern University in Boston back in 2001, I took a class on the Biology of HIV/AIDS. Since that summer of discovery, my interest in HIV/AIDS has only grown. Thirty years after the virus was identified we still know so little about it, yet it remains one of the most impactful biological entities of modern human history.

Fast forward to August of 2010, when I was asked to present a thesis topic for the conclusion of a graduate degree in Public Health; since the beginning of my graduate studies, I knew I would choose a thesis topic in the realm of HIV/AIDS. After much mulling, brainstorming and considering how my potential findings could positively impact the field of public health, I chose my topic: the question “What attitudes and barriers deter against following recommended HIV/AIDS testing practices among ethnic minority communities in Seattle, WA?”

The data I found, the people I met along the way, and the year-long journey I set out on changed and enriched my life forever.

Barriers to HIV Testing and Treatment

Historically, there have been negative attitudes and significant stigma exhibited by ethnic minorities against those living with or perceiving to have HIV/AIDS. This is especially evident in African American and Latino communities in the United States [1]. This stigma affects peoples’ opinions about HIV/AIDS and affects whether or not they seek out HIV testing or take preventive measures against HIV infection.

At the core, stigma and negative attitudes arise from fear and judgment. Since their emergence in the early 1980’s, HIV and AIDS have been associated with homosexuality, drug addiction, prostitution and promiscuity [2], [3, 4, 5] and are incorrectly thought to only affect small sub-groups of the population. Unfortunately, this belief flows down from generation to generation.

An extensive literature search also revealed other barriers to prevention and detection, such as not considering oneself at risk for HIV [5, 6, 7, 8] clinic access [9] and language barriers in health care [10].

The Interview Process

Through 12 qualitative in-depth interviews with both minority community members and experts in the field of public health, the goal of this study was to provide solid recommendations, based on feedback collected during interviews, on how to begin to overcome barriers to HIV testing.

The interviews began with general questions about attitudes and barriers to testing. Once a participant responded, that response was explored further. Questions were asked on where the negative attitudes and barriers arose from, why they continue to exist and whether they have changed over time. Then participants were asked to suggest ways to overcome these attitudes and barriers. Experts were further asked about their organization and background related to ethnic minorities and HIV. Community members were asked about their educational experience when it came to HIV and how they have seen their peers affected by the disease. Both groups were asked for closing thoughts for the public health community.

Digging into the Findings

After months of interviews, several themes emerged from the data. Emotional barriers, such as fear of knowing a positive result, fear of being sick, fear of death, fear of testing confidentiality and loss of anonymity, fear of community judgement, denial of risk and distrust in the medical community, were noted. Non-emotional barriers, such as poor access to healthcare, testing logistics (i.e. childcare while testing), language barriers and poor HIV campaign messaging, were also found.

Most commonly mentioned were attitudes and barriers related to stigma and fear. Expert participant #5 had this to say regarding stigma: “…But again, until we deal with the root cause - religion or machismo; homophobia - we still have not dealt with those bigger, broader issues, we have not. They are just there fueling the disease.”

Additionally, expert participant #4 shared the following, “…you know, it’s a stigmatized disease because it’s sexually transmitted [pause] in the old days it was the four Hs; you could get it if you were one of the four Hs; heroin addict, Haitian, hemophiliac or homosexual [pause] if you didn’t fit the four Hs, then you weren’t at risk.”

Community Member participant #1 touched on a common concern: “…I think there was a lot of misinformation, people didn’t want to be…didn’t want to have any association with it at all, given the idea that they might be a person who is going to be a person with AIDS and get sick and die…that whole idea of the fear around what will you do if the answer is yes, you’re positive?”

Overcoming the Barriers

During the second half of the interviews, participants were asked follow-up questions about how these attitudes and barriers could be overcome, from their perspective. Eliminating the fear of talking about HIV/AIDS was the most frequently mentioned hurdle.

Participants speculated that if HIV/AIDS can be talked about openly, then it will be something that fewer people are afraid of. If we can spread the word that folks are living long lives on current treatments and are healthy then that will encourage more people to get tested. Said Expert Participant #1: “…We definitely have some opportunities to educate… I put it out there and call it like it is. That’s taking the power out of the stigma. Education is a big piece… it’s not, you know, promiscuous gay men in bathhouses spreading the virus anymore, you know, it’s wives and mothers and sisters and brothers and aunts and uncles, you know, the senior population- everybody is impacted by this virus.”

Continuing to talk about the problem will bring it to the forefront and help to resolve it. Key opinion leaders (i.e. church leaders, elected officials) can aid in this process and be more influential. Providing HIV education and awareness through churches in the African-American community is also recommended.
Going hand in hand with an open dialogue is further community education, especially through better HIV awareness campaigns: smarter multi-lingual, culturally-competent campaigns that highlight the universal risk for HIV and help normalize testing and education.

This type of focused education aims to empower people to “own” their health: to take advantage of free or low-cost testing services and to seek out preventive care and treatment.

Conclusion
Like the numerous biotech and pharma companies in our industry that strive to support HIV/AIDS patients and extend their lives with lifesaving treatments, the field of public health can be a partner striving to bring education, community involvement and better health care and testing availability to populations at risk for HIV. Looking forward, we must decrease discrimination, increase tolerance, promote acceptance and encourage individuals to be self-advocates and champions of their own health. We must aim to change the way we view HIV/AIDS as a disease so that it is clear that we are fighting the disease, not those who have it.

References

Victoria Johnson has worked as a Data Manager at Gilead Sciences in Seattle, Washington for the past 5 years. She holds a Bachelor of Science in Biology and is receiving her Masters of Public Health in December of 2011. Outside of work Victoria enjoys running and travelling to new places.
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Speed.
Hepatitis C Virus (HCV) Clinical Trials

By Stephanie F. Finn, MS; John P. MacNeela, MSPH; Rebecca Wilges RN, MSN; Amanda L. Beard, MS; Maggie De Pano, M-A; P. Mark Ward, MS; Lee M. Greiner; Linda M. Lillis, MT, MS

Abstract

The HCV RNA Monitoring System (HCV RNA MS) is a fully integrated, 21 CFR Part 11 compliant, web-based, decision support tool developed by the Duke Clinical Research Institute (DCRI) to monitor viral loads of patients participating in Hepatitis C Virus (HCV) clinical trials. The tool’s application of protocol-specific treatment recommendation algorithms and its presentation of data in a user-friendly fashion enable the DCRI’s clinical team to review treatment recommendations and make final treatment decisions for patients based on their viral loads in near real-time. This ability to monitor viral loads is critical to assessing patient responsiveness to guided therapy, providing patient treatment according to protocol-specific rules, and minimizing the emergence of resistant strains of the virus. Benefits also include the reduction of human error by providing a consistent and standardized approach to all treatment decisions and the elimination of manual effort and paper-tracking associated with performing calculations in spreadsheets and communicating decisions by fax or other manual method.

Hepatitis C and Treatment Overview

Over 180 million people worldwide are infected with HCV, with approximately 3.2 million chronically infected individuals in the United States. This blood borne infection can be transmitted through the exchange of intravenous needles, blood transfusions, and other blood products. The infection may be passed to children born to HCV-infected mothers and healthcare professionals may contract the illness from needle stick injuries. Less frequently, HCV is transmitted through sexual contact or through sharing of razors and other personal items. Individuals infected with HCV can be asymptomatic for many years and may be unaware they are infected until a routine physical exam reveals abnormal liver enzymes or a specific blood test reveals the presence of the disease. Patients chronically infected with HCV are at risk to develop additional liver diseases, including fibrosis, cirrhosis, and liver cancer (1).

For the past decade, patients infected with HCV have primarily been treated with a combination of pegylated interferon and ribavirin (PEG/RBV). There are six major genotypes of HCV and these exhibit very different responses to therapy. Between 70-80% of treatment naïve patients with genotypes 2 and 3 achieve sustained virologic response (SVR) when treated with PEG/RBV. However, treatment naïve patients with genotype 1 are much less responsive to PEG/RBV therapy with only 40-45% of patients achieving SVR. In addition to the large numbers of patients who do not respond to therapy or show only partial responses, the combination of PEG/RBV has many side effects including depression, anxiety, flu-like symptoms, nausea, skin rashes and other skin problems making the treatment difficult to tolerate for many patients (3).

New Therapies and Monitoring Viral Loads in Clinical Trials

The current focus of HCV treatment is the development of a new class of drugs that disrupt the replication of the virus. These drugs known as direct acting anti-virals (DAAs) include protease, polymerase, and helicase inhibitors. Earlier this year, the FDA approved two new drugs for the treatment of HCV. These drugs, telaprevir (Incivek) and boceprevir (Victrelis), are protease inhibitors, which act directly on HCV to slow down its replication. Adding telaprevir or boceprevir to pegylated interferon and ribavirin increases cure rates from less than 50% to approximately 65–75 percent for genotype 1 patients, and potentially shortens the length of treatment from about 12 months to approximately six months (4). This advancement, combined with the 2009 discovery of a variation in the IL28B gene that could assist in predicting treatment response for HCV patients, provides clinicians, researchers, and patients the hope that individualized patient care for HCV is on the horizon (5).

The discovery of the IL28B variation and the development of new DAAs, have led to an explosion in clinical trials targeted at HCV. Managing these trials is challenging for the clinical team and data managers as HCV protocols require frequent monitoring of patients’ viral loads at specified visits -- often weekly -- early in the study. Review of lab data is necessary so clinicians can assess the patient’s response and make treatment decisions based on protocol delineated rules. These decisions might include: continue on study drug/placebo, retest, discontinue study drug/placebo but continue standard of care (SOC), or discontinue all treatment. The number and type of decisions that are possible throughout the course of a study increase exponentially as the number of monitored visits, treatment arms, patient cohorts within each arm, and number of decisions applicable to each visit/arm/cohort combination increase (see Figure 1).

Additionally, real-time monitoring is important as viral resistance is a major risk associated with DAAs (patients who develop viral resistance should be removed from treatment). HCV has a high natural mutation rate which can lead to many millions of copies of virus in any one patient that are resistant to anti-viral therapy. A DAA that decimates non-resistant virions can possibly lead to rapid multiplication of resistant virions in the patient (6). Without a means of presenting viral loads to the study HCV monitoring team and communicating decisions in a timely and accessible manner to the sites, the study and patients are put at increased risk.

Continued on page 8

121 CFR 11 (Part 11) is the regulation that sets forth the criteria under which the FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

2Successful treatment, defined as an undetectable viral load 24 weeks after treatment has ended, is referred to as sustained virologic response at week 24 (SVR24).

3Successful treatment, defined as an undetectable viral load 24 weeks after treatment has ended, is referred to as sustained virologic response at week 24 (SVR24).
Figure 1- Number of Decision Algorithms Increases with the Complexity of Study

![Decision Algorithms Diagram]

Development of an Efficient Clinical Decision Support Tool

The DCRI solution to managing the risks, volume of information, and complexities associated with viral monitoring on HCV clinical trials, was the development in January 2011 of its HCV RNA MS a fully auditable, 21CFR Part 11 and Health Insurance Portability and Accountability Act (HIPAA)-compliant web-based tool. The HCV RNA MS was designed and developed through a collaborative effort of a DCRI cross-disciplinary team which included Clinical Operations, Clinical Research Informatics, Data Management, Information Technology, and Quality Assurance. The goal was to create a flexible, compliant, scalable, robust system that was capable of handling a wide range of study designs and would deliver high quality, valid data to the end users. The process from concept to rollout spanned a period of approximately one year. The tool has since been implemented on a Phase II study designed to test the benefit of adding a DAA to PEG/RBV. By the end of this first study implementation, it is projected that more than 3000 treatment decisions will be made for approximately 250 HCV-infected patients.

On earlier, smaller studies prior to the development of the HCV RNA MS, a DCRI monitor reviewed raw patient data from lab reports, made a recommendation, and forwarded the data and recommendation to a DCRI physician via fax or email. The physician reviewed the recommendation, made a decision, and sent it back to the monitor. The monitor created a site notification containing the decision and faxed it to the study site. The monitor utilized a spreadsheet to track workflow status, i.e., when lab results were received, when the recommendation was sent to the physician, when the physician made their decision, when the site was notified of the decision, and when the site confirmed notification of the decision.

This process was time intensive and involved multiple steps that were difficult to track and prone to transcription, calculation, or communication errors.

HCV RNA MS Prioritizes Users’ Work

With the development of the HCV RNA MS, the process has changed significantly. The system pushes relevant information to team members via user-type specific work lists. The HCV RNA MS user types are the administrator, monitor, physician, and site. The various user types are assigned roles and privileges that grant different levels of access to information in the system (see Table 1) making it easy to maintain the double-blind on studies where it is required. Site users (including site physicians) only have access to rendered treatment decisions and not HCV viral loads as these can reveal the patient’s treatment assignment.

When users log into the system, they are presented with only the work they need to do that day. This is a vast improvement over the earlier method in which monitors had to manually filter reports for newly received lab results and follow the cumbersome process outlined above. Additionally, greater efficiency is achieved because most recommendations go directly to the physician without any pre-processing by the monitor.

As a result of this improved workflow, physicians and monitors can focus their efforts on making a quality decision rather than on managing the quantity of data and documentation generated for each decision.

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<tr>
<th>User Type</th>
<th>Description</th>
<th>Blinding Status</th>
</tr>
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<tbody>
<tr>
<td>System administrator</td>
<td>Administers accounts, configures studies</td>
<td>Unblinded</td>
</tr>
<tr>
<td>Monitor</td>
<td>Monitors workflow, site responses,</td>
<td>Unblinded</td>
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<td></td>
<td>system-generated treatment recommendations, (in</td>
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<td></td>
<td>some cases) makes treatment recommendations and</td>
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<td></td>
<td>releases notifications.</td>
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<tr>
<td>Physician</td>
<td>DCRI physician. Makes treatment decisions</td>
<td>Unblinded</td>
</tr>
<tr>
<td>Site</td>
<td>Receives, confirms, and implements decisions</td>
<td>Blinded</td>
</tr>
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</table>

Table 1 - User Types, Role Description, and Blinding Status

HCV RNA MS Data Integrations, Calculations, and Decision Process

The HCV RNA MS integrates HCV viral load data posted by the central lab on DCRI’s secure FTP site, patient trial status from the Electronic Data Capture (EDC) clinical database, randomization information from the Interactive Voice Response System (IVRS), and subject and visit information from the Clinical Trial Management System.
HCV RNA Monitoring System Meets Critical Need to Monitor Patient Viral Loads in Hepatitis C Virus (HCV) Clinical Trials

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System (CTMS) (see Figure 2). Data from these sources is extracted, transformed, and loaded on a regular and frequent schedule.

After lab results are loaded into the system, the HCV RNA MS runs standard calculations on patients’ viral loads:

- Log10 of baseline viral load;
- Log10 current viral load;
- Log10 lowest recorded viral load post-baseline (nadir);
- Change between current and baseline viral loads: Log10 (current viral load) - Log10 (baseline viral load); and
- Change between current viral load and nadir: Log10 (current viral load) – log10 (nadir of viral loads)

The system then cross-references these calculations with response, nonresponse, and drug resistance protocol rules; and uses algorithms to recommend, e.g., whether a patient should continue study treatment, discontinue study treatment, or should be investigated further for resistance and/or non-response. Importantly, the system conserves the team’s time by only creating recommendations for monitored patients (e.g., patient is on study) and monitored visits.

Although most of the recommendations will post directly to the physician’s work list, in some cases a recommendation will post to the monitor’s work list before being passed to a physician. These cases in which additional human intervention is required include: rule-specified monitor review; the posting of a corrected lab result; an unscheduled lab, or lab with a collection date outside the visit window. The monitor investigates these exceptions before forwarding his/her recommendation to the physician’s work list.

The physician then makes a treatment decision on each system and monitor-generated recommendation. As the physician submits each decision, the system compares the physician’s decision to the system recommendation. If the physician recommendation differs from that of the system, the physician is prompted to either change the decision or confirm the decision. If confirmed as is, the physician must document the reason for the difference. This check serves two functions: it catches simple data entry errors, but also allows the physician’s judgment to trump the system’s recommendation in complex cases. After a decision has been finalized, the system sends an e-mail to the study site indicating that there is a decision pending and prompts site staff to confirm and print the decision for the patient’s record. If a site does not confirm receipt within three business days, the system will issue periodic e-mail reminders and alert the monitor that confirmation is outstanding.

Throughout this entire process, the system maintains a subject level record that contains all lab values, calculations, recommendations, decisions, notifications, and decision confirmations. The monitors and physicians have access to this record and can see the patient’s entire monitoring history at a glance. In addition to this viewable subject details record, the system maintains a detailed audit trail of all user actions.

**Conclusion**

The HCV RNA MS is a fully validated, secure system. The use of the HCV RNA MS for viral monitoring affords the opportunity to obtain high quality data quickly throughout the course of the trial. Rules programmed to the specifications of the study design ensure accuracy and consistency while reducing potential errors associated with workflow processes. This provides the means to make best recommendations and decisions throughout the trial. Proper decisions for guided therapy translate into a high level of patient safety. Communication and confirmation of events along with traceability and verification of data and workflow processes enhance both patient safety and data quality. Efficient processes built into and practiced throughout the course of the trial facilitate a reduction of time from last patient, last visit to database lock.

Continued on page 10
References

**Stephanie Finn** is a data manager with the Duke Clinical Research Institute (DCRI). Since joining DCRI in 2007, she has worked on Phase I, II, and III protocols mainly in the Hepatitis C and cardiovascular therapeutic areas. She is currently serving as Data Management’s Subject Matter Expert on HCV RNA Monitoring. Prior to joining DCRI, Ms. Finn managed databases for the US EPA and other government agencies for more than 10 years.

**John MacNeela** is currently working as a Lead Clinical Research Assistant at DCRI in the Clinical Operations department. His primary focus is on supporting Hepatitis C clinical trials with emphasis on providing support for the HCV RNA Monitoring System. He holds an MSPH and has over 25 years of experience in the life sciences and pharmaceutical areas.

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Understanding the Finer Points of the Electronic Source Documentation Draft Guidance

By Jonathan Andrus, VP, Data and Study Operations - BioClinica; Chair - DIA eClinical SLAC; Board Member – SCDM; Member – CDISC CAB

For those involved with collecting the data generated by clinical trials, the recent draft guidance released by the FDA deserves your scrutiny. The impact of this guidance for sites is significant and the implications for CRAs, data managers and technology vendors could be potential show stoppers. Since getting through this document may not be considered light reading by some, I’ve summarized the major points the guidance (as indicated in the draft guidance) was intended to address as follows:

- To eliminate unnecessary duplication of data
- To reduce the opportunity for transcription errors
- To promote the real-time entry of electronic source data during subject visits
- To ensure the accuracy and completeness of data (e.g. through the use of electronic prompts for missing or inconsistent data)

For the record, I agree that all these targets are laudable but I suggest the guidance needs some adjustments in several key areas.

The Mother of all eCRFs
One of the central points of this draft guidance concerns the role of a redefined eCRF. The guidance promotes the eCRF from its humble origin as the digitized form of a paper CRF to the nexus of all clinical data (electronic and paper-based) associated with a protocol. This is certainly a vision shared by many sponsors and technology vendors (though maybe via a system and not a form), but the reality is that the current standards, embedded technologies, and siloed purchasing habits will not support this goal for many years to come. Directly related to this expanded role of the eCRF is new language describing precisely how investigators should handle the processes surrounding the data flow.

More Work for Overburdened Sites
The data elements that make up the eCRF are the subject of both further definition and added girth. For example: when data elements are transcribed by an individual from a source clinical trial document into an eCRF, the recommendation is that they carry a data element identifier reflecting the originator responsible for entering the transcribed data element. This is just one example of the level of detail contained in this guidance.

Switching to a higher level view, when electronic source is used, the draft guidance indicates the following procedures and practices that add significant overhead for involvement in clinical trials:

- Principal Investigators should generate their own write-protected copy of the eCRF (the newly defined uber-integrated-eCRF) for the study
- Principal Investigators must maintain control of these copies
- A copy of the eCRF should be write-protected (read-only) at the time of Principal Investigator sign-off
- The Principal Investigator must review and sign the eCRF before any data is made available to IRBs or Sponsors
- Procedures for selecting appropriate data elements out of an electronic health record for use in the eCRF must be in place
- A list of prospectively determined originators (persons, devices and instruments) must be maintained, on-site

Are there safety issues if un-reviewed data is unavailable to sponsors and IRBs? Does this mean a return to on-site servers and replicated databases or ‘simply’ gold copy CD’s on site? The current recommendation would appear to require the programming of interfaces to electronic medical records and clinical systems at each site. This is beyond even the largest sponsors’ abilities today. Apart, each of these guidelines could add procedural and administrative overhead at sites for the conduct of clinical trials. Together, they might well convince many investigators that it’s not worth the trouble.

Related to the added site overhead, the job of the CRA just got a lot more technical. CRAs will require a thorough understanding of database design and audit trails as well as becoming experts with the technologies used at the site.

It’s a Small World, Right?
It’s a fact that most Phase III clinical trials are now multinational. Changes as substantial as the ones proposed in this guidance must be synchronized with the other regulatory agencies worldwide to be either effective or practical. Electronic health records (EHRs)? Meaningful integration with EHR systems will probably require an international mandate to standardize those systems, too.

This draft represents a curious mix of recommendations. Some appear to go backwards and ignore the capabilities of current systems and others leap so far ahead that they border on wishful thinking.

There are huge, relatively near-term potential benefits associated with aspects of this guidance such as the remote monitoring of electronic clinical trial data. A clear definition of what is acceptable in this regard could result in worthy savings and operational gains for sponsors. I urge the FDA to clarify guidance supporting near-term efficiencies that can help our industry to thrive on the way to the electronic nirvana.

Originally published in PharmaVoice June 2011
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A case report form (CRF), according to the ICH E6 Good Clinical Practices guidance, is “a print-ed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.” CRFs guide the capture of the trial’s key product, namely the data, and lie at the heart of clinical data management. With few exceptions, all organizations involved in clinical research directly or indirectly produce CRFs, and a body of knowledge has accumulated around their design and use. As with most disciplines in clinical research, forms design has looked primarily within its own ranks for that knowledge, but forms are used in almost every walk of life, and the internet has both fueled a burst of research into what makes a good form (think e-commerce) and also made previous research on paper-based forms more widely available. This article looks at some of that research and suggests ways it can enhance current CRF design practices. It also challenges some long-standing “rules” that appear in virtually every CRF design presentation.

Current Rules
Clinical data management has developed a set of rules about good CRF design that are documented in conference presentations, industry courses and data management references, including Data Basics. These practices are largely supported by forms design research conducted in the last 10 years, but there are some exceptions. Examples are presented in Table 1.

Table 1 - Commonly cited rules or sources of good forms design that should be reconsidered

<table>
<thead>
<tr>
<th>Rule or reference</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Put the fields on the CRF in the same order as the source document.</td>
<td>Every site creates its own source documents, so this is effectively impossible in multi-site trials.</td>
</tr>
<tr>
<td>2 Put the CRFs in the order that follows the flow of data capture at the site.</td>
<td>Most data managers have never been to a site, nor observed a site capturing data, so it is difficult for them to know how to do this.</td>
</tr>
<tr>
<td>3 Design the forms to facilitate source data verification.</td>
<td>Data comes from multiple sources that will vary from site to site.</td>
</tr>
<tr>
<td>4 Bert Spilker’s book “Data Collection Forms in Clinical Trials”.</td>
<td>There are some good pointers in the text. From a layout perspective, the sample CRF quality is poor.</td>
</tr>
</tbody>
</table>

There is, in the author’s experience, enormous variability in the application of these rules. Additionally, some of the rules are inherently contradictory, such as the mandate to create standard CRFs and the first 3 rules in the table, which would require that the forms vary for each site.

New Opportunities
With the advent of the web, this is an excellent time to look outside our industry silo and see what others have to offer, and there is a lot. Because forms have the ability to make or break an e-commerce site, there has been an emphasis on testing layout and content assumptions, especially as doing such testing is relatively easy and inexpensive in the web environment. This testing has consisted both of preference testing, where users say what options they like, and eye tracking studies, where sensors track the users’ eyes and record where they land, for how long and how frequently (Figure 1). This eye tracking has been particularly revealing, as it shows that people’s perceptions of where they look does not always match the test results. Although these tests are on web forms, many of the findings can be applied to the paper world.

Figure 1 - Combination eye tracking study and heat map showing where, on average, users looked most and the paths their eyes took.

Of those involved in web-related research, Caroline Jarrett, the Formulate Information Design group and the Australian Government are three whose findings are particularly robust and well presented. Jarrett’s work can be found online primarily in slide decks on www.slideshare.com and in her forms design books. Formulate Information Design’s observations (including what constitutes valid research) cover a 4 part model for structuring forms design and a wide array of individual design aspects clarifying reasons why some practices are better than others. Some more information about this is presented later in this article. The third worthwhile source is the Australian government, which embarked a few years ago on a major overhaul of its processes and particularly its forms with the goal of making every form perfectly suited to its purpose. They published a number of checklists and guides on “better practices” in forms design that can be found on their website. Their material covers both electronic and print forms.

With respect to paper-based forms, there are two sources in particular that are worth investigating. Robert Barrett, a process expert from Australia, was driven by the need to improve the usability of forms, and spent four decades studying, refining and using forms in the course of improving processes at a variety of large corporate and...
government organizations. His book, Forms for People is a comprehensive text that compiles much of what he knew. The second source is The Form Book, by Borries Schwesinger, which is an English version of a German book and approaches forms design from a graphic design point of view. It is beautifully laid out and contains numerous examples that provide useful insights.

**Additions to the CRF Body of Knowledge**

There isn’t space in this article to cover all the applicable form-related information and research, so the remainder of this article will focus on some highlights that may be particularly useful in CRF design.

**Why do we have CRFs?**

As is discussed below, before ever creating the first draft of a form, one must answer the questions “Is this form really necessary?” and “What need is this form serving?” The first is answered by the second in the case of CRFs, in that they are a tool for capturing protocol-defined data that can’t be acquired in any other way. CRFs are also part of the data quality continuum. Most obviously, they help to ensure that all required data are captured, that they are captured similarly at all sites, and to document the absence of data when none were generated. CRFs contain code lists, otherwise known as controlled terminology, that ensure that data to be analyzed contain values that the computer recognizes as the same. In the case of electronic data capture (EDC), there can be edit checks that help to control the variability of the data.

**Some Overview Observations**

Caroline Jarrett thinks of forms as an asynchronous dialogue between form designer & form filler, where questions and potential answers are predefined, and where no clarification is possible. As a result, the form designer must think about how that dialogue would happen and try to anticipate potential problems. In clinical research, the process is complicated further by the fact that there is often a third party, namely the site coordinator who acts as the form filler but is acquiring the information from the subject and is usually completing the form when the subject is no longer present. Understanding this can help us think about the kinds of instructions that may be needed, and especially about what may not be useful, such as directing sites to initiate the expedited reporting process for serious AEs.

The Formulate Information Design group’s four-stage model for designing forms provides a good reminder that forms are a means to an end, and not an end in themselves. Although it may seem obvious, it is worth thinking explicitly through each step, otherwise there is a greater risk of omitting something important or structuring the form such that the data are not usable. The four stages are:

- **Process**: this must be the first step because forms exist to serve a process, not the other way around. Defining the process includes items such as:
  - Who owns the form?
  - Who has input into its design?
  - How do people access the form?
  - In what ways can the form be submitted?
  - How will the data be entered?
  - What business rules govern what “clean data” look like?

- **Questions and answers**: only after the process has been defined are the questions and answers addressed. This is because the content and format of the questions are affected by the process decisions. While the protocol does dictate what data are needed, it is usually the CRF design process that results in the specific questions to be asked.

- **Flow**: this consists of the relationships between questions in the form, e.g., what forms are collected together and how does the user progress through the form, especially when skip boxes are used (questions that direct users to skip some questions based on the answers to others). The flow usually falls naturally out of the question and answer design.

- **Layout**: this is the physical layout of the form, whether paper or electronic. This is the aspect that most affects the accuracy and completeness of the collected data. Relevant factors include:
  - Margins and spacing
  - Typography
  - Logos, headers, footers etc.
  - Hierarchy and cues
  - Progress indicators and page numbers
  - Multi-domain form with parts labeled

**Some Detailed Findings**

A few specific recommendations that arose from recent forms research are discussed below. Some apply primarily to web-based forms, and some are more general. As one forms researcher noted, form fillers will suffer through a lot, but the more they suffer, the less enthusiastic they are about completing the forms and the lower the quality is likely to be.

- **Object Shapes**
  - Longer boxes imply longer answers, short boxes imply short ones – even if the user can continue typing
  - Make things that are the same, look the same. Format questions and answer boxes the same if they are capturing the same kind of information. Balance this with the need to differentiate between, for example, submit and cancel buttons. These could be varied by shading or texture while still appearing largely the same.
  - Conform to current norms around object shapes, or error rates may increase
    - Radio buttons – pick one
    - Check boxes – pick all that apply
    - Rounded rectangles – action buttons
    - Radio buttons, checkboxes or drop downs: this decision depends upon how many answers are provided and how many are expected (Figure 2). Web convention has settled on radio buttons for ‘pick one’ questions and check boxes for ‘pick all that apply.’ The only exception is that where there is only one choice provided, a check box should be used to allow for deselection.

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The choice of check boxes or dropdown menus is a bit trickier. Humans can only keep between 7 and 9 items of information in mind at a time (think phone numbers or social security numbers). If there are more than 8 or 9 choices in the code list and a single answer is required, then either a dropdown menu or checkboxes can be used. If more than one answer is required, then it is better to use checkboxes grouped by some parameter, because people have to remember not only what the choices on the list are but also what they previously chose. The greater the cognitive load on the form filler the greater the chances that errors will occur.

Figure 2 - Decision tree for selecting the better format for presenting answers on a web form

- Order of answers:
  - For categorical questions, meaning answers that are code lists, it is generally best to choose a consistent order, but there are exceptions.
  - When answers control the flow of the form, put them as close together as possible. For example, if answering ‘yes’ requires completing a series of additional questions and ‘no’ requires jumping to another question, it is best to list the ‘no’ first so that the answers are together, even if the usual practice is to list ‘yes’ and then ‘no’. Especially in paper forms, this reduces the chances of missing the ‘hanging’ answer.
  - Put the most common responses first, as the form filler will see the applicable answer at the top of the list and move on.
  - For ordinal (i.e., ordered) lists, put the answers in the implied order, for example, absent, mild, moderate, severe. When the anchoring answers are assumed to be the top and bottom of a scale, the center is assumed to be a progression and form fillers tend to choose the answer based on position rather than paying attention to the text (Figure 3).

Figure 3 - Example of a poorly designed form, presented by Dr. Leslie Ball, FDA

- Layout and Spacing:
  - The human eye tends to move vertically, so list questions and answers in columns except where users are very used to providing data together, e.g., date and time.
  - If there are too many questions for one page, split them into two columns with a strong separator such as a bold line.
  - Line up answer boxes and text precisely. The fewer “break” lines there are, the more pleasing it is, and therefore the easier it is to navigate. Break lines are invisible lines the eye draws that connect objects on a page, and are the eye’s way of trying to organize the visual information.
  - Place labels above and very close to the list of answers or the text field. If that is not possible, place them to the left and right justify them. It should be very easy to associate the label with the correct field. The labels in Figure 3 are too far from the answer boxes.
  - In check lists, place the box or radio button to the left, and the text response to the right, minimizing the space between them.
  - There is an interesting split in the research on this. Some studies found that users preferred labels to the left of the radio buttons/check boxes, and this is common on web, but not on CRFs. Perhaps CRFs will change as more of the internet generation work with clinical research.
  - Leave white space - Do NOT pack information onto the form – longer and simpler forms are far better than short and dense.
  - Make answer boxes easy to find.
  - Use color minimally and carefully:
    - Color implies meaning, even where there isn’t any.
The Art of Designing Excellent CRFs

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• It can be very effective, for example when used for reverse shading of form, or for identifying action buttons, but do not overdo it.

• Be careful with the choice of colors. About 7 to 10% of the males and a tiny fraction of the females in the US are color blind, including red/green, blue/yellow and complete color blindness.

• Be aware of differences in visual acuity. Avoid the current fashion of grey on grey!

• Don't use tiny fonts. This is especially common on paper AE log forms where the code lists are printed at the bottom of the form in type too small to see. If it's important enough to be on form, it's important enough to be visible.

Testing the Forms

The typical approach to CRF development is to design the forms and send them to the study team for review. At sponsors and CROs, this often involves only the in-house team, and doesn't include the site. The CRAs are expected to speak for them. This is a good process for ensuring that the forms capture the data in the protocol, conform to internal CRF standards, and don't contain typos and the like. It is completely inadequate for testing the usability of the forms. Research has repeatedly shown user (that is, form filler) testing to be critical to successful form design. Designs can have flaws that only appear during use, and the more complex the form the more likely this becomes. It is far better to find these issues prior to study start.

Testing involves more than just sending the forms to a site coordinator and asking for comments. This is valuable, but it is a cognitive review, much like that of the study team. The forms should be tested in a realistic situation, with an observer watching the site coordinator completing the form, whether it is with a study subject or in the process of transcribing information from source data. Pay attention to the body language, where and when the site coordinator looks for guidance, what questions the study subject asks, whether there are any signs of puzzlement or lack of comprehension, and where the site coordinator is unable to answer the study subject's questions. Subject testing can be accomplished by using patients who are ineligible for the study, and indeed in many cases they don't necessarily have to have the condition under study. Only by doing this can forms designers be sure that the forms will really work.

To illustrate the point, the author participated in a study recently and was asked how many people live in the house. As it happens, I am divorced and I live there full time. My son spends half his time with me and half with his dad on an every-other-week basis. I have a home office with a colleague who works here on weekdays. How do I answer the question? A whole number was expected. I didn't know how the information would be used. I suspect it was a proxy for how much social contact I have, but the strictly correct answer would give a very different result from reality. Robust form testing could have revealed this.

Challenges

There are certainly many challenges to incorporating the research findings into CRF and EDC design and production. EDC software often imposes limitations on how fields can be defined and laid out on the screen. This is perhaps surprising, since the vast majority of vendors come from the web world, not clinical, and their world invented web forms, but many don't seem to have incorporated these findings. With respect to testing, it can be difficult to get the cross-functional collaboration necessary to allow forms designer and sites to work together, sites may need payment for the time this takes, and CRF design is often on the critical path to study start, so anything that delays the process is discouraged. In addition, sponsors tend to believe their forms are fine because there may be no reliable way for usability problems to be communicated.

Potential solutions

While there are no quick fixes, there are some potential solutions. Many sponsors and CROs have standard CRF libraries. Starting with these, run a process improvement review to evaluate them against the research results discussed above and available elsewhere. Develop style guides that codify the rules and processes to ensure that future CRFs reflect the same practices. Build a testing phase into the design process that involves sites, and vary the sites chosen so that responses remain fresh. Use multiple sites, because there will be individual variations and it's important to identify what is a personal quirk vs. a real issue. Finally, document the design decisions along with the rationale so that when future forms are developed that knowledge is available.

This may seem like a lot of effort, and it is, but the time to discover design flaws is not during the study, the time is before the study starts. Standard CRF libraries allow the knowledge to be captured and used for future studies, so the results are cumulative. Most importantly, this makes the clinical trials data higher quality, and more efficient to collect, which allows an increased focus on improving the science and getting treatments to patients more quickly. Surely that's worth the effort.

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This article is an excerpt from Kestrel's course "How to Design Excellent CRF", available on kestrelconsulting.trainingcampus.net.

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• Schwesinger, Borries. The Form Book. Thames & Hudson, c. 2010
Kit Howard, the founder and owner of Kestrel Consultants, has almost 30 years of experience in the biopharmaceutical industry and provides consulting in clinical data standardization, quality and management.

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RCRI has a robust team of clinical data experts with experience in clinical trial management, CRF development, database development, data analysis and medical writing. This broad based experience helps RCRI clients ensure their data are collected and analyzed in an efficient and cost-effective manner. Led by Maria Schroeder, MPH, the RCRI Information Management team has extensive experience developing integrated data collection, storage, and analysis solutions for simple and complex medical device clinical trials.

Please contact Maria Schroeder, MPH at 952-224-2255 or mschroeder@rcri-inc.com about your data needs.
The collection of accurate clinical data is the cornerstone of any clinical trial. On average, a drug undergoes 3-6 years of development before it even makes it to the clinical trial phase. Scientists, doctors, and clinicians invest countless hours trying to unlock the mysteries of life altering and life threatening diseases like HIV, Ebola, and SARS. Now imagine that the cure for one of these diseases is not realized through the clinical trial phase due to the collection and possible reporting of inaccurate data.

Edit checks are programmable validations which are used by Data Management to clean data throughout a clinical trial which, in turn, helps ensure accuracy. These edit checks, like any other programming, can be flawed for a number of reasons including programming error or misinterpretation of the specification. This article will outline best practices for edit check testing to help ensure clinical trial data is cleaned thoroughly and accurately.

**Assembling the Testing Lineup**

A common point for debate surrounds who should be involved with and perform edit check testing. A Data Manager, for example, has a solid understanding of the clinical trial protocol and the study requirements mandated by that document. A Data Manager, however, may not fully understand the intricacies of the database setup and might fail to test out a scenario which could lead to future errors.

For a Database Developer, the latter is true. A Database Developer, however, may also be inclined to test an edit check based specifically on the edit check logic without taking into consideration the intent of the check as driven by the protocol.

To ensure accurate and complete edit check testing, it is pertinent to have testing performed by both the Data Manager and the Database Developer. In software validation, this setup is known as White-box/Black-box testing. White-box testing tests the inner programming which often identifies errors in the source code. Black-box testing tests the overall functionality (i.e. ensuring certain outputs are achieved based on certain inputs as outlined in the specification).

Even with this dual testing, it is also important for the Database Developer to read and understand the protocol before testing and similarly for the Data Manager to understand the database. To accomplish the latter it is advisable that the Data Manager who performs the edit check testing be the same Data Manager who performed the database testing. It is also advantageous to organize a meeting between the Data Manager, Database Developer, and Edit Check Programmer to identify and review high risk edit checks.

**Guidelines for Creating Test Data**

Test data are results or responses entered into the database which serve to validate the veracity of the edit checks. The effective creation and utilization of test data is driven off by two main points – sufficiency and accuracy.

**Sufficiency**

Sufficiency refers to the thoroughness and comprehensiveness of the test cases. In other words, how much testing is enough? Though it can be argued that no amount of testing is ever enough, there are certain guidelines to keep in mind.

The first guideline is to always create clean and dirty test data for each edit check. Clean test data refers to responses that are expected for the particular question and which therefore, will not generate a discrepancy. Dirty test data refers to discrepant responses which are expected to be flagged for further review. When creating clean and dirty test data, it is helpful to use one subject id (or a series of like subject ids) for clean data while using a separate subject id (or series of like subject ids) for dirty data. Using two distinct subject id groups without allowing for overlap will make it easier for the tester to remember from which data a discrepancy is expected. In addition to this, being able to distinguish between two different sets of data is also extremely useful when reviewing past documentation, especially for auditing purposes.

The second guideline is to always categorize the complexity of the procedure into one of two groups—simple edit checks with one specification or multifaceted edit checks that involve two or more criteria. An example of a single specification edit check is “missing value check”. If this type of check only involves one question, it is most likely sufficient to only use one instance of clean data and one instance of dirty data. An example of a complex check is one that verifies that one action (such as dosing) takes place before another action (such as a blood draw). This type of check requires the testing of multiple scenarios (of both clean and dirty data) to ensure it is working as specified. Not only does the tester need to verify that the dosing actually took place, but they also need to ensure that it took place before the blood draw occurred. Complex edit checks always require more time to test than simple edit checks. By not creating enough test data to test out complex edit checks, data that appears clean, may not be sufficiently comprehensive to make that determination.

**Accuracy**

Clean and even dirty data that is used for testing should mimic potential real world responses. A common mistake when creating test data is to enter spurious values such as temperatures of 500 degrees and heights of 50 meters. While these values may bring errors to light, they are too far outside the ballpark and may cause the tester to miss a range that was programmed incorrectly.

When creating clean and dirty test data it is important to always check ranges within 1 unit of the intended target. If the protocol requires a temperature value of less than 100 degrees, it is advisable to use 101 as the value for the dirty data (assuming that the temperature value is a whole number).

Range checks involving two values should always be tested on both sides of the range. For example, if the temperature value is expected to fall between 97 degrees and 100 degrees it is important to test
values before and after the lower end of the range as well as values before and after the upper end of the range.

When creating test data for numbers or dates, it is also necessary to develop test data to the nearest unit. The unit should be defined in the database and is often times also described in the protocol.

Not testing to the nearest unit is a common pitfall when validating “date checks”. For example, an edit check specification might indicate that a discrepancy should be generated when the subject's date of birth yields an age that is greater than 18 years. To test both sides of the required value, a tester might enter clean data using a date that is 17 years prior to the current date and dirty data using a date that is 19 years after the current date. The problem with this test data is that it failed to check the precision of the age to the nearest unit (day in this case) by using a date that is 17 years, 11 months, and 30 days from the current date. Using the more precise value will allow the tester to ensure that there are no rounding issues with the programming.

When designing test data, it is important to always test to the nearest year, month, day, hour, minute, whole number or decimal as required.

Summary
Combining an appropriately qualified team of testers with sufficient and accurate test data will lead to effectual testing which will lessen the potential for data cleaning problems throughout the study. This reduction in problems will save time and money that often coincide with changes to a production database. More importantly, it will lead to more precise and reliable clinical research.

Cheryl Silva is a data management professional with expertise in CRF design, database development, application support, electronic data handling, and report programming for both functionally sourced and full service projects. Her experience includes designing and building clinical trial databases for all phases of clinical trials across a wide range of therapeutic areas.

Oliver Ho brings a strong background in data management and database development specifically in the areas of edit check programming and testing. He has also contributed to the validation of several instances of Oracle Clinical and RDC as well as delivered training on the different versions of RDC a countless number of times.
Maximizing Your SCDM Conference Attendance

By Rey Wong, CCDM, Associate Director, Data Management Oncology Product Creation Unit, Eisai, Inc

It's been a little while since the SCDM Annual Conference has passed and perhaps you were pondering whether attending has added value to your professional and personal growth. If you went to the conference this year, count yourself as one of the lucky ones who still works for a company that sponsors attendance. Gone are the days when five or more attendees from one company would show up in these conferences. It's quite obvious that companies have been doing a lot of cutting back on expenses. I have heard from some of my ex-colleagues that their requests to attend have been rejected due to budget cuts. Hence, being approved to come to the conference has become a valuable perk. Some consider it as a reward for a good performance, but in my opinion, that shouldn't be the primary reason for being allowed to attend the meeting. Whether there's economic strain or not, one's attendance should be based on business decisions—meaning participation in a conference should add value to the company. So if you are attending, be a good corporate citizen. Plan ahead. Maximize the experience and plan to share lessons learned from the conference.

Planning Ahead

The first step to achieve the maximum experience from a conference is to plan ahead with your supervisor and colleagues with whom you will be attending. Check the preliminary Conference Program through the SCDM website. Whether your supervisor is attending the conference or not, plan to meet with him or her and ask if there are any presentations that he or she would like you to attend. Also, discuss the presentations you plan to attend. Your supervisor may have an interest in a topic and may want to hear any information that could help your company. Plan to also discuss the pre-conference workshops. While there is an additional cost, these workshops have so much value. You don't have anything to lose when you discuss this option with your supervisor; make a case, but be prepared to take a “No” for an answer. Once you get to the conference and receive the conference attendance packet, review the Conference Program and check the agenda descriptions. Call or email your supervisor the additional details so that you can discuss it. Your supervisor may change his or her choices based on the descriptions given.

Discuss the Conference Program with the colleagues with whom you are attending. I recommend that you split your efforts to cover overlapping presentations. When you get to the conference, try to reach out to the session chair to see if they may be able to offer additional information from what is included in the program.

A few weeks before the conference, ensure that you have back-ups in place for your work while you are away from the office. Communicate this plan to your supervisor. Chances are the ship won't sink while you're not in the office, but you want to show your supervisor and back-up that if needed, you are accessible. It's a good idea to provide them the schedule of presentations you plan to attend, so they don't get frustrated if you are unable to answer your phone while you are intently listening or taking notes on an interesting topic. Also be cautious about how much “work” you would like to handle while you are at the conference. Try not to make a hard commitment to your colleagues that you will respond to them as quickly as you can. There is a perception that since the company is paying for your attendance you are still “on the clock” and that project work takes precedence over the conference. This is why it is important that you thoroughly discuss with your supervisor what you want to accomplish at the conference, so alternative plans for your work can be arranged whenever possible and you can maximize your conference experience.

Maximize the Experience

Once you register, check the packet thoroughly for any loose flyer announcements. Review the final conference program. Confirm connectivity within the meeting area. Communicate as soon as possible to your back-up and supervisor if there may be a substantial gap with your communication and arrange alternatives for urgent matters. The sooner they know that, the better.

This advice is tough for many of us: leave your inhibitions behind and start meeting people. We often look for familiar faces or in some cases avoid crossing paths with them. It's always nice to catch up with ex-colleagues or acquaintances, but your goal should be to network with other people outside your circle. If your ex-colleague or acquaintance is with someone new whom they fail to introduce to you, introduce yourself. When meeting new people, try to find commonalities with them. Be humble and leave some room for them to talk about themselves. However, try not to stick with them the entire time; join them for one presentation. Now, if you decide to introduce yourself to someone and they give you the cold shoulder, then let it be. In my experience there are very few of these people at conferences, so don't let it dissuade you from meeting more people.

Unless you have a photographic memory take notes during the presentation. This may seem like obvious advice, but try to focus on the presenter and avoid texting, surfing on your smart phones or having side conversations with the person next to you. During the Q/A session, you may not have questions related to the presentation itself, but it is your opportunity to seek advice about a like process you have internally. You can direct your question to anyone on the stage, including the session chair, or even to the audience. Most likely someone will respond, but after the presentation someone may indeed approach you and share their knowledge. During the presentation, there's no guarantee that you'll bring back information that can improve your department's process or solve an issue you have, but likely, you will learn that many companies are in the same boat as yours. You can report that back to your supervisor. Then perhaps you can be a catalyst on how to change things within your company by coming up with a more innovative way of performing a process rather than relying on one that everyone is using and that is not really working.

One crucial tip: the format of the conference in the past has been two simultaneous tracks/sessions, so you have to choose the session most applicable to your needs. If you attend a session and early in the session you feel that the content is not what you expected, evaluate waiting for the next speaker to see if that content is what you expected or simply change sessions.

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Maximizing Your SCDM Conference Attendance

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Ensure you stay to attend the last day of the conference. The SCDM Business Meeting and the Annual FDA–SCDM forum are typically held at the end of the conference. You probably have heard from some colleagues that the FDA forum doesn’t offer definitive information since the speakers always have a disclaimer that their presentation doesn’t necessarily reflect the FDA’s opinion. This may discourage you from attending it, but I would encourage you to attend and form your own opinion. There is always useful information discussed at this session.

Try your best to provide feedback about the presentations. The comments you provide, will give ideas for improvements for the next conference. It’s alright to be honest, but do remember that the presenters and session chairs are industry colleagues. Be constructive and avoid personal attack.

One of the activities you should do is to visit the vendor booths. Don’t do this just to collect candies, coffee, plush animals or pens. Do it to meet the representatives of the vendors you have existing contracts with. You get to know the company’s new product information that your current contact at that company isn’t able to provide you with. You get a sense of the company. You can gain insight into your current contact’s behavior and performance. Check out the booths of their competitors and ask to view their demonstrations. This will be handy when a vendor comes to your company to present their services and you can advise your supervisor on the technology or services they provide in advance of the meeting. And of course, then you can take their pen.

Make sure you also set aside some time to see the host city. Take your new acquaintances with you. Keep the conversation light, and avoid airing grievances about your company. You are the ambassador of your company and should project a positive image. Always remember not to divulge intellectual property.

Sharing what you have learned

This is probably the most difficult part one can do after a conference - summarizing what you have learned. I would advise you to write what you have learned about the conference overall in an email. It sounds corny but a couple of things are achieved by this for both you and the company. For your company, you are able to bring information to the company who has paid your expenses to attend the conference and perhaps make baby steps towards changes in your company. For you, it shows your supervisor that you are the one they can send to future conferences.

Hopefully the advice I have given you will make your attendance at the 2012 SCDM Conference in Los Angeles a better experience. One may say that what I have shared is common sense and I would concur with that. However, one should always think that the conference is an extension of your work and that your involvement should have a direct impact to your company. Although the conference offers professional and personal growth, these personal gains are secondary to your company’s business needs.

Rey Wong has worked in clinical research since 1992, and started his career in Clinical Data Management in 1995. Prior to being in clinical research, he was an Advanced Medical Laboratory Technician in the US Navy. Rey holds a Master of Science in Management from College of Elizabeth. He is currently an Associate Director at Eisai Inc, Oncology Product Creation Unit, Data Management.
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