From: FREELANCE automatic digest system (LISTSERV@LISTSERV.AMWA.ORG)
To: FREELANCE@LISTSERV.AMWA.ORG
Date: Thursday, March 12, 2009 3:37:28 PM
Subject: FREELANCE Digest - 11 Mar 2009 to 12 Mar 2009 - Special issue (#2009-86)

There are 17 messages totalling 10172 lines in this issue.

Topics in this special issue:

1. MacQ: iWork (5)
2. Informed Consent Forms (7)
3. Implications of PIs (4)
4. Implications of recent events

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sjdodgsonphd@YAHOO.COM
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Hello,
I've been using Macs for years and years--with but a brief foray into the Dark Side of Windoze. I haven't had any problems with cross-platform conversions in--oh, about 8 or 9 years. With respect to iWork, I just made the switch a few months ago, but have had zero problems. Although Word 2009 for Mac is far better than its predecessor, I have found the rest of the Office programs to be miserable. Numbers is a pleasure to work with--much more intuitive than that other program and much easier to operate. I'm relieved not to have to push, pull, and tug to make what should be a simple chart. Keynote allows you to easily create beautiful presentations, and Pages is also great. I've also been running Leopard since Day 2, and have no problems--not with the OS itself and not with iWork and not even with non-Mac programs like Office. Yes, there is a little learning curve--until you realize how easy the whole Mac thing really is.

Jill

Jill Zaklow
Conceptual Pharmaceutical Promotion
ph: 201-655-0303
e: zaklow@verizon.net

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I'm preparing a course on "Informed Consent" (background, content, writing style, reg. requirements, etc).

Can your share your thoughts/info on the following points:

1. any existing official and unofficial guidelines, templates, standard outlines for ICs
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I would like the course to be as comprehensive as possible; the target audience is non-industry research organizations in Europe. All comments and shared information would be greatly appreciated.

Kind regards,

Colette

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Colette D. Lukan, MD, FRCPC
CRC Partners s.r.o.
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921 01, Piestany
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Tel: +421 33 774 36 33
Mobile: +421 (0)910 363 313
NEW EMAIL: crcpartners@profi.sk

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Colette: I often fought with lawyers about editing text they HAD to have included in consent forms. I solved the problem by alternating paragraphs of legalese with those in plain English. For example, I would present the plain English and then say something like "The legal language for this situation is as follows: . . ." Made everybody happy.

For what it's worth.

Tom

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Tom Lang, MA

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Webinar information:
http://editage.eventbrite.com/

Author of:
- ***How to Report Statistics in Medicine***
- ***How to Write, Publish, and Present in the Health Sciences***

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There is a lot of discussion about readability and comprehension level, but it is important to include all the required information. There are checklists for this. In the US HIPPA comes into play.

21CFR Subpart B has a lot to say about Informed Consent of Human Subjects, including exception from informed consent requirements for emergency research.
ICH guidelines cover informed consent in detail.

I have to take my daughter to school right now so perhaps someone can provide relevant websites?

Good luck - this is quite a bit of information to digest and present.

Martha

From: CRC Partners [mailto:crcpartners@PROFI.SK]
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Colette:
Let me direct you to some good resources that will answer your questions below (about Informed Consents)
Always remember that www.fda.gov is a great resource. Always start there.

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=50
this has the Code of Federal Regulations (CFR) itself

http://www.fda.gov/oc/ohrt/irbs/informedconsent.html
- and you will see these topics
Consent Document Content
IRB Standard Format
Sponsor prepared model consent documents
Revision of Consent during the Study
General Requirements, 21 CFR 50.20
FDA Approval of Studies
Non-English Speaking Subjects
Illiterate English Speaking Subjects
Assent of Children Elements of Informed Consent, 21 CFR 50.25
Compensation v. Waiver of Subject's Rights
The Consent Process
Documentation of Informed Consent, 21 CFR 50.27

www.fda.gov/cdrh/devadvice/ide/informed_consent.shtml
for devices

if you "google" informed consent, you will get alot of information as well.
Looks like WHO offers templates. . .
www.who.int/entity/rpc/research_ethics/**informed_consent**/en/index.html

some thoughts. . . talking through the study while "walking through" the consent form is a good first step - and some research facilities give the consent form to the individual to take home and discuss with family members and then come back. One clinic told me that this has reduced the number of patients who quit the study after signing up and become lost to follow-up. This may not be practical if the patient has driven a long distance or the institution is huge and hard to get to and park, etc. It's so important to take time to explain everything to the patient - there have been lawsuits from patients saying "I wasn't told" whereas it has been in the consent form BUT NOT STATED CLEARLY - so all of this preliminary stuff is so critical - it has to be a perfect document.

any consent form has to be written in a language that is basic and understandable - I've heard the expression "8th grade language" (you'll find that in the above resources) AND it MUST be approved by an IRB (Institutional Review Board) - and you will get good information if you "google" IRB - and aim for protection of human subjects. I just googled and was lead to this http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116. If you can talk to a local IRB, you might be able to get their template - BUT know that one size does not fit all - one template is not appropriate for all studies. The template is just the "skeleton" - the protocol specifics have to be integrated in the Informed Consent - what is going to happen to the patient over time. ..

Also, know your audience. . . if it is composed of people who write informed consent forms, going through the requirements will be laborious for them. They've heard it many times. I've done presentations on Informed Consent and this part is hard to make "lively" and "interesting"

Amount charged by Medical Writers to do an IC - please know that Study coordinators have written consent forms. If you have the 'knack' (as seasoned study coordinators do) and have the template of the IRB who will be approving the consent form, then it can take maybe a few hours to do - but then it's good to have other people review it up against the protocol to see if everything is in it. I've written them - they do take a skill. If one has never done them before, it's best to get some internal review to make sure the lingo is correct.

Length - all information must be included - no matter what - so don't be concerned with the length - it is what it is. It's good to have a line at the bottom for the patient to initial all pages to acknowledge that they have read it.

The last part (for signature) - has to have a place for a patient signature and a witness - some have a line for the investigator as well. It just depends on the template. If the investigator is going to sign it, it's best to know that this person has also written a progress note to say that he/she were involved in the consent process AND that the signature (and date) is the same date that the patient signed.

That's what I can offer.

Good Luck
Doris Davis
GCP Compliance person and member of AMWA
San Carlos, CA (near SF)

(650) 654-0101 H/O

On Mar 12, 2009, at 12:39 AM, CRC Partners wrote:

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1. Description of the research, purpose of study, procedures, how long it will last

2. Description of any procedures that may result in discomfort or inconvenience

3. Expected risks of study

4. Expected benefits of study

5. Other treatments available

6. Use of research results

7. Payment or cost to patient

8. Voluntary nature of participation, right to withdraw

9. What happens in the event of injury or adverse events related to the study

10. Contact information for PI, Coordinator and any other appropriate study personnel

Most of this information would come from the study protocol or an organization's policy & SOP documents.

Pediatric studies require parental/legal guardian assent, so the primary IC would be written for the perspective of the guardian (i.e., "your child" rather than "you"). There is also a child consent process, which can be scripted and includes a basic child IC (written at a low literacy level), so the script and basic IC would also need to be developed.

When working with populations with limited cognitive abilities, the consent process may require a post-IC questionnaire that asks the participant questions about the consent form to test whether they really understood what they were reading.

For length, the IC should be as long as is needed to contain all the elements of informed consent.

For translation, some IRBs may require bidirectional translation as a quality measure, which means you'd write the IC in

English, translate it to the desired non-English language, then translate that version back into English. There are pros and cons of this approach. An individual investigator will follow whatever his/her IRB requires.

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Jill:

I'm wondering if you have experience in converting Keynote presentations to PowerPoint and/or vice versa.

I suspect many of us make much of our living doing slides. I certainly do. The one reason I converted from Mac to PC when went full-time freelance was the maddening cross-platform incompatibility issues with PowerPoint. Specifically, special characters such as Greek letters in Mac converted to different and often bizarre special characters when opened on a PC (and vice versa).

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Do you (or anyone else) have enough experience in this area to have an opinion?

Kevin Kehres
387 Planters Creek Rd.
Fletcher, NC 28732
Phone: 828-684-8913

From: J Zaklow [mailto:zaklow@VERIZON.NET]

Sent: Thursday, March 12, 2009 12:47 AM
To: FREELANCE@LISTSERV.AMWA.ORG
Subject: Re: [FREELANCE] MacQ: iWork

Hello,
I've been using Macs for years and years--with but a brief foray into the Dark Side of Windoze. I haven't had any problems with cross-platform conversions in--oh, about 8 or 9 years. With respect to iWork, I just made the switch a few months ago, but have had zero problems. Although Word 2009 for Mac is far better than its predecessor, I have found the rest of the Office programs to be miserable. Numbers is a pleasure to work with--much more intuitive than that other program and much easier to operate. I'm relieved not to have to push, pull, and tug to make what should be a simple chart. Keynote allows you to easily create beautiful presentations, and Pages is also great. I've also been running Leopard since Day 2, and have no problems--not with the OS itself and not with iWork and not even with non-Mac programs like Office. Yes, there is a little learning curve--until you realize how easy the whole Mac thing really is.

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Jayne:
your thoughtful comment. . .

> The only thing I'd like to add is that in most instances completion will take more than a few hours.

My response:
Understood - I guess I've written them in less than a day's time because I've had lots of experience with writing them. Been in the biz for 25 yrs.
Thanks for your feedback - I agree it can take longer than a few hours. I was just thinking of the simpler ones. It does, of course, depend on the template provided (how complete it is) and how complex is the study. A "quality of life" or a "salve applied at home to the knee" ICF would take less time than a study that requires multiple tests and visits over a long period of time (such as a cancer trial that is complex).

I should mention that this process takes place. .
- The approving board (IRB) provides template to WHOMEVER is writing the consent (could be a person at the study site)
- Using the template, the ICF is drafted and subjected to internal review at the source (study site) - it's always good to have another fresh eye read it
- The proposed consent is offered to the SPONSOR first to see if they have any input - and this begins an internal review there
- The SPONSOR will be particularly concerned with the stated info about "compensation for injury" (and other items of course)
- THEN the consent (with everyone's opinions and input) gets sent to the IRB for approval
- THEN all prior versions (red lined, etc) should be destroyed at the site and at the sponsor's - only the final approved version should be kept.
(keeping the prior versions - which I have seen in the Reg Binders and I always suggest holding in a different place OR destroying them- can give a red flag to the FDA because what if there was a red lined item that didn't get in the final version. . .)
and who OWNS the consent? the study center. The SPONSOR cannot IMPOSE their style - they can say, however, that we would like to have this stated and usually, if the Principal Investigator WANTS to work WITH the SPONSOR, he/she will comply.

All parties involved - the SPONSOR, the IRB, and the STUDY SITE should have Standard Operating Procedures on file about the Informed Consent and the PROCESS (see how I think as a Compliance person? I look for evidence of SOPs). This SOP should be

reviewed and updated periodically (annually or at least every 2 yrs).

And, the PI (Principal Investigator) AND/OR the Sub-Investigator(s) need(s) to have a role in the PROCESS of obtaining an informed consent. I look for a progress note written by the PI or the Sub who is listed on the Form 1572 (OK, go to www.**fda**.gov/opacom/morechoices/**fdaforms/FDA-1572** for info. on a 1572 - or google Form 1572). I just did three GCP Compliance audits in Feb and found that I had to remind the PI that FDA looks for evidence of HIS/HER oversight in a clinical trial and if I see that the Study Coordinator has written all the Progress Notes about the consent process and has witnessed all the consent forms, what role did HE/SHE play as the person in charge? (see the back of the Form 1572 and you'll see why I'm asking this). What ever isn't written is presumed as NOT DONE. They all listened and one of the sites revised their SOP before I was done with my visit. They were well intentioned and they DID have a role in the consent process (it came out when we met and talked about it) but I encouraged them to WRITE a Progress Note to SAY IT. DId the patient have an opportunity to meet with the Investigator, ask questions and were the questions answered to the patient's satisfaction? This is what I look for. . .

Last points I'll make - the ICF MUST be compared to the protocol - AND an important point I will make - the FINAL protocol - not a draft version!! AND the consent form should have a VERSION Date or a VERSION number at the bottom because if the protocol gets amended, the ICF might get amended and the study site has to track which patient signed which version. If the protocol & consent has changed and an approved version of the consent form affected Patient #11, HE/SHE (#11) should sign the NEW version EVEN IF he/she signed the former version when HE/SHE enrolled originally. ALWAYS, ALWAYS, the patient gets a copy of the signed consent form to keep.

NO ICF can be presented to a patient without first getting approval. IF the study is rockin and rollin with enrollment, then the old consent form can be signed and then they can sign the new version if necessary. If they have finished the study, no need to have them sign it UNLESS it has to do with advising the patient of a new RISK. ALL patients must know of ALL RIsks. I guess you can figure out that as an Auditor, I look at protocol and changes over time, did the changes affect the consent form, and did the patients all sign the appropriate versions.

Oh, translations. . . must be done by a qualified certified translation service.. . . not someone on staff who speaks Spanish (as an example). The best process is to have it translated and then to have it BACK translated. I know a terrific service provider who offers translation services (can offer off line). There are many translation services, but you have to be careful who you chose. Often, an IRB knows of a service. Guess what - BOTH the translated version AND the English version must be approved by the IRB and the translated version should be accompanied by the credentials of the translator. Yep, I check for that as well (when I audit).

Feels like I'm giving a little seminar on consents and GCP Auditing (my field). . . hope that this is not "too much" but it does seem that the AMWA List serve is composed of interested learners. I've heard from some of them on an individual basis - as they've said "thanks for the info"

I better get back to my work at hand - i just got on a roll with this - just wanted to help Colette - and I noticed she's in SLOVAKIA so maybe she didn't know about FDA web sites, etc. and about "googling" - oh, gosh, so much can be found out thru googling - but the resource they offer must be a credible one.

Gotta scoot,
Doris Davis
GCP Compliance Auditor in the Bay Area
(650) 654-0101 H/O

On Mar 12, 2009, at 7:16 AM, jayne wrote:

> Doris,
>
> You have provided Colette with a very good detailed guidelines for her ICF project. That is great! The only thing I'd like to add is that in most instances completion will take more than a few hours. ICFs need to be reviewed by multiple reviewers with various backgrounds and qualifications in order to assure accuracy, completeness and clear understanding.
>
> Jayne Grossmann, Pharm.D.
>
> On Thu, Mar 12, 2009 at 7:58 AM, Doris Davis <dordavis@earthlink.net> wrote:
>
> > Colette:
> >
> > Let me direct you to some good resources that will answer your questions

below (about Informed Consents)

Always remember that www.fda.gov is a great resource. Always start there.

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=50

this has the Code of Federal Regulations (CFR) itself

http://www.fda.gov/oc/ohrt/irbs/informedconsent.html

- and you will see these topics

Consent Document Content

IRB Standard Format

Sponsor prepared model consent documents

Revision of Consent during the Study

General Requirements, 21 CFR 50.20

FDA Approval of Studies

Non-English Speaking Subjects

Illiterate English Speaking Subjects

Assent of Children Elements of Informed Consent, 21 CFR 50.25

Compensation v. Waiver of Subject's Rights

The Consent Process

Documentation of Informed Consent, 21 CFR 50.27

www.fda.gov/cdrh/devadvice/ide/informed_consent.shtml

for devices

if you "google" informed consent, you will get alot of information as well.

Looks like WHO offers templates. . .

www.who.int/entity/rpc/research_ethics/informed_consent/en/index.html

some thoughts. . . talking through the study while "walking through" the consent form is a good first step - and some research facilities give the consent form to the individual to take home and discuss with family members and then come back. One clinic told me that this has reduced the number of patients who quit the study after signing up and become lost to follow-up. This may not be practical if the patient has driven a long distance or the institution is huge and hard to get to and park, etc. It's so important to take time to explain everything to the patient - there have been lawsuits from patients saying "I wasn't told" whereas it has been in the consent form BUT NOT STATED CLEARLY - so all of this preliminary stuff is so critical - it has to be a perfect document.

any consent form has to be written in a language that is basic and

understandable - I've heard the expression "8th grade language" (you'll find that in the above resources) AND it MUST be approved by an IRB (Institutional Review Board) - and you will get good information if you "google" IRB - and aim for protection of human subjects. I just googled and was lead to this http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116. If you can talk to a local IRB, you might be able to get their template - BUT know that one size does not fit all - one template is not appropriate for all studies. The template is just the "skeleton" - the protocol specifics have to be integrated in the Informed Consent - what is going to happen to the patient over time. ..

Also, know your audience. . . if it is composed of people who write informed consent forms, going through the requirements will be laborious for them. They've heard it many times. I've done presentations on Informed Consent and this part is hard to make "lively" and "interesting"

Amount charged by Medical Writers to do an IC - please know that Study coordinators have written consent forms. If you have the 'knack' (as seasoned study coordinators do) and have the template of the IRB who will be approving the consent form, then it can take maybe a few hours to do - but then it's good to have other people review it up against the protocol to see if everything is in it. I've written them - they do take a skill. If one has never done them before, it's best to get some internal review to make sure the lingo is correct.

Length - all information must be included - no matter what - so don't be concerned with the length - it is what it is. It's good to have a line at the bottom for the patient to initial all pages to acknowledge that they have read it.

The last part (for signature) - has to have a place for a patient signature and a witness - some have a line for the investigator as well. It just depends on the template. If the investigator is going to sign it, it's best to know that this person has also written a progress note to say that he/she were involved in the consent process AND that the signature (and date) is the same date that the patient signed.

That's what I can offer.

Good Luck

Doris Davis

GCP Compliance person and member of AMWA

San Carlos, CA (near SF)

(650) 654-0101 H/O

On Mar 12, 2009, at 12:39 AM, CRC Partners wrote:

I'm preparing a course on "Informed Consent" (background, content, writing style, reg. requirements, etc).

Can your share your thoughts/info on the following points:

any existing official and unofficial guidelines, templates, standard outlines for ICs

IC requirements/guidelines for clinical trials in Brazil, Russia, India, China (BRIC) and Japan (I sent a clear and concise email request in English to each gov. agency and didn't receive 1 reply).

ICs for pediatric trials (as a responsible adult would sign the IC does the document have any additional statements)

any writer's tips that would be useful writing an IC in English knowing that it will be translated into a foreign language

overall length (I've heard various opinions on this one but having practiced as an oncologist and participated in trials I think that many patients absorbed only the first 3-4 pages of information

amount charged by medical writers to do an IC

what documents/info sources are used to write the IC: study protocol, IB, PI (if available)

I would like the course to be as comprehensive as possible; the target audience is non-industry research organizations in Europe. All comments and shared information would be greatly appreciated.

Kind regards,

Colette

_____

Colette D. Lukan, MD, FRCPC

CRC Partners s.r.o.

Sturova 4915/13

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Mobile: +421 (0)910 363 313

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---

dordavis@EARTHLINK.NET

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So I guess the question still stands, although the work-around seems simple enough.

Back to work (on PowerPoint). :-(

Kevin Kehres
387 Planters Creek Rd.
Fletcher, NC 28732
Phone: 828-684-8913
-----Original Message-----
From: Kurt Ullman [mailto:kurtullman@SPRINTMAIL.COM]
Sent: Thursday, March 12, 2009 10:29 AM
To: FREELANCE@LISTSERV.AMWA.ORG
Subject: Re: [FREELANCE] MacQ: iWork

On Mar 12, 2009, at 10:18 AM, Kevin Kehres wrote:

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> Even though I am a "Mac person" through and through, I have been PC
> based professionally because of this issue. I would be thrilled to
> convert back to Mac when the time comes for me to upgrade my
> computer systems; but the thought of going through these issues
> again stops me cold. I think it would be dicey enough trusting
> PowerPoint to do the job correctly; adding the extra hurdle of
> Keynote-to-PowerPoint conversion gives me the shivers.
>
> Do you (or anyone else) have enough experience in this area to have
> an opinion?
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Why bother with conversions on a new Mac? With Leopard you can set-up a Windows side fairly easily and go with the "regular" Windows based
stuff for that and Mac for the rest of your life. Know quite a few people who have gone that route and been satisfied.

---

k.kehres@MCHSI.COM
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I am looking into medical writing and editing, and I'm new to this list.

I find the discussion of PIs particularly interesting because of my recent service on a federal grand jury that focused on health care fraud.

I've heard a lot of testimony from government investigators and sales reps of drug companies on the subject of off-label marketing. Some of the latter were aware of a line that they should not be crossing and went to fairly elaborate lengths to deny having crossed it; some did not appear to know that the line was there. But all were responding to pressures to make sales targets.

My impression was that a lot of physicians really do rely on sales reps for drug information. The reps drop by at least once a week, and over time, they build a relationship of trust with busy physicians. When reps join a new company, they frequently continue to call on the same doctors.

I've spent most of my career in large corporations, and I understand both the immense pressure to hit a projected level of profitability by reducing costs (in this case, by not running the clinical trials to get the drug approved for the population, disease, or dose that seem to be effective) and the power of the groupthink that can set in when you are in the trenches (what upper management is pushing us to do is pretty stupid and ineffective but probably isn't illegal or wrong).

What I took away from this experience was to question my doctor very closely about anything that she prescribes. And I'm starting to read the PIs.

Susan Hunziker

>>>>>
A few points:
Physicians should not be getting their drug information from company sales rep's, nor from the PI. They should get it from the drug label or from the published literature of studies not funded by drug companies. Reality may be different, but in that respect drugs are not unique; the same is true for many medical devices, and is certainly true for surgical/medical procedures, such as lung volume reduction surgery, or ABMT or peripheral stem cell transplant in support of high dose chemotherapy for breast cancer. After years of use, one of those procedures was found to be of marginal benefit and the other more likely to be harmful than helpful.
I disagree with the concept of limiting use of approved drugs to labeled indications. That would eliminate much of the use of oncology drugs and many of the newer biologics. If all "unlabeled uses" were prohibited, the FDA could never keep up with the supplementary NDAs industry would have to submit. Most unlabeled use (not casual use) in oncology, immunology, cardiology, and rheumatology is supported by good quality published studies.
There is another consideration. When drugs are studied under protocol in an IND, the inclusion and exclusion criteria are appropriately precise. But often this results in the selection of patients that are likely to be different than the broad spectrum of patients who may be given the drug post approval. For a non-drug example, in the Mar 5th NEJM, a large multinational study compared PCI to CABG for coronary artery disease (the SYNTAX trial). More than 70% of the screened patients were admitted; prior PCI/CABG comparison studies enrolled a much lower percentage of screened patients (some as low as 10%). This is a critical factor in making a judgment as to how the research data applies to your own patients, or even whether it applies at all.

----- Original Message ----- From: "FREELANCE automatic digest system" <LISTSERV@LISTSERV.AMWA.ORG>
To: <FREELANCE@LISTSERV.AMWA.ORG>
Sent: Thursday, March 12, 2009 12:01 AM
Subject: FREELANCE Digest - 10 Mar 2009 to 11 Mar 2009 (#2009-85)

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I checked with a family member who uses MAC/PC and Keynote/PowerPoint -- he's had no compatibility issues, but, as he puts it, "There are only a few greek letters used in what I teach - sigma and pi, mostly."

Anyone else out there use our medical favorites on both systems -- alpha, beta, gamma, mu, and a few "<" and ">"?

I'm also switching back to MAC after years of PC. For the immediate future, I plan to keep one PC computer to use for formatting issues that may arise. As others noted, though, creating a PC environment on your MAC is simple enough to do these days. Unfortunately, that means buying separate software products going forward, something I'd rather avoid.

Mary

Mary E. King, PhD, DABCC
Medical & Scientific Communications
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Office: 303-494-3888
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Use medscicomm@gmail.com for large attachments (>4 MB total)

www.medscicomm.com

-----Original Message-----
From: Kevin Kehres [mailto:k.kehres@MCHSI.COM]
Sent: Thursday, March 12, 2009 9:21 AM
To: FREELANCE@LISTSERV.AMWA.ORG
Subject: Re: [FREELANCE] MacQ: iWork

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The question then becomes, who has the deepest pockets <-- I must disagree. The question is -- who is responsible? While it is tragic that someone lost their livelihood, to automatically say an entity must pay for it just because they have more money than the individual who actually made the mistake is wrong.

Just because you have more money than I do, does not mean you should pay for a mistake I make. If I don't properly mix the cement you made or sold me, should you be sued by someone who breaks a leg when the steps I built crumbled, just because your business has more money than I do?

There may be some legitimate debate concerning the adequacy of the warnings in the PI. Having used this drug in my clinical practice for nearly 30 years, I think they are more than adequate. Someone less familiar with the drug might feel differently.

A crucial point in this specific case that seems to be continually overlooked is the drug was given improperly -- into an artery instead of a vein. This is carelessness on the part of the individual giving the drug -- not the manufacturer who sold it. If I don't verify that I inserted the needle into a vein, rather than an artery (or muscle or fat), I, not the manufacturer, have failed in my responsibility, and should be held liable.

there's a question as to whether this drug should still be on the market <-- It most definitely should.

the minor benefits <-- Not so minor. Since the removal of thiethylperazine a few years ago, this is my preferred agent for nausea and vomiting not responsive to initial prophylactic therapy in oncology patients receiving antineoplastic chemotherapy or radiation. It is my first choice for most non-drug/radiation-related nausea or vomiting.

das

Dominic A. Solimando, Jr., MA, BCOP

President
Oncology Pharmacy Services, Inc.
4201 Wilson Boulevard
#110-545
Arlington, VA 22203
OncRxSvc@aol.com

Subject: Re: [FREELANCE] Implications of recent events
Date: 11-Mar-09 11:36:49 AM Eastern Daylight Time
From: g_steen_medicc@YAHOO.COM
To: FREELANCE@LISTSERV.AMWA.ORG

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To me, there's a question as to whether this drug should still be on the market, given the major risks and the minor benefits.

R. Grant Steen, *PhD*
President, MediCC!
Medical Communications Consultants, LLC
G_Steen_MediCC@yahoo.com

Website: http://MedicalCommunicationsConsultants.com

Blogsite: http://theevolvingbrain.blogspot..com

From: David K. Schroeder <dschroeder10@VERIZON.NET>
To: FREELANCE@LISTSERV.AMWA.ORG
Sent: Tuesday, March 10, 2009 5:30:41 PM
Subject: [FREELANCE] Implications of recent events

Did anyone have any reactions to the recent supreme court decision involving Wyeth, the merger activities of several companies, and the potential implications for the future of healthcare innovation provided by pharmaceutical manufacturers? Two lead editorials from *The Wall Street Journal* provide compelling perspectives:

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Since innovation (new products and indications) drives so much of what I write about, I was wondering how other people see it.

Best regards,
David K. Schroeder

dschroeder10@verizon.net
610-896-1531 (office)
610-896-1532 (fax)

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The question then becomes, who has the deepest pockets <-- I must disagree. The question is -- who is responsible? While it is tragic that someone lost their livelihood, to automatically say an entity must pay for it just because they have more money than the individual who actually made the mistake is wrong.

Just because you have more money than I do, does not mean you should pay for a mistake I make. If I don't properly mix the cement you made or sold me, should you be sued by someone who breaks a leg when the steps I built crumbled, just because your business has more money than I do?

There may be some legitimate debate concerning the adequacy of the warnings in the PI. Having used this drug in my clinical practice for nearly 30 years, I think they are more than adequate. Someone less familiar with the drug might feel differently.

A crucial point in this specific case that seems to be continually overlooked is the drug was given improperly -- into an artery instead of a vein. This is carelessness on the part of the individual giving the drug -- not the manufacturer who sold it. If I don't verify that I inserted the needle into a vein, rather than an artery (or muscle or fat), I, not the manufacturer, have failed in my responsibility, and should be held liable.

there's a question as to whether this drug should still be on the market <-- It most definitely should.

the minor benefits <-- Not so minor. Since the removal of thiethylperazine a few years ago, this is my preferred agent for nausea and vomiting not responsive to initial prophylactic therapy in oncology patients receiving antineoplastic chemotherapy or radiation. It is my first choice for most non-drug/radiation-related nausea or vomiting.

das

Dominic A. Solimando, Jr., MA, BCOP
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Arlington, VA 22203
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Candice

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www.hughesbiopharma.com

Author Blog- Medical Thrillers
www.candicehughes.com

-----Original Message-----
From: jayne [mailto:jgg2014@GMAIL.COM]
Sent: Wednesday, March 11, 2009 12:47 AM
Subject: Re: Implications of PIs

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It is late now; otherwise I could continue with examples and suggestions how to revisit this issue in a more serious manner.

Jayne Grossmann, Pharm.D.
Medical Writing and Regulatory Strategies Consultant

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Candice: Have they published this research?

Tom

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I get your point, but I really don't see how physicians could take or make the time to get drug information from published literature or studies (...). Other than my years of experience in a variety of medical settings working with physicians, many of my friends are also physicians and I can tell you that after they have tended to their various obligations (including conferences, medical journal reading, etc.), they don't have the time or energy required to take the time to read studies.

----- Original Message ----- From: <holohanmd@CLINICALEVAL.COM>
To: <FREELANCE@LISTSERV.AMWA.ORG>
Sent: Wednesday, March 11, 2009 9:58 PM
Subject: Re: [FREELANCE] Implications of PIs

A few points:
Physicians should not be getting their drug information from company sales rep's, nor from the PI. They should get it from the drug label or from the published literature of studies not funded by drug companies. Reality may be different, but in that respect drugs are not unique; the same is true for many medical devices, and is certainly true for surgical/medical procedures, such as lung volume reduction surgery, or ABMT or peripheral stem cell transplant in support of high dose chemotherapy for breast cancer. After years of use, one of those procedures was found to be of marginal benefit and the other more likely to be harmful than helpful.
I disagree with the concept of limiting use of approved drugs to labeled indications. That would eliminate much of the use of oncology drugs and many of the newer biologics. If all "unlabeled uses" were prohibited, the FDA could never keep up with the supplementary NDAs industry would have to submit. Most unlabeled use (not casual use) in oncology, immunology, cardiology, and rheumatology is supported by good quality published studies.
There is another consideration. When drugs are studied under protocol in an IND, the inclusion and exclusion criteria are appropriately precise. But often this results in the selection of patients that are likely to be different than the broad spectrum of patients who may be given the drug post approval. For a non-drug example, in the Mar 5th NEJM, a large multinational study compared PCI to CABG for coronary artery disease (the SYNTAX trial). More than 70% of the screened patients were admitted; prior PCI/CABG comparison studies enrolled a much lower percentage of screened patients (some as low as 10%). This is a critical factor in making a judgment as to how the research data applies to your own patients, or even whether it applies at all.

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>> Sara Lou O'Connor
>> www.WholeHealthMedia.com
>> Medical Communications
>> 818-360-8263
>> ----------jgg2014@GMAIL.COM
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I get your point, but I really don't see how physicians could take or make the time to get drug information from published literature or studies (...). Other than my years of experience in a variety of medical settings working with physicians, many of my friends are also physicians and I can tell you that after they have tended to their various obligations (including conferences, medical journal reading, etc.), they don't have the time or energy required to take the time to read studies.

----- Original Message ----- From: <holohanmd@CLINICALEVAL.COM>
To: <FREELANCE@LISTSERV.AMWA.ORG>
Sent: Wednesday, March 11, 2009 9:58 PM
Subject: Re: [FREELANCE] Implications of PIs

A few points:
Physicians should not be getting their drug information from company sales rep's, nor from the PI. They should get it from the drug label or from the published literature of studies not funded by drug companies. Reality may be different, but in that respect drugs are not unique; the same is true for many medical devices, and is certainly true for surgical/medical procedures, such as lung volume reduction surgery, or ABMT or peripheral stem cell transplant in support of high dose chemotherapy for breast cancer. After years of use, one of those procedures was found to be of marginal benefit and the other more likely to be harmful than helpful.
I disagree with the concept of limiting use of approved drugs to labeled indications. That would eliminate much of the use of oncology drugs and many of the newer biologics. If all "unlabeled uses" were prohibited, the FDA could never keep up with the supplementary NDAs industry would have to submit. Most unlabeled use (not casual use) in oncology, immunology, cardiology, and rheumatology is supported by good quality published studies.
There is another consideration. When drugs are studied under protocol in an IND, the inclusion and exclusion criteria are appropriately precise. But often this results in the selection of patients that are likely to be different than the broad spectrum of patients who may be given the drug post approval. For a non-drug example, in the Mar 5th NEJM, a large multinational study compared PCI to CABG for coronary artery disease (the SYNTAX trial). More than 70% of the screened patients were admitted; prior PCI/CABG comparison studies enrolled a much lower percentage of screened patients (some as low as 10%). This is a critical factor in making a judgment as to how the research data applies to your own patients, or even whether it applies at all.

> Hi Slo,
>
> I feel I have to comment on your comment:
>
> First, PI's are developed under the guidance of the FDA and the format
> is standardized in cooperation between the industry and the
> government. So, currently, you may see information repeated in
> multiple sections (i.e. Contraindication, Warnings, Adverse Events,
> etc.). Furthermore, as someone stated previously (and in the court's
> proceedings, as well), PIs are "approved" by the FDA, based on the
> clinical study reports submitted with an NDA.
>
> The question is: How many prescribers are reading a PI? How many
> prescribers prescribe medications that they know very little about?
> How many prescribers are prescribing medications based on the
> information they obtained from the sales rep or from colleagues (the
> herd mentality). And if you as a patient alert them to the PI (because
> it contains information that may make the drug contraindicated in that
> patient) he/she will advise the patient "not to worry" based on
> his/her experience with the drug ...."that contraindication is very
> rarely applicable"..."just follow my directions"...
>
> Perhaps it is time to curtail the "freedom" of using a drug in any way
> and shape by a physician just because he/she is a physician; as you
> know physicians can use a marketed drug for any unapproved indication,
> under any circumstances. I believe this is where most of the problem
> lies in dangering patients' well being; not in an incomplete or
> unclear PI.
>
> It is late now; otherwise I could continue with examples and

> suggestions how to revisit this issue in a more serious manner.
>
> Jayne Grossmann, Pharm.D.
> Medical Writing and Regulatory Strategies Consultant
>
> On Tue, Mar 10, 2009 at 10:11 PM, <WholeHealthMedia@aol.com> wrote:
>>
>>
>> In a message dated 3/10/2009 6:55:49 P.M. Eastern Daylight Time,
>> dschroeder10@VERIZON.NET writes:
>>
>> if the learned intermediate (in this case, a PA) ignored 6 warnings in the
>> product labeling, would a 7th warning have made a difference? The jury
> seems
>> to have concluded that the 6 warnings were not sufficient. Is it possible
>> that PIs contain so much information that key safety issues get lost in
>> clinical practice? That's another discussion.
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