



Medical Device Standards for Review

Webinar: [How to Review the New Draft CDISC Medical Device Data Standards](#)

Hosted by: [SCDM and CDISC](#)

When: [10 am CDT, 18 August 2011](#)

Cost: **FREE!**

Registration: www.scdm.org, click on [Webinars](#) and select the first listing

Registration closes at noon CDT on Wednesday, 17 August

On Thursday, 18 August 2011, SCDM and CDISC are presenting a webinar to launch the review of the new draft data submission standards for medical devices. These standards have been in development for several years, and the draft will be published in early September. The purpose of the webinar is to introduce the standards to the medical device community and to explain how to review them.

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The standards describe the structure for submitting electronic data to the US regulatory authorities. While submission in this CDISC format is not currently required, the FDA has indicated that regulation requiring its use is in development.

Eventually almost all regulatory submissions will have to use these standards, including those to CDRH (the FDA device division) as well as CDER and CBER (drugs and biologics, respectively). These standards allow the FDA to receive clinical data from PMA and 501(k) studies so that they can perform their own analyses, which allows them to verify the sponsors' claims. The CDISC standards complement, but do not replace, the eCTD standards for structuring electronic documents such as study reports.

Komen 3 Day Walk Opening ceremony, survivors touched by the morning sun.



Fun Pharma Facts

Did you know?

Helminthic Therapy: Infecting yourself with hookworms for the purpose of asthma and allergy symptom suppression.

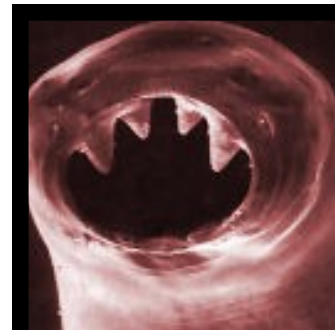
Many people afflicted with the above conditions are willing to try anything for a cure. However infecting yourself with hookworms as a treatment may be dubious at best.

Jasper Lawrence, a lifetime sufferer of allergies and asthma, lauds the use of hookworms to combat extreme allergic reactions. He began reading research performed by many universities from all over the world that noticed that people in developing societies did not suffer from allergies nor from asthma, and the answer he came across over again was immune suppressing parasites, or more specifically the hookworm. He wanted relief from his allergies and asthma so much that he traveled to Cameroon, Africa and walked barefoot through what passes for sewers there until he was infected. He reports that, ever since, he has been free from the severe allergic reactions to his environment from which he used to suffer.

It is possible that the hookworm, and perhaps some other types of gut parasite, are able to suppress the kind of immune reactions which are oversensitive in asthmatics and extreme allergy sufferers. When weighing the pros and cons many may find that being symptom free may not be considered a reasonable trade-off for being infected with the parasite. For example, in susceptible children, hookworms cause intellectual, cognitive and growth retardation, as well as intrauterine growth retardation, prematurity and low birth weight among newborns born to infected mothers.

As with any form of treatment, prior research and careful consideration must be taken into account, but you might find that housing an immune suppressing parasite could be the best option for treating your condition.

* thanks to astmahookworm.com and radiolab.org



Walking in the Komen 3-Day for a Cure for Breast Cancer

By Kit Howard

This article is a bit different for K-News as it focuses on the patient side of our work. We hope you enjoy it.

Last weekend I had a most remarkable and inspiring experience. I participated in the Michigan Susan G. Komen 3-Day for a Cure walk, an event that raises money to find the cures for breast cancer. The idea is that individuals ask for donations, and as a sign of their commitment to the cause, walk 60 miles over 3 days.



To some people, the idea may seem a bit odd – why would people donate money to sponsor someone walking? I’m not quite sure why it works, but it does. Committing to the training necessary to achieve this (I certainly wasn’t in good enough shape when I started!) and to raising the minimum funds (\$2,300 per walker) created a sense of participating in something much bigger than myself, something that could make a real difference. And I deeply believe in making a difference – it is the primary driver in my professional life. My business is about helping to make clinical research as high quality and efficient as possible, so all those research dollars produce the most valuable and true results possible.

There were a couple of other reasons too. My mother is a breast cancer survivor – she is “a year in the clear” - and she is one of my best friends. Then there is the fact that I turn 50 next year, and while I certainly like myself, there are things I’d like to do differently for my second half century, not least of which is to become a lot more fit. So it all came together in early June, about 10 weeks before the event.

Ten weeks is not a lot of time to raise \$2,300 and become fit enough to walk 60 miles! The shortest training program provided by Komen was for 16 weeks, but I plunged in at Week 10 (they count backwards) and quickly learned about good shoes, good socks and blisters! The training walks were long – it takes about 7 hours to walk 18 miles with potty breaks and stretching, and this was a serious time commitment. That, I think, was the hardest part. I don’t have much free time, and I trained 6 days a week. Sometimes I listened to the news, sometimes I recorded work-related ideas, but most of the time I learned about wildflowers. I took a small camera, photographed each species as it came into flower and later identified them. As the days passed, I tuned into the rhythm of the season, and the walks became my time to find my center and my quiet. It was a gift.

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*Medical Device Standards for Review cont.**(Continued from page 1)*

A long line of Pink

Current CDISC standards cover the core data required for most drug studies, including adverse events, demographics, concomitant medications, vital signs, study drug exposure, and others. The new device standards cover the additional core data needed for most device studies, and should be used in conjunction with the existing SDTM (submission) and CDASH (data capture) standards. As with all other CDISC standards, the intent is not to tell sponsors what data should be collected, but rather to provide a place and structure for the data that the sponsor determines are necessary.

Six new domains (groups) of data were developed, as follows:

1. Device Information (DI): this serves 2 purposes

A. Defines key information about the device under study that won't change during its deployment, e.g., model number, expiration date, shelf life

B. Defines the level of granularity at which the device will be tracked in other domains, e.g., serial number, lot number, box number

2. Device In-Use (DU): captures information about how the device was used for a specific subject or deployment.

These are characteristics that do not change for the device, but may be set for a deployment, e.g., slice thickness on an MRI image.



Keeping the walkers safe

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Walking in the Komen 3-Day for a Cure for Breast Cancer cont.

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The fundraising was more intimidating than the training. I could control the training, but the fundraising required other people's participation! Using the resources Komen offered, I sent an email request to my family, friends and many of my business colleagues. The response was wonderful, and I raised just over \$2,800 without having to resort to other means. That too was a gift.

The culmination of it all was the walk. On Friday before dawn the opening ceremony began. We were treated to an inspiring talk by the Komen spokesperson telling us about how Komen was founded on the promise of a woman to her dying sister that she would stop at nothing to see this disease cured. Then as the music swelled, survivors crossed the stage with banners that spoke of those who suffer – My Mother, My Grandmother, My Sister, My Father, My Daughter, My Brother... And the crowd parted to let them through to a stage where they placed the banners, and a flag was raised with the names of walkers' loved ones who had passed on, and as the flag rose and the survivors raised their joined hands the sun broke the horizon and bathed them in the day's new light. That is why we walk. To fight for the living, to honor the memory of dead, and to ensure that breast cancer will never again strike our mothers, our sisters, our fathers, our daughters...

As we, the 1,500 walkers, streamed from the ceremony on our first day's walk, friends, families and survivors cheered us on, and thanked us, and hugged us, and gave us high-fives. We looked into the faces of the people for whom we did this.

The high of the ceremony took us out onto the route, and while it faded somewhat as the hours and miles passed, there were constant reminders. Many of the walkers, me included, wore sashes or ribbons or photos or lists of the people whom they were honoring. I had embroidered a sash with the names of those my donors wanted to honor. Heading my list was my mother, with friends of hers and of mine, and then others. Some had just been diagnosed, some were in treatment, some were victorious, and others had been defeated. Their names, and those I saw on other walkers, were a constant inspiration.

Then there were the people we passed. Many folks had set up tables along the route and offered us water, and candy (way too much candy!), iced watermelon, frozen grapes, and pink ribbon pins, charms, mardi gras beads and bracelets. Cheerleaders from the schools we passed lined the paths and chanted cheers they had created for the walkers. Elderly people waved from their verandas. Toddlers offered us sweets. Folks formed long lines down the sidewalks and high-fived us all the way through. The outpouring of caring and support was almost overwhelming at times.

I think it was the signs that touched me the most. "You go Cindy!" "Aunt Natalie would have been so proud of you." "Two, four, six, eight, what will we annihilate? Cancer!" "30 year survivor." "Thank you for walking." "Speed limit 20 miles per day!" "One survivor, two survivors, three survivors, four. Five survivors, six survivors, because you walk there's more."

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3. Device Exposure (DX): records characteristics of the deployment of the device in or with a subject, e.g., start and end dates, dose, method of application. It is distinct from the current EX domain in that EX is specifically for exposure of subject to study drug. DX may or may not be used for non-subject-specific modalities such as diagnostic equipment.
4. Device Events (DE): defines various kinds of events that may happen to or with the device. It is currently modeled for device malfunctions, e.g., breakage, software failure, device migration after implantation, or whatever is deemed to be a malfunction by the sponsor.
5. Device Tracking (DT): captures the tracking and disposition information about each device. It can be used to capture the details for each shipping or transfer event for each device, or can be used just to record the final disposition of each device.

**Amazing Cheerleaders!***(Continued on page 9)*

Walking in the Komen 3-Day for a Cure for Breast Cancer cont.

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There was a mix of seriousness and humor that took what was normally a topic that one doesn't really discuss every day – breasts – and found a way to make it acceptable. There were sweep vans that would pick up walkers who needed a lift to the next rest stop, and each was decorated with a theme. One was covered in pink plastic milk jugs and had "Save Our Jugs" painted on the side. Another was the Bra-mobile, and sported dozens of wild bras. Guys were wearing t-shirts stating "I love b**bies," something they certainly couldn't do at any other time or place!

The walkers were a mix as well. There were quite a number of men, and mother/daughter and mother/son teams. At least one was in a wheelchair, and at least two were either recently done with or still doing chemo. Two were on crutches and a couple more had casts on one foot. Each person did what they felt they could, and there was no shame in hailing the sweep van. People took care of themselves, and very much took care of each other.

The weather was beautiful for the first 2 days, and lightly rained most of the third day, which was fine as it kept things cool. On Friday and Saturday the walk ended at camp, where hundreds of bright pink tents awaited those who decided to camp. I stayed with a friend who lives near the route as thunderstorms were forecast for Saturday and my days of sleeping in leaking tents and wet sleeping bags are over! Camp also had the expected shopping opportunities (all in pink), a set of massage chairs with attached wi-fi laptops that were a little piece of heaven on earth, medical help, and very passable food. Breakfast and dinner were available at camp, and lunch was brown bagged from one of the pit stops.

The third day ended at the site of the closing ceremony. As I crested the final hill I could see the buildings on the ceremony site. As each walker walked that final 100 yards, drummers beat a wild rhythm, kazoos buzzed and flappers clapped and they were cheered and high-fived and congratulated by hundreds of people. The triumph of taking that last step of those 60 miles, buoyed by the love and support of all those who had helped me, was one of the most exhilarating moments of my life.

For the closing ceremony, the walkers formed rows 8 across and took our victory walk down the lane formed by cheering friends and family. We were followed by the crew, who were loudly applauded by walkers and family alike. And finally, the survivors, both those who walked and those who supported, brought the banners back. As the music swelled, the walkers as one sank to one knee and in their hands raised their walking shoes as the symbol of their commitment to the survivors and those gone, and to a future free from breast cancer. And then with amazing energy, the music pounded out a beat and everyone, walkers, crew, survivors, staff, family and friends began to dance as the speaker announced that the Michigan 3 Day Event had raised \$4.1 million!

Every step was worth it, and yes, I'm already registered for next year.

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Consultant's Corner

In every issue, we highlight members of our consulting community by listing their company's name, contact information and specialty. The goal is to present our readers with a resource to utilize if and when a consultant's expertise is needed.

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6. Device-Subject Relationship (DR): a centralized location to access the list of the subjects and their related devices. It is a special purpose domain, and is not structured like other CDISC domains. It is more like an index table, and can accommodate a one subject to one device relationship, one subject with many devices (e.g., bone reconstruction) or one device with many subjects (e.g., blood glucose meters).

Kestrel's Kit Howard is a co-leader of the CDISC Medical Devices team, and strongly encourages everyone involved with devices to review these standards. The more uses cases that can be applied, the better the standard will work. The draft should be issued in early September, as soon as the Device team has addressed the remaining internal comments. Instructions for downloading the standard and the comments document will be on the CDISC website (www.cdisc.org), and Kestrel will issue a brief email alert when it is available. In the meantime, the webinar on Thursday will provide additional information about the standard and its review.

Kestrel's Kit Howard is a co-leader of the CDISC

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