



**November-26-09**

## **Progress Report on MICYRN Data Management CORE**

### **Highlights:**

The Data Management Core, chaired by Dr. Lawrence Richer in Edmonton, Alberta, has been working with the data management group from the Women's and Children's Health Research Institute (WCHRI) based at the University of Alberta/Stollery Children's Hospital to trial both data management software and electronic data capture systems.

Recently the WCHRI group met with the Vancouver CFRI group based at BC Women's and Children's Hospital by videoconference to discuss the DM systems that have been recently trialled as well as some newer systems that look promising.

### **1. Data Management Systems – WCHRI**

The WCHRI group has been trialling two different data management systems, with a good deal of success.

The first of those two is OpenClinica. The advantages of OpenClinica are that it is fully compliant with privacy and security regulations (CFR 21, Part 11 of the Canada FDA regulations), has both an audit trail and electronic signature tracking, and is fully query-able at different levels (ie. Can be queried by users, monitors, or the system itself if the data is non-compliant). The WCHRI group feels that OpenClinica has advanced a lot in the last year, and takes part in Open Source upgrades such as WCHRI's own addition of a tool that allows data to be pulled out and transferred directly into SAS. In addition, they feel the support both from OpenClinica and from the OpenClinica partner group Akaza has been excellent.

The second system WCHRI has been working with is an Open Source system called RedCap, which is based out of the United States. RedCap is an alternate system which would be a potential option for simpler trials that don't need to be CFR 21 compliant but require a good solution for their data management. RedCap also has many advantages. It offers an audit trail system, responsive support, branching logic options, an attractive price (free), and allows the user to pull data from the system into many different programs including SAS and Excel. The Vancouver CRSU group was impressed with the ease of use of RedCap and the user-friendly interface and will be looking into this system further as well.

### **2. Data Management Group - CFRI**

The CFRI group has been trialling the Dacima system. Dacima offers many of the same benefits that OpenClinica does. Dacima is also CFR21, Part 11 compliant and although the interface differs somewhat from the OpenClinica interface, the operations are essentially the same. In addition, the CRSU group has constructed their own entry portal website for users from Children's Hospital.

### **3. Surveys**

Another consideration of the DM group is survey software. With electronic surveys becoming such a popular way to gather data these days there are many survey systems being developed, again, each having pros and cons. Depending on what options are required there is also great variability in price.

One popular free survey tool which is widely used is Survey Monkey. Although the options are limited with this program it is easy and quick to use and this tool has proved to be quite popular.

Another survey tool that the MICYRN group has been using is provided through a web-based communications site called Constant Contact. The tools available are quite flexible but the output can be provided in Excel or pdf format, which can be limiting. Another issue with this software is limited follow-up communication features.

In 2008 MICYRN bought survey software called CheckBox for the DM Core to work with, and this has been well received. This software offers flexible tools and output capacity and the DM group has used it to create surveys of different levels of intricacy for a variety of users. However, the software is quite costly at almost \$3600 plus yearly licensing fees for each user.

RedCap and Lime Survey also both have good survey tools available for use, with good branching logic options, but neither are as sophisticated as CheckBox.

### **4. Future Considerations**

Overall, the data management systems available are very good and quite easy to use. They offer a good degree of variance in both options and price range, and generally the support for the systems is very responsive. Unfortunately it is more difficult to get people interested in using them vs. simply storing their data in Excel spreadsheets as has been customary for so many years. A significant hurdle is present just in prompting investigators to approach the WCHRI/CFRI for assistance.

A few potential solutions were raised including encouraging the consideration of data management systems through ethics/privacy rules. It was agreed that the first step to be trialled locally is meeting with research program managers to discuss the systems available and the services the CFRI/WCHRI can provide. This should give us an idea of how well people respond and whether this leads to an increase in the use of these services, and give us a platform to base our national strategy on.