



Thai Academic Researchers Embrace CDM



In the US, there is a debate raging about the future of data management – whether it will continue to exist as a function within sponsor organizations, or be completely contracted out, whether it is primarily about building EDC applications (and therefore mostly an IT function), or about sending and resolving queries and therefore can be off-shored. With a few exceptions, data management is again being seen as a clerical or IT function that focuses mostly on CRF design, data cleaning (whatever that might mean) and database building.

In some parts of the world, exactly the opposite view is being taken. Along with a colleague, I recently had the privilege of teaching a class on data management-related topics to a remarkable group of people in Thailand. The class was the capstone of a 5 month program organized by BIOPHICS, (Center of Excellence for Biomedical and Public Health Informatics), which is a non-profit largely government-funded organization supporting health research, medical informatics and education. Dr. Jaranit Kaewkungwal, a well-respected researcher, is its director and a sponsoring force behind the training. The class consisted of select individuals invited from the top clinical research hospitals in Thailand, including doctors, researchers, nurses, statisticians and data managers, as well as a representative from the Thai FDA.

The goal of the course was to study data management through review and discussion of the Society for Clinical Data Management’s Good Clinical Data Management Practices (GCDMP) document, chapter by chapter, with an eye to the attendees

Table of Contents

- Page 1.....Thai Academic Researchers
- Page 2Speaker’s Schedule
- Page 4.....Consultants’ Corner
- Page 5.....Fun Pharma Facts
- Page 6.....Cutting Edge Edu.
- Page 7.....Fan Forum!

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(Continued on page 3)

Speaker's Schedule

Kestrel's own Kit Howard, is scheduled to speak at several trade conferences in the upcoming months. Below are the conferences she will be attending and the topics she will be speaking on. If you are attending, please say hello to Kit, if you see her.

Oct 17 – 20 : **Society for Clinical Data Mgmt, Minneapolis, MN**, Debate speaker on topic "This body is resolved that within five years CDM activities will be conducted exclusively at service provider organizations, and the CDM role will disappear in study sponsor organizations." . www.scdm.org

Oct 25 – 27: **MAGI West Coast Conference, San Francisco, Ca**, speaker, "Demystifying the Data Query Process." <http://www.iibig.com/P1004>

Oct 31 – Nov 5 : **CDISC North American Interchange, Baltimore MD**, Attending

Nov 3: **FDANews 5th Annual Inspections Summit, Bethesda MD**, workshop leader for 3 hour pre-conference workshop, "Clinical Trial Data Quality and Validation."

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Thai Academic Researchers Embrace CDM cont.

(Continued from page 1)

becoming certified clinical data managers. Our participation provided the group with an opportunity to hear from and ask questions of two certified clinical data managers. We covered topics in standards, metrics, quality and data design, and also talked about the specifics of how to prepare for and take the certification exam. The attendees were enthusiastic, and by the end of the class were eager both to take the exam and to apply what they had learned back at their universities.



It is probable that most of the participants will not pass the exam the first time they take it. It is a difficult exam, and CDM is a relatively new discipline in Thailand. But then, many who take the test in the US don't pass the first time either. The important point is that this mix of participants, including clinical researchers with doctorates and research nurses, recognizes that it is impossible to design, develop, conduct and analyze high quality clinical trials without understanding the nuances of defining, capturing and managing the data, knowledge that extends way beyond just CRFs or queries or setting up databases.

(Continued on page 4)

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Consultant's Corner

Kestrel is pleased to bring a new feature to K-news, the Consultant's Corner. In every issue, we will 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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(Continued on page 7)

Thai Academic Researchers Embrace CDM cont.

(Continued from page 3)

In other words, they understand that, in order to generate quality data, the clinical researchers must understand what quality data are, and how every function participates in the process, and that requires understanding CDM, and understanding it deeply enough to become certified.



It was extraordinarily energizing to teach individuals who are on the front lines of managing major public health threats such as malaria and dengue. They are intensely committed to improving the health and wellbeing of their fellow Thai citizens, and are doing everything they can to enhance their ability to do so. They intend to repeat the classes annually, in the belief that all of the clinical researchers, statisticians and data managers in Thailand should be certified CDMs. We can only hope that their foresight and wisdom will someday influence the US as well.

ers, statisticians and data managers in Thailand should be certified CDMs. We can only hope that their foresight and wisdom will someday influence the US as well.

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Fun Pharma Facts

Did you know?

The earliest known medical document describing the virtues of plants as medicine is a 4,000 year old Sumerian clay tablet that recorded plant remedies for various illnesses.

The Ebers Papyrus (1550 BCE), is among the most important medical papyri of ancient Egypt. It contains hundreds of plant remedies such as mandrake for pain relief, and garlic for the treatment of heart and circulatory disorders.

The Greek physician, Hippocrates (460-377 BCE), so influential that he is known as the "Father of Medicine", believed that disease had natural causes and used various herbal remedies in his treatments.

The Greek physician, Pedanius Dioscorides (circa 40–90 CE), compiled the knowledge he gained while traveling as a surgeon with the Roman army, in *De Materia Medica*, which contains an account of over 600 species of plants with medicinal value.



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Fan Forum!

Kit is a thought leader in the data management community for her extensive work with clinical data standards. Her vision, which she has turned into reality through her Data Lifecycle Plans and through her work with CDASH, is well-recognized throughout the clinical data management industry and her knowledge and foresight should be considered by any organization looking to bring their data standards up to world-class. Having known and worked with Kit for many years, I find I always learn something when we spend time together."

*Doug Schantz, Senior
 Director, Neuroscience
 Clinical Project Management,
 Pfizer*