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Successful CDISC German-speaking User Group Meeting

The 10th German-speaking CDISC User Group took place in Munich on March 11th. Already the evening before, about 10 participants met at the italian restaurant just opposite to the hotel. After that some still went for a bear, so extending the SDTM discussions to almost midnight.

The topic of this meeting (hosted by Kendle) was "SDTM mapping". The organizers had asked the participants to come with problems they had with specific situations and mappings, give a short presentation about it, and then discuss possible solutions with the audiance.

This worked very well: we had over 10 presenters (among the 42 participants), and the discussions were very vivid. For me, it was nice to see that there is not always an "out of the box" solution, this as I regards mapping to SDTM as an interpretation and categorization step.

Before closing, we then had a separate presentation from Johannes Drepper (TMF e.V.) bringing us up to date about the situation of using electronic health records for use in clinical research in Germany. There still are some legal barriers here, and probably a change is legislation is necessary before electronic health records can be used during the course of a clinical study.

A number of photographs I took during the meeting can be found at the end of this newsletter.

SDTM-ETL™ movies on the web

During the German-speaking User Group Meeting, we also showed a short movie about the strategy that is used in SDTM-ETLTM, our mapping tool to generate SDTM-compliant submissions, for generating the records in the CO ("Comments") domain. This movie, along with a number of other ones about the usage of SDTM-ETLTM (which can also be regarded as a set of tutorials) can be found on our demo application server at:
www.XML4PharmaServer.com/SDTM-ETL

XML4Pharma to present about "define.xml good practices" at the European CDISC Interchange

Our paper "Define.xml: Good Practices and Stylesheets" has been selected for an oral presentation at the European CDISC Interchange in Brussels. Our presentation is currently scheduled for Wednesday April 13th at 2 pm in the session "ODM Innovations".
Unfortunately, the organizers have put this session (with two presentations about define.xml) in parallel with a session about "SDTM compliance", which in my opinion is not a very good idea, as define.xml good practice is also about SDTM compliance, and as people that create the define.xml are usually the same that generate the SDTM datasets.

As usual, the Interchange has first two days of trainings, followed by the two-day conference, and then an extra day of training on Friday. Also as usual, there will be a conference social event, this time at the famous "Brussels Comics Strip Center". Although I was born in Brussels, and raised up with comics strips, I haven't had the opportunity to visit this center. So I am curious too to meet many of my "youth heroes"!

Cool Technology: KNIME

More or less by accident, I came across KNIME, the "Konstanz Information Minor", a software system developed at the (for me nearby) university of Konstanz, for data mining and visualization.

KNIME seems to be used a lot in bioinformatics and drug research, but I haven't heard about users in the clinical world yet. The software package is open-source, and free, though there are also enterprise extensions and services.

KNIME has been designated as "cool vendor" in 2010 by Gartner, the world's leading information technology research and advisory company.

The nice thing about KNIME is that an analysis is regarded as a workstream, starting with a "File Reader" node or a "Database Reader" node, followed by "Data manipulation" nodes and usually finally by a number of "Visualization" nodes. Such a very simple workstream is shown in fig.1 below. Everything is done graphically by "drag-and-drop" and then configuring the node. No programming, no SAS code, no macros are necessary at all (although KNIME supports the R- statistical language).

I used it to read in clinical data, assign coloring modes to the data, and then produce a set of scatter plots. Even though I did not know anything about KNIME before, it took me less than 5 minutes to get everything ready and produce my first scatter plots, without having to write a single line of code.
You can see some of the results in fig.2 below.

Although KNIME does not have an import for XML data, I am seriously thinking about interfacing KNIME with our own ODM Viewer. The latter already produces nice tables of clinical data arranged by subject and per CRF, and allows some simple statistics, but an interface with KNIME would allow starting doing serious analysis of clinical data starting from ODM, in a very intuitive way, without any programming.

KNIME is open-source and free, and provides functionality that otherwise costs a 5- or 6-digit amount of money for a single license. So it may be a very interesting choice especially for smaller CROs that cannot afford expensive licenses.

New versions of the ODMChecker available

Our free and famous (over 200 installations) ODMChecker has been updated - it also now supports ODM v.1.3.1.

Furthermore, we have decided to change the licensing schema. As of now, three versions will be available.

- the "Base" edition remains free-of-charge for CDISC members and allows validation of a single ODM file or a chain of ODM files (supporting the ODM "Include" mechanism) against the standard

- the "Professional" edition has all the features of the "base" version, but also supports any vendor extensions (Medidata, PhaseForward, Lilly, etc..) for which there is an "extension schema" available. These "extension schemas" are usually provided by the EDC vendors and can be used directly with the ODMChecker. The price for this version is US$ 1,000 or € 725.

- the "Entreprise" edition is tailored individually to the requirements of each enterprise customer, and can be interfaced with or integrated into the existing systems of the customer. It also allows to add additional company-specific rules. Prices are available on request.

Users that still have an older version of the free version of the ODMChecker can simply obtain an upgrade to the "base" version by sending us an e-mail.

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Photographs taken at the German-speaking CDISC User Group Meeting in Münich

Over 40 attendees listening carefully during one of the many presentations

Kendle also offered us an excellent lunch (thanks!)

CDISC Interchange, Europe
11 – 14 April 2011 | Brussels

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Interchange Europe

**Join us at the European CDISC Interchange in Brussels !**

Cool Technology: KNIME (Konstanz Information Miner)
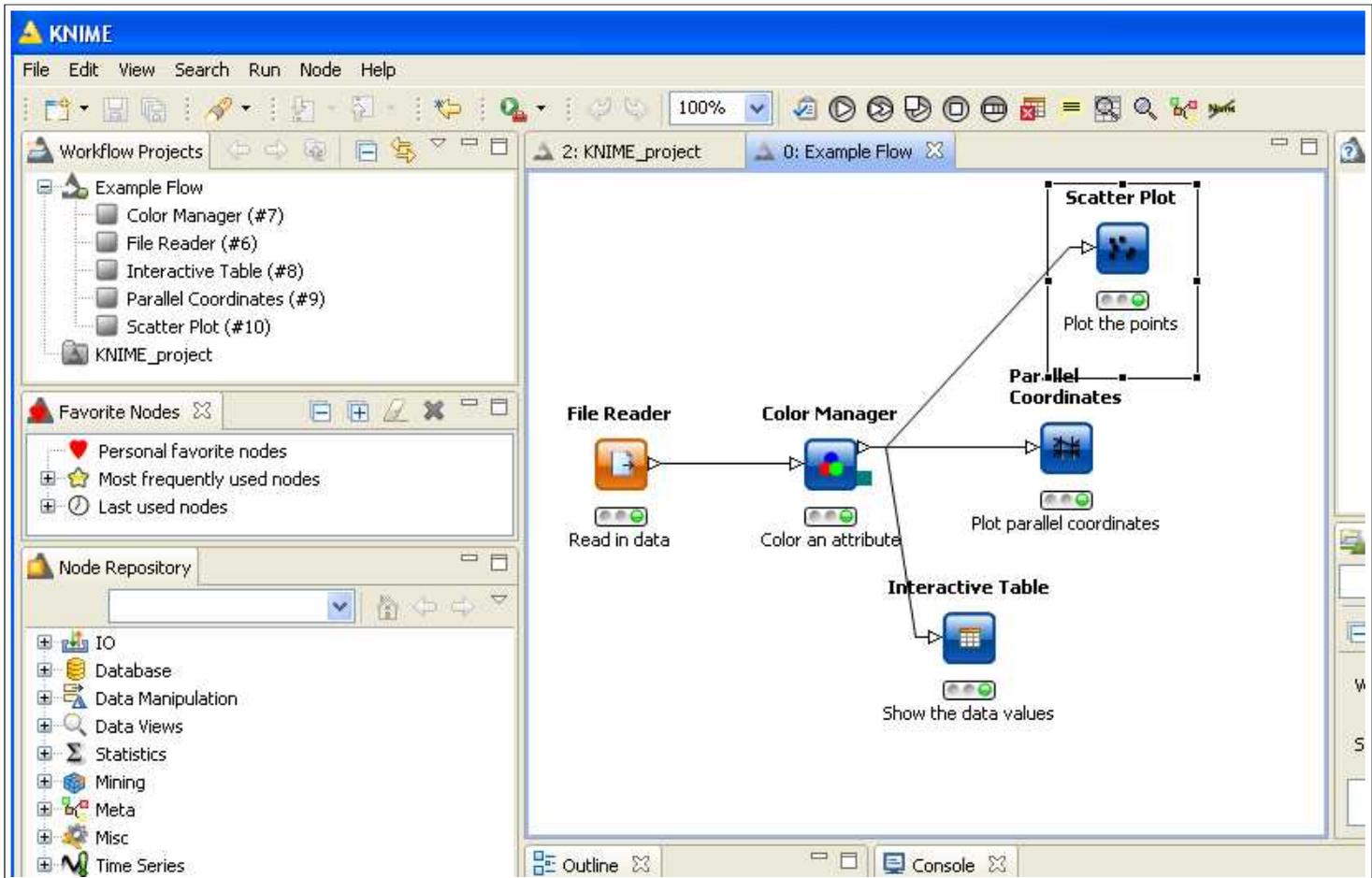
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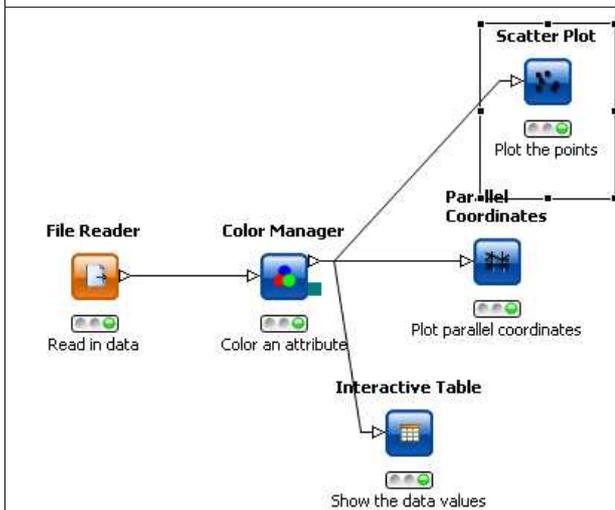
Using the workflow editor ...
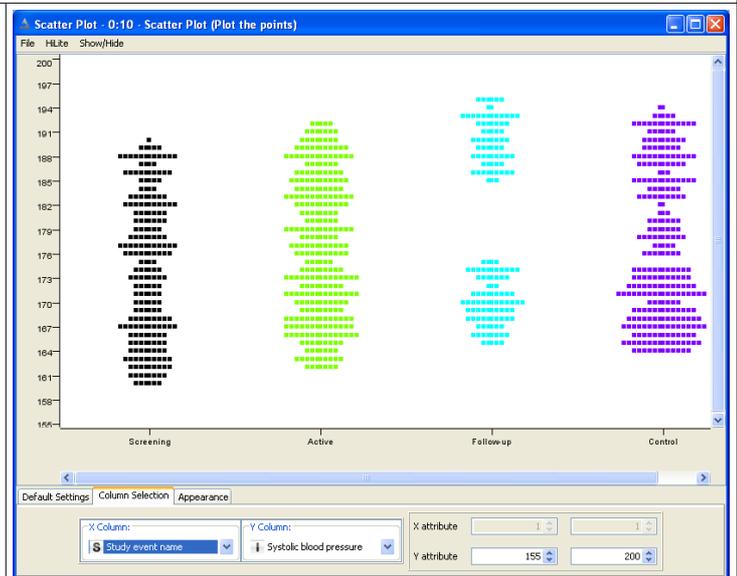
Scatter plot of systolic blood pressure versus visit. Remark the general trend of the increasing systolic blood pressure, and especially the splitting up in two groups for the "Follow up" visit.