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Professorship at the Joanneum University Graz

I was recently offered a professorship in Medical Informatics at the University of Applied Sciences Joanneum (FH Joanneum) in Graz, Austria, and accepted.

This professorship will allow me to further work on the development of CDISC standards, and especially on integration with healthcare. Also, it will enable me to teach young people about medical informatics, databases and XML technologies.

The job is especially interesting as Austria is currently implementing a nationwide system of electronic health records, named ELGA ("Elektronische Gesunheidsakte). With my knowledge I hope to be able to contribute to the "secondary" use of electronic health records, not only in the area of clinical research, but also in the field of epidemiology, telemedicine, diagnosis support, and many other fields.

As a true european citizen (I have lived in Belgium, the Netherlands, Switzerland, Germany, and am now moving to Austria) I also want to contribute to projects that have the goal to enable exchange of electronic health records between different countries, even if these systems are based on different standards (e.g. HL7-CDA, OpenEHR, etc.). This can e.g. be accomplished by contributing the epSOS project of the European Union.

The future of XML4Pharma

My professorship, which is not full time, of course has some consequences for the future of XML4Pharma. It means that we will need to decrease our consulting services (existing consultancy customers will of course keep getting full support). Also we will not be able to offer training courses anymore.

In the future, XML4Pharma will further concentrate on the development of software for the use with the CDISC set of standards, even **increasing** the activities in this field. For example, we are already working on a new version of both the "ODM Study Designer" and of the "SDTM-ETL"(TM) software, in both cases implementing the new "Study Design Model" (SDM-XML) which was very recently published by CDISC.

CDISC publishes the "Study Design Model in XML" (SDM-XML) v.1.0 final

It was hard work, but now the result is there: the new "Study Design Model in XML", an extension to the existing ODM Standard v.1.3.1.

This extension treats a number of aspects of study design and of the study protocol (in a machine-readable way) that were failing in the existing ODM[1]. As such, it can be regarded as the electronic version of the protocol. The most important aspects implemented in SDM-XML are:

- trial parameters
- inclusion/exclusion criteria

1 And that I wanted to have in the ODM standard for already many years.

- study structure: arms, epochs, cells, segments
- study activities
- workflows (of activities)
- timings (between activities)

We strongly believe this new standard is a major breakthrough. In a pilot, we already proved that clinical research workflows defined in SDM-XML can easily be transformed into XML that can be imported into caBIG's Study Patient Calendar[2] (PSC – TODO: LINK), and into BPMN-2.0 XML, which is a worldwide standard for describing workflows (also see the images at the end of this newsletter). This also means that clinical workflows defined in SDM-XML, can easily be transformed into a format that can be imported into hospital information systems (HIS), and merged with patient care workflows.

But not only that: as the inclusion/exclusion criteria in SDM-XML are defined in a machine-readable format, they can be used to search systems with electronic health records for eligible subjects. Similar for the trial paramters.
This usage will surely be one of the topics of my research at the university.

The SDM-XML standard will further enable to set up studies automatically in EDC systems in a better way than ever before. Also it will enable to automatically generate the SDTM datasets for study design (though these use the SAS-XPT format) from this electronic version of the protocol. This is something I want to prove in the near future.

SDTM-ETL v.1.4

Our newest version of SDTM-ETL (v.1.4) has been very well received. Many of our customers have ordered an upgrade, and we were able to win some new customers.

More and more CROs and SDTM service providers become aware that it does not make sense to use expensive statistical software (that even does not have any build-in SDTM knowledge), for which expensive programmers need to write non-reusable macros or programs, to generate SDTM datasets from operational data. Instead, they see that SDTM-ETL provides an extremely user-friendly way to generate and execute mappings between operational and submission data, and to reuse these mappings over and over again on different studies.

But the software will be further improved and new features added. As already stated, the new SDM-XML standard allows to define study design information that later also needs to be submitted to the FDA. So we are currently working on further extending the software to enable to automatically generate study design SDTM datasets from SDM-XML information. Once this has been done, we will release a new version 1.5.

Gartner analyst discusses HL7-v3 XML messages

Remember our 3-year-old article "Ten good reasons why HL7-v3 XML is not a good format for SDTM submissions"? You can find it here.
In a very recent article, Gartner analyst Wes Rishel discusses the failure of HL7-v3 XML messages (except for CDA, which is not a message, but a document) to get any significant "market share" in the healthcare world. It is interesting to compare his article with ours.

For example:
XML4Pharma:"it is observed that over 99% of the implementations are HL7 version 2 implementations (not using XML), and that less than 1% are version 3 implementations (using XML). So the 'market share' of HL7-XML within HL7 is less than 1%.".
Gartner (W.Rishel): "V3 Messaging is close enough to having had zero impact".

The Gartner article is a reaction on several blog entries written by Graham Grieve, one of the main developers of HL7-v3, but also a critical mind. Graham is also one of the initiators of the "Fresh Look Taskforce", an initiative within HL7 to develop a new generation of standards for healthcare, less complicated, easier to understand, and much much easier to implement. Nothing is sacred in the current discussion, even not the use of XML (e.g. why not use JSON?) and XML-Schema. In the last few weeks, I had a few discussions with Graham on the matter – he has my full support.

2 I am currently writing a scientific article on this topic.