Bimonthly newsletter of XML4Pharma,
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XML4Pharma is a CDISC Registered Solutions Provider

Join us at the European CDISC Interchange in Brussels

The European CDISC Interchange is taking place in Brussels from April 11th to April 15th. As usual, the first two days will be devoted to training courses. There is however also a set of user group meetings on Tuesday (starting at 5 p.m.) followed by a reception. So if you would like to attend a user group meeting (and the reception of course), check with your local user group representative. In Europe, the user groups are organized based on language, so there is a German-speaking, a French-speaking, an English-speaking, Italian-speaking (and so on) user group. There is also a Nordic (Skandinavian) user group (of which I heard they speak english during the meetings).

The main conference is on Wednesday 13th and Thursday 14th. We will give a presentation titled "Define.xml: Good Practices and Stylesheets" on Wednesday at 2 p.m.. So if you have troubles understanding and generating define.xml for submssions to the FDA or stylesheets for it, then this session that is well worth attending.

Also not-to-miss is the conference social event, this time at the famous "Brussels Comics Strip Center". I presume there will also be some good food (so you will not be forced to a visit to one of the famous belgian "fritkot" establishments) and plenty of belgian beer (definitely the best in the world).

On Thursday, I will also contribute to the "ODM breakout session" as the session lead, where implementors of the ODM standard discuss their experiences with the standard, and provide suggestions for improvements. The latter are especially important for the further development of the standard. So I will be very happy to take up your suggestions for further improvements and for the next version.

XML4Pharma takes part in the SMART Challenge

The US Government regularly publishes "challenges" in areas it believes progress is not fast enough and requires a bottom-up approach.

One of this challenges recently published in the "SMART" challenge, asking developers to develop "apps" for healthcare. The organizers make a web-container available (the SMART container) and an API (using REST - a simplified form of web services) which allows to extract the electronic medical record (EMR) for a chosen patient in the (mimicked) hospital information system. One of the special things here is that the EMR is not returned as an HL7-message (e.g.CCD), an Open-EHR extract nor as an ASTM CCR. It comes as a RDF (Resource Descriptive Framework) XML structure. Another is that the SMART container is organized just like your smartphone: you can just add your own applications to it to use the information from the EMR. A provided sample "app" is the calculation of cardiac risk from laboratory data and from demographic and other factors, such as blood pressure, tobacco consumption and cholesterol level (picture see below).

Our own "app" uses the medications records of the patient (with start and end dates) to prefill a CDASH form with prior/concomitant medication data information. It uses server-based XForms for the prior/concomitant medications form (eCRF), but this is not visible at all to the user as the "app" runs in the SMART container. For example, some of the

patients have up to over 80 medications in their record, whith start date and (in a good number of cases) end date, dose form, unit and frequence. So for each medication, this makes up to 8 fields in the case report form. So if there was no integration with the electronic health record through our "app", the investigator would need to fill in up to 480 fields (for one subject!) in order to have a complete set of prior/concomitant medications for that subject for that clinical study. With our "app" however, all that needs to be done by the investigator is to check the information and then submit it to the clinical data server.

In our "app", the submitted information is further transformed (for demo purposes) to CDISC ODM, and a tabular overview in PDF is generated of all the information that has been submitted, and which can be used as an entry to the archive of the investigator.

Additional information can be found on our website at: www.xml4pharma.com/Smart_Challenge/. It also has a number of screenshots of our "app" running in the SMART container, and a short demo movie.

One of the great things of this approach is that different applications running on different servers run in the same container without that the user is seeing this. So in our case, the "app" uses at least 3 servers, one being an XForms server, whereas the transformation to ODM and PDF is done by another application server. This all goes unnoticed by the user however. Also, as the container can use different "apps" (a choice is listed on the left side of the screen) it allows to quickly switch between different "views" on essentially the same EMR data of a single patient.

Electronic Health Reords exchange: messages or services?

The "SMART" approach raises the question whether messaging standards such as HL7-v3 are still necessary to exchange electronic health records information between systems. "SMART" uses a REST interface with a published API, which is similar (but easier to implement technically) to a web service approach.

The disadvantage of this approach is of course that each provider of such a service may have a different API, meaning that if there are several providers, one need to write several adaptors in order to retrieve information from the different providers.

Ideally, in the case of messaging, the format in which the transmitted information is exchanged is standardized. In healthcare however, there is no such a single standard (although some Standardization Organizations (SDOs) claim that their standard is the truly one). In healthcare, the main players are ASTM, HL7 and OpenEHR. There is a multitude of other smaller ones. This is called the "standards jungle in healthcare".

So one may ask whether the "SMART" initiative has been started because of this "standards jungle" as an easier-to-implement alternative. The "SMART" website states: "*Currently, innovation in health informatics is limited by disparate vendor APIs and ambiguous data standards*".

Heavy discussions again about the value of HL7-v3 and the RIM

Heavy discussions about the value of HL7-v3 and of the RIM have been popping up in several blogs and discussion groups during the last weeks. One of the triggers may have been the recent "President's Council of Advisors on Science and Technology (PCAST)" report titled "*Realizing the full potential of Health Information Technology to improve Healthcare for Americans: the Path forward*" and comments on it e.g. at the "geekdoctor" blog. The PCAST report proposes to develop a "universal language" for exchange of information in healthcare. The "geekdoctor" blog also mentions the "green CDA", an attempt to simplify the HL7's "Clinical Data Architecture" standard, that has been found to be unimplementable by most informaticians in healthcare. One of the blog entries here stated "*I would hope that the country does not start from scratch to build a new Universal Exchange Language. Wise people can take the best of CCR, CDA Templates, Green CDA, and other existing XML constructs to create implementation guides which fulfill the PCAST recommendations*". I can only fully agree on that if they also add a few XML specialits to the "wise people" as the way these "standards" have been implemented in XML is pretty catastrophic at this moment.

The "SMART" challenge claims to address the call for a "Universal Exchange Language" but I presume it will only be one of the many proposals to do so.

At the same time, the RIM itself is heavily criticized again by ontologists, e.g. at the "HL7-watch" blog website. Now I do not know the RIM well enough to judge (I wish I did, but just haven't got the time to study the details), but I have seen the catastrophic result if one automatically generates XML-schemas from such a model, ignoring any XML basic data type. The trigger of the heavy discussions here has been the statement of the CEO of iNTERFACEWARE, a company specialized in HL7-integration, that they believe HL7-v3 is doomed to fail, and they will concentrate on JSON-

based web services in the future (JSON-webservices is another lightweight version of webservices, like REST is one - see previous article on the "SMART challenge").

Status of the ODM-SDM extension

As already reported in a previous issue of this newsletter, a volunteer team at CDISC (of which we are part) has been working hard on an extension to the ODM standard, named the "Study Design Model" and which is essentially a technical implementation of the CDISC Protocol v.1.0 standard.

Our team has now made an important next step: the draft speficication, XML-schemas and sample files have now been made available to a broader group of CDISC volunteers, including the "XML technology team" and the "Protocol team". These will now review the draft, after we might have to implement some changes. When that is done, the specification, schemas and sample files will be published on the CDISC website for public review.
Personally, I hope that this will not be later than early summer.

Over 250 entries from XML4Pharma on the CDISC Public Discussion Forum

We always like to help people that encounter difficulties with interpretation of the CDISC standards or their implementation. Therefore we have been very active on the CDISC Public Discussion Forum. We have now reached the milestone of 250 entries on the discussion forum, in most cases providing answers or hints to people that had questions around the ODM, Define.xml, SDTM or Controlled Terminology standards. In some cases we asked questions ourselves, especially in case the standard or implementation guide is not clear, or when it is too open for interpretation.

Of course we will also keep helping people in the future that have posted questions on the discussion forum.

More educational movies on SDTM-ETL™

We have added a few new educational movies on the use of SDTM-ETL™ for defining mappings between operational clinical data and submission data (SDTM or SEND) and for generating the submission datasets (in SAS Transport 5) and the define.xml that is always fully synchronized during the mapping definition process.

SDTM-ETL™ is one of these tools (there are a few others) that allow to generate SDTM submissions in a very user-friendly way, mostly using drag-and-drop, and without the necessity to do any SAS programming.

This family of "non-SAS" tools is gaining market share, but in our experience, most companies that do SDTM submissions still completely rely on statistical software, although the latter is much more expensive, less user-friendly, offers less reusability, and requires a steeper learning curve. Is this the traditional conservatism of the clinical world? I don't know, but I have seen some more other tools (see our "Cool Technology" articles) from smaller vendors that are really extremely user-friendly and come at low cost, but that are nearly used in the clinical world.

One of the things we are currently also doing is to extend the SDTM-ETL™ templates with the newly (but still draft) published SDTM oncology domains. More news about these and their implementation in SDTM-ETL™ in the next newsletter.

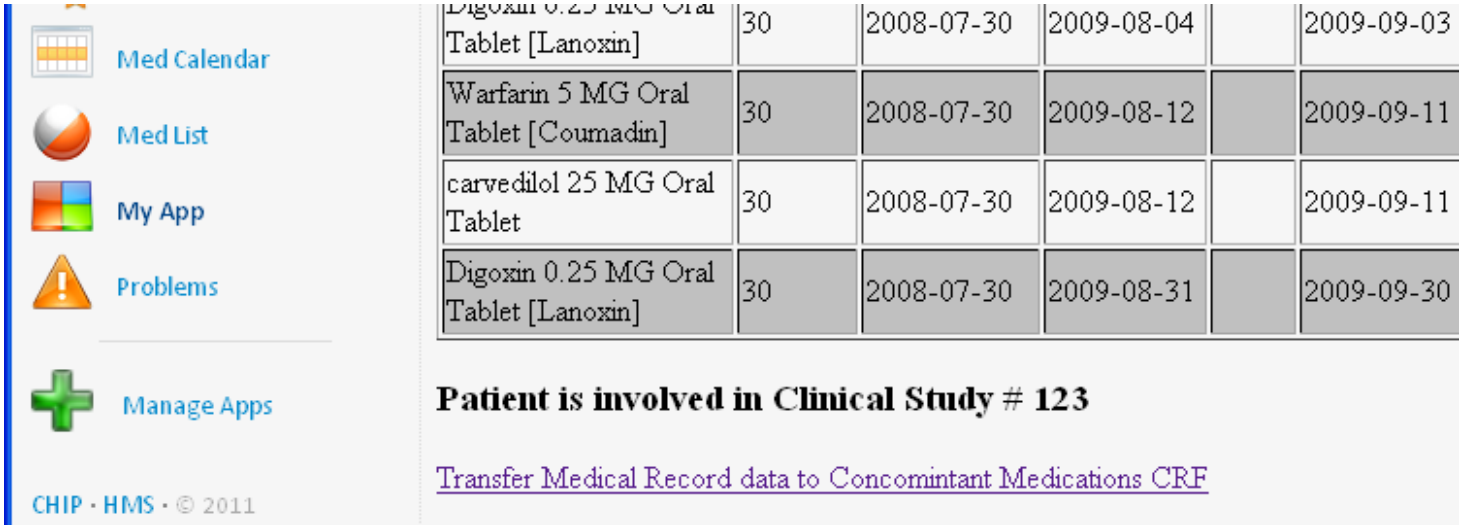
Cool Technology

I came up this due to John Halamka's blog which follow very regularly. It has again to do with integration between systems in healthcare.

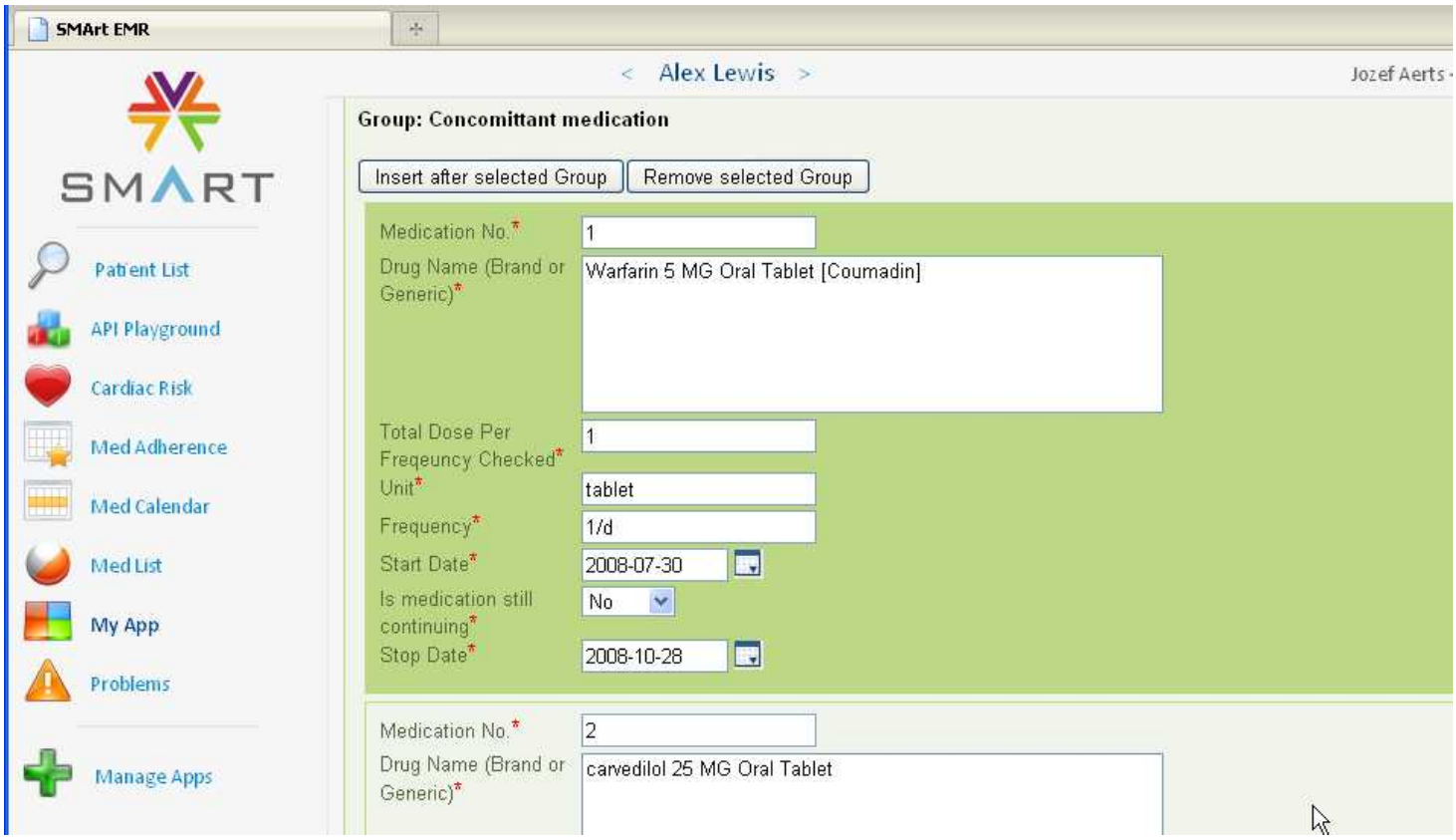
Dr. Halamka tells us about a system that is used by the hospital he is the CIO of (Beth Israel Deaconess Medical Center - BIDMC) to share data between their own Hospital Information System (HIS) and the Atrius Epic system. Information of patients that have data in both systems can now be made visible through a single graphical interface in the own HIS, by just providing a hyperlink that connects using a REST service (like in the "SMART" challenge) to the Epic system. Patient matching is still done using a combination of name, gender and birthdate, which provides 95% matching with no false positives. In Holland, I presume the match would be >99.9% as everyone in Holland has a "social-fiscal number" a unique identifier for each person living in Holland (even newborns). In contrast, in Germany, my tax number even changes when I earned more (or less ...) than the year before.

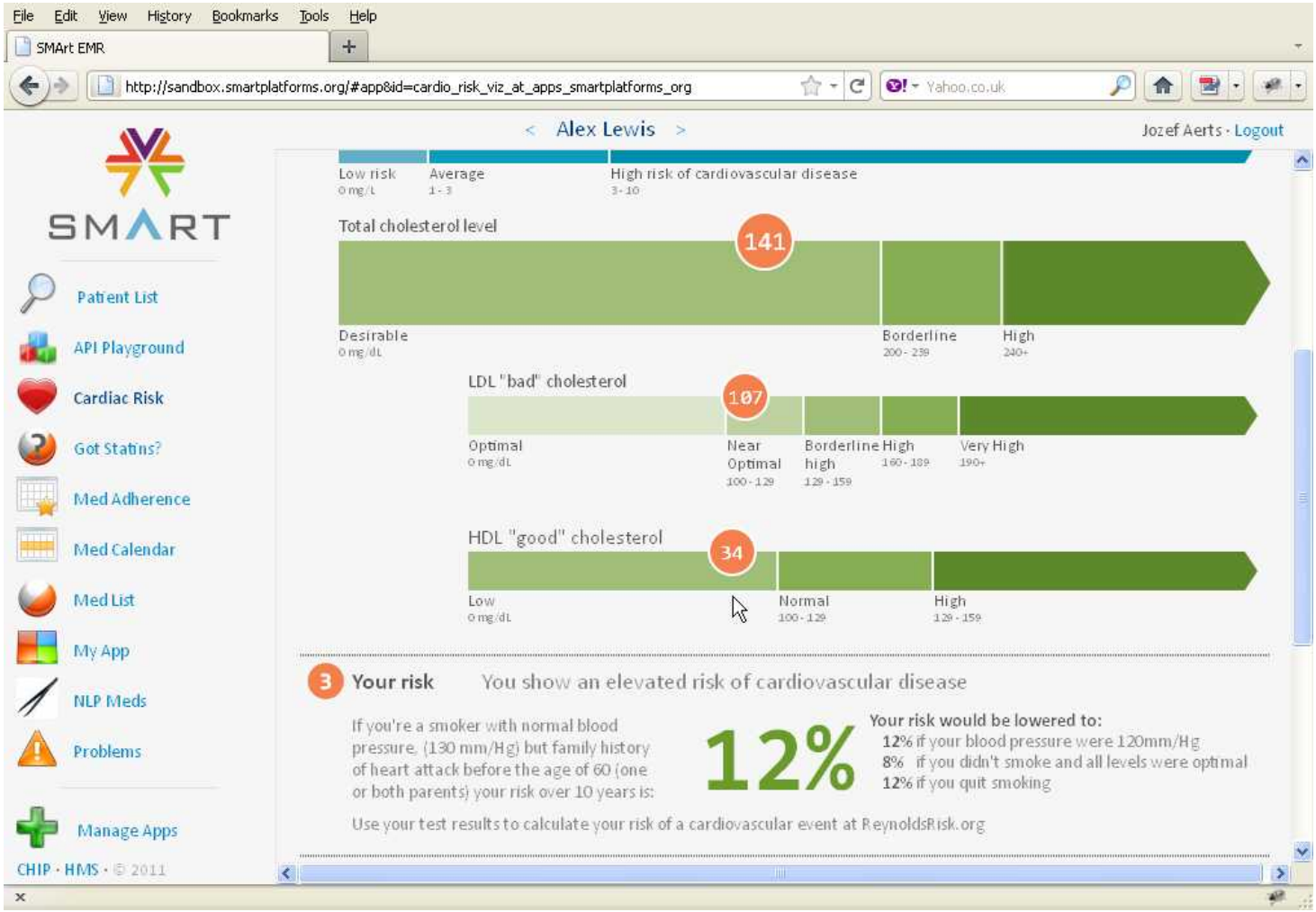
Dr. Halamka even provided a roadmap on how they will extend this to also share data from other providers they are working with such as Meditech and eClinicalWorks.

As stated before, the problem with such an approach is that an interface needs to be developed for each new system that is added. So, better have an exchange standard though?



The SMART Challenge: our app extracts the list of medications from the EHR/EMR (upper image) and uses them to prefill a CDASH form for Concomitant Medications in the EDC system (lower image)





Another app working on the same EHR: calculation of cardiac risk
(this was one of the demo apps from SMART - so not from us)

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