Hurdles for Implementation

The IHE RFD profile describes one possible implementation for integration. The generalised implementation of the profile is hindered by a number of factors, some of them technical, some of them of a political or regulatory nature.

First of all, EHRs are not standardised. Even the concept of ‘electronic health record’ is not clearly defined. In reality, only a few hospital information systems are able to produce something like a portable EHR; an EHR that can also be used by other caretakers outside the hospital. The introduction of standardised EHRs is in many countries more a political than a technical issue, due to factors such as concern about the privacy of data. Different authorities in different countries also understand different things by EHR.

The lack of a worldwide standard for EHRs means that, in order to integrate healthcare records with EDC, an interface must be defined for each different HIS. The problem is smaller on the EDC side: a well-accepted international standard for exchange of clinical study data has existed for many years: the CDISC ODM standard (5).

In a recent project, a number of volunteers from IHE and CDISC built an interface between the ODM and the HL7-CCD (one of the possible formats for an EHR-extract) (6), implementing CDASH standardised case report forms (CRFs) (7). The author then further extended this interface to also support EHRs in the OpenEHR format (8).

The technology used for extracting information from EHRs to eCRFs (using the CDISC ODM standard) is based on XML and XSLT, the ‘XML stylesheet transformation language’ (9). Almost all HIS systems can produce XML, but for each HIS, a separate transformation to ODM (written in XSLT) will need to be developed. This hurdle prevents many EDC vendors from implementing integration within healthcare systems. So only if a hospital or HIS vendor is prepared to invest financially in such an interface will the EDC vendor develop and implement it.

Regulatory Aspects

The regulatory rules regarding the inclusion of data from EHRs in clinical data are not clear. Although the FDA is very interested in the concept of the integration, it has not yet made any statements about how to deal with data coming from EHRs.

In my view, the dream of single-source data (data that is entered once) that is automatically transferred from the HIS to the EDC system is not realistic. First of all, it would mean that HISs must be...
validated, which would be an enormous cost. Secondly, there is a data quality problem. I suspect that at least five per cent of the birth dates entered into any HIS are not correct, as either the hospitalised patient did not give the correct information, or it was incorrectly typed into the system by administrative personnel. Alternatively, should the FDA rule apply that administrative personnel ‘take legal responsibility’ for the data that is entered into the HIS?

Current thinking (though not formally approved by the FDA) is that any data coming from an EHR or HIS being prefilled into an eCRF must be checked for accuracy by the investigator. As such, a data point coming from an EHR or from the HIS is just like any other data point, as if it were captured by the investigator themselves.

TECHNOLOGICAL MISCONCEPTIONS

The FDA is currently discussing the possibility of replacing the data format for electronic submissions from SAS Transport 5 (an old format stemming from the era of the IBM mainframe) by an HL7-v3-XML message (10). The argument for this is integration with EHRs.

Although the idea for an XML-based format is excellent, the choice of an HL7-XML message is based on a number of misconceptions about EHRs in general, and about XML technology specifically.

First of all, it is wishful thinking to suggest that HL7-v3-XML is the only possible format for EHRs. Many other (and better) formats exist. Secondly, there is a misconception that in order to integrate clinical research with healthcare, both need to use the same meta-format for the data records. HL7-v3 describes only a framework format in which healthcare data can be described. As such, different HL7-v3 messages are often not comparable at all. Furthermore, the development of HL7-v3 messages for submission of clinical data to the FDA sends a negative (and very confusing) signal to the clinical standards community that has invested in other, superior, XML-based standards.

In order to enable integration between clinical research and EHRs, one needs tools, not yet another format. These tools will typically be based on XML technologies, such as XSLT, XPath and XQuery. So, the FDA would be better off investing in XML knowledge, rather than in the development of another HL7 message.

THE FUTURE

“Prediction is very difficult, especially about the future”, but in my own opinion the use of information from HIS or EHRs will slowly but steadily grow, just as the use of EDC has steadily grown over the last 10 years. The lack of international standards for EHRs, the scale of operations needed to introduce EHRs in different countries, with their individual preferences for technologies and national policies, will further hinder fast progress.

We can also expect that companies will dawdle with the integration, as long as the regulatory rules remain unclear. Essentially, the problem is not technology (as demonstrated by CDISC), but the lack of a generally accepted single standard for EHRs, the politics, and the scales of operation for their introduction.

References
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About the author

Jozef Aerts is CEO of XML4Pharma, a consultancy and software development company specialising in XML technologies for the pharma industry. Jozef is one of the lead developers of the CDISC ODM standard, and also contributes to other CDISC standards. He is also involved in CDISC’s efforts to integrate clinical research with healthcare. Email: jozef.aerts@xml4pharma.com