Biometrics News
Summer Edition 2016

WELCOME

Data is becoming increasingly important in making predictions and decisions. We are no longer *moving towards* a data-driven era; we are *in* it.

With this newsletter we intend to share news on topics that we find interesting and relevant about data science within the life sciences community.

Enjoy the newsletter and enjoy your summer!

Biometric Support Services

CTR-XML

Submitting your clinical trials to registries such as EudraCT and ClinicalTrials.gov can be a cumbersome effort. With Clinical Trial Registry XML (CTR-XML) CDISC provides a means to ease such submissions by promoting their automation. The first version of the standard is nearly finalised and covers all common elements mapped between the registries. A future version will include registration and results, protocol, and IDMP compliance as well.

"Version 1.0 of the CDISC CTR-XML standard is a provisionally approved standard based on the CDISC Operational Data Model (ODM) for clinical trial registry submissions primarily to the: World Health Organization (WHO), European Medicines Agency (EMA) EudraCT Registry and United States ClinicalTrials.gov.

CTR-XML provides a means for generating harmonized messages to each of the registries listed above. The intent of the CTR-XML standard is to provide technology vendors with the ability to implement tools that support a "write once, use many times" solution based on a single XML file that holds the information needed to generate submissions for multiple clinical trial registries. This standard is based upon the common elements mapped between the registries, which are based upon the 20-item WHO Trial Registration Data Set."

For more information visit cdisc.org/ctr-xml

CDISC

Data De-Identification / EMA POLICY/0070

Public disclosure of clinical study data has made its way into the industry and affects study conduct processes in many life sciences companies. The European Medicines Agency (EMA) has recently released its "policy on publication of clinical data for medicinal products for human use" (EMA POLICY/0070) which is applicable for clinical reports and individual patient data submitted as part of a marketing authorisation application (MAA) from 1 January 2015 onwards. Other regulatory agencies have or will have similar policies.

Personal (patient) data needs to be protected. Any data publicly disclosed needs to be anonymised to the extent that patients cannot be (re-)identified retroactively in order to protect their privacy. Recently PhUSE, the not-for-profit organisation and *voice of the industry*, has prepared and published guidance on the de-identification of clinical data. This guidance, the 'PhUSE De-Identification Standard for CDISC SDTM 3.2', provides detailed instructions on how to ensure that any Personally Identifiable Information (PII) is removed from the data while ensuring that data can still be reviewed and used adequately. This guidance is freely available from the PhUSE website at www.phuse.eu.

Recently OCS Consulting has been involved in projects where data and patient de-identification has been an important consideration.

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PhUSE CSS

by Jules van der Zalm

The PhUSE Computation Science Symposium (CSS) is a platform for collaboration between the pharmaceutical industry, service providers, and regulatory agencies such as the FDA, EMA, and PMDA. On 21 and 22 June 2016 PhUSE has seen its first European CSS after having been held in Silverspring, Maryland (USA) annually since 2012.

OCS Consulting attended the event and participated in three of five project groups. These projects look into a variety of topics such as the evaluation and prototyping of alternative data transport formats for clinical submissions (i.e. the successor of the infamous XPT files), the development of a Frequently Asked Questions document for SDTM mapping and implementation, and the collecting of user requirements for the ultimate statistical computing environment to serve as a basis for the development of future software.

Actively participating in communities such as PhUSE allows OCS Consulting to both share its experience with the industry, and to stay involved in the most current industry developments.

The importance of validation

by Remco van der Meer

When clinical trials are conducted to establish safety and effectiveness of a product, a clinical study report is generated to support registration with the authorities. Key decisions are made throughout the conduct of the trial that affect both the trial itself as well as the health of people that are exposed to the investigational product. For both purposes, study results are visualised in tables, listings, and figures. It stands to reason that such output should be subject to extensive checks for correctness before results are eligible for release. Therefore it is important to have a well-established validation process in place. OCS Consulting will release a whitepaper that elaborates on the importance of the process, the benefits of standardisation on multiple levels, and how this all will make your output better and your life easier.

Please request your full copy of the whitepaper via marketing.nl@ocs-consulting.com

NEWS/ EVENTS

OCS Consulting will attend the Annual PhUSE Conference, to be held in Barcelona from 9 – 12 October.
Our team members will present 3 papers:

- **DIY: Create your own SDTM mapping framework** by Bas van Bakel
- **How to effectively deal with hard-coding and CDISC Controlled Terminology in clinical studies** by Lennert van der Zee
- **The hardships of finding your way in Biometrics** by Evi Creebsburg

For more information or to receive final papers after the conference, please send a message to marketing.nl@ocs-consulting.com

OUR ACTIVITIES

- Statistical programming (SAS, R)
- Clinical data warehousing
- CDISC implementation
- Standard programs and macros
- Data visualisation (SAS JMP, VA)
- Tables, listings, and graphs
- Electronic Data Capture
- Risk Based Monitoring
- Data cleaning and coding
- Protocol and SAP writing
- Data science
- Statistical analysis
- Pharmacokinetics
- Validation of data and systems
- Programming training
- CDISC training

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