OCS Life Sciences

MATURING STANDARDISATION

The switch from spreadsheet-based standards to an MDR

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STANDARDISATION

In order to work consistent, structured, and time efficient throughout multiple studies, standardisation is key. Standardisation can be relatively simple with having the company standards in a spreadsheet and using this spreadsheet to share study-specific metadata requirements. However, with a growing number of compounds, indications, studies, and number of CRO's involved in creation of the SDTM package (aCRF, SDTM datasets Define-XML and SDRG), it gets harder and more important to have and maintain the standards.

Furthermore, individual studies can have specific requirements which may result in deviations even within a compound or indication.

When the number of studies grows, a simple spreadsheet may no longer be sufficient to capture all subsets of metadata requirements. When the standards cannot keep up with the growing number of studies, this can result in an overgrowth of different annotated CRFs and Define-XML files leading to undesirable inconsistencies.

METADATA REPOSITORY (MDR)

To prevent overgrowth and to keep as much consistency as possible, a solution is the implementation of a metadata repository (MDR). But how to make this switch from having standards in spreadsheets to an MDR? Here are several things we considered when going through this process.

First of all, what are the requirements for such a system and how can it be implemented within the organisation? What do we want to get out of an MDR? Is it purely about the storage of metadata or do we want additional features, such as the ability to build an actual industry

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compliant Define-XML? How does such a system work and does it have to adhere to GxP standards? And following on the GxP discussion; how will the system be validated?

Secondly, how will we govern these processes? Who is going to build the standards? Are we going to have general standards, or will we create indication specific standards? How often will these standards be updated? Are we going to upload the current standards into the system or will we start from scratch? Will we use the existing CRF questions or are we going to transform them to CDASH questions?

Finally, how will we collaborate regarding the standards? What will the internal review and approval process look like and which functional areas will take part in this? How will we create study-specific metadata and who will be involved in the set-up? How are we going to collaborate with external parties after implementing the metadata repository and how will it affect their processes? These considerations are important when setting up a solid standardisation process. During this presentation we will guide you through our most important findings and conclusions so far in our process of implementing an MDR.