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Abstract

Data Review Model Version 2 (DRM V2) is an upgraded version of a Janssen proprietary data model that is integrated into an automated data flow designed to enhance review and visualizations of clinical trial data. DRM V2 provides full traceability and describes both clinical and operational data consistently across studies and is considered as the Single Source of Truth, that eliminates multiple and inconsistent views of the same data. It enables all stakeholders to access the same data at the same time. DRM V2 incorporates CDISC SDTM data structures and follows proper adherence to the CDISC SDTMIG to reduce the effort necessary for data mapping to SDTM. This new version of DRM has now been implemented in numerous trials from different therapeutic area and is showing great accomplishment for the easiness of data consumption and early access to critical data.

Introduction

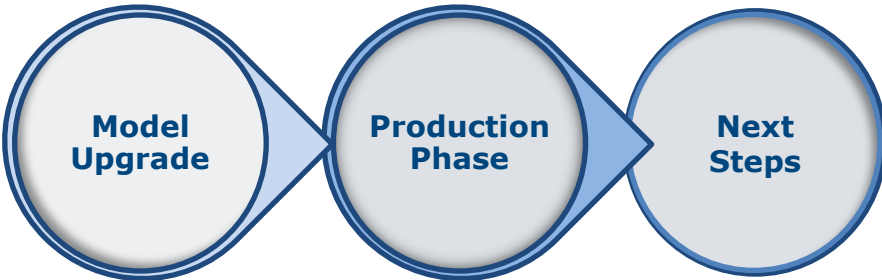
In 2016 Janssen identified the need to expedite clinical data review. After a proof of concept that has demonstrated the value of pursuing a new and proprietary data model for data review, serving as single source of truth, the Data Review Model (DRM) was introduced [1], [2].

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Originally designed on an CDASH/SDTM hybrid model, Data Review Model version 2 (DRM V2) has been upgraded to fully incorporate CDISC SDTM data structures and metadata. This standard follows proper adherence to the CDISC SDTMIG to reduce the effort necessary for data mapping to SDTM.

This poster will describe the new structure of DRM V2 and the associated features. You will also learn how this upgraded standard has been implemented in Janssen and how end-users are consuming it.

Project Life Cycle



Model Upgrade:

- Model compliant with SDTM rules
- Allows addition of any non submission variables
- Identification of SDTM vs DRM variables
- Reusability of tools developed for DRM V1 project

Production phase results:

- Validation of new model in production studies for Raw to DRM conversion
- Test of DRM to SDTM conversion
- Creation of a automated data flow

Next steps:

- Pilot phase of DRM to SDTM conversion
- Full portfolio to implement DRM
- Consumption of DRM model in an interrogated MDR environment

Conclusion

This upgraded version of DRM has already shown benefits of being SDTM aligned. Programming teams require less training as SDTM is a well-known standard. The different tool to produce DRM and to consume it have been easily adapted from DRM V1 to V2. The concept of having in DRM all the SDTM variables for submission reduce the time and effort for the creation of SDTM mapping specification and then expediate the conversion of DRM to SDTM data sets.

References

1. Lieke Gijbbers, OCS Life Sciences, 's-Hertogenbosch, the Netherlands, Tom Van der Spiegel, Janssen R&D, Beerse, Belgium, A proprietary, CDASH/SDTM-hybrid data model to expedite clinical data review, PhUSE 2018, Paper SI25
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