Consolidating Study Outcomes in a Standardised, SEND-Compatible Structure

Philip Drew¹, Robert Thomas², Salvador Capella-Gutierrez³
¹PDS Consultants (UK), ²Lhasa Ltd (UK), ³Barcelona Supercomputing Center (Spain)

Retrieval of critical toxicological findings and differentiating these from incidental ones is a key requirement for the analysis of large pre-clinical data sets. The eTRANSAFE project has identified the need to consolidate pre-clinical study outcomes, as expressed in study reports, with the corresponding study measurement data it holds in its SEND-based pre-clinical data warehouse.

It has created a Study Report (SR) ‘Domain’ which allows sponsors to assemble the important findings from a study report in a structured, SEND-compatible format.

The SR Domain has been populated manually by eTRANSAFE consortium members (EFPIA) and found to be fit for purpose. Methods for automatically populating the SR Domain using text mining and data analytics are currently under investigation.

Since the linking of treatment effects to measurement data is critically important, the SR Domain could form the basis of a standard that is adopted and maintained by CDISC, as an extension to the SEND standard.