Introduction

SDRG and ADRG are now part of e-submission package, providing FDA reviewers a single point of orientation of submission datasets. These documents incorporate additional information as well as some duplication from other submission documents. The authoring process of these two key documents could be time-consuming and tedious, considering most of the included information may exist in different datasets, documents. Keeping up with changes on an ongoing basis and inconsistency may be a potential problem as well.

Data Flow and Working Process

How does this new process work?

Method

To simplify the authoring process, a centralized metadata-driven method is proposed to streamline and automate this activity. All data sources, including but not limited to study-level metadata repository, SDTM/ADaM datasets, central comments log, OpenCDISC validation reports, etc. will be identified in advance and retrieved them into a central structured database or spreadsheet. A corresponding VBA tool or user-friendly interface application will be developed to facilitate this authoring process by incorporating all of the related information and generating the SDRG/ADRG documents automatically, making sure all contexts be consistent across different sources accordingly.

Results

The use of new process will result in:

- Substantially improved quality of SDRG/ADRG authoring due to the standardization of methods across the team members as well as projects/studies.
- Greater productivity and efficiency by being able to deliver common SDRG/ADRG documents in a few hours, compared to a few days with the traditional way.
- Highly consistency and real-time synchronization of major contents when multiple sources of the SDRG/ADRG have been updated or changed accordingly.

Conclusion

This process proposal, together with the development of an user-friendly interface, could significantly facilitate the SDRG/ADRG authoring process with higher efficiency and quality. Moreover, this proposal could minimize the inconsistency between the SDRG/ADRG documents when multiple sources were used.