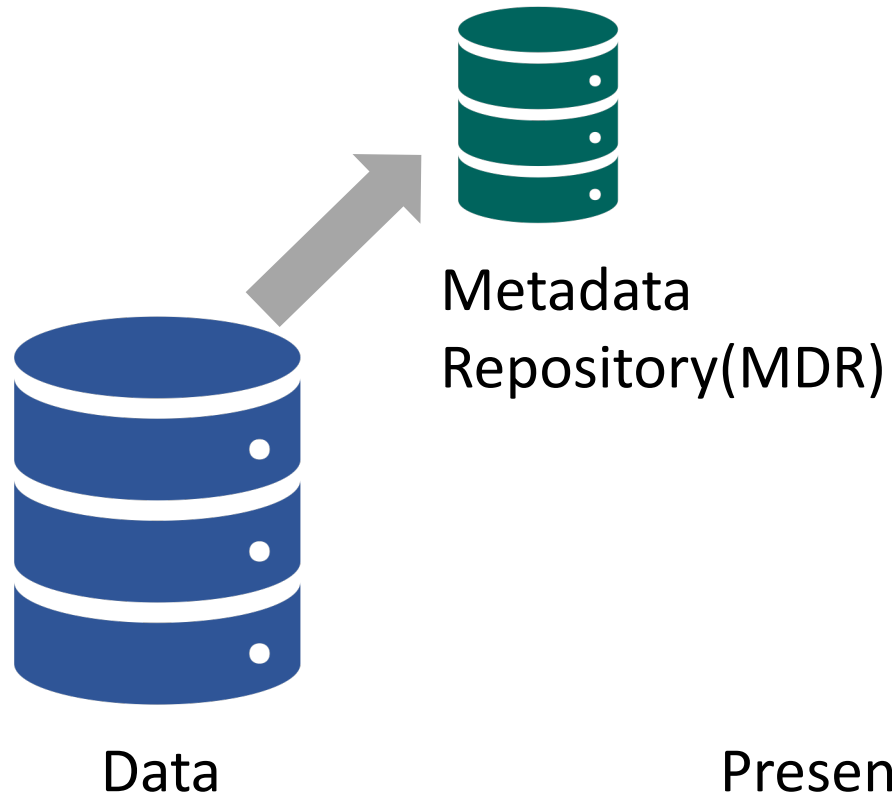


Metadata Driven Case Report Tabulation for Regulatory Submissions

- Rajashekar R Thota, Associate Principal Scientist, Merck & Co., Inc., Kenilworth, NJ, USA
- Rama Kudaravalli, Associate Principal Scientist, Merck & Co., Inc., Kenilworth, NJ, USA
- Jacques Lanoue, Associate Director, Merck & Co., Inc., Kenilworth, NJ, USA

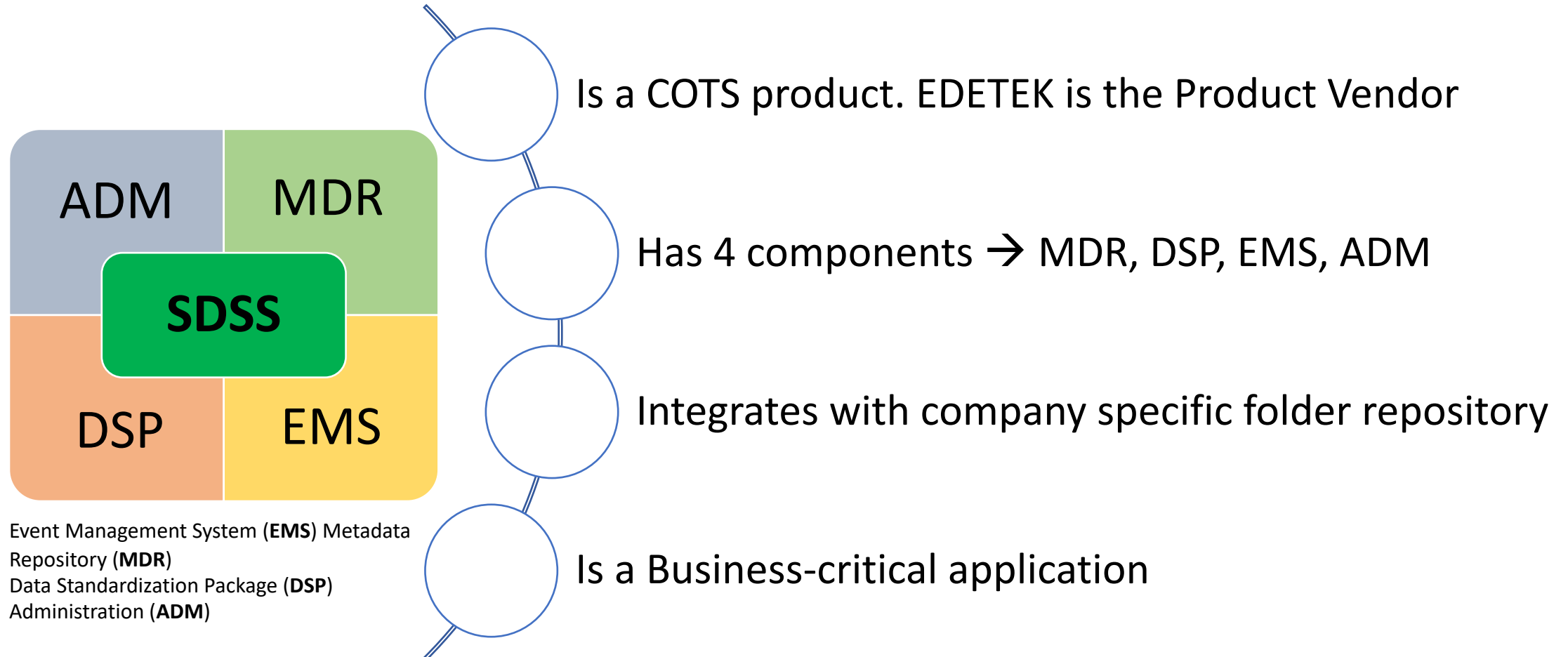
- **May 1-4, 2022**

Presentation Outline

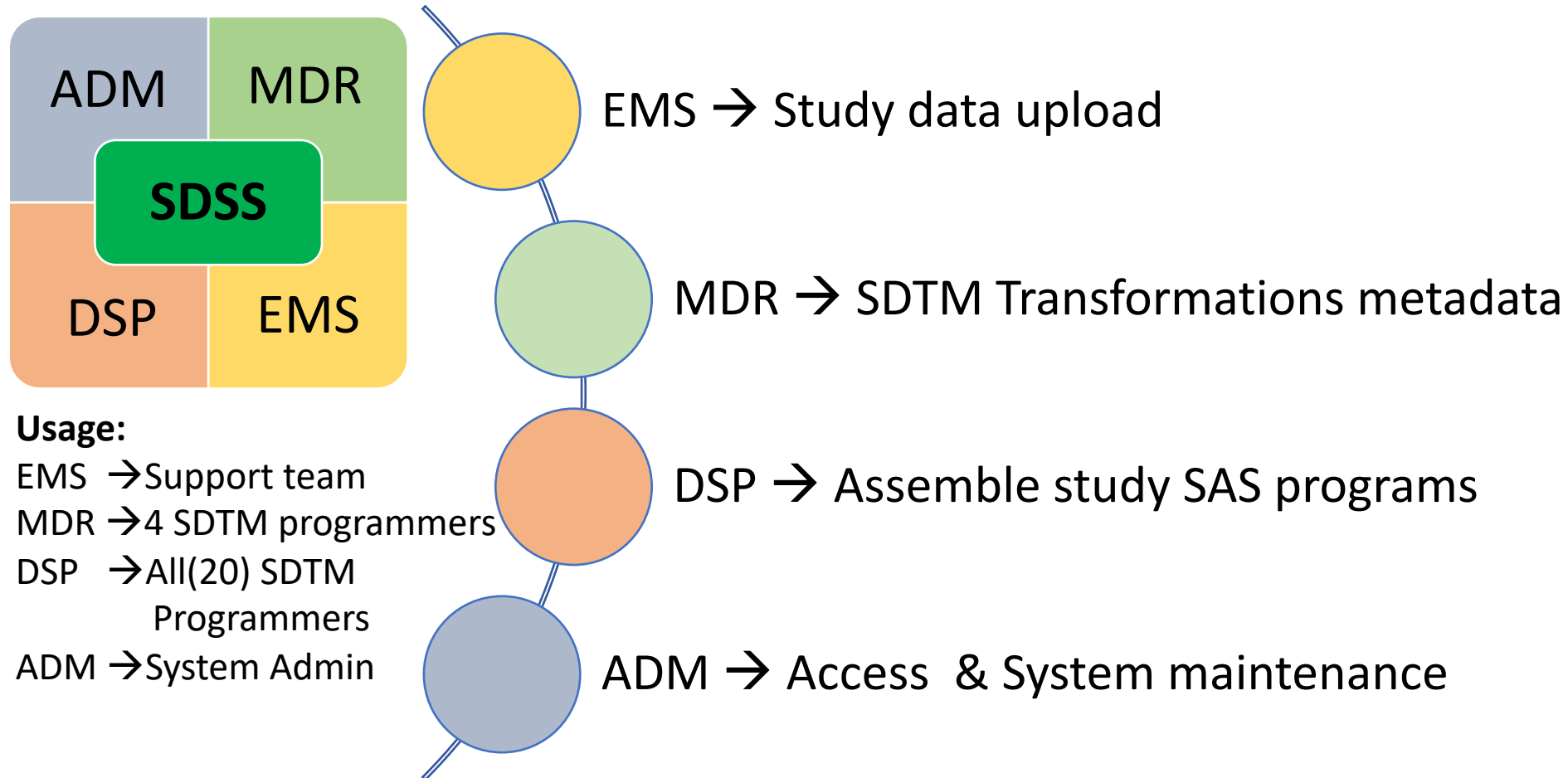


Presenting our implementation
experience

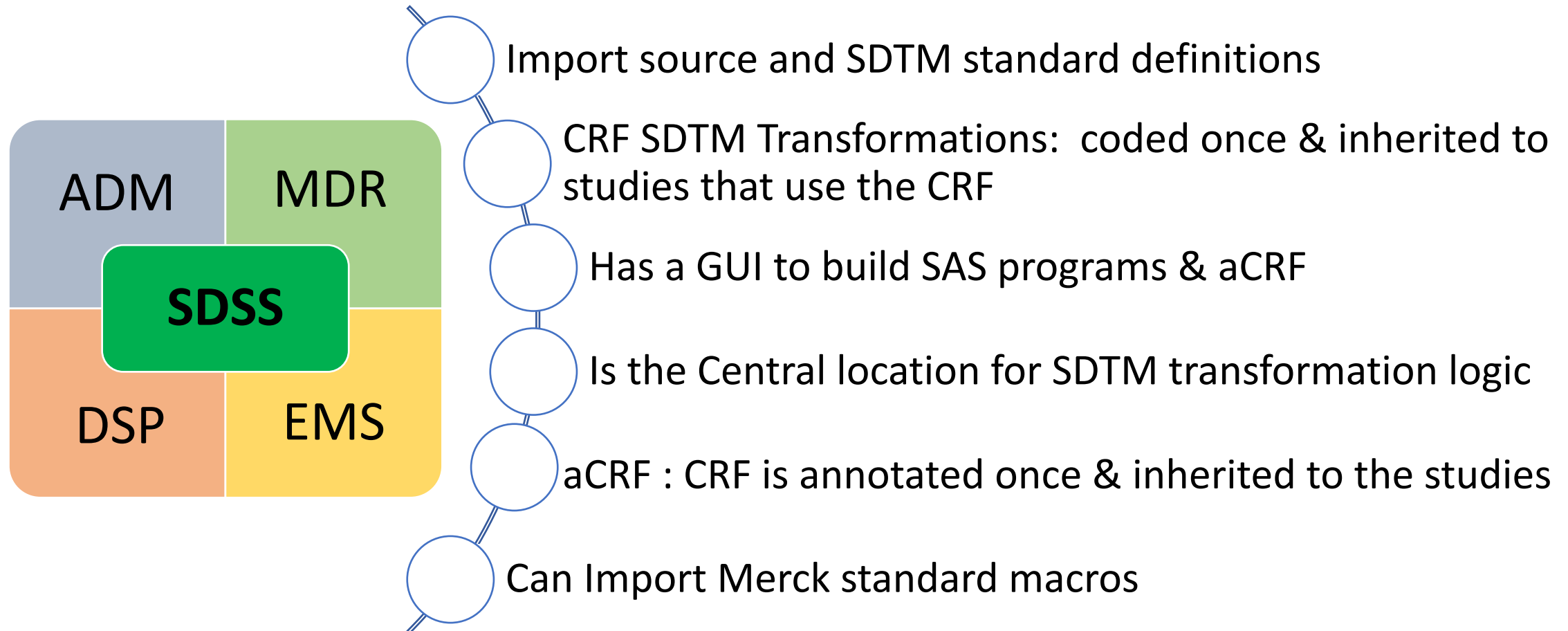
The Components of the Study Data Standards System (SDSS)



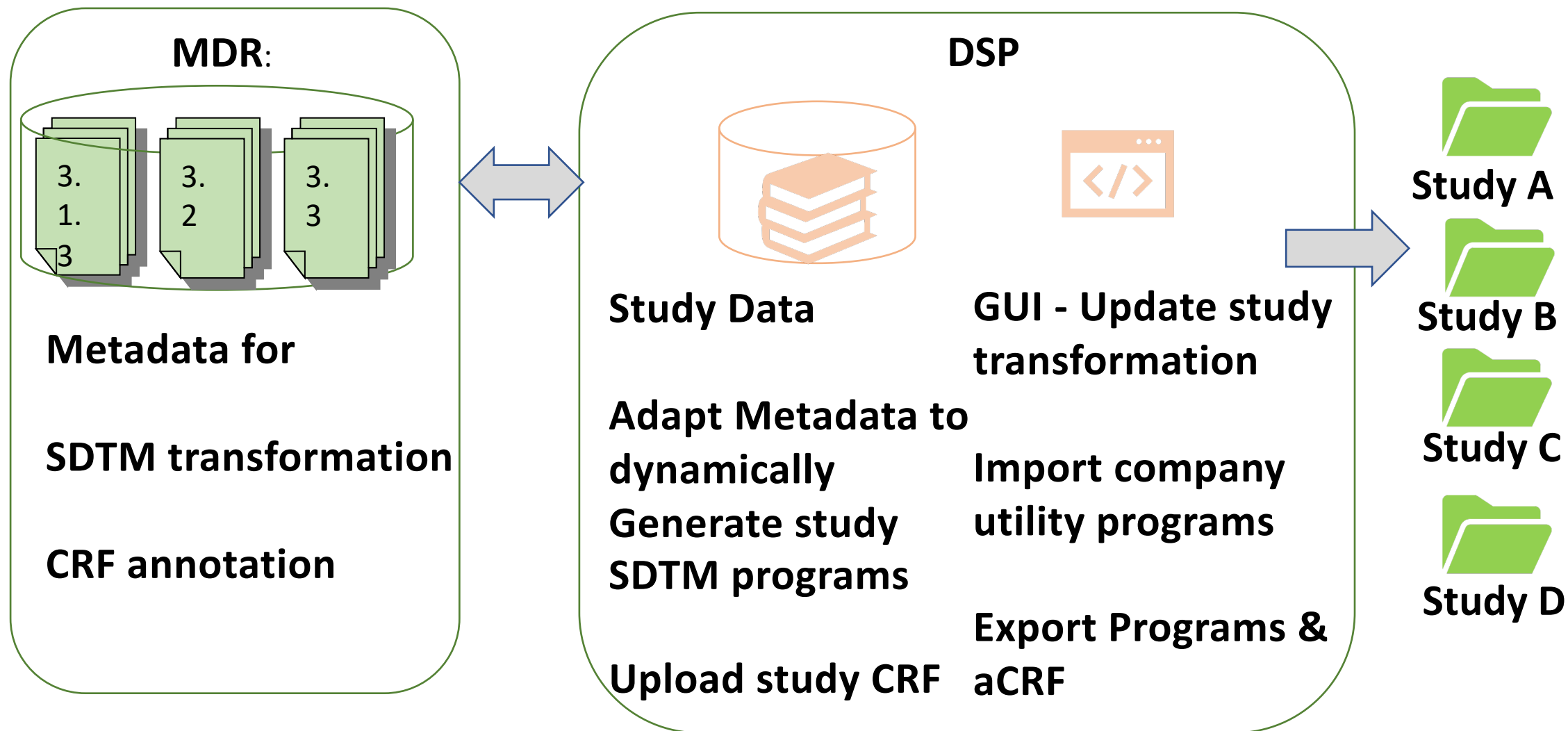
SDSS components and usage



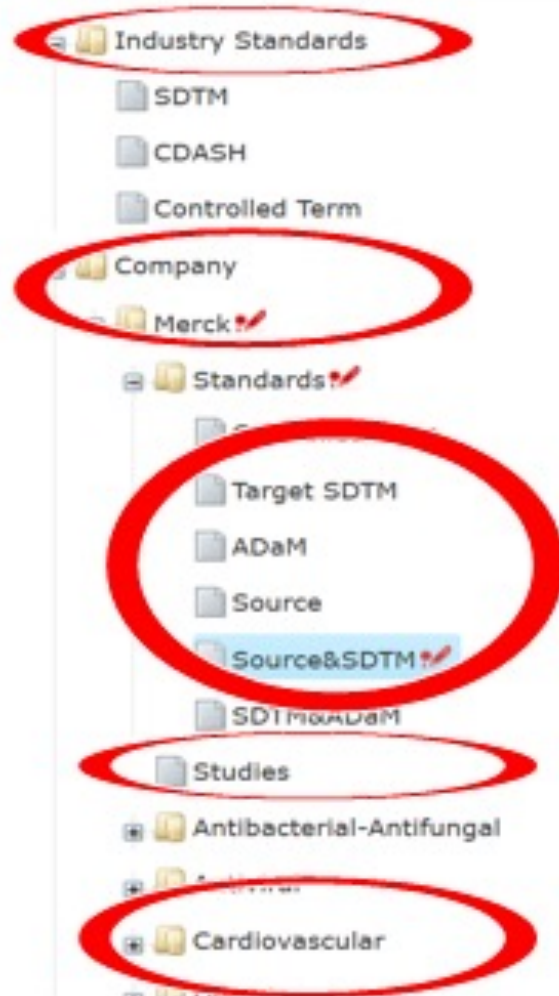
SDSS features



Metadata organization in MDR



Metadata organization in MDR



Industry Standards(CDISC)

Company Standards

Metadata update per company standards

Study

Therapeutic Area

SDTM Transformation logic

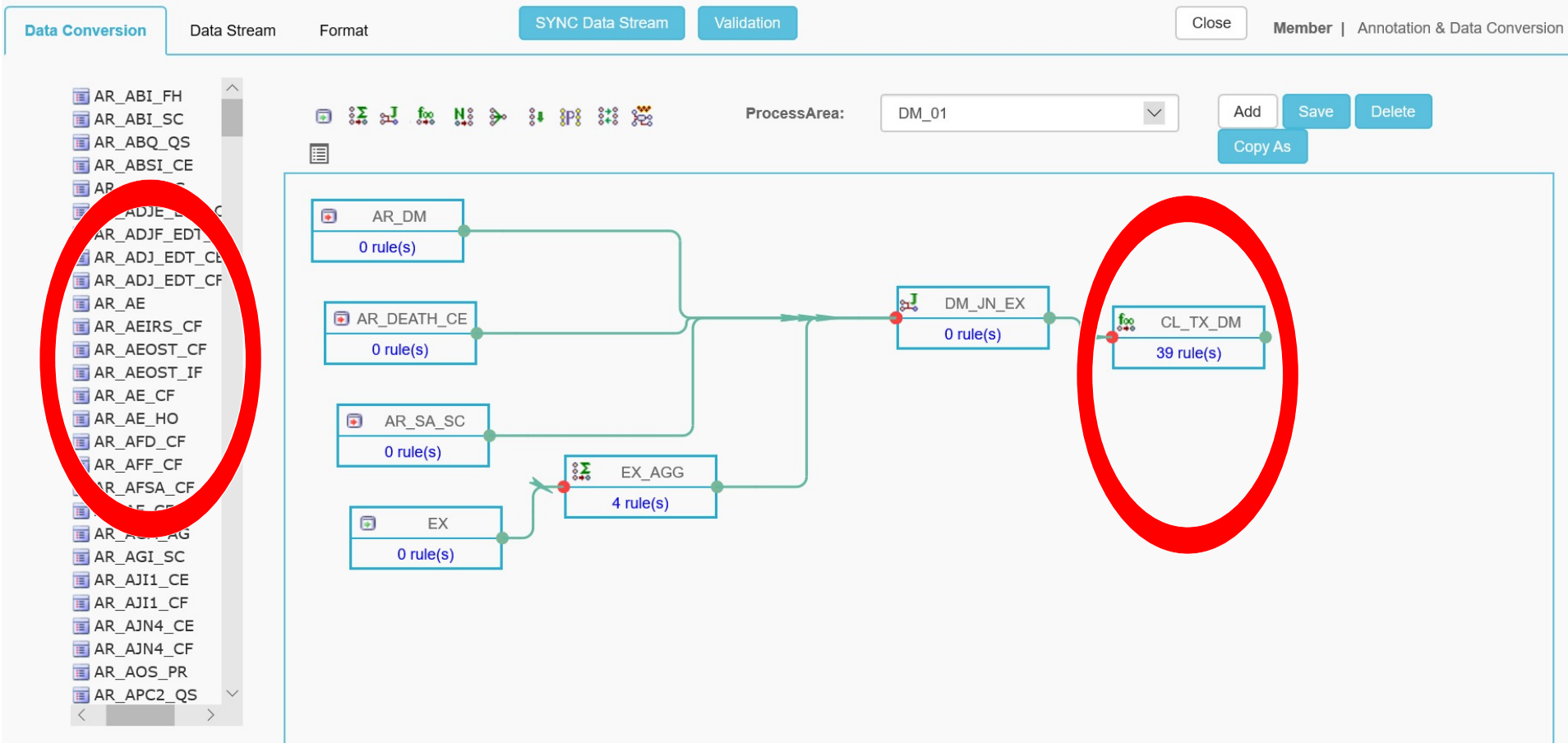
The screenshot displays the 'Target Designer' application window, specifically the 'Transformation' tab. The interface is organized into three main panes, each highlighted with a red oval:

- Source (Left Pane):** A tree view showing the source data structure. The 'ARMCD' element is selected and highlighted in yellow. Below the tree, the 'Name' field is empty and the 'Type' is set to 'Char'.
- Transformation (Center Pane):** A table listing transformation rules. The rule 'source.AR_DM.ARMCD' is highlighted in yellow. Below the table, the 'Rule Text' field contains the expression 'source.AR_DM.ARMCD'.
- Target (Right Pane):** A tree view showing the target data structure. The 'ARMCD' element is selected and highlighted in yellow. Below the tree, the 'Name' field is set to 'ARMCD' and the 'Type' is set to 'Char'.

Source(CRF, eDT) Transformation

Target(SDTM)

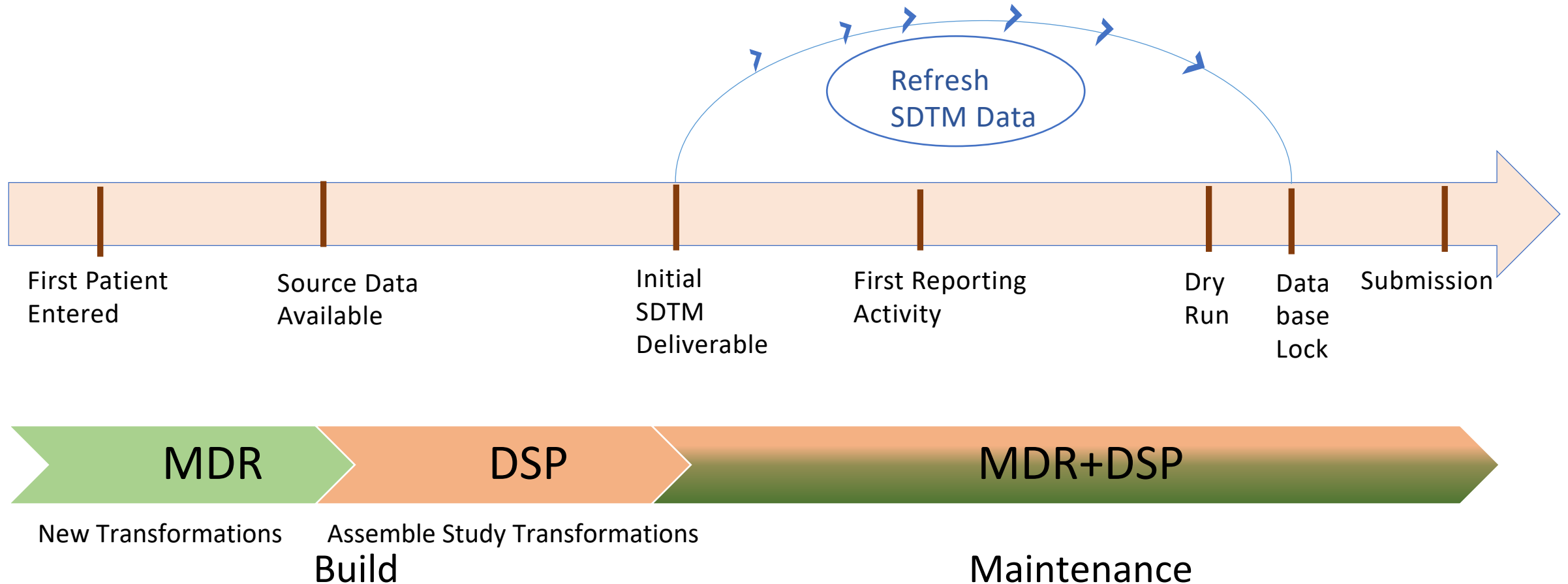
SDTM Transformation GUI



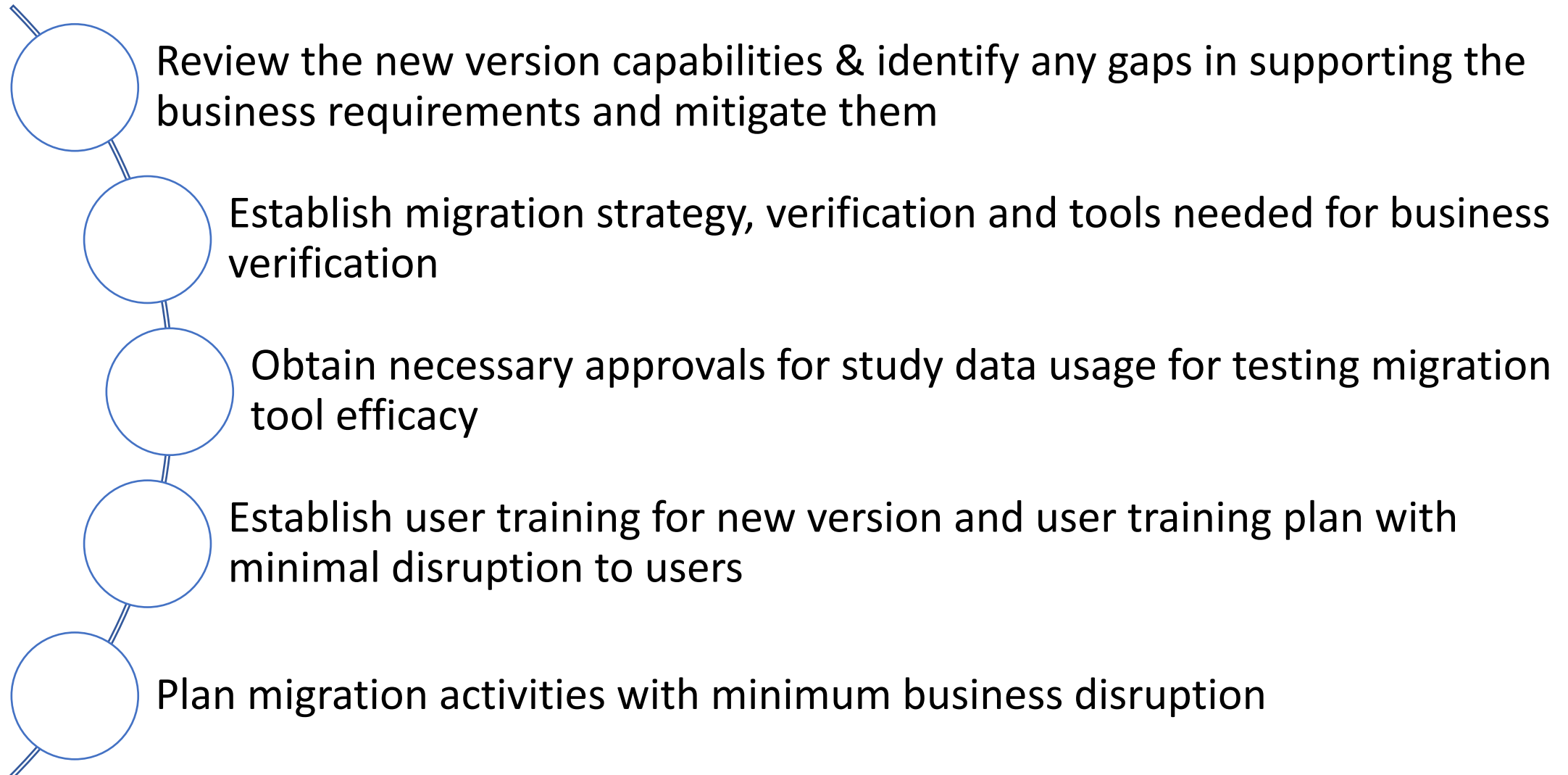
CRF Transformations

Drag and drop GUI to build SDTM domain (DM)

SDSS metadata usage during life of a study



SDSS migration to new Version



Summary of Benefits



We achieved a level of 90% metadata reusability across trials



We achieved a 33% reduction in programming resources

