Goals/ Definition

Check that data quality is on track to meet target clinical study report date.

Monitor data cleaning process to expedite database lock, data analysis, and data submission.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Initiate data cleaning process as data becomes available to allow access to high integrity and quality data and expedite data analysis and submission *NOTE: Data cleaning process and plan should be clearly defined at the beginning of the study. Readiness for database lock should be considered at patient level and entire data base level.*	a) Streamlined data cleaning process to expedite clinical data analysis and submission b) Provide estimated time to database lock, data analysis, and data submission c) Report SAEs and any other issues	▪ Notification of milestone achievement, any delay, mitigations and revised timeline