

## Goals/ Definitions

**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
<ul style="list-style-type: none"> <li>▪ Initiate data cleaning process as data becomes available to allow access to high integrity and quality data and expedite data analysis and submission</li> </ul> <p><i>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.</i></p>	<ul style="list-style-type: none"> <li>a) Streamlined data cleaning process to expedite clinical data analysis and submission</li> <li>b) Provide estimated time to database lock, data analysis, and data submission</li> <li>c) Report SAEs and any other issues</li> </ul>	<ul style="list-style-type: none"> <li>▪ Notification of milestone achievement, any delay, mitigations and revised timeline</li> </ul>