GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Leading indicator of availability of study analyses.

Track the time of database lock that informs the lag between the last subject dosed and the availability of study analyses.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Action taken to prevent further changes to the clinical trial database	a) Database review and query resolution completed b) All pharmacokinetic, laboratory safety data and CRF data transferred to Data Management c) Database review and quality checks complete, data queries identified d) Query resolution completed	▪ Notification of milestone achievement, any delay, mitigations and revised timeline