Paper PH147

How to Build Study Quality Surveillance for a Clinical Study?

Angela Teng, Eisai Inc., Woodcliff Lake, NJ

ABSTRACT

Study Quality Surveillance (SQS) provides oversight of the quality of the study by reviewing and monitoring study data in a blinded fashion. The purpose of SQS is to mitigate the risk of compromising study assumptions and to take corrective actions as early as possible, if necessary, to enhance or improve the quality of the study data and therefore, to ensure that the study results are valid and credible. SQS is not meant to replace edit checks; however, data errors may be found and noted during the SQS review. If data errors are noted, the logic used to find these errors will be communicated to Data Management so that Data Management can incorporate new edit checks in their specifications as appropriate. This paper emphasizes the importance of SQS and describes process of generating SQS outputs and key components of a SQS report. In addition, it will provide example of SQS figures that can be used for both SQS and risk-based management.

INTRODUCTION

Study Quality Surveillance (SQS) is to provide oversight of the quality of a study by reviewing and monitoring study data in a blinded fashion. The purpose of SQS is to determine the critical risks that could affect subject safety, data quality or compliance so that key issues can be quickly identified early and prevented from recurring, therefore, to ensure that the study results are valid and credible. Data errors may be found and noted during the SQS review. If data errors are noted, the logic used to find these errors will be communicated to Data Management so that Data Management can incorporate new edit checks in their specifications as appropriate. Also, all outputs will be blinded and no information will be included that might risk unblinding.

This paper describes the process of generating SQS outputs and key components of a SQS report. In addition, it provides examples of SQS figures that facilitate data review. (Note: more detailed information regarding SAS figures will be provided in my presentation.)

1. Prepare a Study Quality Surveillance plan

A SQS plan should be created during study planning, and be reviewed and updated throughout the trial to mitigate risks. It is important to create a SQS plan that identifies risks and defines critical data to ensure that cross-functional teams focus on the risks that are most important to safety and efficacy profile and data quality.

2. Define a fixed schedule and timing for output generation and review meeting

It is important to define a fixed schedule for SQS to run. For example, SQS can be run monthly or weekly depends on study enrollment. It also can be run based on data accumulation, such as 10% of subject visits have occurred, after the first 50 subjects enrolled, or after the first 30 subjects completed treatment.

3. Critical data and output displays

Working with cross-functional teams is necessary to ensure critical data are identified appropriately to avoid duplication of efforts across functions. Critical data include data that

support primary and key secondary objectives and data critical to subject safety. Other critical data also include data that will be used to make decisions about the drug's safety and efficacy profile. Once decisions are made, critical data will be summarized by site or country or region and overall. Automated reporting is recommended. Graphics are also recommended since they are easier to show outliers and trends than tables. For instance, box and whisker plots show outliers as well as median and inter-quartile range and line plots show trends of data.

Examples of critical data include:

1. Study Population
2. Subject Disposition (Completion and Discontinuation)
3. Serious Adverse Events, Death, Adverse Events Leading to Discontinuation of Treatment, Events of Interest
4. Protocol Deviations (Inclusion and Exclusion Criteria and Prohibited Medications)
5. Drug Exposure (Dose Intensity, Dose Reduction, Treatment Duration)
6. Treatment Compliance (e.g, <80%, 80%-120%, >120%)
7. Out of Window Visits (Assessments Outside of Scheduled Windows or Skipped)
8. Efficacy: (Study Specific) Primary and Key Secondary Endpoints.
9. Safety: Adverse Events, Labs, ECG, Vital Signs. For example, Events of Clinical Significance and Abnormal Findings.

CONCLUSION

Study Quality Surveillance can proactively mitigate risks through detecting critical issues early in the trial and taking prompt corrective actions while the study is ongoing. A great benefit of building SQS into the study planning for clinical trial oversight is to enhance or improve the quality of study data and therefore, lead to cost saving. Identification of critical data is essential. Biostatistics group needs to collaborate with cross-functional teams for contents and frequency of data review before finalize the SQS plan. Considering automated reporting system and standard reporting templates to identify outliers and trends can gain greater efficiency and save time and cost.

CONTACT INFORMATION

E-mail: Angela_Teng@eisai.com