In January 2023, the Early Drug Development (EDD) service was alerted to trial and regulatory management concerns from a study sponsor that could lead to an FDA inspection of two protocols. Given the operational constraints during the COVID-19 pandemic, the time during which most patients were enrolled in these trials, management staff began an in-depth review of all aspects of the trials. The comprehensive review conducted in preparation for this inspection is a process that can be utilized to maintain quality and for future potential audits.

**METHODS**

- Recruited additional staff, including internal QA auditors, to support preparation efforts.
- Listed all known safety events. Tracked initial and follow-up reports and their timelines. Submitted deviations for non-compliant AE reporting.
- Conducted systemic patient reviews including eligibility, consent processes and other supporting source documentation.
- Completed a regulatory review of DOAs, FDAs, 1572s. Reviewed amendment submissions, protocol trainings, and sponsor safety reports.
- Created Notes to File to address corrections and discrepancies discovered during regulatory review.
- Conducted a review of all monitoring visit follow-up letters to ensure they were all filed. Reviewed the filed follow-up letters to ensure all findings were addressed and deviations filed accordingly.

**LESSONS LEARNED**

- The need for comprehensive and standardized audit preparation procedures to ensure inspection readiness.
- The importance of collaboration amongst the study team to maintain the quality of the trial throughout its lifespan.
- Observations of deficiencies which led the team to re-evaluate current operational workflows.