**NEED**

- PK and ADA sample analysis using a proprietary Enzyme-linked Immunosorbert assay (ELISA) was required to support a PI oncology study in subjects with metastases.

- Immediate analysis was required for adverse events for this clinical study over a four year period. The sample arrival dates were not predictable however turnaround time for sample analysis and data delivered to the client was to be within one week after sample arrival.

**APPROACH**

- Implemented a process in collaboration with the client and supply chain, to ensure key reagents would be available for the duration of the clinical study.

- Developed a flexible scheduling approach within specific timelines, and ensured trained staff were available to perform the required assays to meet the client’s needs.

**BENEFITS**

- Data delivered to the client within their requested timelines to ensure they were able to assess the adverse events based on the available PK and ADA results.

- Drug dosages could be adopted appropriately to assure patient well-being.