



SYNTEREX

# CASE STUDY:

## Clinical Study Report and Narratives Initial Draft in Record Time with AgileWriter.ai®

### Background & Introduction:

Medium-sized biotech needed a clinical study report (CSR) shell and first draft done in 2 weeks, with no lead time, to meet reporting obligations and other internal metrics.

### Challenges:

- Not all data were available up front or in the optimal format (i.e., .rtf files).
- Sponsor had limited time, staff, and budget to address the inherent source issues, but they could give us alternative formats such as SDTM dataset files. This was also only the company's second CSR, and the study design in personalized medicine for oncology was complex.

### Case Summary

A CSR was delivered with high quality in a 2-week timeframe (vs 6+ weeks for Shell + Draft 1). Areas for continued model training included CIOMS text in narratives and program safety profile language. The model is well positioned to do future program CSRs with increased efficiency.



### Solution:

We trained the AI in real time to automate completion of the CSR by mapping the planned content to our CSR template and the SDTM datasets, training the model incrementally as new information became available. We kept the human in the process and had the medical writer oversee production of the first draft report and narratives so that what the AI produced could be refined if needed.

\*This value is based on a system-generated QA report that measures how accurate the mapping was to the expected output.

### AgileWriter vs Standard Timeline (CSR Shell + Draft 1)



### Benefits:

The CSR was delivered to the Sponsor with high quality in the 2-week timeframe and required minimal manipulation prior to finalization for the agreed elements to be included in the first draft. Areas identified for continued model training were consolidation and refinement of CIOMS text and training on the specific safety profile of the client's program (e.g., AESI and their related features for context). The model is well positioned to do future program CSRs with increased efficiency. Compiling the narratives reduced burden on internal staff, who had previously written these using a fully manual process.