CASE STUDY:

Informed Consent Form Initial Draft Taken Off the Critical Path of an IND Submission with AgileWriter.ai®

Background:

Small biotech needed an informed consent form (ICF) done as part of an IND submission.

94%
ACCURACY*

Challenges:

Lead time was limited following Agency feedback on the protocol before the final ICF was due, and updates needed to be made to the study design features. Given the size and stage of company, there was a paucity of prior materials to train the model on, and the template had not gained broad company feedback.

Case Summary

An ICF was delivered with high quality in a 2-day timeframe (vs 4+ weeks for Draft 1). Areas for continued model training included refining memory training to enhance the performance of updated source. The model is well positioned to do future program ICFs and other patient-facing documents with increased efficiency.

Solution:

We pretrained the model by mapping to the draft source and reviewing the interim outputs; updates to the template were performed incrementally and the model was retrained. The ICF was run again once the source protocol updated with Agency feedback became available and a final team review was performed. While a second deliverable was unplanned, the model output was also able to be leveraged to produce a pregnant partner ICF for the same study.

*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 (ICF Draft 1)

Week 1   Week 2   Week 3   Week 4

Benefits:

Given the timeline constraints, this pretraining approach balanced risk and reward in this particular scenario. The IND submission was made on time with the ICF included. Areas for future development included additional training on future materials for this Sponsor to give the model more client-specific context as well as refining memory training so that when it receives updated source the model remembers what it did well without retaining outdated study design information (manual QC review noted one minor endpoint that had been incorrectly retained in the ICF while it had been removed from the source). The model is well positioned to execute on future ICFs efficiently and to help keep the ICF off the critical path for IND submissions.