P1 - The Impact of the EU Clinical Trials Regulation (CTR)

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INTRODUCTION

The Clinical Trials Regulation (CTR) harmonizes the processes for the assessment and supervision of clinical trials throughout the EU. Prior to the CTR, clinical trials were submitted to competent authorities and ethics committees in each EU member country to receive regulatory approval per the Clinical Trials Directive (CTD). The impact of the CTR on pre-submission medical writing processes and timelines for single- site studies was investigated at the Phase 1 clinic at ICON plc in the Netherlands.

METHODS

The medical writing processes and timelines for all regulatory submissions in the first year after full CTR implementation (Feb 2023 to Jan 2024) were compared to those in the last year of the CTD (Feb 2022 to Jan 2023).

RESULTS

The time needed from start of protocol development up until regulatory approval increased under CTR. This increase was attributed to the introduction of redaction activities, changed processes for linguistic alignments of Dutch and English subject-facing documents, and the need to have final documents available earlier. Regulatory preparations for the actual submission took longer than previously. In addition, the lay protocol synopsis is a new type of document that needs to be prepared for CTR submissions.

CONCLUSIONS

While the CTR has harmonized the submission process throughout the EU, it has increased timelines for the regulatory submission process of Phase 1 studies at the Phase 1 clinic at ICON plc in the Netherlands. Parallel document development, detailed resource planning, and agreements on expedited timelines with regulatory authorities have partly mitigated the increase.