

P8 - Update On Master Clinical Study Protocol Preparation: Roll Out and Future Considerations

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INTRODUCTION

We developed a master clinical study protocol (CSP) to evaluate the clinical activity of a new drug across multiple indications, following the structure presented at the EMWA 2024 Conference in Valencia, Spain.

METHODS

The master protocol included the common trial elements, while disease-specific aspects were presented as separate sub-study protocols. To enhance clarity and avoid confusion, we outlined the overall protocol structure at the beginning of the master protocol. Recognizing the complexity of a master CSP, we briefed internal reviewers and the quality control (QC) team prior to their evaluations.

RESULTS

As medical writers we prioritized clear, unambiguous language and a consistent structure, aiming for simplification to facilitate efficient trial implementation and execution. This approach has been validated by successful submissions and approvals in multiple countries, with no issues regarding structure, complexity, or readability raised by regulatory authorities or ethics committees.

The flexibility of the master CSP enables compliance with country-specific requirements while maintaining a harmonized global protocol and allows for adaptations as the study progresses. Careful documentation of amendments and version relationships will be essential for quality assurance.

CONCLUSIONS

The successful development of this master CSP demonstrates the potential for innovative trial designs to accelerate drug development and sets a precedent for our future clinical initiatives. This experience underscores the importance of strategic planning, regulatory alignment, and cross-functional collaboration in the effective implementation of complex clinical trials, ultimately demystifying the process of preparing a master CSP.