P25 - Master Protocols: Implementing innovation in an evolving field

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INTRODUCTION

Master protocols are being proposed as a way to expedite drug development across therapeutic areas. These studies are highly complex and pose challenges for medical writers and subject matter experts. Currently, there are no standard protocol templates for different types of master protocols (e.g., umbrella, platform, basket), and consultations are ongoing among Health Authorities, Sponsors, Clinical Research Organizations, and professional associations to maximize their benefits and provide guidance on their execution.

METHODS

To develop a master protocol, we are holding discussions with our stakeholders to accelerate the development of a novel drug while maintaining our scientific, medical, and statistical standards and ensuring patients' safety. We are considering best-practice recommendations and Health Authority guidance, including the recent FDA draft guidance on umbrella and platform studies, previous FDA guidance on basket protocols in oncology, and EMA guidelines, as well as initiatives by EU-PEARL and TransCelerate.

RESULTS

In this evolving landscape, the Medical Writers and the Regulatory Affairs counterparts are playing a crucial role in guiding and leading multifunctional teams to structure the protocols and incorporate the flexibility for adaptive designs that the study team requires. At the conference, we will provide information on our experience and decision process following the state-of-the-art guidance and the potential protocol designs that best suited our case scenario.

CONCLUSIONS

Overall, master protocols offer opportunities for expediting drug development, but their successful implementation requires careful planning and strong collaboration with and early involvement of internal and external stakeholders.