

P12 - Role of a Disclosure Manager – much more than study registration and results disclosure

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INTRODUCTION

The clinical transparency landscape is an ever evolving one, with revised regulations and requirements changing the way we publicly disclose study information. At the heart of these processes are disclosure managers or data transparency specialists. They bridge the gap between the complex regulatory clinical research environment and the public. But how exactly do they do this and how does their expertise complement the work we do as medical writers?

METHODS

Disclosure managers are involved in a study throughout its entire lifecycle – from protocol draft to sharing of individual patient data. Along the way, they interact with many stakeholders, including medical writers, trial leads, statisticians, programmers, regulatory affairs specialists, pharmacologists, and patent attorneys.

This poster aims to explore the typical day of a disclosure manager. We show with examples how a disclosure manager liaises with the medical writer and others to ensure that trial protocols and reports, before finalisation, are ready for disclosure on public registries, and that structured data are properly disclosed.

RESULTS

We present results of how the disclosure manager's valuable input throughout a study's lifecycle results in fit-for-purpose disclosure data. We show specific examples of how they ensure that disclosed endpoints match study objectives, study synopses meet regulatory requirements, and adverse event reporting among others is properly implemented. Through their input at the draft stages of study documents, multiple revisions and review rounds are prevented.

CONCLUSIONS

We highlight how strong interdisciplinary communication between transparency specialists and medical writers and other stakeholders is imperative for successful disclosure activities.