P5 – Turning waterfalls into swirls – can regulatory MW transform into agile MW?

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INTRODUCTION

Agile working practices were developed for the incremental development and deployment of products. The agile mindset allows a rapid and flexible response to change, often required for frequently changing product needs. We wanted to know if and how agile practices can be applied during clinical drug development, focusing on document preparation processes, to enhance collaboration, quality, and process efficiency.

METHODS

We combined a scientific literature search to collect recent published experience and examples for agile practices in document authoring, and compared those results to agile methodology in general and our own experience in document authoring to identify how existing processes can be improved by agile practices. We also evaluated if agile concepts are already followed during document authoring.

RESULTS

Few real-life-examples for agile document authoring have been published; some in the context of Covid-19 vaccines development and the corresponding challenges including short timelines and changing requirements. Agile (medical) writing requires a dedicated and well-defined team including writers and content contributors. This team should be empowered and self-organized using shared agile methods. We compiled an overview of real-life examples for agile practices related to clinical document authoring and show an example workflow for agile Briefing Book authoring.

CONCLUSIONS

Some sponsors and CROs tried to implement agile practices for circumstances requiring rapid adaptation to change. Agile practices might be easy to implement during the preparation of documents that are not strictly regulated, while modified agile practices can still be implemented when preparing more rigidly structured and tightly regulated documents.