Open Source Technologies for Regulatory Submissions

Project Scope

While interoperability and standardisation have been goals of the Pharmaceutical Data Science Industry for years, much of the work to create and validate a submission package is done manually or with proprietary software. Integrating tabular study data, study metadata, STF data, and visualisations are low-hanging fruit for a collaborative industry solution. Open-source tools have matured in their reliability and flexibility. This project will explore their emerging use in regulatory submissions. The topics of tools that assist in creating a submission package, the cost of these tools, and the necessary controls and validation needed to create and maintain a compliant eCTD package will be discussed

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Objectives and Deliverables	Timelines
Finalise White Paper	Q2 2021

CURRENT STATUS Q22021
Concluded, link to final White Paper

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