

Treatment Emergent Definitions Recommendations



Project Scope

This Project team will create a White Paper with recommendations for Treatment Emergent Definitions, with a focus on Phase 2-4 clinical trials. This White Paper will build upon a White Paper that outlines results from a survey on current practices, indicating variation that can likely be reduced. Recommendations will be based on the desired end-in-mind, and may or may not be consistent with current practices.

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Objectives & Deliverables	Timelines
Project team review final White Paper	Q2 2023
PHUSE Steering Committee & Public Review	Q3 2023
Publish White Paper	Q4 2023

CURRENT STATUS Q1 2024

- The writing sub team finalised the draft white paper and submitted to the wider project team for review; should be submitted for PHUSE Office review before the end of the quarter