

Adverse Event Collection Recommendations



Project Scope

This project team will create a White Paper with recommendations for Adverse Event Collection Instructions, with a focus on Phase 2-4 clinical trials. This project will build upon a 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
Publish White Paper	Q2 2024

CURRENT STATUS Q1 2024

- The AE collection white paper went out for public review – comments due 14 February.

Published Deliverables	Date
Blog – Investigator Assessment of Causality – Opportunity for Simplification?	15-Dec-2021
Adverse Event Collection & Treatment Emergent Collection: Version 1.0	27-Aug-2020