

FDA Oncology Full Consolidated Comments



Overview

This file contains the consolidated comments from the FDA Oncology Safety Data Standards Project Team. The goals of this phase of the project was to obtain broad industry and CRO feedback on version 1.3 of the OCE/OOD standard safety data request. The comments in the following tabs should not be considered as the consolidated opinion of the project team but the complete set of feedback collected from project team members for consideration to be included in a future version of the specifications. No indication is given to the status of the comments.

Standard Safety Data Requests

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