FDA Oncology Safety Data Standards

Project Scope
The goals of this project is to obtain broad industry and CRO feedback on the current publicly available OCE/OOD standard safety data request (found at: https://www.fda.gov/media/133252/download) and assist with the development of resources to assist Sponsors with implementation of these data specifications. There is tremendous variability and inconsistency in the use of the CDISC ADaM data standard in safety datasets for oncology NDA/BLA applications submitted to FDA. This variability leads to inefficiency in review for the FDA and multiple information requests to applicants during the course of the review to resolve inconsistencies in analyses between FDA and applicants. The Oncology Centre of Excellence (OCE)/Office of Oncologic Diseases (OOD) has developed a pilot standard safety data request for datasets submitted with NDA/BLA applications and instructions for conducting select safety analyses to create a common set of data elements with common use of these variables for safety analyses. The Stakeholders include FDA reviewers and analysts, industry, CROs, and software developers.

CURRENT STATUS	Q3/4 2022
This project is currently on hold, the team will reach out for volunteers for the kick off of phase 2	

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Deliverables	Timelines
Feedback on publicly available OCE /OOD safety data request.	Q2 2021
Development of basic resources for sponsors to assist implementation (e.g. CRF design to collect relevant data and linkages for adverse events and dataset preparation for laboratory analyses or other resources requested or found to be needed during the feedback process).	Q2 2021

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