An Overview of the Office of Computational Science Core DataFitness Service

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What is the OCS Core DataFitness service?

The Office of Computational Science (OCS) provides CDER reviewers innovative and reliable solutions that improve and strengthen the scientific review process by integrating data, tools and training. This poster details OCS’s Core DataFitness (CoreDF) service, designed to help reviewers understand the quality of clinical study data, including identifying data conformance issues to data standards, early in the review cycle. The CoreDF service includes:

- A set of data quality reports consisting of an overview tab and issue-specific reports
- A deskside support service to help reviewers navigate the reports

Summary Section

The summary section contains useful links to important documents, at-a-glance study information such as MedDRA version, subject counts and metadata about the data package.

Reports Section

Reports are provided to expedite common medical reviewer tasks. These include reports related to subject deaths, adverse event and disposition coding quality reports, and a report listing supplemental domains and variables included with the submission. These reports enable medical reviewers to complete common review tasks more quickly and without having to organize, sort or join data on their own. These reports also highlight potential records of interest that would otherwise be very time-consuming to identify.

Adverse Events Coding Quality Report

The CoreDF reports include an adverse event coding quality that contains a comparison of the Reported Terms (AETERM) against the Lower Level Terms (AELLT) and Dictionary-Derived Terms (AEDECOD). An algorithm generates a “score” from 0 (“Could not match”) to 100 (“Direct Match”). Review teams can use this report to:

- Check how a specific reported term is coded
- Check all terms coded to a specific AEDECOD
- Systematically review all mapping

How does CoreDF relate to other OCS services?

CoreDF is an important component of the OCS service portfolio which includes JumpStart, KickStart, the OCS Service Desk and others. Currently, CoreDF serves as the primary effort to provide automated data quality reporting to FDA medical reviewers for all new applications. It is also a complementary service to the JumpStart and KickStart services, both of which provide high-touch, in-depth support on data quality and safety analyses tailored to specific applications for a limited number of applications. OCS ensures that its portfolio of services meets the wide variety of reviewer needs through both automated processes and high-touch, tailored approaches.

Overview Tab of the Core DataFitness Reports

Example Finding – Not Treated Subjects

This example finding pertains to subjects who have values for ARM and ACTARM that indicate they were treated but who are missing records in the Exposure (EX) domain. This could indicate that the subjects were not treated or that the subjects are truly missing exposure information.

Example Finding – Missing AE Severity/Toxicity

This example finding pertains to records in the Adverse Events (AE) domain missing values for Severity (AESIV) or Toxicity (AETOXGR). Severity or toxicity is a required variable and should be collected on the CRF and transmitted to the dataset. Records missing severity/toxicity may be excluded from certain analyses or lead to discrepancies in results.

Other Core DataFitness Efforts

Partnerships: OCS seeks to partner with more offices within CDER who are interested in automated data validation in order to reduce the time it takes to understand the submission data package. OCS has already partnered with the Office of Clinical Pharmacology and the Office of Oncological Diseases to meet the more specific needs of these offices. SDTM to ADaM Traceability: OCS is currently working to include traceability reporting as part of the CoreDF service. This reporting would help reviewers trace Analysis Data Model (ADaM) data elements back to their SDTM origins.

Nonclinical Data: OCS will expand the CoreDF service to support nonclinical reviewers providing a set of data quality reports identifying data conformance issues to Standard for Exchange of Nonclinical Data (SEND) in nonclinical studies early in the review cycle.

Conclusion - Benefits of CoreDF Service

The CoreDF service helps reviewers understand the quality of clinical study data, including identifying issues related to conformance to data standards, early in the review cycle. By leveraging the CoreDF service reviewers increase their understanding of the overall SDTM data package, leading to more informed communications with the applicant and the identification of potential information requests (IRs).