CDISC Operating Procedure 002
ODM Product Certification

Revision History

Date	Revision	Description	Author
15 March 2014	1.0	Initial Version	Shannon Labout
8 September 2017	2.0	Major Revisions	Saad Yousef
7 December 2023	3.0	Major Revisions	Marcelina Hungria / Sam Hume / CDISC Certification Team

Table of Contents

1 Purpose

The purpose of this CDISC Operating Procedure is to describe the process of certifying Operational Data Model (ODM) capable software tools to provide a level of assurance that the specific tool is compliant with a specific version of ODM.

2 Background

Established in 2007, the ODM Certification Program allows vendors to demonstrate that their software tools conform to the specifications in the CDISC ODM standard, and to provide industry with a level of assurance that certified ODM tools are compliant. This certification is a benefit to the CDISC community in that certification allows vendor products recognition for their ODM capabilities.

3 Preliminary requirements for CDISC ODM Certification

The applicant vendor organization/company must be and must remain a CDISC member in good standing to obtain and maintain ODM Certification for their software tools and to be included in the ODM Certified listing on the CDISC website.

The applicant vendor organization/company must pay an initial fee for the certification process, the certificate and the company listing in the ODM Certification table on the CDISC website. There will also be an annual renewal fee to maintain the certification and listing. Additional fees apply to update the product certification. Vendor Size based on number of employees, plus Membership level, determines the fee structure as is listed on the website and in this COP.

4 Fee Structure

Gold Members

Total # of Employees in Organization	Initial Fee	Annual Fee	Update Fee
1-99	$9,360	$1,000	Time and Materials + Travel
100-999	$11,520	$2,000	Time and Materials + Travel
≥1000	$13,680	$3,000	Time and Materials + Travel

Platinum Members

Total # of Employees in Organization	Initial Fee	Annual Fee	Update Fee
1-99	$8,580	$600	Time and Materials + Travel
100-999	$10,560	$1,200	Time and Materials + Travel
≥1000	$12,540	$2,500	Time and Materials + Travel

***The Initial Fee* is fixed and** provides the following benefits to vendor:

Professional certification by an ODM Expert selected by CDISC. The number of hours of the Expert's time available to complete the stated Certification Process to include issuing final report depends on the Vendor Size bracket:
- 52 hours for vendors from '1-99' employees,
- 64 hours for vendors from '100-999' employees, and
- 76 hours for vendors that have '≥1000' employees.

If the application is approved, the corresponding version of the software tool is eligible for ongoing inclusion as an ODM certified product.

For an approved product, the ***Initial Fee and subsequent Annual Renewal Fees*** provide the following benefits to the vendor:

- Inclusion of the vendor's name and certified product in the ODM Certified Product listing for a period of one year from the initial invoice,
- Inclusion in any advertising CDISC does on behalf of the ODM Certified Products, for a period of one year from the initial invoice.

The Annual Renewal Fee applies starting in Year 2.

The Update Fee is required in either of the following situations: (1.) when a vendor wishes to have their product certified against another version of ODM or (2.) when the vendor issues a new version of a certified product. CDISC will charge time, materials, and any travel necessary, to complete the certification process, assuming the vendor has maintained

CDISC membership and ODM Certification Annual Fees.

Travel expenses will be added to the *Initial Fee* if travel is necessary.

5 Certification Process

A. Vendor submits an application for ODM Certification through the CDISC website.

B. CDISC will confirm the membership of company. If the company is not a member, CDISC will invite them to apply for membership before the application is processed.

C. Once membership is confirmed, CDISC will invoice the vendor for the *Initial Fee* based on the Fee Structure section and provide an ODM Certification Agreement based on the template in Appendix A ODM Certification Agreement Template for vendor's signature.

D. Once the application fee has been paid and the ODM Certification Agreement signed, a preliminary assessment of the vendor's ODM tool will be done to determine the complexity of the certification process for that tool.
   a. The preliminary assessment depends on the Vendor Size bracket: 12 hours for the '1-99' bracket, 16 hours for the '100-999' bracket, and 20 hours for the '≥1000' one.
   b. If the preliminary assessment indicates the certification will require more than the stated Certification Process hours, or the preliminary assessment requires longer than the preliminary assessment hours, the applicant will have the option of continuing the certification process on a Time and Materials basis or withdrawing the application.
   a. If the application is withdrawn, the application fee will be refunded less a non-refundable fee for the preliminary assessment as indicated in the signed ODM Certification Agreement.

E. During the certification process, the following activities will be performed by an ODM expert:

Conformity testing of ODM files produced or processed by vendor's software:

   a.   Product testing using ODM documentation and test data designed to exercise ODM features
   b.   Product documentation review
   c.   Certification final report
   d.   The ODM Certification process may cover some or all of the following 7 use cases to the degree these are supported by the vendor's products:
      i. Metadata Export
      ii. Metadata Import
      iii. Metadata Interoperability
      iv. Snapshot Data Export
      v. Snapshot Data Import
      vi. Transactional Data Export
         Transactional Data Import

F. When the certification activities have been completed, CDISC will issue a final invoice for any costs that have been incurred above the ***Initial Fee*** (e.g., time overstated Certification Process hours, materials, travel expenses). CDISC will also issue Code of Ethics and Conflict of Interest Policy (CDISC Policy 001) for signing.

G. If the certification is successful and once the final invoice has been paid by the applicant, CDISC will issue the ODM Certification certificate to the vendor and publish the vendor's product in the ODM Certification listing.

H. If a software tool fails to pass the certification process, or an application is withdrawn before successful completion of the certification process, the application fee will be refunded minus time, material, and travel costs already incurred.

6. Certification Maintenance

Vendors who wish to maintain ODM Certification on their products must maintain their CDISC membership, pay the Annual Renewal Fees, and affirm adherence to all CDISC policies and procedures, including the CDISC Code of Conduct and Professional Ethics and the Intellectual Property Policy.

7. Good standing

CDISC reserves the right to remove any product from the list that is found to be non-compliant. CDISC reserves the right to remove any product of any vendor which does not maintain their CDISC membership in good standing. CDISC reserves the right to remove any product from any vendor which does not pay Annual Renewal Fees. CDISC reserves the right to remove any product from the list where the vendor engages in gross or inappropriate behavior in CDISC's sole opinion such that affiliation with that vendor harms CDISC's brand or reputation.

CDISC publishes information available in the ODM Certification list as a service to vendors and their potential clients with the assurance that the listed version of a product has been certified to have the identified ODM capabilities. Explicitly, CDISC makes no assurance regarding other versions of the product or other products with any of the ODM versions unless those other product versions have been specifically tested through the ODM Certification Process against specific ODM versions.

CDISC does not express any warranty or guarantee any ODM certified product for any non-ODM functionality or for services provided by Vendors. Contract details (e.g., cost, timing) should be negotiated directly between the Vendor and the customer.

8. Authorization

This document has been approved and is in effect on this date:

Name	David Evans, President and CEO
Date	07 December 2023

Appendix A: ODM Certification Agreement Template

Refer to the attached document "ODM Certification Agreement Template.docx".

ODM Product Certification Agreement

(Date)

CDISC will test the ODM vendor's software tool (Product) against a series of validation rules. Once the application fee has been paid, a preliminary assessment of the vendor's ODM tool will be done remotely to determine the complexity of the certification process for that tool. If the preliminary assessment indicates the certification will require more than <#> days (<#> hours), or the preliminary assessment requires longer than <#> day(s) (more than <#> hours), the applicant will have the option of continuing the certification process on a Time and Materials basis, or withdrawing the application. If the application is withdrawn, the application fee will be refunded minus a fee of $<#> for the preliminary assessment.

The certification process will be conducted either on-site or online, at the discretion of CDISC, and if done on-site, expenses will be invoiced to the applicant as a pass-through cost.

During the certification process, the following activities will be performed by an ODM expert:

- Conformity testing of ODM files produced by vendor's software tool
- Product testing using ODM documentation and test data designed to exercise ODM features
- Product documentation review
- Certification final report

The ODM Certification process may cover some or all of the following 7 use cases to the degree these are supported by the vendor's Product:

- Metadata Export
- Metadata Import
- Metadata Interoperability
- Snapshot Data Export
- Transactional Data Export
- Snapshot Data Import
- Transactional Data Import

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ODM Product Certification Agreement

The applicant vendor organization/company must be and must remain a CDISC member in good standing to obtain and maintain ODM Certification for a specified version of their software tools and to be included in the ODM Certified listing on the CDISC website.
The Certification is valid for one year from the date the final report is issued (Certification Date). The certification renewal fee must be paid annually in order to maintain ODM certification beyond that first year.

Costs for ODM certification are estimated as follows:

Product Name	Product Version	Vendor	Current Version of ODM Used	Cases to be Certified	Certification Initial Fee	Certification Annual Fee	Certification Version Update Fee	Estimated Travel Expense	Total Estimated Fee

(Company Contact Name)
(Title)
(Phone)
(E-mail)
(Company Address)

Accepted and agreed:

_____
Printed Name and Title

_____
Name of Organization

_____

ODM Product Certification Agreement

Signature

_____
Date

_____
David Evans, President and CEO

_____
Purchase Order # (if applicable)

_____
Date

_____
Cost Center # (if applicable)