



**CDISC Operating Procedure 002
ODM Certification**

Revision History

Date	Revision	Description	Author
15 March 2014	1.0	Initial Version	Shannon Labout
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CDISC Operating Procedure 002 ODM Certification

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 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 and Registered Solutions Provider listings 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. Membership level determines fee structure as is listed on the website and in this COP.

4 Fee Structure

- 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 application fee based on the following table:

ODM Certification Fees						
	Gold Members			Platinum Members		
Total number of Employees in your Organization	ODM Certification <i>Initial Fee</i> (Includes RSP fee)	ODM Certification <i>Annual Renewal Fee</i> (Includes RSP fee)	ODM Certification Version <i>Update Fee</i> (must be current with annual fee)**	ODM Certification <i>Initial fee</i> (Includes RSP fee)	ODM Certification <i>Annual Renewal Fee</i> (Includes RSP fee)	ODM Certification Version <i>Update Fee</i> (must be current with annual fee)**
>=1000	\$10,000	\$3,000	T&M + travel	\$9,000	\$2,500	T&M + travel
100 - 999	\$9,000	\$2,000	T&M + travel	\$8,000	\$1,200	T&M + travel
1 - 99	\$7,000	\$1,000	T&M + travel	\$6,000	\$600	T&M + travel

The Initial Fee provides the following benefits to vendor:

- Professional certification by an ODM Expert selected by CDISC including up to 40 hours of that expert's time
- Documentation of the certification in a final report

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

For an approved product, the Annual Renewal fee applies starting in Year 2 and provides 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 the CDISC Registered Solutions Provider list for ODM
- Inclusion in any advertising CDISC does on behalf of the ODM Certified Products, for a period of one year from the initial invoice.

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 update certification assuming the vendor has maintained CDISC membership and ODM Certification Annual Fees.

5 Certification Process

A. Once the application fee has been paid, a preliminary assessment of the vendor's ODM tool will be done to determine the complexity of the certification process for that tool.

a. If the preliminary assessment indicates the certification will require more than 40 hours, or the preliminary assessment requires longer than 8 hours, the applicant will have the option of continuing the certification process on a Time and Materials basis, or withdrawing the application.

b. If the application is withdrawn, the application fee will be refunded less a non-refundable fee of \$1,500 for the preliminary assessment.

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

Conformity testing of ODM files produced 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 Clinical Data Export

v. Snapshot Clinical Data Import

vi. Transactional Clinical Data Export

vii. Transactional Import

D. When the certification activities have been completed, CDISC will issue a final invoice for any costs that have been incurred above the application fee (e.g., time over 40 hours, materials, travel expenses). CDISC will also issue Code of Ethics and Conflict of Interest Policy (CDISC Policy 001) for signing.

E. 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 Table. CDISC will also publish the vendor's name in the CDISC Registered Solutions Providers (RSP) table as an ODM RSP.

F. 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 of 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 is making the 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 this 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 product or service provided by RSPs. Contract details (e.g., cost, timing) should be negotiated directly between the RSP and the customer.

8. Authorization

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

Name	David R. Bobbitt, President and CEO
Date	8 September 2017