# ODM Certification Services Request for Information (RFI)

## 1 Introduction

### 1.1 About CDISC

CDISC is an open, multidisciplinary, non-profit organization that has established global industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. *The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.*

For more information on CDISC strategy and principles, please see the CDISC website at [www.cdisc.org](http://www.cdisc.org).

### 1.2 Objectives of this RFI

The objective of this RFI is to solicit Information from those who can provide a service under CDISC’s aegis to test conformance of third party software products with the CDISC Operational Data Model (ODM) standard. This will be considered as an ODM Certification Service. Information solicitations for services to test conformance with other CDISC standards may be solicited at a future time.

### 1.3 Who Should Respond

CDISC encourages consultants or service providers with a deep and thorough understanding and experience implementing the ODM standard as well as an interest in providing ODM certification services to respond to this RFI. However, to avoid any potential conflict of interest, respondents must not offer a commercial product that uses ODM that would potentially compete with products submitted by others to CDISC for certification.

## 2 Scope

CDISC Registered Solution Providers as well as others claim that their tools conform to ODM specifications, but there is a need to produce objective evidence to verify such alleged conformance. Also, biopharmaceutical companies in some cases may want to ensure that internally developed applications can read and write ODM compliant files, such as to support software validation requirements. It is also in the best interests of CDISC to ensure that products that claim to use ODM can be objectively verified to be doing so correctly. CDISC began offering this ODM certification service through Assero beginning in 2007. We are now soliciting for other providers interested in providing the same service.

We are requesting for interested parties to provide ODM certification services that can verify that a candidate toolset (defined in this document as any application, program or commercial available software product) uses the CDISC ODM standard correctly. The service will provide a thorough examination of the candidate toolset to examine how ODM is used and ensure that ODM files exported by the toolset are correct and free from error and,
where applicable, import of ODM files into an application occurs without errors or loss of information. Toolsets that successfully pass the tests can be labeled and marketed as “CDISC Certified” for the ODM version tested. ODM certified products are also listed on the CDISC website.

CDISC currently has some software tools to support the ODM Certification process, which will be made available to those selected to provide this service. These tools will need to be updated periodically to effectively validate any new versions of ODM, which will be the responsibility of those selected. While the selected provider will have full right to use these tools on certification projects, the set of tools used to certify ODM will remain the intellectual property of CDISC.

Those selected to provide this ODM certification service will be asked to sign a non-compete agreement with CDISC for similar or identical services.

3 Information Being Requested

This RFI requests information in the following 6 categories. Please be as specific as possible with each response:

1. Description of your organization’s experience with CDISC’s ODM and specifics as to length of experience and version(s) of ODM.
2. Description of how your organization would provide services, including any tools currently available or in development. Keep in mind that CDISC will provide the current version of the ODM Certification tools for use by those selected.
3. Description of your organization’s expertise in similar certification programs or how your organization would develop expertise in ODM certification, if lacking that expertise.
4. Description of how your organization would keep abreast of changes to the ODM standard and provide updates to the certification tool set for different versions.
5. Pricing: Please provide time estimates and pricing to provide the service including initial test, retest and final report. (Include information on how pricing would vary for commercial vs. non-commercial applications or size of company or any other pricing variations you see as necessary). Also, provide estimated or sample pricing to update and maintain the tools including updates and new releases necessary to test new releases of ODM.
6. List of assumptions made in developing your response
7. Date when you would be prepared to begin work on offering this service.

4 Instructions for Responding

4.1 Format of RFI Responses

Cover letter and Word document that addresses the information requested in Section 3.

4.2 How to Submit Responses

Send via email to Frank Newby (fnewby@cdisc.org) with subject of “ODM Certification RFI Response”.

4.3 Reimbursements

CDISC will not reimburse any expenses for preparation of responses to this RFI.
5  Response Review Process and Schedule
   18-Jul-2012   RFI Issued and posted on the CDISC web site
   24-Aug-2012   RFI responses due
   28-Sep-2012   RFI responses reviewed by CDISC and selection complete

6  For More Information
   Please contact Frank Newby - fnewby@cdisc.org - for more information.