



## **ODM CERTIFICATION PROGRAM**

The ODM Data Standard is increasingly recognised, as the ideal transport method for data across the entire clinical trial enterprise. In order to ensure consistency across toolsets and interoperability between ODM implementations, the ODM Certification Program has been developed.

### **The Importance of Certification**

In order to improve user confidence in the ODM and to ensure interoperability among available ODM toolsets, CDISC has initiated the ODM Certification program. This program is in direct response to requests from CDISC members. With Certification comes an increased level of confidence in the ODM standard, thereby increasing its adoption and use.

### **How to obtain Certification**

Assero Ltd has been selected as the service provider for the ODM Certification Program, as a result of an open RFP process. Assero Ltd can be found on the CDISC members' website: <http://www.cdisc.org/our-members?alpha=A> and Assero Ltd can be contacted via email: [amanda.demontjoie@assero.co.uk](mailto:amanda.demontjoie@assero.co.uk)

### **The certification process is as follows:**

- Contact Julie Evans at CDISC [jevans@cdisc.org](mailto:jevans@cdisc.org) and register your interest
- Assero Ltd will contact you and assist with application. This initial consultation with Assero Ltd will determine whether both ODM import and export use cases are to be assessed
- Your application will then be lodged with CDISC
- Before consultation takes place, sample files should be sent to Assero Ltd in order for an informal check to be completed which ensures that time is used efficiently
- A day's off site preparation follows for planning and setting up tests
- Exhaustive on site tests are then conducted over two days to check your toolsets with results recorded and observations made
- Certification is completed off site with a fully documented report being produced for you
- The report is then communicated to interested parties
- The process will be repeated as necessary to obtain Certification

### **Benefits of Certification**

ODM Certification provides wide ranging benefits to the pharmaceutical industry as a whole, particularly to those companies who have already leveraged the standard or indeed those considering adoption.

#### *For FDA Regulated Product Manufacturers*

- Certification ensures that an ODM tool is making proper and consistent use of the standard.
- Certified tools and products give assurance of interoperability

#### *For Vendors and CROs*

- Certification of a vendor developed ODM tool will enable the vendor to provide a better quality, verified product to their pharmaceutical customers.
- Vendors can provide assurance that ODM toolsets are interoperable with other certified ODM tools.



- Certification protects vendors and CROs from unexpected interoperability challenges. This can prevent rework or redevelopment of ODM tools to suit different customers.
- Certification reduces the risk to a vendor or CRO, as they can be confident of interoperability with certified partners.

#### *Benefits to the Industry and CDISC*

- Certification ensures correct and consistent use of the CDISC data standard. This in turn increases industry confidence and wider adoption.
- Certification maintains CDISC's excellent reputation as a major developer of consensus based standards for clinical trial data.

### **Value of Certification**

Certified sites will receive:

- A Best Practices Report
- Certification logo for use on marketing materials and corporate website
- Listing on the CDISC website as a certified service provider
- Announcement of your certification in the CDISC newsletter

### **Charges for Undertaking Certification**

Initial Evaluations Charges:

This service has a fixed price of \$4800 plus expenses (hotel, flights etc). If an application does not achieve certification from the initial evaluation, additional evaluations will be charged at half the cost plus expenses. This charge covers the cost of achieving Certification status.

CDISC Charges:

Upon Certification being achieved companies will receive the right to use the Certification logo and be listed on the CDISC website. The charges are as follows:

Number of employees in organization	List Price	Corporate Benefactor, Government, Academic, non-profit	Corporate Sponsor	Corporate Member	Associate Members
	<b>No discount</b>	<b>75% discount</b>	<b>55% discount</b>	<b>35% discount</b>	<b>25% discount</b>
<b>10000 &amp; Up</b>	<b>\$18,000</b>	<b>\$4,500</b>	<b>\$8,100</b>	<b>\$11,700</b>	<b>\$13,500</b>
<b>1000 - 9999</b>	<b>\$12,000</b>	<b>\$3,000</b>	<b>\$5,400</b>	<b>\$7,800</b>	<b>\$9,000</b>
<b>500 - 999</b>	<b>\$8,000</b>	<b>\$2,000</b>	<b>\$3,600</b>	<b>\$5,200</b>	<b>\$6,000</b>
<b>100 - 499</b>	<b>\$5,000</b>	<b>\$1,250</b>	<b>\$2,250</b>	<b>\$3,250</b>	<b>\$3,750</b>
<b>1-99</b>	<b>\$2,500</b>	<b>\$625</b>	<b>\$1,125</b>	<b>\$1,625</b>	<b>\$1,875</b>

If you require any further information regarding certification, please contact Dave Ibersen-Hurst at Assero Ltd: [dave.iberson-hurst@assero.co.uk](mailto:dave.iberson-hurst@assero.co.uk)

Additional information on CDISC can be found on the CDISC website at [www.cdisc.org](http://www.cdisc.org).