



CDISC Operating Procedure CDISC-COP-006 Software Tools for Use With CDISC Models

Revision History

Date	Revision	Description	Author
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27 June 2003	0.2	Redrafted	Sally Cassells
1 August 2003	0.3	Edits from Kaplan Levy & TCC	Sally Cassells
12 August 2003	1.0	Final Version	Sally Cassells
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CDISC Operating Procedure CDISC-COP-006

Software Tools for Use With CDISC Models

1 Introduction

1.1 Purpose

The purpose of this CDISC Operating Procedure is to outline guidelines for CDISC members for access and use of software tools posted on the CDISC website.

1.2 Background

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.

CDISC is a leader in the development of standard data models that improve process efficiency in the handling of clinical trial data and metadata. Data models developed by CDISC Working Teams may be supported by software tools developed to assist in the examination, evaluation and adoption of CDISC models. These software applications, developed by CDISC members and partners (Licensor), may be posted on the CDISC website for use by CDISC members.

CDISC and their partners in software development have an inherent interest in maintaining control of the software in order to ensure that the software application is used appropriately and to ensure that any modifications to the software are appropriate and made correctly for full functionality. To this end, such software tools will be posted in the Members Only areas of the CDISC website.

For more information on CDISC objectives and principles, please see the CDISC website at www.cdisc.org.

1.3 Authority

This document is approved by the CDISC President and should be followed by all CDISC Operations staff, team/project leaders, CDISC consultants and representatives, including volunteers participating in teams/projects or in user networks.

1.4 References

The following information sources are referenced in this document:

- **CDISC Website:** www.cdisc.org

2 Procedure for Contributing CDISC tools

- Contributions may be from CDISC Benefactors, Sponsors, Members or Associate Members. They may also be from working team members.

- Software tools designed to assist in the review, evaluation and adoption of CDISC models will be posted on the CDISC website in areas accessible to members only and/or to CDISC working team members.
- Software is posted according to the procedures defined within this document. However, posting contributed software on the CDISC web site does not constitute an endorsement nor any warranty on the part of CDISC, including fitness for a particular purpose. CDISC shall not be responsible or liable in any manner in connection with the posting of or use of software posted on the CDISC website, and users of the website and/or such software shall look solely to the contributor of such software for the satisfaction of any claims in connection therewith.
- The software is provided without charge to CDISC members.
- The software may be distributed without charge to CDISC working team members.
- Demonstration versions of commercially available software may be contributed for posting as long as it is clearly stated and purchase contact information is also provided.
- Information about contributed software, including a list of the available tools and their contributing organizations may be posted in the open section of the CDISC web site.
- Contributing companies may also provide the tools they have contributed on their own web sites according to whatever terms they may choose.

2.1 Documentation Required for Contributed Software

Contributed software must include a document that will be posted with the software. The documentation must include the following information:

1. A brief description of the tool.
2. The CDISC model and version supported by the tool.
3. Name of the organization contributing the tool.
4. Name and contact information for an individual within the contributing organization. Ideally both a technical and business contact will be provided.
5. Minimum software requirements for installing the tool. At a minimum any required 3rd party components must be identified.
6. Location of the installation instructions.
7. (Optional) Link to the software user's manual. If documentation is included as a separate file as part of the tool download, identify the name of the file and any 3rd party components required for reading the documentation.
8. (Optional) Validation information. This may be the name and contact information for an individual within the contributing organization or a link to an online validation package. This is recommended that this information be provided but not required.
9. (Optional) Technical support contact information. The contributing organization is not required to provide technical support. However, if

technical support is not provided it should be clearly stated within the summary document and/or in the software license agreement.

10. Purchase information, if applicable. If the version of the software posted on the CDISC site is a demonstration or time-limited trial use copy, information about where and how to purchase a full license version should be included.
11. (Optional) Sample data. Identify sample data provided for testing purposes.

2.2 Software License

It is strongly recommended that contributors provide their own software license agreements. The license should apply to the software identified on the agreement and, as applicable, to associated media, printed materials and “online” or electronic documentation. A sample licensing agreement is provided as an appendix to this document.

3 Review, acceptance, posting

Contributors must provide their own software license agreements, and users must agree to the terms of those agreements. The contributed software, summary documentation and software license agreement should be addressed to Julie Evans (jevans@cdisc.org).

At the TCC meeting following the submission, a technical team leader will be assigned to review the contributed software. In cases where a tool is designed to work with more than one CDISC model, a reviewer will be assigned from each team and a lead reviewer (usually the team leader) will be assigned to coordinate the review among the teams.

The review procedure will include:

1. Test installation
2. Test of tool operation with provided sample data.

The review procedure will be completed within 60 days of submission of the tool. In the event that the tool review cannot be completed for whatever reason, the contributing organization or individual should be notified as soon as possible.

4 Updates & Withdrawal

Following the release of new versions of CDISC models, contributors are encouraged to provide updates of their software tools or documentation.

If a new version of contributed software or updated documentation is not provided within 12 months of the final release of a new CDISC model version, the software posting will be moved to a section labeled “Software tools for older model versions”.

The Licensor may terminate the License Agreement at any time. Upon termination, users must agree to destroy or return to the Licensor the software application, segments of the software or copies of the software.

5 Terms of Use

All users must agree to the Terms of Use prior to downloading any software.

- Download of software tools requires acceptance of a terms of use agreement in addition to any license agreement provided by the software contributor.
- CDISC reserves the right to collect information about users who download contributed software.
- The software may be used only on a single computer owned, leased or otherwise controlled by the person accepting the terms of the license agreement. In the event of inoperability of that computer, operation on a back-up computer is acceptable. Neither concurrent use on two or more computers nor use in a local area network or other network is permitted without the authorization of the Licensor.
- One copy of the software may be made for back-up purposes. Any copy of the software or related documentation shall include the Licensor's copyright and other proprietary notices. No other copies of the software or any portion thereof may be made.
- Acceptance of the License Agreement means that the user agrees not to assign, sublicense, transfer, pledge, lease, rent or share his/her rights under the terms of the License Agreement.
- Acceptance of the License Agreement means that the user agrees to be bound by the terms of the End-User License Agreement, which may include warranty disclaimers, limitations of liability and termination provisions.
- Users agree not to modify any software downloaded from the CDISC website but to use the application as provided. Any errors or malfunctions in software should be reported to Licensor. Any suggested modifications to the software should also be proposed to the Licensor. The Licensor will consider all proposed modifications for inclusion in subsequent versions of the software application.
- Acceptance of the License Agreement means that the user will not reverse assemble, reverse compile or otherwise translate the software.

6 Review and Authorization

Date	Representation	Name
1 January 2006	CDISC President	Rebecca Kush

Attachment 1-SAMPLE ONLY

END-USER LICENSE AGREEMENT FOR CDISC ODM VIEWER (the "Software")

IMPORTANT -- READ CAREFULLY: This End-User License Agreement ("Agreement") is a legal contract between you (either an individual or a single business entity) and <<CONTRIBUTING COMPANY>> ("Licensor") for the Software identified above, which includes computer software and, as applicable, associated media, printed materials, and "online" or electronic documentation (the "Software Application").

BY CLICKING THE **ACCEPTED** ICON BELOW, OR BY INSTALLING, COPYING, OR OTHERWISE USING THE SOFTWARE APPLICATION, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT, **INCLUDING THE WARRANTY DISCLAIMERS, LIMITATIONS OF LIABILITY AND TERMINATION PROVISIONS BELOW.** IF YOU DO NOT AGREE TO THE TERMS OF THIS AGREEMENT, DO NOT INSTALL OR USE THE SOFTWARE APPLICATION, AND EXIT NOW.

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4. Termination. Licensor may terminate this Agreement at any time. Upon such termination by Licensor, you agree to destroy or return to Licensor the Software Application and all copies and portions thereof.

5. No Warranties. The Software Application is provided "AS IS, WHERE IS," without any representation or warranty whatsoever, including without limitation any warranties of title, noninfringement, merchantability or fitness for a particular purpose. ANY LIABILITY OF LICENSOR FOR A DEFECTIVE COPY OF THE SOFTWARE APPLICATION WILL BE LIMITED EXCLUSIVELY TO REPLACEMENT OF YOUR COPY OF THE SOFTWARE APPLICATION WITH ANOTHER COPY OR REFUND OF THE INITIAL LICENSE FEE LICENSOR RECEIVED FROM YOU FOR THE DEFECTIVE COPY OF THE PRODUCT. IN NO EVENT WILL LICENSOR OR ITS SUPPLIERS BE LIABLE TO YOU FOR ANY CONSEQUENTIAL, INCIDENTAL OR SPECIAL DAMAGES, INCLUDING ANY LOST PROFITS OR LOST SAVINGS, EVEN IF A LICENSOR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OR FOR ANY CLAIM BY ANY THIRD PARTY.

You are asked to report any error or malfunction in the Software to Licensor. Licensor assumes no legal obligation with respect to your use of the Software Application.

The Software may be subject to or cause human and machine errors, omissions, delays and losses, including loss or corruption of data or media. You should adopt such measures as you believe proper to limit the impact of those problems, including backing up data and verifying the accuracy of input data; examining and confirming results prior to use; and adopting procedures to identify and correct errors and omissions, replace lost or damaged media, and reconstruct data.

6. Governing Law. This Agreement shall be construed and governed in accordance with the laws of the Commonwealth of Massachusetts.

7. No Waiver. The failure of either party to enforce any rights granted hereunder or to take action against the other party in the vent of any breach hereunder shall not be deemed a waiver by that party as to subsequent enforcement of rights or subsequent actions in the event of future breaches.

8. U.S. Government Restricted Rights. The Software Application and documentation are provided with RESTRICTED RIGHTS. Use, duplication, or disclosure by the Government is subject to restrictions as set forth in subparagraph (c)(1)(ii) of the

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