



CDISC Operational Procedure CDISC-COP-007 CDISC Translations

Revision History

Date	Revision	Description	Author
July 2015	0.1	Initial Draft	Andrea Vadakin and Rebecca Kush
September 2015	0.2	Comments from 3Cs	Andrea Vadakin
August 2017	1.0		Marine Laurent

CDISC Operational Procedure CDISC-COP-007

CDISC Translations

1 Introduction

1.1 Purpose

This CDISC Operating Procedure (COP) provides guidance on the translation process for CDISC standards and related documentation, which constitute CDISC Intellectual Property, to develop CDISC authorized, publically accessible translations of the CDISC standards and related materials, and ensure that a single authorized product results.

1.2 Scope

This CDISC Operating Procedure applies to individuals, teams of volunteers or organizations that intend to translate CDISC standards, courses and/or related documentation and materials.

2 CDISC Translation Process

- Translations of CDISC standards may be conducted by a CDISC User Group, a team of volunteers, a volunteer organization such as a research institute or other appropriate organization (“translating party”). A translating party must include qualified translators with appropriate knowledge of the standards and have the ability to conduct quality checks to ensure accuracy of the translated materials.
- Proposed translation works must be approved in advance by the CDISC Leadership team with input from the CDISC Coordinating Committee (3C) in the region or country where the translation was developed (if such as 3C exists), to ensure that there is no duplication of efforts.
- Upon approval, both CDISC and the translating party will determine a single point of contact for each organization. The translating party should direct all question to the CDISC point of contact who may then redirect them to internal expert(s) as necessary.
- It is recommended that the translating party employ appropriate QC methods to ensure translation quality, such as peer review and/or back translation, prior to submitting the document for internal review. Such QC methods should be communicated to the 3C and/or CDISC Operations prior to submission.
- Once the 3C or CDISC Operations receives the translated standard or document, there will be a 30-day window for internal review and necessary feedback. Should there be changes required, such changes should be made and, following

resubmission of the corrected document, another 30-day timeframe may be required for additional follow up with the 3C and/or CDISC Operations.

- Following internal review, the translated document will be posted to the CDISC website for an open, 30-day public review period, to be coordinated by the local 3C and/or CDISC Operations.
- The final draft of the translated document will be submitted to the CDISC Leadership team, who will have a 30-day window to approve it. In case a regulatory authority has requested / agreed to review the translated document, that final draft will be submitted to them for approval according to their own approval guidelines.
- Upon final approval, the translated document will be posted on the CDISC website and any other relevant repository, such as SHARE.
- Once posted, this will become the official, authorized translation of the CDISC standard, course or document. In the case where a regulatory authority or CDISC partner is involved in the translation process, the regulatory authority or CDISC partner may also place the authorized version of the translated document on their official website to ensure visibility and awareness.
- Should any discrepancy between the original CDISC documentation and its translation be recognized, the original CDISC documentation shall prevail. In light of this, the translated version of a standard or related documentation will include a disclaimer noting to use the original version of the document for any clarification.
- Regardless of other organizations or individuals' involvement in the translation process, the translated version of the standard or related materials will be considered the sole property of CDISC, protected under the [CDISC Intellectual Property \(IP\) Policy](#), as are all CDISC standards.
- Should any corrections to the translated document be required, these changes will be the responsibility of the translating party.

3 Authorization

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

August 2017	D. Bobbitt - President and CEO
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