



CDISC Policy 003 - Intellectual Property

Revision History

Date	Revision	Description	Author
16 July 2004	0.1	Original draft	MS Legal Counsel and Independent
21 Sept 2004	0.2	CDISC-specific draft, following teleconference with Frank Newby and MS	Rebecca Kush
12 October 2004	0.3	Gray Cary Input (CDISC Legal Counsel)	Rebecca Kush
27 October 2004	0.4	Follow-up with Jim Thatcher (MS) and Frank Buono (Independent Legal Counsel)	Rebecca Kush
29 Nov 2004	0.5	Input from CDISC Operations (Frank Newby)	Rebecca Kush
7 Mar 2005	1.0	Recommendations from Board and TCC	Rebecca Kush
15 August 2014	1.1	Revisions	Rebecca Kush and Wayne Kubick
14 October 2019	2	Revisions	Legal Counsel
22 April 2024	3	Revisions	Legal Counsel

CDISC Intellectual Property Policy

1 Purpose

In its role of leading the development of standards, CDISC must protect those standards to ensure that, to the extent practicable, they remain neutral, open, compensation (royalty)-free, and without encumbering ties to prior intellectual property.

This Intellectual Property Policy (“**Policy**”) is designed to facilitate the activities of CDISC in promotion of such open Standards, to maximize the adoption of such Standards by protecting against the ownership of such Standards by one party and to protect the legitimate intellectual property rights of Contributors (as defined below).

This Policy ensures that CDISC is in accordance with its Bylaws, other Policies and basic Principles.

For more information on CDISC, its Bylaws, Strategic Plan, other Policies and basic Principles, please see the CDISC website at www.cdisc.org.

BY JOINING, TAKING PART IN, OR MAKING A CONTRIBUTION TO CDISC, EACH PARTICIPANT AGREES TO BE BOUND BY THE TERMS AND CONDITIONS OF THIS POLICY. IF SUCH PARTICIPANT DOES NOT AGREE WITH ALL OF THE TERMS AND CONDITIONS OF THIS POLICY, SUCH PARTICIPANT SHOULD NOT JOIN, TAKE PART IN, OR MAKE A CONTRIBUTION TO CDISC.

2 Definitions

- 2.1 **“Affiliate”** means any entity that directly or indirectly controls, is controlled by, or is under common control with, another entity, so long as such control exists. “Control” means direct or indirect beneficial ownership of or the right to exercise (a) more than fifty percent (50%) of the voting stock or equity in an entity; or (b) more than fifty percent (50%) of the relevant ownership interest or decision-making authority representing the right to make the decisions for the subject entity in the event that there is no voting stock or equity. In the event such control ceases to exist, such Affiliate will be deemed to have withdrawn as a Member, pursuant to the terms set forth in the withdrawal provisions in Section 8.
- 2.2 **“CDISC”** means the Clinical Data Interchange Standards Consortium.
- 2.3 **“CDISC Group”** means any team or group sanctioned, organized, or supported directly by CDISC.
- 2.3 **“Contribution”** means any material, suggestion, or other submission offered by a Participant in the process of developing a Draft Standard or Final Standard for the purpose of incorporating such submission into a Final Standard, provided that such submission either (a) exists in a tangible form of expression (including in electronic media); or (b) is a verbal statement that is memorialized in written documentation (such as meeting minutes or a draft standard) and is either confirmed or not objected to by such Participant within fifteen (15) calendar days after its receipt of such memorialization.
- 2.4 **“Draft Standard”** means any CDISC standard or specification developed by a CDISC Group, prior to adoption and publication as a Final Standard.
- 2.5 **“Final Standard”** means any CDISC standard, in any version and in any format, adopted and published by CDISC for public use.
- 2.6 **“Licensee Product(s)”** means only those specific portions of products (software, tools, functionality, data formats, services, other products or combinations thereof), not the product as a whole, that implement and are compliant with the relevant Required Portions of a Final Standard.
- 2.7 **“Member”** means all classes of CDISC membership as set forth in CDISC documentation and their Affiliates.
- 2.8 **“Necessary Claims”** means those claims in any patent or patent application in any jurisdiction in the world, excluding design patents and design registrations, that would necessarily be infringed by an implementation of those portions of a particular Final

Standard within the scope of the CDISC Group charter in effect at the time such Final Standard was developed. A patent claim is “necessarily infringed” only when it is not possible to avoid infringing it because there is no commercially reasonable, non-infringing alternative for implementing the Required Portions of such Final Standard. Notwithstanding the foregoing, Necessary Claims do not include any claims: (i) that may be contained in the same patent as Necessary Claims but are not themselves Necessary Claims; (ii) that cover solely any portions of any product and any combinations thereof that are not required for compliance with the Final Standard; (iii) that cover any enabling technologies that may be necessary to make or use any product or portion thereof that complies with a Final Standard, but are not themselves expressly set forth in the Final Standard (e.g., semiconductor manufacturing technology, compiler technology, object oriented technology, operating system technology, computers, networks, connectivity protocols, or the like); (iv) that cover implementation examples or reference implementations in the text of a Final Standard; or (v) that cover the implementation of other published specifications/standards developed elsewhere and merely referred to in the body of a Final Standard.

Since this definition of Necessary Claims focuses solely on Final Standards, not Draft Standards, for purposes of applying the disclosure obligations in Section 5 of this Policy, references to disclosures of Non-Contributed Necessary Claims “covering a Draft Standard” shall be understood to assume that the Draft Standard at issue would ultimately be adopted, without modification, as a Final Standard.

- 2.9 **“Non-Contributed Necessary Claims”** means those Necessary Claims that cover not a Participant’s own Contribution but either: (a) the Contribution of another party; or (b) material that is otherwise included in a Final Standard.
- 2.10 **“Participant”** means any party that: (1) formally joins a CDISC Group as a listed participant; or (2) makes a Contribution to a CDISC Group; or (3) attends one (1) or more meeting(s)/teleconference(s) of a CDISC Group (in person or by telephone) within a one-year period. Note: A Participant may be an individual acting in its own individual capacity or as a Representative of an organization, and may or may not be a CDISC Member organization or from a CDISC Member organization.
- 2.11 **“Representative”** means an individual who is identified to CDISC as having authority to participate in CDISC or a CDISC Group on behalf of the Participant organization by which s/he is employed. The actions and statements of such individual(s) will be deemed to legally bind such Representative’s Participant organization and its affiliates.
- 2.12 **“Required Portion”** means a portion of a Final Standard that is required for an implementation to comply with a Final Standard (also known as a “normative” or “mandatory” portion), but not including any elements that are required solely for conformance with any optional (i.e., “non-normative,” “non-mandatory”) portion(s) of a Final Standard; provided, however, that where a Final Standard contains a choice of two or more portions, and implementing any one of the portions is required to comply with the Final Standard (i.e., mutually exclusive required options), each such portion shall be deemed to be a Required Portion.

3 Compensation-free Patent License Commitment

Each Participant agrees that, upon request and subject to Sections 5.1 and 8, it will grant, to all parties implementing a Final Standard developed by a CDISC Group in which it was a Participant, a nonexclusive, compensation-free (i.e., no royalty or other fee), nontransferable, non-sublicensable, worldwide, and otherwise reasonable and non-discriminatory license under such Participant's Necessary Claims covering such Final Standard, solely to make, have made, use, import, offer to sell, sell, lease, and otherwise distribute and dispose of the Licensee Products that implement such Final Standard; provided, however, that such commitment to license shall not apply to any Necessary Claims for which the Participant does not have the right to license without obligation of payment of royalties or other material consideration by such Participant to an unaffiliated third party. The commitment to license arising under this Section shall be effective as of the date the party was first deemed to be a Participant in the applicable CDISC Group.

4 Copyright Ownership and Licenses

- 4.1 Copyright Ownership in Final Standards. CDISC shall own the copyright in Final Standards developed by CDISC or taken ownership by CDISC through mutual agreement, subject to the underlying copyright rights of the contributing Participants and other copyright owners. Any publication of a Final Standard shall contain an appropriate copyright notice in the name of CDISC.
- 4.2 Copyright License for Contributions. Upon submitting a Contribution, each contributing Participant grants and agrees to grant (i) to each Participant a non-exclusive, worldwide, perpetual, nontransferable, compensation-free license under the Participant's copyright rights in the Contribution to reproduce, publish, display, perform, distribute, and create derivative works of the Contribution, solely for the purpose of creating and promoting the Draft Standard and Final Standard for which such Contribution was submitted, and (ii) to CDISC a non-exclusive, worldwide, perpetual, irrevocable, compensation-free license to reproduce, publish, display, perform, distribute, and create derivative works of such Contribution (including any Draft Standard, Final Standard, or portion or derivative thereof incorporating the Contribution), and to freely sublicense such rights through multiple tiers, for the purpose of creating and promoting the Draft Standard and Final Standard and for other CDISC activities. Upon the adoption of a Final Standard, CDISC hereby grants and agrees to grant to all Participants and without limiting the generality of the licenses granted herein is also authorized to grant to other parties, a nonexclusive, compensation-free, non-transferable, non-sublicensable, worldwide, perpetual, copyright license to reproduce, publish, display, perform, and distribute the Final Standard pursuant to the license terms provided on CDISC website for each format of the Final Standard offered by CDISC, as applicable. CDISC may also sublicense such copyright rights to reproduce, publish, display, perform, and distribute the Final Standard to another standard development organization solely for the purpose of adopting the same standard, subject to the relevant CDISC approval procedures, if any, for such further distribution by other organizations as may be established by the CDISC Board of Directors. All reproductions of a Draft Standard or Final Standard by Participants shall include all copyright notices, disclaimers, limitations of liability, and other such statements contained in the original.

5 Treatment of Non-Contributed Necessary Claims

5.1 Review Period / Licensing Obligations for Non-Contributed Necessary Claims. To ensure that all Participants have the opportunity to review each proposed Draft Standard as a complete document for purposes of identifying Non-Contributed Necessary Claims, CDISC shall, at least thirty (30) calendar days prior to the finalization of the Draft Standard, post the Draft Standard on the CDISC website for open review. During the review period, each Participant in the CDISC Group that developed the Draft Standard under review (as well as others that choose to take part in such review) shall:

- (a) review the Draft Standard;
- (b) disclose, pursuant to Section 5.2, any of its Non-Contributed Necessary Claim(s) covering such Draft Standard that the Participant is not willing to license to all implementers of the resulting Final Standard under the compensation-free and otherwise reasonable and non-discriminatory commitment of Section 3; and
- (c) submit, prior to the end of the review period, a written licensing declaration for any Non-Contributed Necessary Claim disclosed under subclause (b) indicating whether the Participant will commit to license such disclosed claim(s) at least on reasonable and non-discriminatory (“**RAND**”) terms and conditions (note, Necessary Claims that cover one’s own Contributions must be licensed compensation-free pursuant to Section 3).

If a Participant declares its intent under subclause (c) to license the disclosed Non-Contributed Necessary Claim on a RAND basis, it will have a RAND licensing obligation for such disclosed claim to all implementers of the Final Standard. If instead the Participant declares its intent under subclause (c) not to commit to at least RAND licensing for such disclosed claim and withdraws prior to the end of the review period, such Participant will have no licensing obligation for such disclosed claim. If, however, the Participant fails to comply with either of these two options, it will be deemed to have committed to the compensation-free and otherwise reasonable and non-discriminatory licensing obligation of Section 3 (“**Default Licensing Obligation**”) for such disclosed claim. Any other Non-Contributed Necessary Claims of such Participants that were not disclosed prior to the end of the review period shall also be subject to the Default Licensing Obligation. For the avoidance of doubt, the Default Licensing Obligation (which obligation actually arose under Section 3 and which the Participant failed to avoid by complying with the disclosure/licensing declaration and (if applicable) withdrawal provisions of this Section) applies to all of a Participant’s undisclosed Non-Contributed Necessary Claims covering the Final Standard ultimately resulting from the Draft Standard under review, despite the lack of actual and personal knowledge thereof by any individual Representative who participates in such CDISC Group on behalf of such Participant.

In the event that a Participant discloses its intention not to make at least a RAND licensing commitment for certain of its Non-Contributed Necessary Claims, the CDISC Group that developed the affected Draft Standard will, in consultation with the CDISC Board of Directors, determine how best to proceed, such as by attempting to develop a revised

version of the Draft Standard that works around the potentially blocking patent claims. If, after the review period ends, a Draft Standard is substantially modified, a subsequent review period shall be conducted, under the terms of Section 5.1, before the revised Draft Standard is adopted and published as a Final Standard.

- 5.2 Minimum Contents of Disclosure. With respect to Non-Contributed Necessary Claims on issued patents and published patent applications subject to disclosure under Section 5.1, a Participant must disclose, at a minimum, the identity of the patent rights holder and/or applicant and the patent number or application number. With respect to unpublished patent applications subject to disclosure under Section 5.1, a Participant must disclose, at a minimum, the existence of the application containing the asserted Non-Contributed Necessary Claim(s) and identify the portion(s) of the Draft Standard on which such asserted claim(s) read(s), but need not disclose identifying information (e.g., application number, application contents). Nothing herein precludes broader disclosure of unpublished patent applications on a voluntary basis or pursuant to a non-disclosure agreement. If any disclosed patent or patent application contains Necessary Claims which, if licensed, would require a payment of royalties or other material consideration to an unaffiliated third party, the Participant must also highlight this fact in its disclosure statement. Nothing in this Section or this Policy imposes any duty on any Participant to perform a patent search or other search of intellectual property portfolios.

6 CDISC Processes; Statement Regarding Patent Disclosures and Other Issues

- 6.1 CDISC Records of Patent Disclosures / Licensing Declarations. The CDISC President shall promptly provide to the CDISC Board of Directors, in writing, the information contained in any patent disclosure. CDISC shall maintain a file, accessible by the public, which includes all patent disclosure statements and licensing declarations received for any Draft Standard or Final Standard. CDISC shall also provide such information to any party, upon request, in order to facilitate such party's ability to seek and obtain all known patent licenses necessary to implement a Final Standard in a Licensee Product.
- 6.2 CDISC Patent Disclaimers. After CDISC's adoption of the CDISC IP Policy, all published Final Standards shall include the following disclaimers (or their equivalent):

"It is possible that implementation of and compliance with this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any claim or of any patent rights in connection therewith. CDISC, including the CDISC Board of Directors, shall not be responsible for identifying patent claims for which a license may be required in order to implement this standard or for conducting inquiries into the legal validity or scope of those patents or patent claims that are brought to its attention."

In addition, when CDISC receives from a patent rights holder a written licensing declaration indicating that a license will be required from such patent rights holder by implementers of a Final Standard, then such published Final Standard shall also add the following statement to the end of the above disclaimer:

"Certain patent rights holders have filed a statement of willingness to grant a patent license

to all implementers of this standard, consistent with the requirements of the CDISC Intellectual Property Policy. CDISC, including the CDISC Board of Directors, makes no representation as to the reasonableness of any terms or conditions of the license agreements offered by such patent rights holders, and all negotiations regarding such terms and conditions must take place between the individual parties outside the context of CDISC. Further information regarding those parties who have claimed patent rights in the standard and expressed their willingness to provide a license may be obtained from the CDISC President. The user should be aware, however, that it is also possible that other patent rights that have not been disclosed to CDISC may be implicated by implementation of or compliance with the standard.”

- 6.3 CDISC Statements Regarding General Disclaimers, Limitation of Liability, and Copyright License to End Users. All published Final Standards shall also include statements of warranty, disclaimer, and limitation of liability statements substantially similar to those in Section 9.4 and Section 9.5, as well as a copyright notice to end users.

7 Confidentiality

All Contributions and information disclosed as a part of CDISC activities shall be deemed non-confidential, and neither CDISC nor any Participant assumes any confidentiality obligations. **If such participant does not agree with all of the terms and conditions of this policy, such participant should not join, take part in, or make a contribution to CDISC.**

8 Withdrawal/Termination

- 8.1 Withdrawal. A Participant may withdraw from CDISC, or from any CDISC Group, at any time by sending a written notice to CDISC. Withdrawal shall be effective upon receipt of such written notice by CDISC.
- 8.2 Effect of Withdrawal/Termination. Notwithstanding the Participant's withdrawal or termination, and except (as applicable) as provided in Section 5.1 or Section 8.3, a Participant's agreement to grant a license under Section 3 or Section 5.1 (as applicable) shall remain in full force and effect for: (1) Necessary Claims covering a Contribution made by the withdrawing/terminating Participant that is incorporated into a Final Standard to which such Contribution was offered (even if such Final Standard is adopted after such Participant's withdrawal/termination); or (2) Non-Contributed Necessary Claims covering a Final Standard as such Final Standard (or the Draft Standard from which it arose) existed on the date of withdrawal/termination (even if such Final Standard is adopted after such Participant's withdrawal/termination); and (3) Necessary Claims covering a Final Standard adopted by CDISC after the effective date of the Participant's withdrawal/termination that: (i) are necessary for the later-adopted Final Standard to be backwards compatible with a prior Final Standard; and (ii) are used in a substantially similar manner, extent, and result as such Necessary Claims were used in such prior Final Standard for which the Participant is obligated to grant licenses. All rights and obligations of the withdrawn/terminated Participant other than those specifically referenced in this Section 8.2 or Section 3, 5.1, or 4.2 shall cease upon such withdrawal/termination.

9 General

- 9.1 No Other Licenses. Except for the rights expressly provided under this Policy, neither CDISC nor any Participant grants or receives, by implication, or otherwise, any rights under any patents, copyrights, or other intellectual property rights.
- 9.2 No Proprietary Software Code in Required Portions of Standards. Except for data interchange formats, no Draft Standard or Final Standard, and no Contribution, may include proprietary software code (*i.e.*, source code or object code), except for code that will be used for illustrative purposes only and will not be deemed to be a Required Portion of a Draft Standard or Final Standard.
- 9.3 Representations and Warranties. Each Participant shall be deemed to represent, warrant, and covenant, at the time of a Contribution by such Participant, that to the best of its knowledge and ability: (a) it holds or has the right to grant all relevant licenses to any of its Contributions in all jurisdictions or territories in which it holds relevant intellectual property rights; (b) there are no limits to the Participant's ability to make the grants, acknowledgments, and agreements herein; and (c) the Contribution does not subject any Contribution, Draft Standard, Final Standard, or implementations thereof, in whole or in part, to licensing obligations with additional restrictions or requirements inconsistent with those set forth in this Policy, or that would require any such Contribution, Final Standard, or implementation, in whole or in part, to be either: (i) disclosed or distributed in source code form; (ii) licensed for the purpose of making derivative works (other than as set forth in Section 4.2); or (iii) distributed at no charge, except as set forth in Sections 3, 5.1, and 4.2. If a Participant has knowledge that a Contribution made by any Participant or any other party may subject any Contribution, Draft Standard, Final Standard, or implementation, in whole or in part, to one or more of the licensing obligations listed in Section 9.3, such Participant shall give prompt notice of the same to the CDISC President who shall promptly notify all Participants.
- 9.4 No Other Warranties/Disclaimers. **ALL PARTICIPANTS ACKNOWLEDGE THAT, EXCEPT AS PROVIDED UNDER SECTION 9.3 AND UNLESS REQUIRED BY APPLICABLE LAW, ALL DRAFT STANDARDS AND FINAL STANDARDS, AND ALL CONTRIBUTIONS TO FINAL STANDARDS AND DRAFT STANDARDS, ARE PROVIDED "AS IS" WITH NO WARRANTIES WHATSOEVER, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, AND THE PARTICIPANTS, CDISC, AND CDISC'S CONSTITUENT PARTS (INCLUDING, BUT NOT LIMITED TO, THE CDISC BOARD OF DIRECTORS, THE CDISC PRESIDENT, CDISC STAFF, AND MEMBERS) EXPRESSLY DISCLAIM ANY WARRANTY OF MERCHANTABILITY, TITLE, NONINFRINGEMENT, FITNESS FOR ANY PARTICULAR OR INTENDED PURPOSE, OR ANY OTHER WARRANTY OTHERWISE ARISING OUT OF THIS POLICY, FINAL STANDARDS, DRAFT STANDARDS, OR CONTRIBUTIONS.**
- 9.5 Limitation of Liability. **IN NO EVENT AND UNDER NO LEGAL THEORY, WHETHER IN TORT (INCLUDING NEGLIGENCE), CONTRACT, OR OTHERWISE, UNLESS REQUIRED BY APPLICABLE LAW (SUCH AS DELIBERATE AND GROSSLY NEGLIGENT ACTS) OR AGREED TO IN WRITING, WILL CDISC OR ANY OF ITS CONSTITUENT PARTS (INCLUDING, BUT NOT LIMITED TO, THE CDISC BOARD OF**

DIRECTORS, THE CDISC PRESIDENT, CDISC STAFF, AND MEMBERS) BE LIABLE TO ANY OTHER PERSON OR ENTITY FOR ANY DAMAGES OF ANY CHARACTER, INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS, LOSS OF USE, DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, OR SPECIAL DAMAGES, WHETHER UNDER CONTRACT, TORT, WARRANTY, OR OTHERWISE, ARISING IN ANY WAY OUT OF THIS POLICY, FINAL STANDARDS, DRAFT STANDARDS, OR CONTRIBUTIONS, WHETHER OR NOT SUCH PARTY HAD ADVANCE NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

- 9.6 Publicity. Each Participant consents to the public disclosure and use of its name for purposes of publicly promoting Final Standards, including the use in statements regarding the compliance of the Participant's Licensee Products with a Final Standard, unless such Participant explicitly indicates in writing to the CDISC President such Participant's refusal to consent to such public disclosure and use of its name.
- 9.7 Governing Law / Jurisdiction / Venue. This Policy shall be construed and controlled by the laws of the State of *Texas* without giving effect to conflict-of-law principles. The parties agree that all disputes arising in any way out of this Policy will be heard exclusively in, and all parties irrevocably consent to jurisdiction and venue in, the state and Federal courts of the State of *Texas*.
- 9.8 Complete Agreement. This Policy (including all documents referenced herein) sets forth the entire understanding between CDISC and its Members and Participants regarding the treatment of patent, copyright, and related issues regarding Contributions and supersedes all prior agreements, representations, and understandings related thereto.

10 Authorization

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

Name	CDISC Board of Directors
Date	21 August 2024

11 Change Control

This Policy is the complete and exclusive statement of the Clinical Data Interchange Standards Consortium, Inc.'s ("CDISC") Intellectual Property policy, consistent with the CDISC Bylaws. Once this Policy has been approved by the CDISC Board of Directors, it will apply to Members and other parties to the extent they are Participants in one or more CDISC Groups. Any future revisions to this Policy (or any document referenced herein) will become effective only upon approval of such revisions by the CDISC Board and only after: (a) CDISC notifies Members and Participants in writing (such as posting to the CDISC website) of such revisions; (b) Participants are afforded at least thirty (30) calendar days from the date of receiving notice of such revisions to withdraw from CDISC or from particular CDISC Groups; provided, however, that ministerial changes to this Policy, such as proofreading corrections or formatting changes, may be executed by the CDISC Board and, upon CDISC Board approval, shall be immediately effective as to all existing and new Participants, so long as a revised version of the Policy containing such ministerial

changes is posted on the home page of the CDISC website. Any Participant that withdraws from CDISC or from a CDISC Group prior to the end of this thirty (30)-day period will be subject to the version of the Policy that was in effect prior to the Board-approved revisions, in accordance with its terms and the withdrawal provisions of such version, but will not be subject to new or revised terms of the revised Policy. Any existing Participant that does not so withdraw prior to the end of this thirty (30)-day period is deemed to have ratified and accepted the revised Policy in its entirety even without written agreement to such revised Policy by such Participant.