ICH and CDISC Memorandum of Understanding

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Clinical Data Interchange Standards Consortium (CDISC) wish to enter into a Memorandum of Understanding (MOU) covering the points and activities outlined below.

PARTIES

ICH is an international non-profit Association with its principal offices at Route de Pré-Bois 20, 1215 Geneva, Switzerland.

The Clinical Data Interchange Standards Consortium (CDISC) is a global, non-profit organization with its office at 401 West 15th Street, Suite 520, Austin, Texas 78701.

AGREEMENT TERM

This Agreement will last three (3) years from its effective date, and will renew automatically, unless terminated by either Party by written notice provided in accordance with this Agreement at least 30 days prior to the termination of any given one-year term. The services provided by CDISC under this Agreement are at no cost to ICH.

MATERIAL CHANGE

In the event ownership or incorporation changes, this MoU will no longer be in effect. The material created and maintained by CDISC will be made available in a central and accessible location independent of CDISC. In the case where CDISC ceases to operate or the agreement is terminated as described above, ICH will have access to all the generated content so they can choose to provide it to another entity of their choice.

BACKGROUND

ICH Overview

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) is a global organization that brings together regulatory authorities and the pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical development, including, quality, safety, efficacy, terminologies, and electronic standards, with a goal to develop international guidelines and, as relevant, technical specifications.

Much of the focus of ICH is on the development of guidance in the areas of safety, quality and efficacy associated with the development, registration and maintenance of human pharmaceutical products. Such guidance is published by ICH via the ICH website (www.ich.org) and by individual regulatory authorities both from the ICH regions and beyond. In some instances, these guidelines include controlled terms and definitions for implementation of information standards by the industry and regulatory authorities.
While ICH has developed its own technical specifications and terms and definitions to be used for the transfer of standardized information between parties, ICH has endeavored to collaborate with global Standards Development Organizations (SDO) to develop the standard terms and definitions to be used in the technical specifications and guidance documents.

CDISC Overview

CDISC creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. CDISC standards enable the accessibility, interoperability, and reusability of data. With the help of CDISC standards, the entire research community can maximize the value of data for more efficient and meaningful research that has invaluable impact on global health. CDISC focuses on standards for collection, transformation, analysis, and submission of clinical research data as well as standards and controlled terminology for other sources of clinical research information including but not limited to protocol design, trial master file, and exchange information.

CDISC is a 501(c)(3) global nonprofit charitable organization and is headquartered in Austin, Texas, with hundreds of employees, volunteers, and member organizations around the world. The CDISC website is located at www.cdisc.org.

CDISC has been developing and managing controlled terminology as a cornerstone of a rigorous standards governance process to ensure the quality, consistency and interoperability of research and healthcare data. A well-established and robust framework for creating, managing, and disseminating terminology with over 130,000 terms and 30,000 unique concepts organized in 1,325 value sets provides a semantic foundation for CDISC standards and supports regulatory compliance, adherence to guidelines, and best practices for data collection, analysis, and reporting in clinical research and healthcare.

ICH – CDISC AGREEMENT

Scope

For ICH members to adopt and implement a clinical information standard it is critical that all terminology components, including but not limited to definitions described in the technical specification, are part of a greater international controlled terminology resource managed by an internationally recognized standards development organization (SDO). CDISC has been identified by ICH as a reputable SDO with the qualifications and capabilities to support the maintenance and facilitation of the governance process for ICH controlled terminology.

This Memorandum of Understanding (MOU) sets forth the roles and responsibilities of each party as they relate to the governance of the ICH terms and definitions developed in collaboration with CDISC. This MOU is intended to describe the goals, the high-level governance process, and how each party will collaborate. Specific projects (e.g., M11 controlled terminology) will be defined in detail as part of an annex to this MOU mutually agreed upon by CDISC and ICH.

Goals

As a collaboration between ICH and CDISC, the goals of the agreement are to:

1. Use a unified governance process and terminology services for the long-term support of ICH controlled terminologies.
2. Curate and maintain ICH controlled terminologies.
3. Follow a robust process for the public review and publication of ICH terminologies.
4. Ensure the terminologies are freely available to the public following CDISC public review.
5. Ensure there is a transparent process with the public.

Both ICH and CDISC will support these goals and will align activities to support the development, adoption, and implementation of the ICH/CDISC controlled terminologies to be used for a specific ICH Project.

DCB
ML

CDISC Controlled Terminology Governance Process

CDISC terminology governance process has been developed and refined over many years to ensure:

An open and simple change request mechanism implementable by any individual or organization

- A rigorous change request and internal review process to ensure the request is valid and the draft concept semantics are correct.
- A fixed and well-defined external public review process step to gather feedback from industry.
- A well-documented and transparent public review dispositioning step to review public comments.
- A consistent publication schedule and easy/open access to terminology publications that is consistent making the terminology available for use.

CDISC terminology development adheres to CDISC operating procedures, which specifies the terminology standards development process by and for the CDISC user community including public review and comment on all content. The CDISC user community interacts directly with the CDISC terminology teams, which are themselves made up of individuals from the CDISC community. The terminology is maintained within a publicly available library that anyone can access.

Roles and Responsibilities

The roles and responsibilities during the Terminology Standards Development Process will follow the Operating Procedures of each party. Engagement between CDISC and ICH will happen as explained in the activity table (Table 1). ICH retains the ownership of ICH specific controlled terminology published by CDISC. Specific engagement processes may be considered and agreed upon by both parties for a specific project.

The ICH M2 Expert Working Group (EWG) will be the Point of Communication for ICH.

CDISC President and CEO will be the Point of Communication for CDISC.

In general, CDISC and ICH will have the following responsibilities agreed upon by both organizations described in Table 1.

Table 1

Activity	ICH EWG Responsibility	CDISC Responsibility
Definition of ICH specific terminologies	Own	Informed/Consulted
Facilitation and management of the CDISC public review cycle	Informed/Consulted	Own
Review, reconcile, and approve changes to terminologies from public review cycle	Own	Informed/Consulted
Publication and ongoing maintenance of the terminology	Informed/Consulted	Own
Publication of all ICH technical documents and associated references to ICH terminology	Own	Informed

Promotions

- ICH and CDISC may each reference this relationship in each entity's materials describing the Project and the work of this collaboration. ICH and CDISC authorize a limited license to each use the other entity's name and logo for this purpose.

- Any other use of the other party's name or logo is not covered by this Agreement and requires written pre-authorization.

Intellectual Property

- Each Party agrees and acknowledges that it shall be the sole owner of any and all copyright and other ownership rights and to all templates, metadata, programs, and other materials or intangible property that it authors or creates in connection with activity described in this Agreement.

  In cases where ICH and CDISC agree to jointly develop metadata, controlled terminology, or a standards document related to a specific project, the two parties agree to joint copyright on that specific metadata, controlled terminology, or standards document. As joint copyright holders, both ICH and the CDISC agree:

  - To include the logos of both parties and a statement acknowledging their joint copyright on all published copies of the metadata, controlled terminology, or a standards document.
  - That the metadata, controlled terminology, or a standards document may be published on both parties' websites or otherwise made available to their respective memberships on a date agreeable to both parties. Publication prior to the agreed upon date is prohibited.
  - To license the metadata, controlled terminology, or standards document free of charge or agree in advance to a fee that both parties shall charge to access/secure a copy.
  - That updates to the metadata, controlled terminology, or a standards document shall be jointly undertaken by both parties on a regular basis.

ENTIRE AGREEMENT

This document is the entire agreement between parties, notwithstanding any verbal or written communications outside this agreement.

EFFECTIVE DATE

The effective date of this agreement is the last date of ratification, as noted below.

In order to fully execute this agreement, the below parties must sign and date below:

For ICH

Name: Nikoleta Zuluaga / Dawn Rowan
Title: Senior Manager for ICH Activities / Director, ICH Secretariat

Signature and Date

11 July 2024

For CDISC

Name: Chris Decker
Title: CDISC, President and CEO

Signature and Date

28JUN2024

ANNEX 1: ICH M11 CeSHarP Terminology Project

Project Scope

The ICH-CDISC Memorandum of Understanding (MOU) Collaboration Agreement set forth the goals, roles, and responsibilities of CDISC and ICH as it relates to the governance of ICH terms and definitions. ICH M11 and ICH M2 have been engaged to deliver Protocol Template Technical Specification which contains protocol terms and definitions that will require their governance and maintenance.

For ICH members to adopt and implement the electronic clinical protocol template it is critical that the terms and definitions described in the technical specification are part of a greater international controlled terminology library managed by an international standards development organization (SDO). The SDO will provide the governance needed for long term maintenance of the terms and definitions. The Clinical Data Interchange Standards Consortium (CDISC) has been identified by ICH as an organization with qualifications to provide the governance of the ICH M11 CeSHarP terms and definitions.

Project Goals

The goals of the project are to:

1. Use a unified governance process and terminology services for the long-term support of ICH controlled terminologies.
2. Curate and maintain ICH controlled terminologies.
3. Follow a robust process for the public review and publication of ICH terminologies.
4. Ensure the terminologies are freely available to the public following CDISC public review.
5. Ensure there is a transparent process with the public.

Both ICH and CDISC will support these goals and will align activities to support the Project. Both parties will mutually agree to the M11 Workplan which will be posted and updated on the ICH Webpage (ICH Official web site : ICH) under the CeSHarP section.