



Clinical Data Interchange Standards Consortium (CDISC)

and

Pharmaceutical Users Software Exchange (PhUSE)

Memorandum of Understanding

THIS MEMORANDUM OF UNDERSTANDING (“MOU”), is made by the Clinical Data Interchange Standards Consortium (CDISC) with its principal place of business located at 401 West 15th Street, Suite 800, Austin, TX 78701, and the Pharmaceutical Users Software Exchange (PhUSE), with its principal place of business located at Kent Innovation Centre, Millennium Way, Kent, CT10 2QQ, England, UK. Both CDISC and PhUSE may hereinafter be referred to as “Party” or “Parties”.

This agreement is effective 1 January 2018 through 31 December 2019, and may be extended with mutual agreement or terminated early by either party according to Section III.

About PhUSE

PhUSE is an independent, not-for-profit organization run by volunteers. Since its inception, PhUSE has expanded from its roots as a conference for European Statistical Programmers, to a global platform for the discussion of topics encompassing the work of Data Managers, Biostatisticians, Statistical Programmers and eClinical IT professionals.

About CDISC

CDISC is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global data standards that enable information system interoperability to improve medical research and related areas of healthcare. CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website.

I. PURPOSE

CDISC and PhUSE aim to (1) achieve greater exposure of their aims and activities with each other’s members to promote the interests of both organizations; and (2) collaborate on alignment of synergistic standards development and implementation projects. Together, the Parties enter into this agreement to mutually promote each other’s events and activities to their respective members while not competing in areas considered to be the intellectual property of either

organization. Specifically, CDISC focuses primarily on standards development and education while PhUSE focuses primarily on topics related to the implementation and use of standards.

II. COOPERATIVE INITIATIVES

CDISC and PhUSE will engage within a collaborative framework around two key initiatives. The first initiative is the joint marketing and communication of each organizations activities and the second initiative focuses on alignment of the PhUSE Working Group activities.

a. Marketing and Communications Initiative

- Two free conference registrations and a free conference booth at each other's conferences in Europe and the US.
- Conference pack inserts will be included at no charge at CDISC and PhUSE annual conferences, if provided.
- Ongoing advertising of events, projects and deliverables on each others' websites (www.cdisc.org and www.phuse.eu) refreshed once per quarter year or as needed. Content provided by each others' organizations will be included in social media, email blasts and periodic eNewsletters. An appropriate communications schedule will be coordinated by the Parties' respective communications departments.
- To provide relevant material for each other's newsletters (maximum of 1 per edition) and to circulate targeted mailings to the relevant distribution lists.
- Quarterly meeting to ensure continued alignment of activities and communications
- PhUSE and CDISC will actively identify interactions with other organizations that may be relevant to the other party and share knowledge about these activities and provide introductions to the external party.
- PhUSE and CDISC will identify opportunities to invite each other to their respective webinars as both presenters and attendees on relevant topics. CDISC will host at least one webinar each year to highlight the joint activities of CDISC and PhUSE.

b. PhUSE Working Group Projects & CDISC Projects

The PhUSE Working Groups bring together academia, industry, technology providers and regulatory agencies to collaborate on projects relating to clinical data science. Each Working Group executes a set of projects designed to improve the overall product development and review processes to improve patient's lives. A number of projects directly involve the testing and implementation of CDISC standards.

CDISC is developing therapeutic area standards to complement and enhance core CDISC standards (e.g. CDASH, SDTM) and seeks collaboration with PhUSE in the review of draft standards and the development of associated implementation tools.

CDISC and PhUSE will meet on a regular basis to evaluate the following:

- PhUSE Working Group projects
- CDISC standards initiatives
- New collaborative opportunities.

- Opportunities to drive forward deliverables

CDISC will be invited to join the PhUSE working group oversight committee as an important partner of PhUSE.

PhUSE and CDISC agree to offer reciprocal invitations to a session at their respective BOD F2F meetings based on the agenda for the meeting.

III. AGREEMENT TERMS

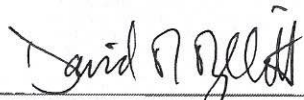
1. Signature below indicates you have read and agree to comply with requirements as stated above.
2. There is no financial arrangement as a result of signing this agreement.
3. By signing this agreement both parties acknowledge each other as collaborators of the identified events, this agreement does not serve as an endorsement.
4. Either Party may terminate this Agreement by providing forty-five (45) days written notice to the other at the address first written above.
5. If this agreement is terminated, each organization reserves the right to continue its membership by paying the appropriate membership dues.

Authorized Signatures:

**For
PhUSE**

Signed: 
Chris Price
Working Groups Co-Director

**For
CDISC**

Signed: 
David R. Bobbitt
President and CEO