PHUSE De-identification Standards

Project Scope

There are current efforts by regulators and sponsors to make Clinical Study Reports (CSR) and Individual Patient Data (IPD) from clinical trials shared more widely. The PHUSE De-Identification Project work on defining de-identification standards for CDISC standards and released in 2015 the PHUSE De-Identification standard for SDTM 3.2. The goal is to define standards to reduce efforts for companies to de-identify IPD and provide consistent data to researchers where data utility is considered.

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CURRENT STATUS

Project concluded.

Resources	
PHUSE De-Identification Working Group:Providing De-Identification Standards to CDISC Data Models, Ferran et al., PHUSE Conference DH01 2015 (Paper) (Presentation)	PHUSE De-Identification Standard for SDTM 3.2, 2015
Data De-Identification Made Simple, Jørgen Mangor Iversen, LEO Pharma, PHUSE Conference DH02 2016 (Paper) (Presentation)	Data De-Identification Standard for SDTM 3.2 –Date offsetting appendix updated to address the case of imputed dates in Analysis Dataset (e.g. ADaM)
PHUSE Data De-identification Standard for CDSIC ADaM 2.1 IG 1.0, and Updates for SDTM IG 3.2, Sherry Meeh, Johnson & Johnson, 2017	Data De-Identification Standard for SDTM 3.2 – Appendix 2: Low Frequencies Version 1.0

Referenced In

Project Members		
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- EMA Policy 0070 External Guidance
- De-identification Guidelines for Structured Data, information and Privacy Commissioner of Ontario
- De-Identification and and Anonymization of Individual Patient Data in Clinical Studies, TransCelerate, 2016
- Practical Applications of Secure Computation for Disclosure Control, Luk Arbuckle, Khaled El Emam, 2016
- Protecting patient privacy when sharing patient-level data from clinical trials, Tucker et al, 2016