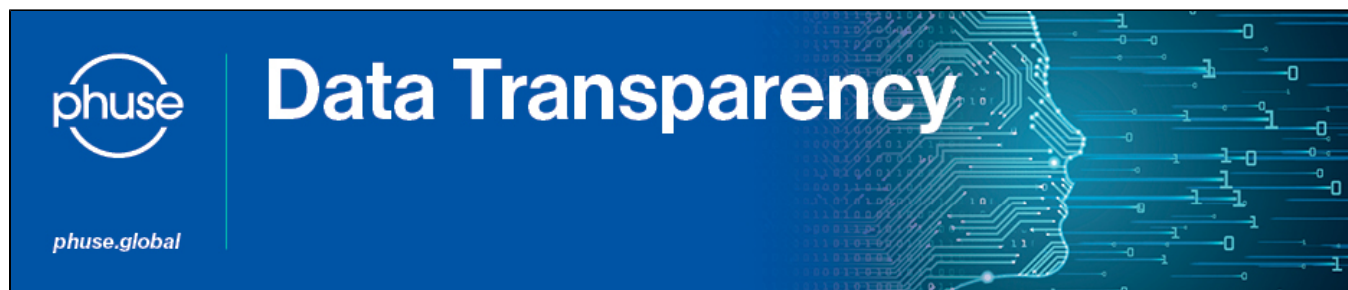


Terminology Harmonisation in Data Sharing & Disclosure Deliverables



Project Scope

Currently there is inconsistency in terminology used in the field of data sharing and disclosure. These inconsistencies exist across industry and regulatory agencies as well as within PHUSE and cause unnecessary confusion. This project aims to collect, align and standardise terminology and their definitions used in future deliverables. Previous PHUSE deliverables as well as key publications in the field, will be examined to create proposal for baseline list of terms and definitions to be used moving forward.

| Project Leads | Email |
|--|--|
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| Objectives and Deliverables | Timelines |
|--|-----------|
| Publish first set of terms, definitions and guidance (White Paper) | Q2 2021 |
| Publish remaining terms and definitions | Q2 2021 |

CURRENT STATUS Q3/4 2021

- Published V2 of terms/definitions and guidance document.
- Project Concluded

| Published Deliverables | Date |
|---|------------|
| Terminology Harmonisation in Data Sharing and Disclosure Deliverables Guidance V2 (Version 2) | 3-Nov-2021 |
| Terminology Harmonisation in Data Sharing and Disclosure Deliverables Terms and Definitions (Template Link) (Version 2) | 3-Nov-2021 |

| Project Members | Organisation |
|-------------------|--------------------------------|
| Bhavna Nanda | Kinapse |
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| Sowmya Gabbula | Alnylam Pharmaceuticals |

| | |
|--|-------------|
| Terminology Harmonisation in Data Sharing and Disclosure Guidance (Version 1) | 19-May-2021 |
| Terminology Harmonisation in Data Sharing and Disclosure Terms and Definitions (Version 1) | 19-May-2021 |