



Cross-Network Pregnancy Data Standards Version 1.1

Release Notes

Prepared by the
Cross-Network Pregnancy Outcomes Data Working Group

1 Orientation

This release notes document was developed to capture the purpose, history, and intended use of the Cross-Network Pregnancy Data Standards v1.0.

1.1 Purpose

The Cross-Network Pregnancy Data Standards were developed to address a need to strengthen standards, improve cross-study and cross-network data sharing, and increase alignment in the collection of pregnancy outcomes data across the HIV/AIDS clinical trials networks funded by the Division of AIDS (DAIDS) of the U.S. National Institutes of Health (NIH).

The standards are intended to be used by the statistical and data management centers (SDMCs) of the HIV/AIDS clinical trials networks. These standards present a harmonized approach for capturing pregnancy outcome data variables in the clinical database by standardizing identifiers and naming, question text, SDTM annotations, data type, and response options for variables that appear on generic pregnancy case report forms (CRFs). The standards do not mandate inclusion of specific variables on pregnancy related CRFs or dictate the format for CRFs. However, *Recommended Use* cases are offered for variables best applied in specific study contexts, such as perinatal or non-perinatal studies.

The *Field OID Standard (SCHARP convention)* indicates the preferred convention for object identifier (OID) naming. Due to Frontier Science's current process and procedures, Frontier Science uses a separate set of field OIDs, *Field OID (FSTRF convention)*, that differ from the preferred convention laid out in this standard. It is the intent that as Frontier Science forms come up for updates and review, the OIDs will be updated to the preferred format in this guide.

2 History

The first version of the Cross-Network Pregnancy Data Standards was published in September 2020. The standards were developed by the Pregnancy Outcomes Data Working Group (PODWG), which included representatives from the Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Frontier Science, and the Office of HIV/AIDS Network Coordination (HANC). The cross-network standards were developed through a consensus process based upon existing pregnancy CRFs and SDMC practices, and further reviewed by the PODWG for alignment with CDASH terminology. Final approval of the cross-network standards was obtained from the HANC-facilitated Cross-Network Data Management Center

Working Group (DMCWG), which includes representatives from Frontier Science and SCHARP senior management teams, and by the PODWG.

3 Components

The Cross-Network Pregnancy Data Standards v1.0 consists of the standards, release notes, and revision history supplement. All documents can be accessed on the HANC website, Data Management & IT Resources page: <https://www.hanc.info/resources/sops-guidelines-resources/data-management-it.html>. Excel spreadsheet versions of the standards and revision history are available upon request by emailing hancadmin@hanc.info.

File Name	Description
XN_PregnancyDataStandards_v1.0	The Cross-Network Pregnancy Data Standards V1.0 in PDF format
XN_PregnancyDataStandardsReleaseNotes_v1.1	The Cross-Network Pregnancy Data Standards V1.1 Release Notes in PDF format
XN_PregnancyDataStandardsRevisionHistory_v1.0	The Cross-Network Pregnancy Data Standards V1.0 Revision History in PDF format

3.1 Update Schedule

The Cross-Network Pregnancy Data Standards will be updated by the PODWG biennially during even-numbered years.

4 References

1. [CDISC Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials \(CDASHIG\) v2.1](#)
2. [HIV Therapeutic Area User Guide \(TAUG\) v1.0](#)
3. [Study Data Tabulation Model \(SDTM\) v1.4](#)
4. [Study Data Tabulation Model Implementation Guide \(SDTMIG\) v3.2](#)
5. [U.S. Food and Drug Administration Study Data Technical Conformance Guide v4.5.1](#)

5 Revision History

Date	Version	Summary of Changes
01 September 2020	1.0	Final version of document.
01 August 2022	1.1	Biennial document review, no changes made to v1.0 Data Standards or Revision History. Updated hyperlinks in Release Notes.