



PDS4 | 2018-10-R1

Periodic Dataset 4

Documents Index

Version 2018-10-R1

Enroll-HD

A worldwide observational study for Huntington's
disease families

A CHDI Foundation Project

The following documents can be found on the [Enroll-HD website](#).

1. General Documents

- a) Enroll-HD User Guide: Provides a summary of the study aims and objectives, how to access the data and biosamples, the quality control process used for the data and reference to the publication policy that should be adhered to by researchers.
- b) Data Handling Manual: Detailed description of how to handle the periodic dataset (for example, exporting, transforming and converting data files, handling missing and/or aggregated data values).
- c) Publication Policy: Describes the full publication policy that should be adhered to by researchers.
- d) Enroll-HD ISCED: Reference tables for each country's ISCED levels (education codes) and how they correspond to the respective national education system.
- e) Enroll-HD Acknowledgement List: A list of site members contributing to the Enroll-HD study.
- f) PDS4 Quick Start-Up Sheet: One page guide about the PDS4

2. Current Periodic Dataset Documents

- a) Enroll-HD Protocol: Full description of the study aims, population, design, assessment protocol and procedures.
- b) REGISTRY 2.0 Protocol: Full description of the study aims, population, design, assessment protocol and procedures.
- c) REGISTRY 3.0 Protocol: Full description of the study aims, population, design, assessment protocol and procedures.
- d) Enroll-HD Periodic Dataset Data Dictionary: Describes all the data files and variables used in the periodic dataset.
- e) Enroll-HD Annotated CRF: Brochure of the Enroll-HD case report forms that illustrates the data capture for each data field in the periodic dataset. Includes the data variable names which can be cross-referenced to the data dictionary.
- f) REGISTRY Annotated CRF: Brochure of the REGISTRY 2.0 and 3.0 case report forms that illustrates the data capture for each data field in the periodic dataset. Includes the data variable names which can be cross-referenced to the data dictionary.

- g) Adhoc Annotated CRF: Brochure of the Adhoc case report forms that illustrates the data capture for each data field in the periodic dataset. Includes the data variable names which can be cross-referenced to the data dictionary.
- h) Enroll-HD Guidelines for data collection and data entry: Defines how data captured as part of the study should be collected and entered onto the EDC.
- i) REGISTRY 2.0 Guidelines for data collection and data entry: Defines how data captured as part of the study should be collected and entered onto the EDC.
- j) REGISTRY 3.0 Guidelines for data collection and data entry: Defines how data captured as part of the study should be collected and entered onto the EDC.

The following documents are only visible after logging into the website:

- a) Enroll-HD Coverage Chart: Summary of the available data broken down by study, participant category, and study visit.
 - b) Enroll-HD Quick Tutorial: Description of the dataset file structure.
 - c) Enroll-HD Coding Systems: Description and explanation of the various coding systems used in the Enroll-HD study.
 - d) Enroll-HD Quick Reference Guide for CSV files: A walk-through guide to illustrate how to import the Enroll-HD PDS CSV files into Excel.
 - e) Enroll-HD Change Log: Description of the dataset changes identified when comparing the previous periodic dataset release to the current periodic dataset release.
 - f) Enroll-HD Unusual Findings: Summary of cases reported in the dataset that have unusual findings.
3. Request Forms
- a) Enroll-HD Biosample Request Form: A form completed by researchers who would like to access Enroll-HD biosamples. Details about the quantity and type of biosamples required should be given, along with a detailed project description.
 - b) Enroll-HD Specified Dataset Information and Request Form: A form completed by researchers who would like to access specific datasets that are not included in the periodic dataset. Details about specific variables and the quantity of data should be given, along with a detailed project description.

4. Agreements

- a) Data Use Agreement: Template of the data use agreement that must be executed ahead of access to the dataset(s).
- b) Biosamples Use Agreement: Template of the material transfer agreement that must be executed before biosamples can be shipped to researchers.

Revision History

| Version | Summary of changes |
|------------|---|
| 2015-10-R1 | Initial version for the second Enroll-HD periodic dataset |
| 2016-10-R1 | Version for the third Enroll-HD periodic dataset |
| 2018-10-R1 | Version for the fourth Enroll-HD periodic dataset |