PDS3 Overview

Contents

1. Dataset

Extraction

The data contained in HDClarity PDS3 was extracted from the Enroll-HD electronic data capture (EDC) database on October 27, 2023 at 01:41 UTC.

Data sources

The PDS3 dataset encompasses data exclusively from HDClarity participants, collected from one or two sources: HDClarity and Enroll-HD.

Study specific protocols, annotated eCRFs, and data collection guidelines are housed on the [Documentation](#) page of the Enroll-HD website.

Participant inclusion

To be included in the PDS3 release, participant's data had to meet several requirements. **Figure 1** illustrates the number of participants whose data met each of the predefined inclusion requirements and illustrates how the final sample size of PDS3 was determined.

Figure 1. *Participant flow chart for inclusion in HDClarity PDS3.*
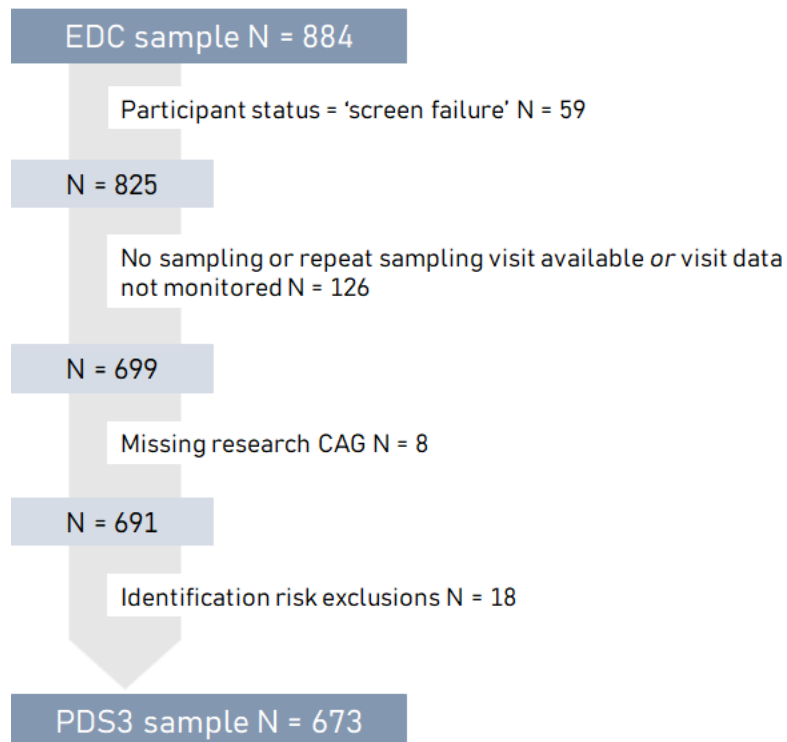
Due to data exclusion requirements, not all participants enrolled in HDClarity at the time of PDS3 data cut are included in PDS3. Similarly, not all participants included in PDS2 are included in PDS3. Data from 11 participants who were included in PDS2 were not included in the current PDS release.

2. Sample Size

PDS3 contains data on 673 HDClarity participants. Sample size by PDS release is presented in **Figure 2**.

Figure 2. HDClarity sample size by PDS release.

3. Visits

PDS3 contains data from 832 'visit packages'. Each HDClarity 'visit package' includes between two and four visits. A visit package contains, at minimum, an **HDClarity screening** visit ("Screening" / "SCR"), and an **HDClarity sampling** visit ("Sampling" / "BS") collected 0-30 days after screening. Some visit packages also include a **HDClarity repeat sampling** visit ("RPT Sampling" / "BS2"), conducted 4-8 weeks after the first sampling visit. Most visit packages also include an **Enroll-HD** study visit ("Baseline" / "ENR/BL" or "Follow Up" / "ENR/FUP"). Further information on visit packages is provided in the 'Understanding Dataset Structure' document. The number of HDClarity visit packages by PDS release is illustrated in **Figure 3**.

Figure 3. HDClarity visit packages by PDS release.
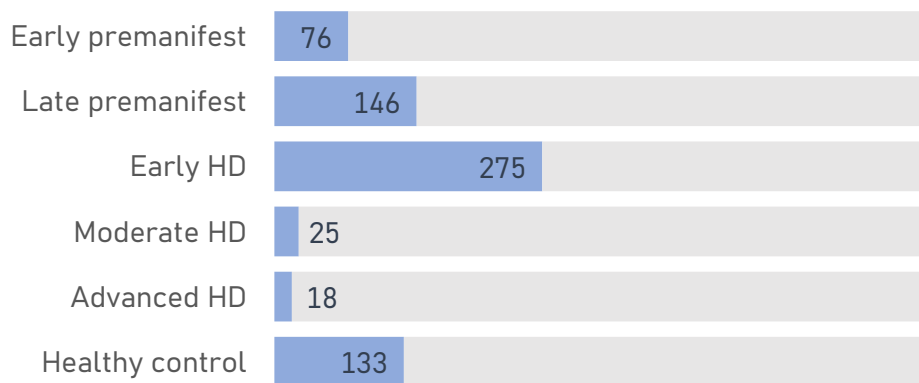
HDClarity

4. Sample Characteristics

The PDS3 sample is characterized below with respect to participant category, HD-ISS stage, sociodemographic variables, and clinical characteristics (**Figures 4** to **14**).
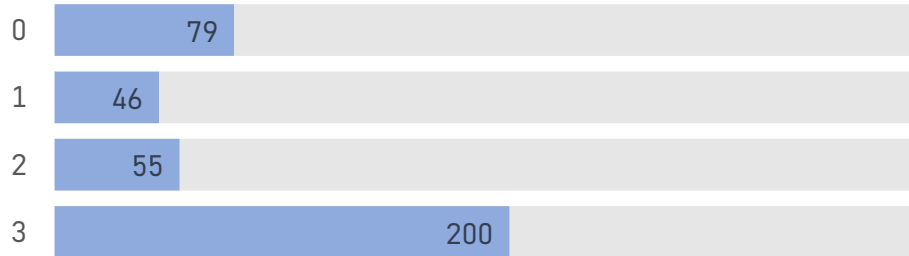
Figure 4. Participant category (hdcat) *at first HDClarity screening visit.* Full sample represented (N = 673; Missing N = 0)
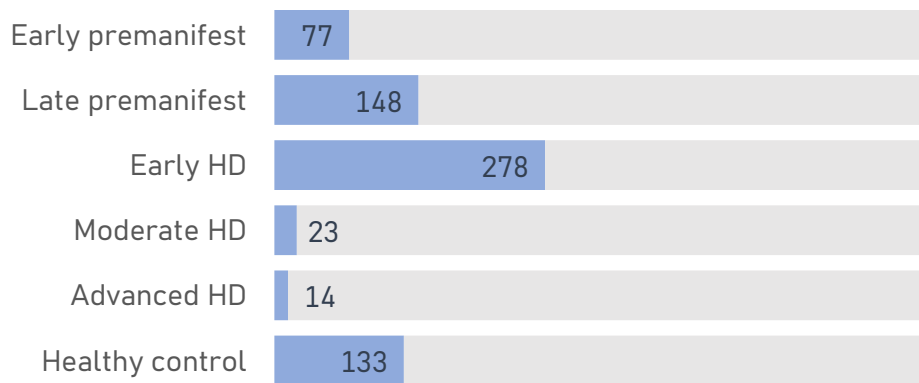

Figure 5. Participant category (hdcat) *at latest HDClarity screening visit.* Full sample represented (N = 673; Missing N = 0)
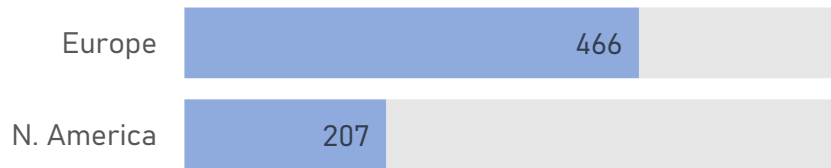
HD**Clarity**

Figure 6. HD integrated staging system (HD-ISS) imputed stage (hdiss_stage_imp) *at first HDClarity screening visit.* Only individuals with a research CAG length of ≥ 40 and a screening visit shared with Enroll-HD are represented (N = 380).

| Stage	Count
0	79
1	46
2	55
3	200

Figure 7. HD integrated staging system (HD-ISS) imputed stage (hdiss_stage_imp) *at latest HDClarity screening visit.* Only individuals with a research CAG length of ≥ 40 and a screening visit shared with Enroll-HD are represented (N = 380).

| Stage	Count
0	71
1	47
2	60
3	202
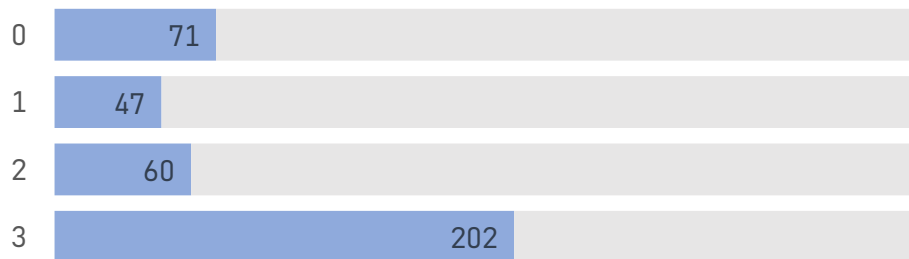
Figure 8. Geographical region (region). Full sample represented (N = 673; Missing N = 0)

Region	Count
Europe	466
N. America	207

Figure 9. Sex (sex). Full sample represented (N = 673; Missing N = 0)

Sex	Count
Male	337
Female	336
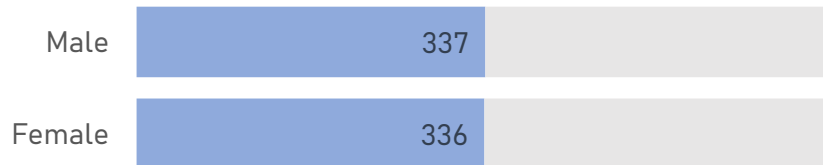
Figure 10. ISCED (isced) at first HDClarity screening visit. Only individuals with a screening visit shared with Enroll-HD are represented (N = 598; Missing N = 75)
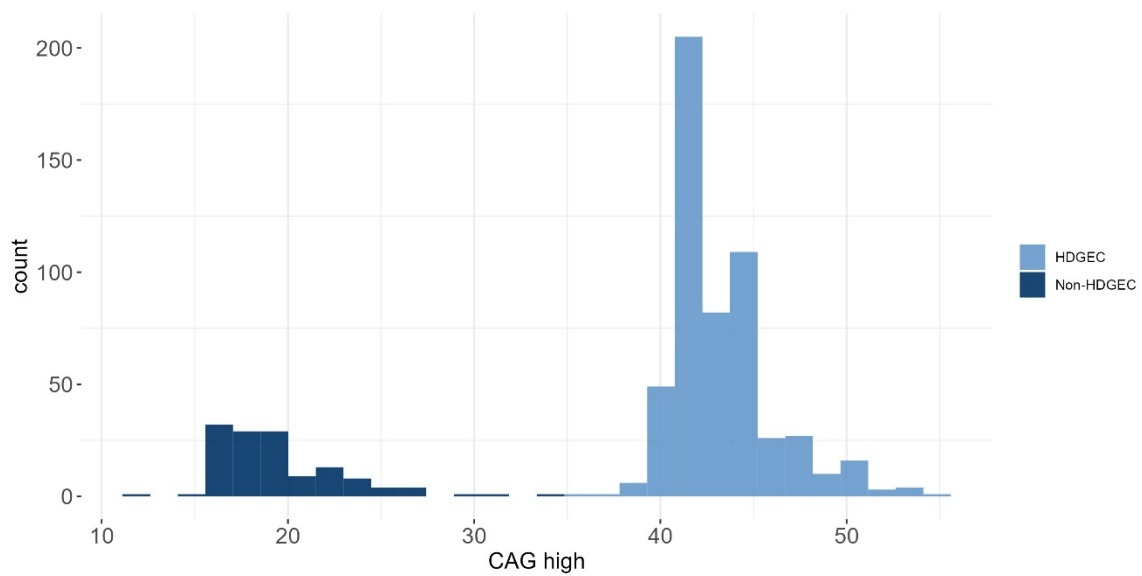
ISCED	Count
0	1
1	5
2	66
3	146
4	143
5	222
6	15
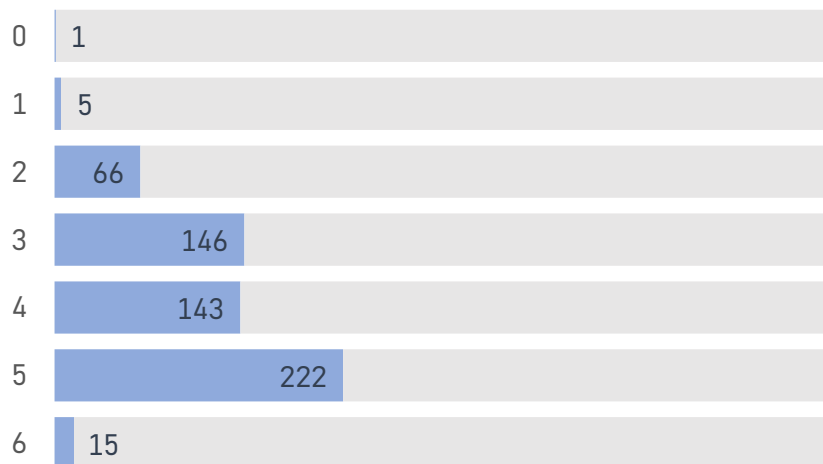
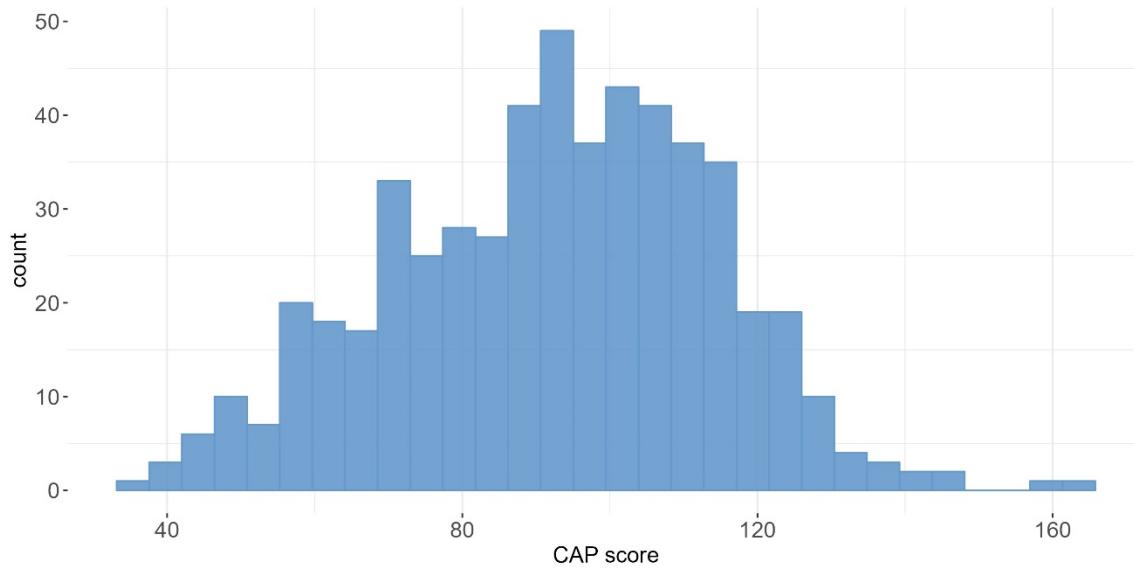*Figure 11. Age (age) at first HDClarity screening visit.* Full sample represented (N = 673; Missing N = 0).
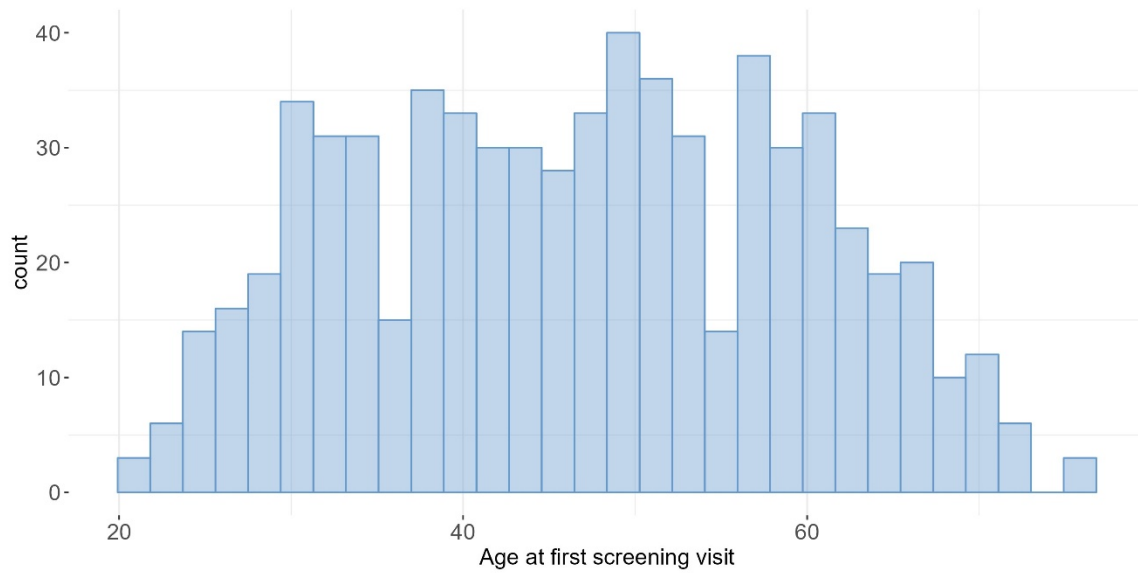
	N	Mean	SD	Median	Min	Max
Age (first screening visit)	673	46.8	12.6	47	21	76

Figure 12. Research CAG length (caghigh). Full sample represented (N = 673; Missing N = 0).

	N	Mean	SD	Median	Min	Max
Research CAG length (HDGEC)	540	43.2	2.8	43	36	55
Research CAG length (non-HDGEC)	133	19.7	3.2	19	12	34

Figure 13. CAP score (capscore) at first HDClarity screening visit. Calculated using the CAP score formula in Warner et al.[1] Only individuals with a research CAG of ≥ 36 are represented.
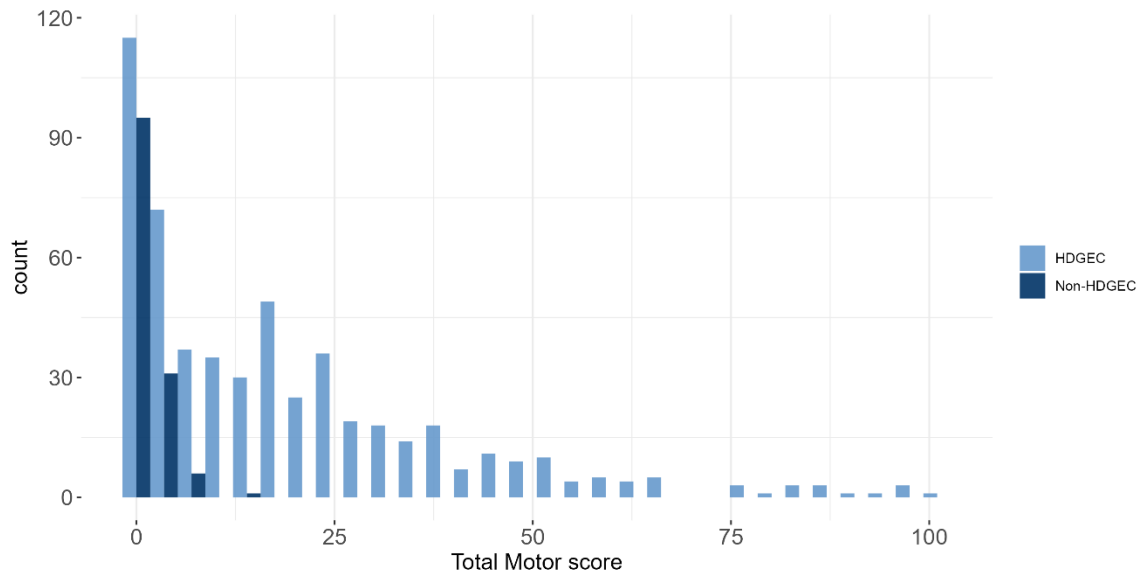

	N	Mean	SD	Median	Min	Max
CAP score	540	92.4	21.9	94.8	37	165

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[1] Warner, J. H., J. D. Long, J. A. Mills, D. R. Langbehn, J. Ware, A. Mohan, and C. Sampaio. 2020. "Standardizing the CAP Score in Huntington's Disease I: Predicting Age-at-Onset."

Figure 14. UHDRS total motor score (motscore) *at first HDClarity screening visit.* Full sample represented (N = 672; Missing N = 1). HDGEC = individual with CAG ≥ 36; Non-HDGEC = individual with CAG < 36.

	N	Mean	SD	Median	Min	Max
TMS (HDGEC)	539	18.7	20.3	14	0	101
TMS (non–HDGEC)	133	1.2	2.0	0	0	13

5. Geographical coverage

HDClarity PDS3 data were collected from 28 clinical sites located across 6 countries (**Figure 15**).

Figure 15. *HDClarity PDS3 map.* HDClarity data in PDS3 were collected from clinical sites in 6 countries.