Enroll-HD: A Prospective Registry Study in a Global Huntington’s Disease Cohort A CHDI Foundation Project

First published: 01/02/2024

Last updated: 17/10/2024

Data source | Human | Biobank | Disease registry

Administrative details

Administrative details

Data source ID

35258

Data source acronym

Enroll-HD

Data holder

CHDI Foundation

Data source type

Biobank

Disease registry

Main financial support

Funding by own institution

Care setting

Hospital outpatient care

Other

Secondary care – specialist level (ambulatory)

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

Yes

Description of the qualification

EMA Qualification Opinion for the use of Enroll-HD as a data source and infrastructure support for post-authorisation monitoring of medical products

Data source website

https://www.enroll-hd.org/

Contact details

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Main

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Data source regions and languages

Data source countries

Argentina

Australia

Austria

Belgium

Canada

Chile

Colombia

Czechia

Denmark

France

Germany

Ireland

Italy

Netherlands

New Zealand

Norway

Peru

Poland

Portugal

Spain

Switzerland

United Kingdom

United States

Data source languages

English

Data source establishment

Data source established

15/06/2011

Data source time span

First collection: 25/07/2012

The date when data started to be collected or extracted.

Publications

Data source publications

Landwehrmeyer, G. B., Fitzer-Attas, C. J., Giuliano, J.D., Gonçalves, N., Anderson, K. E., Cardoso, F.,Ferreira, J. J., Mestre, T. A., Stout, J. C. and Sampaio,C. (2016), Data Analytics from Enroll-HD, a GlobalClinical Research Platform for Huntington's Disease.Mov Disord Clin Pract.

Sathe S, Ware J, Levey J, Neacy E, Blumenstein R, Noble S, Mühlbäck A, Rosser A, Landwehrmeyer GB, Sampaio C. Enroll-HD: An Integrated Clinical Research Platform and Worldwide Observational Study for Huntington's Disease. Front Neurol. 2021 Aug 18;12:667420. PMID: 34484094; PMCID: PMC8416308.

Qualification opinion of the use of Enroll-HD (a Huntington’s disease patient registry) as a data source and infrastructure support for post-authorisation monitoring of medical products

Data elements collected

The data source contains the following information

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

Yes

Disease details

Huntington's disease

Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

Yes

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

No

Hospital admission and/or discharge

No

ICU admission

Is information on intensive care unit admission available?

No

Cause of death

Captured

Cause of death vocabulary

Not coded (Free text)

Prescriptions of medicines

Not Captured

Dispensing of medicines

Captured

Dispensing vocabulary

ATC

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

No

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

No

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Captured

Indication vocabulary

MedDRA

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

Administration of vaccines

Yes

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Not Captured

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

No

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

Yes

Genetic data

Are data related to genotyping, genome sequencing available?

Captured

Genetic data vocabulary

Other

Genetic data vocabulary, other

Not coded, free text (CAG repeats)

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the

patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Not Captured

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

Yes

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

Yes

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

No

Unique identifier for persons

Are patients uniquely identified in the data source?

Yes

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-10

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Dosage regime

Dose

Route of administration

Medicinal product vocabulary

WHO Drug

Quality of life measurements

Captured

Quality of life measurements vocabulary

other

Quality of life measurements, other

SF-12

Lifestyle factors

Captured

Lifestyle factors

Alcohol use

Other

Tobacco use

Sociodemographic information

Captured

Sociodemographic information collected

Age

Education level

Ethnicity

Gender

Living in rural area

Marital status

Type of residency

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated percentage of the population covered by the data source in the catchment area

EU area: Utilizing estimates of HD prevalence in predominantly Caucasian populations, i.e., 9.71 per 100,000 (Rawlins, 2016), we estimate that Enroll-HD

currently provides 18% coverage of the European manifest HD population. Coverage of the European premanifest population in Enroll-HD is estimated to be between 3% and 4%. Global estimates will be provided in the future.

Family linkage

Family linkage available in the data source permanently or can be created on an ad hoc basis

Ad hoc

Population

Population size

25550

Active population size

12905

Population by age group

Age group	Population size	Active population size
Paediatric Population (< 18 years)	38	14
Children (2 to < 12 years)	13	5
Adolescents (12 to < 18 years)	25	9
Adults (18 to < 46 years)	11164	6205

Age group	Populationsize	Active populationsize
Adults (46 to < 65 years)	11001	5460
Elderly (≥ 65 years)	3347	1226
Adults (65 to < 75 years)	2691	1049
Adults (75 to < 85 years)	613	168
Adults (85 years and over)	43	9

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source

3.00

Median time (years) between first and last available records for unique active individuals (alive and currently registered) capt

2.00

Data flows and management

Access and validation

Governance details

Documents or webpages that describe the overall governance of the data source and processes and procedures for data capture and management, data quality check and validation results (governing data access or utilisation for

research purposes).
https://www.enroll-hd.org/enrollhd_documents/Enroll-HD_DataUseAgreement_CHDI_E-Version_RevNo003(052418).pdf

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

Yes

Biospecimen access conditions

All details relating to biosample libraries and access procedures are provided on the Enroll-HD website, including links to the biosamples (https://enroll-hd.org/for-researchers/biosamples/) and access (https://enroll-hd.org/for-researchers/access-data-biosamples/) pages.

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

Yes

Description of data collection

The data collected by the study sites are entered electronically into the Enroll-HD electronic data capture system (EDC) .The system ensures that the format and definitions of data entered are consistent on an intra- and inter-site level, cross-sectionally and longitudinally. EDC updates are performed periodically as controlled and documented releases, following detailed user testing to ensure the data continues to be stored correctly in the updated EDC. To ensure data completeness, the EDC facilitates data collection by presenting all mandatory (core) assessments as mandatory case report forms (CRFs). Dependent on the applicability, all fields within the CRFs are mandatory (e.g., gender is required for all participants, but the number of cigarettes smoked per day is only required for smokers). The system is set up to guide the user to enter all

required data. Drop-down menus, help text, and system prompts, as well as linked guidance documents, are also provided next to specific data entry fields to guide data collection and help ensure that the site staff enter the correct information, in the correct format.
To maximise data accuracy at the point of data collection and entry, the EDC contains automated data validity checks (“edit checks”). It imposes data entry thresholds for specific fields, preventing entry of ‘out-of-range’ values (e.g., height of a person cannot exceed 230 cm). The EDC also cross-checks variable field entries within a CRF (e.g., in the motor examination - a large discrepancy between left- and right-hand assessments), across CRFs within the same visit (e.g., discrepancy in assessment of participant capability for employment in two different functional scales), and across visits (e.g., an unreasonable difference between assessments conducted in consecutive years).
The EDC messaging system alerts the data entry person of missing or discrepant entries. When a system alert is activated, the data entry person can choose to change the value, if inco

Event triggering registration

Event triggering registration of a person in the data source

Other

Event triggering registration of a person in the data source, other

Self-selection into the study

Event triggering de-registration of a person in the data source

Death

Loss to follow up

Other

Event triggering de-registration of a person in the data source, other

Participant request

Event triggering creation of a record in the data source

Specialist visit

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

Yes

Linkage description, possible linkage

A unique 9 digit identifier (HDID) is assigned to each participant. The HDID is used in multiple studies of Huntington's disease to linkdatasets (e.g Enroll-HD, Track-HD, clinical trials and observationalstudies)

Linked data sources

Pre linked

Is the data source described created by the linkage of other data sources?

No

Data source, other

REGISTRY: an Observational Study of the European Huntington's Disease Network (EHDN) -
ClinicalTrials.gov Identifier: NCT01590589. Additional linked studies can be found on https://enroll-hd.org/for-researchers/hd-studies/"

Linkage strategy

Deterministic

Linkage variable

HDID

Linkage completeness

Linkage completeness data is not available yet but the team is planning to include this on the Enroll-HD website (www.enroll-hd.org), when available in the future.

Data management specifications that apply for the data source

Data source refresh

Yearly

Informed consent for use of data for research

Other

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

Yes

Data source preservation

Are records preserved in the data source indefinitely?

No

Data source preservation length (years)

50 years

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

No

Informed consent, other

All data have been consented by participants for Huntinton's Disease research and development, and other diseases.

Data source last refresh

04/11/2022

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

No