

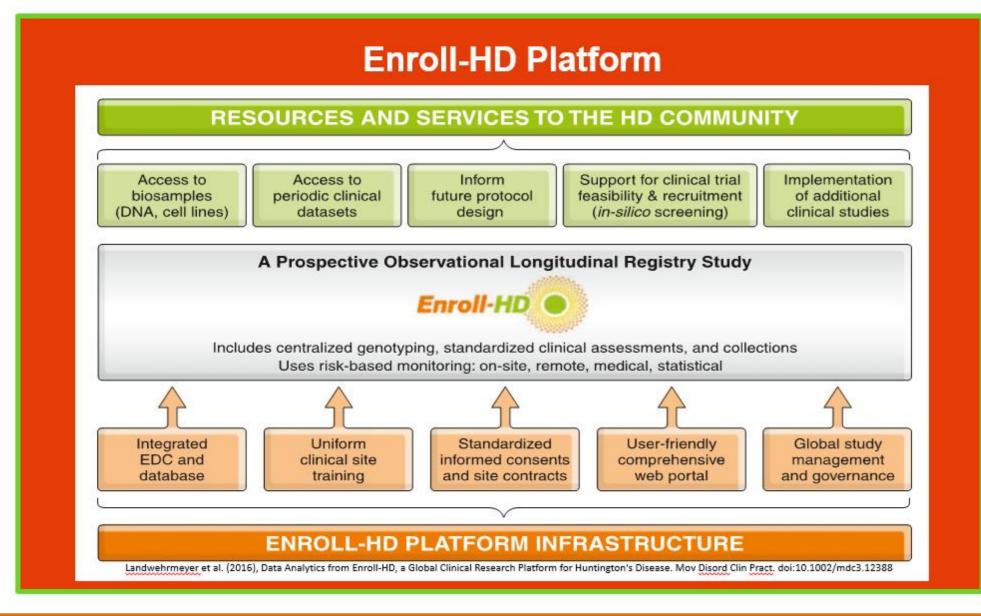
Enroll-HD: A Prospective Registry Study in a Global Huntington's Disease Cohort

Accelerating therapeutic development for Huntington's disease

The Enroll-HD Platform Team

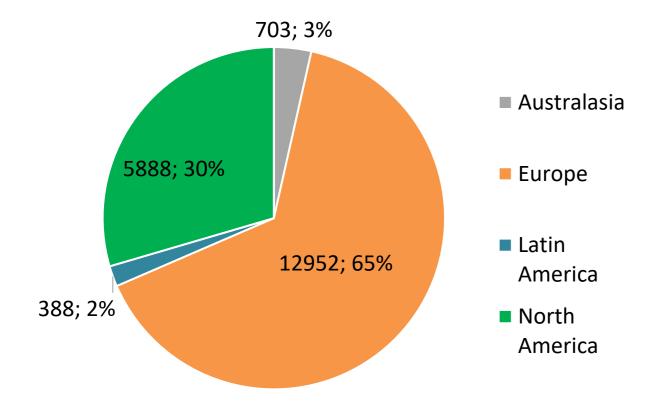
Enroll-HD as research platform

Enroll-HD is a global research platform designed to expedite clinical trials, advance HD research, and improve clinical care. Input from study sites, HD families, Enroll-HD governance and lay associations enable a dynamic infrastructure to develop and support a host of platform resources and services. For further details on the Platform Services please see poster "Enroll-HD Platform Support for Industry and Academic Sponsors"



Current study status

- 21 active countries on 4 continents
- 157 actively recruiting sites
- 24 sites in start-up
- 25,927 participants recruited since study start (as of 1 July, 2021)
- 19,931 active participants (as of July 1, 2021). Active participants are defined as participants who have had an Enroll-HD visit (in person or phone contact) in the past 2.25 years



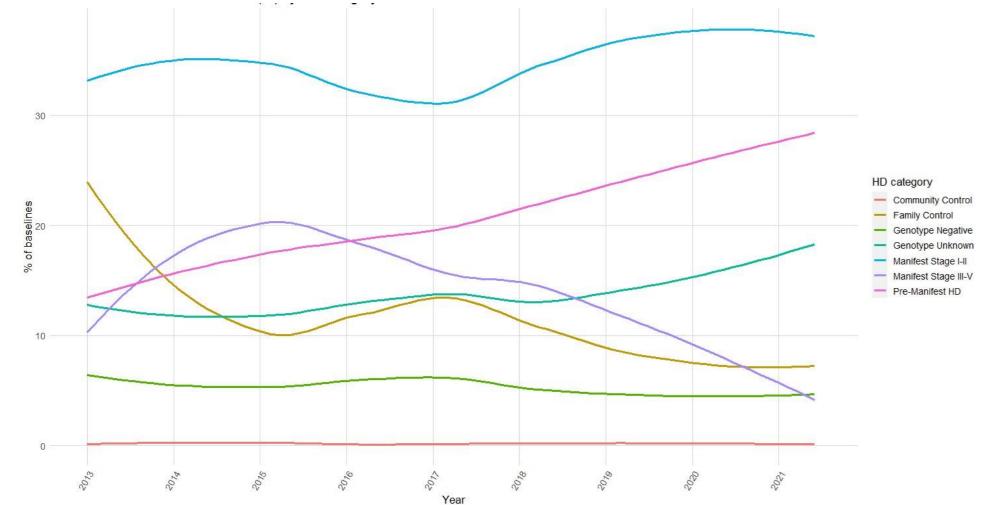
Region	Active	In Start-up
Australasia	7	0
Europe	90	16
Latin America	4	3
North America	56	5
Total	157	24

Recruitment by region (active participants)

Site status by region

Study population

At the end of 2017, a new recruitment strategy aiming at increasing the percentage of premanifest and early-manifest participants in the study was implemented. The goal is to target recruitment towards a cohort needed to support ongoing and future clinical trials.



Total new recruitment (%) by HD category and disease stage

Enroll-HD study

At the core of the Enroll-HD research platform is the Enroll-HD study, a global, prospective, longitudinal observational study of HD.

Study population: HD gene-expansion carriers (manifest and premanifest), genotype unknown, genotype negative, family controls, community controls (selected sites only).

Core assessments: Demographics, concomitant medication, medical history and comorbidities, motor, behavioural, cognitive, functional data and research CAG genotyping are collected on ALL participants.

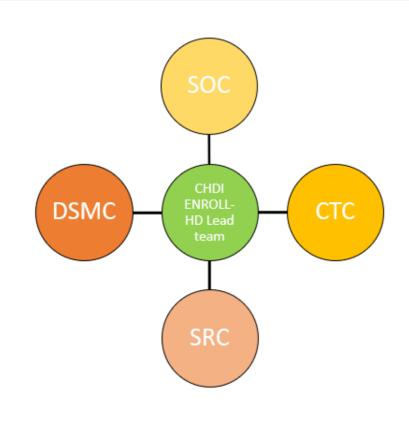
Extended assessments: Self-report questionnaires on quality of life, behaviour, health economics, extended cognitive tests.

Optional components: Donation of biosamples for research, family history, participation in sub-studies, contact between visits, contact about other research opportunities, contact about post-mortem tissue donation, linking data from previous studies.

Recoded data and biosamples are made available to researchers.

For further details on data and biosample sharing, see posters "Enroll-HD platform data resources" and "Enroll-HD platform biosample resources"

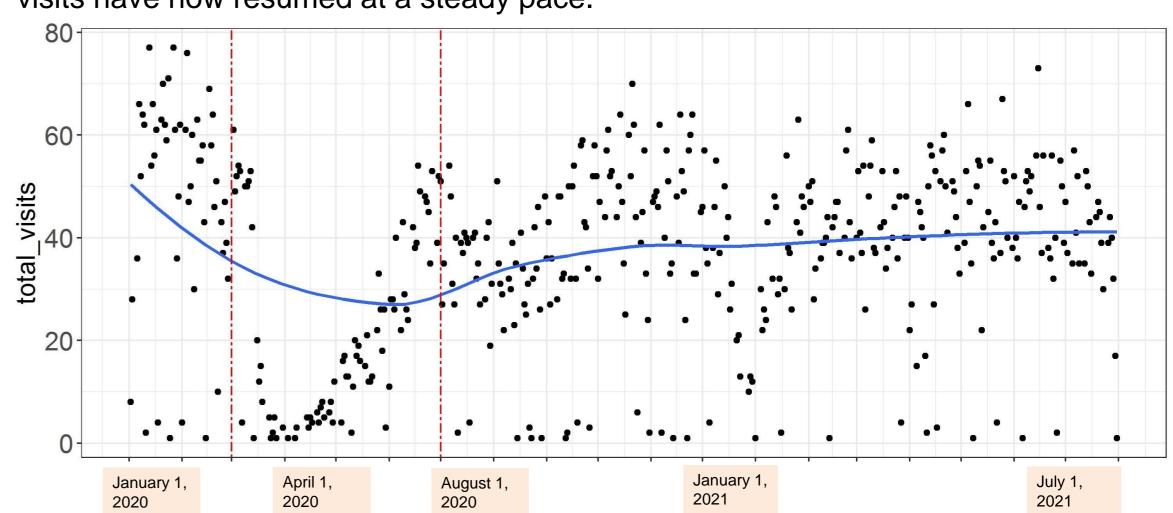
Enroll-HD governance



- Scientific Oversight Committee (SOC) –Ensures the Enroll-HD platform scientific integrity and reviews platform study proposals.
- Data Safety Monitoring Committee (DSMC) Reviews reportable events, addresses issues related to overall safety, addresses CAG discrepancies between research genotyping and local CAG results.
- Scientific Review Committee (SRC) Ensures an ethically sound, fair and scientifically rigorous review of data and biosample requests.
- Clinical Trial Committee (CTC) —provides recommendations and guidance to clinical trial sponsors for clinical development and/or review of trial protocols for acceptance for operational support using Enroll-HD resources.

Impact of COVID-19 on study visits

The COVID-19 pandemic had a major impact on the number of in person visits conducted at the study sites, with the lowest number of visits conducted in April 2020, however study visits have now resumed at a steady pace.



Global number of Enroll-HD study visits (daily)

Conclusions

The Enroll-HD global research platform has generated a series of resources and services that are available to the HD community. Enroll-HD continues to deliver on its goal to expedite HD clinical research with the development of these tools and more in the future. For more information please visit www.enroll-hd.org or contact lnfo@Enroll-HD.org