Enroll-HD Platform Support for Clinical Trials and Studies

The Enroll-HD Platform Team

Enroll-HD Study and Research Platform

Enroll-HD Platform: a global research platform designed to expedite clinical trials, understand more about Huntington's disease, and improve clinical care.

Enroll-HD Study: a prospective, observational, longitudinal study; the core of the platform

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

Annual Assessments:

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

Extended: Self-report questionnaires on quality of life, behaviour, health economics, extended cognitive tests. This data is available for a subset of participants.

Optional: 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.

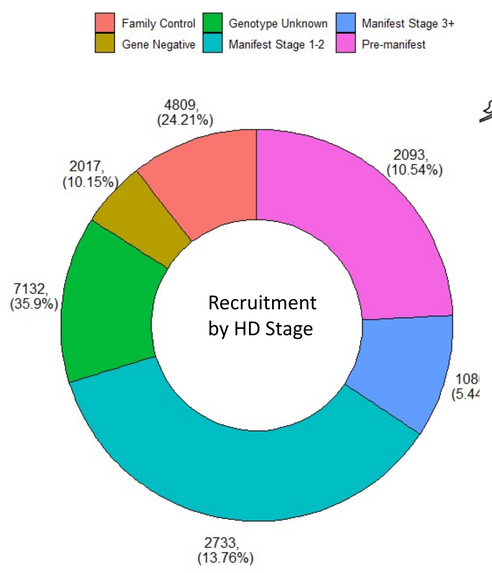
Enroll-HD spans 21 countries on 4 continents

157 recruiting HD clinical sites

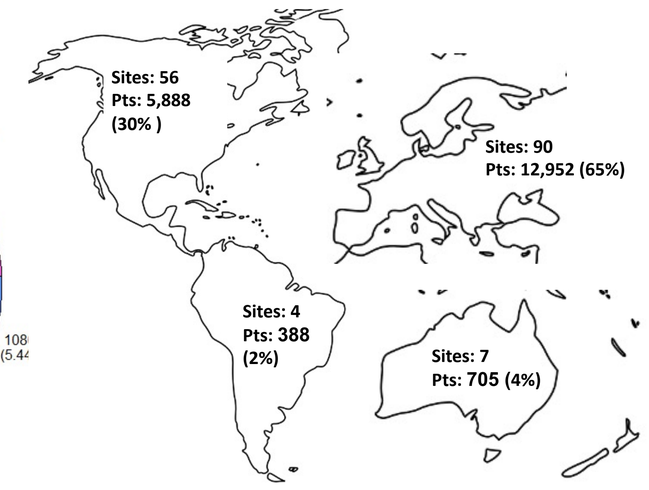
133 clinical trial ready HD Clinical Trial Certified sites

19,931 active participants (25,927 participants total).

Active participants are defined as participants who had an Enroll-HD visit (in-person or phone contact) in the past 2.25 years



Clinical sites and Participant Recruitment (active)



*24 sites in start-up: , 16 EU, 4 LA, 5 NA

Enroll-HD Platform Clinical Trial and Study Support

Protocol development

- Clinical outcomes
- Biomarkers
- Enroll-HD Clinical Trial Committee (CTC): expert feedback on clinical development questions
- Modelling
- Imaging

Data and Biosamples

Clinical datasets and biosamples from Enroll-HD, HDClarity, TRACK-HD/Track-On HD and other studies are available to researchers

Clinical Operations

- Study planning and start-up
- Study execution
- In silico feasibility
- Participant recruitment
- Site identification
- Issue resolution
- Training

Advisory and review activities – available on request:

- Expertise in relevant fields: imaging; biomarkers, modelling, clinical outcomes, clinical trial conduct and HD specialists.
- Expert opinion on protocol development issues and questions
- The CTC review and advise on a protocol synopsis, protocol and any additional materials/questions and return a written response

Country/Site Feasibility

- Advise on countries/sites based on study criteria & requirements

Site Identification and Selection based on evaluation of:

- Enroll-HD site database
- HD Clinical Trial Site Certification status (including non Enroll-HD sites)
- Potential access to eligible participants
- Historic performance and recruitment

Clinical training platform

- Standardized UHDRS Motor & GCP training

Participant Selection and Recruitment

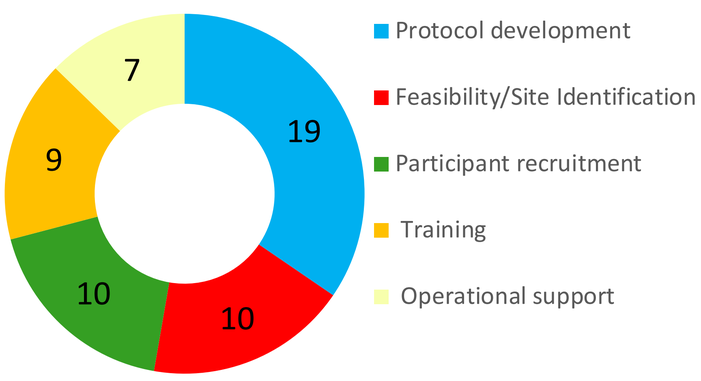
- In-silico participant screening via Enroll-HD study database
- Site referral networks and lay association links
- Support development of study & site-level recruitment plans

Other support

- Site communications and issue resolution; regional staff with established communication route and long relationships with sites

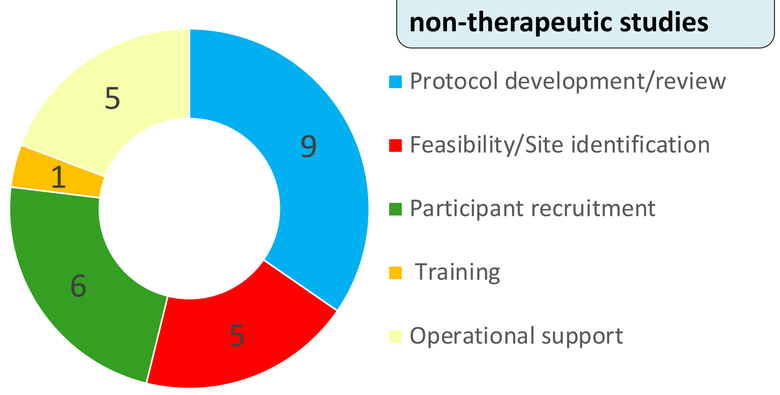
Platform support for therapeutic and non-therapeutic trials

Support provided for HD Phase I-III interventional therapeutic trials



Number of companies accessing different types of support

Support provided for HD non-therapeutic studies



Number of studies accessing different types of support

Contact us with any questions or to discuss platform support

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Acknowledgements: Enroll-HD is funded by the CHDI Foundation, a nonprofit biomedical research organization exclusively dedicated to developing therapeutics for HD. Enroll-HD would not be possible without the vital contribution of the research participants and their families.