



Newsletter

May 22 Issue 28

7 Nations Participating

28 Clinical Sites Worldwide

656 Participants Screened
(including longitudinal visits)

Dear HDClarity Teams,

Thank you to everyone for your hard work and dedication this year, we have now completed 590 Sampling visits and 95 optional repeat Sampling visits, with these numbers increasing regularly.

A significant milestone for HDClarity was achieved in February 2022, with Royal Devon and Exeter Hospital (UK) becoming the first site to recruit a participant under Protocol V4.1. Congratulations to Prof Tim Harrower and his team for this fantastic work! Additionally, this would not have been possible without the dedicated work of CHDI and Central Coordination, who have worked tirelessly to approve the new protocol, ensuring HDClarity continues to grow as a study, becoming the largest biomarker repository for Huntington's disease research.

In March 2022, our newest site, University College London Hospital (UK), recruited their first participant into the study, also under protocol V4.1. Prof Wild is the CI of HDClarity and previously contributed to HDClarity via the HD-CSF study, and University College London acts as Central Coordination. However, this is the first time he and his team are participating as an active HDClarity clinical site, and we would like to congratulate them on a successful first visit.

We are confident that more sites will transition to protocol V4.1, with our site in Birmingham (UK) set to receive their amendment training in May 2022.

March 2022 saw the return of the CHDI Annual Therapeutics Conference in Palm Springs. The conference showcases some of the finest HD research and this year was the first year in which studies using HDClarity bio samples were presented to the audience!

- Dr Beth Stevens from Boston Children's Hospital used HDClarity samples to study the complement system (CS) in HD. Her team discovered clear signs of increased CS activation in the CSF of HD patients! Annexon biosciences has developed a drug which reduced CS activation, with a small trial now underway in HD patients.
- Dr Jim Rosinsky from CHDI presented amazing results of the SomaLogic analysis of HDClarity samples. This assay measures up to 7,000 different proteins and was applied to HDClarity samples, helping to identify hundreds of novel leads and validate existing biomarkers.

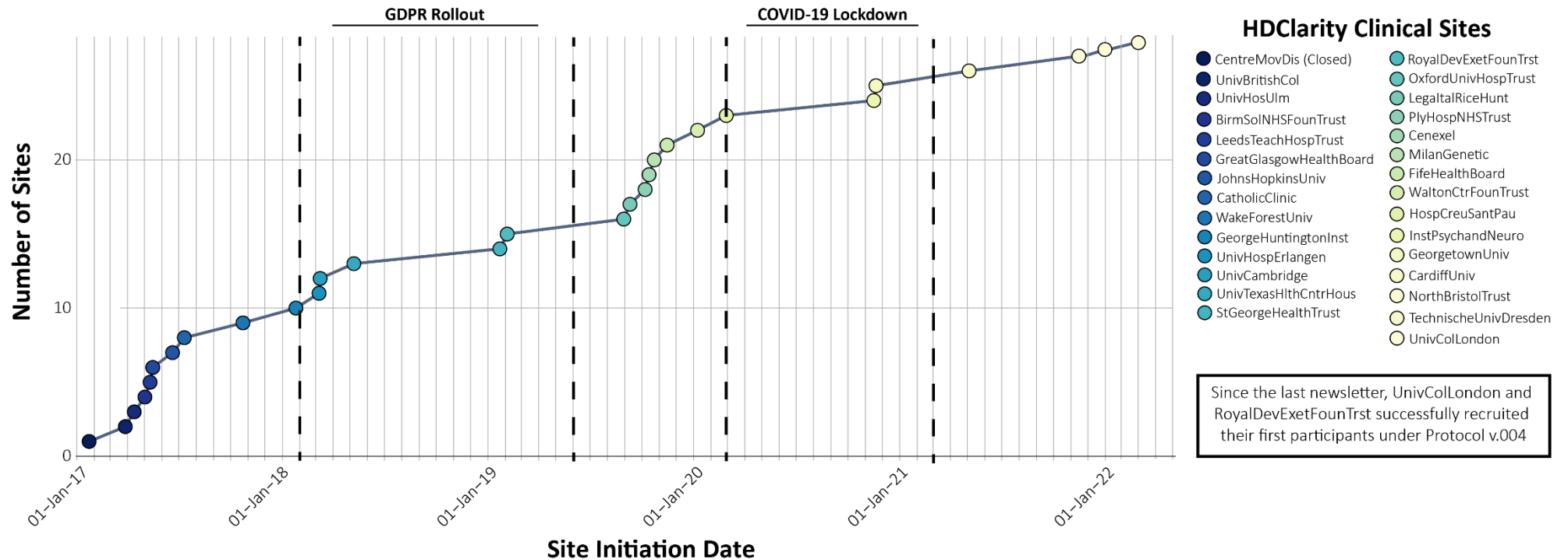
These studies are perfect examples of how HDClarity samples can be used effectively and contribute to the development of clinical trials and foster new discoveries, providing hope for HD families around the world.

HDClarity Clinical Site Updates

Since the last newsletter, we have added one new site to HDClarity, taking our total number of active clinical sites to **28**.

We are confident that more sites will soon follow, and recently completed a successful Site Initiation Visit with Vanderbilt University in Nashville (USA).

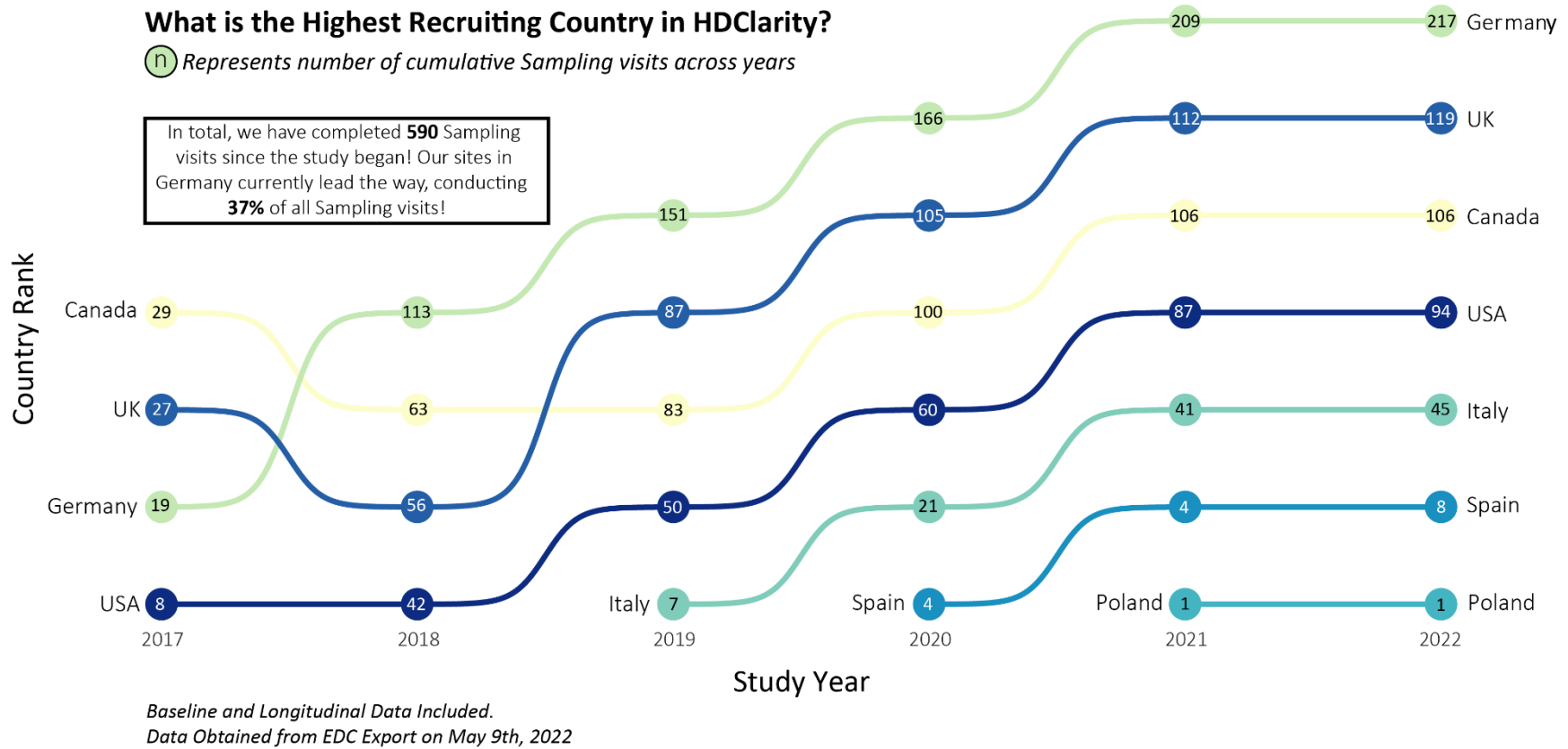
HDClarity Clinical Sites Initiation (Jan 2017 - Present)



Data Obtained from EDC Export on May 9th, 2022

Our clinical sites span across 7 countries, making HDClarity a truly global study. We are working hard to open more sites across North America, Europe, and Australasia.

Germany continues to be the highest recruiting country for HDClarity. However, we are seeing increased recruitment numbers elsewhere, with the USA and Italy showing large increases in recruitment post-pandemic. This is largely driven by the fantastic effort of study teams at Cenexel (previously Rocky Mountain) and University of Texas (USA), and Lega Italiana Ricera Huntington (Italy).



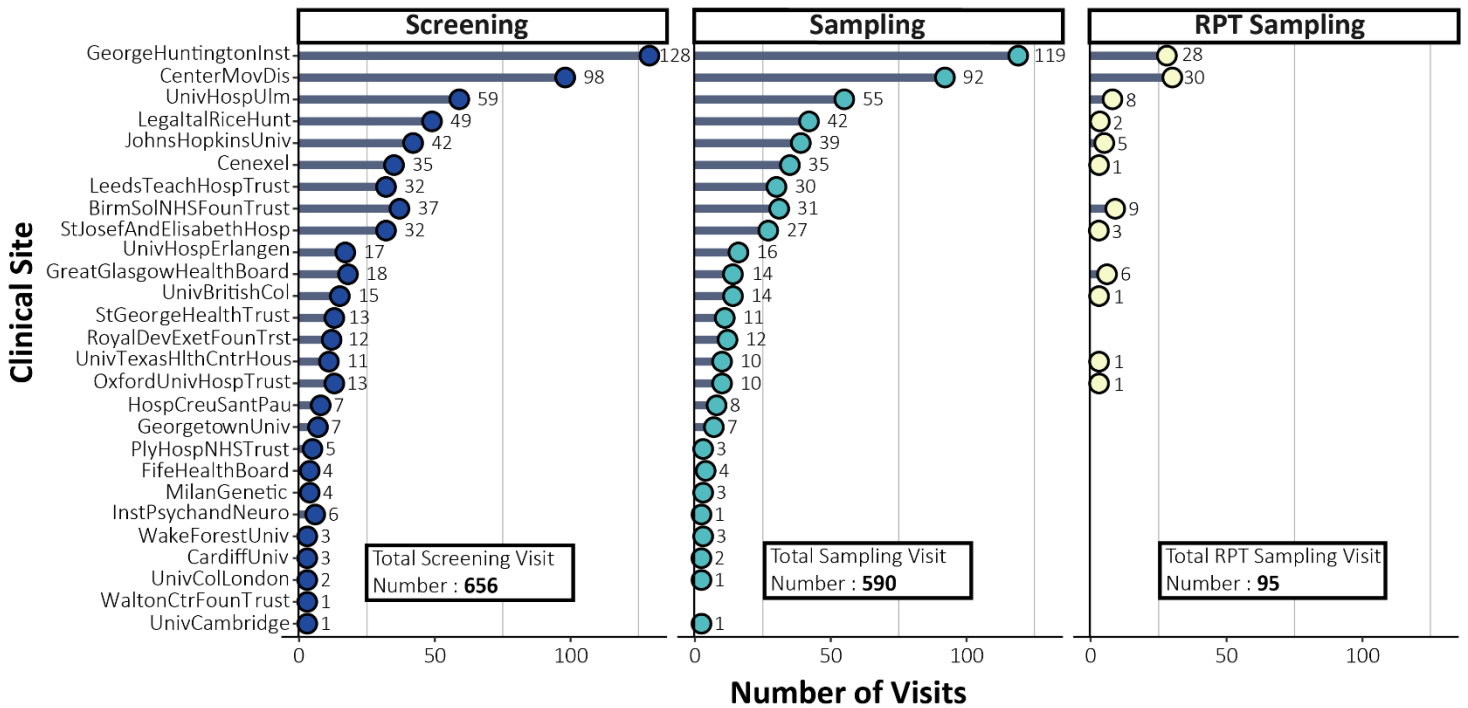
HDClarity Recruitment Updates

Since the last newsletter, we have conducted **36** Screening visits and **28** Sampling visits.

It was Cenexel who have led the way, completing 5 sampling visits since Jan 2022. This was closely followed by Hospital de la Santa Creu I Sant Pau (Spain), Lega Italiana Ricera Huntington (Italy) and University Hospital Ulm (Germany), who have all obtained samples from 4 participants.

Our recruitment total currently stands at 656 participants screened and 685 samples obtained. These numbers truly are impressive and serve to demonstrate the fantastic dedication of all site staff and the HD community.

Total HDClarity Visits by Site Baseline and Longitudinal Visits Included



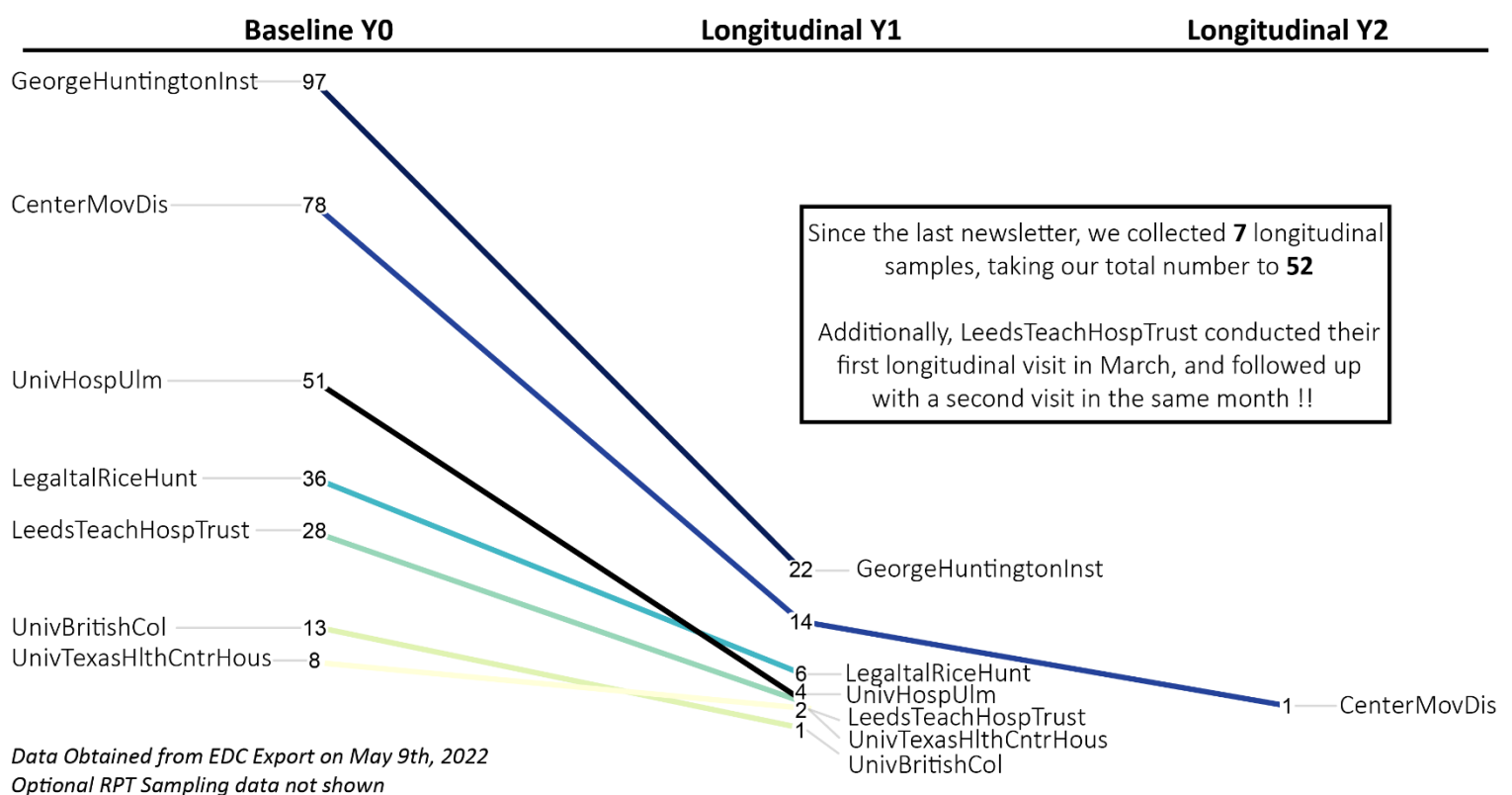
Data Obtained from EDC Export on May 09th, 2022
Sites are ordered by total recruitment number

Longitudinal recruitment continues to be a priority for HDClarity. Samples obtained from longitudinal visits provide researchers a unique opportunity to study biomarker trajectories across time. This is an important mechanism in establishing the validity of a proposed biomarker, ultimately allowing research findings to transition into a clinical setting.

Since Jan 2022, our sites collected samples from 7 longitudinal visits. University Hospital Ulm (Germany) led the way, completing 3 visits, and were closely followed by Leeds Teaching Hospital Trust (UK).

We would like to take this opportunity to thank all sites for prioritising this visit type and to remind all sites who are operating on protocol V3/4.I that they can invite participants back for repeat HDClarity visits >11 months after the previous enrolment. Longitudinal visits are open to all participant categories.

HDClarity Total Longitudinal Recruitment



REMINDERS

- Please contact CC when you intend to restart HDClarity. We will provide you with detailed instructions on how to proceed.
- When shipping samples, it is important that the shipment notification on the EDC is completed accurately (e.g., quantity and type of samples, site name/ID, LabID) and corresponds to the samples in the shipment.
- Please be conscious of the 5 'maximum' rules in place during HDClarity lumbar punctures. They are as follows:
 - Maximum LP duration of 20mins
 - Maximum of 20ml CSF should be collected
 - Maximum of 3 LP attempts per participant
 - Maximum of 5 needle passes per participant
 - Maximum of 5ml lidocaine per lumbar space (total maximum of 10ml allowed)
- Please always check HDClarity biokits expiry dates and do not use or discard expired items as replacements can usually be provided. Please contact CC to arrange replacements for expired components at least 14 days in advance. Expired components may include:
 - Polypropylene pipette tips – Please do not locally replace, contact CC instead.
 - Serum Vacutainers – You may use a locally sourced replacement if you prefer, but please inform HDClarity CC of the replacement make and model and include a photo at least 7 days before the visit.
 - Butterfly Needles - You may use a locally sourced replacement if you prefer, but please inform HDClarity CC of the replacement make and model and include a photo at least 7 days before the visit.
 - Pasteur Pipettes - Please do not locally replace, contact CC instead.

Thank you.