



## Newsletter

Oct 22 Issue 29

7 Nations Participating

29 Clinical Sites Worldwide

699 Participants Screened  
(including longitudinal visits)

Dear HDClarity Teams,

Thank you to everyone for your hard work and dedication the last few months. Since the previous edition (May 2022), we have completed an additional 43 Screening visits, 30 Sampling visits and 4 RPT Sampling visits!

We would like to congratulate our newest sites in Bristol, Dresden and Nashville who have all successfully enrolled their first participants into HDClarity! We are very excited to see how these contributions increase in the coming months.

Additionally, 10 UK sites have successfully transitioned to Protocol V4, with 5 sites having recruited participants using this new protocol version. Protocol V4 allows juvenile HD participants and those with CAGs of 35-39 to take part in HDClarity. Congratulations to Prof Roger Barker and his team at the University of Cambridge, who became the first HDClarity site to recruit a participant in this new cohort, providing the study with additional depth and allowing researchers to explore a lesser-studied aspect of Huntington's disease.

September 2022 saw the return of the EHDN Plenary Meeting in Bologna. This year, we held the Inaugural HDClarity Investigator Meeting, which provided an opportunity for Central Coordination, CHDI and UK and European clinical sites to meet face-to-face, discuss study progress and share knowledge to improve recruitment. The visit was a complete success and featured several talks by the esteemed scientists listed below who had used HDClarity biosamples in their research:

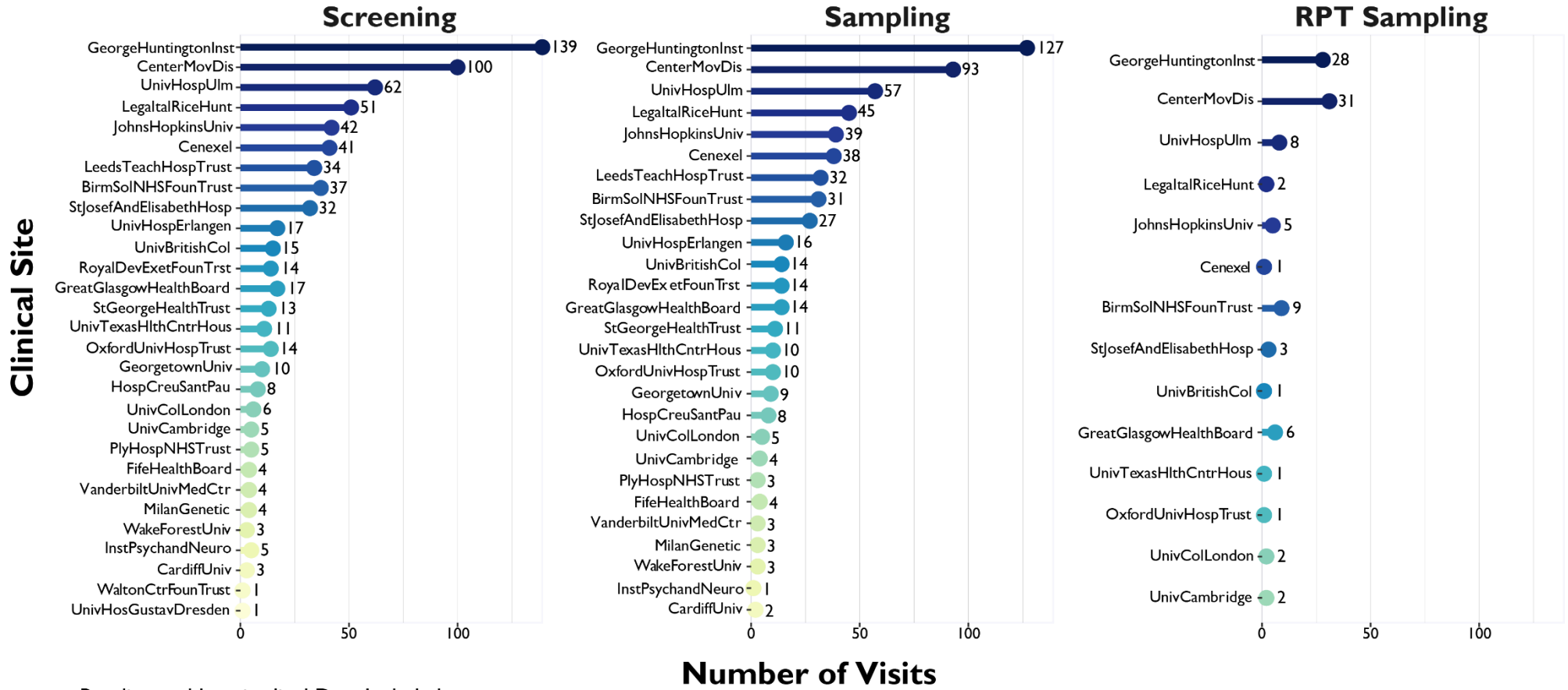
- Dr Beth Stevens from Boston Children's Hospital used HDClarity samples to study the complement system (CS) in HD.
- Dr Jim Rosinsky from CHDI presented amazing results of the SomaLogic analysis of HDClarity samples. This assay measures up to 7,000 different proteins to identify hundreds of novel leads and validate existing biomarkers.
- Dr Douglas MacDonald from CHDI showcased his work using HDClarity samples for biomarker assay development, specifically an assay designed to measure total Huntingtin!
- Dr Ann Mongan from AnnexonBio presented her work on complement activation to develop strategies for precision medicine.
- Dr Hilary Wilkinson from CHDI provided a fantastic overview of how HDClarity is the flagship study for biomarker development in Huntington's disease.

These talks were 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 Recruitment Updates

In total, we have now completed 699 Screening visits, 623 Sampling visits and 99 RPT Sampling visits. These numbers truly are impressive and serve to demonstrate the fantastic dedication of all site staff and the HD community.

## HDClarity Visits per Site



Baseline and Longitudinal Data Included.  
Data Obtained from Export on 3rd October, 2022

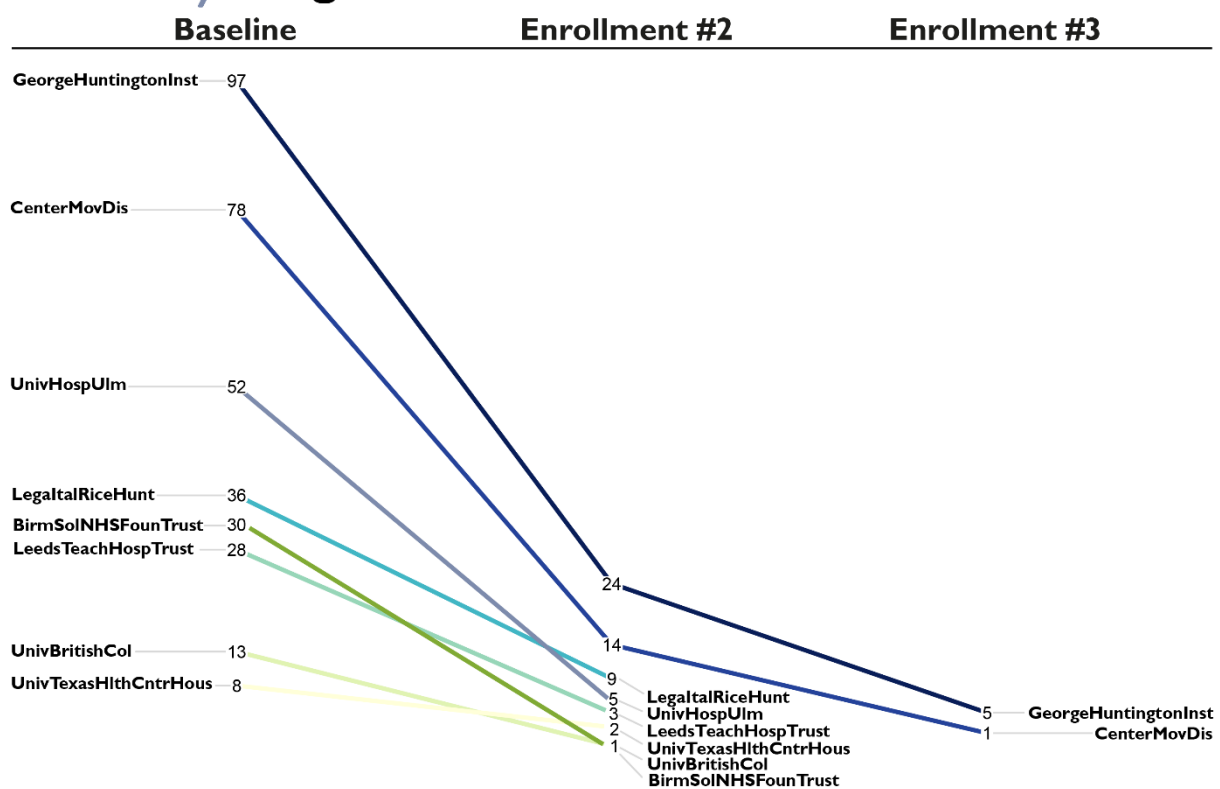
We have broken this down by Protocol version and time point in the below table:

Visit Type	Total Recruitment			Total
	CLR 2/3	CLR 2/3	CLR 4	
	Baseline Visits (% of total)	Longitudinal Visits (% of total)	Y0 Visits (% of total)	
Screening	613 (88%)	71 (10%)	15 (2%)	699
Sampling	546 (88%)	65 (10%)	12 (2%)	623
Optional RPT Sampling	94 (95%)	2 (1%)	4 (4%)	99

We are seeing a rapid rise in CLR 4 recruitment numbers with UnivCollondon currently leading the way, closely following by UnivCambridge, RoyalDevExetFounTrst, LeedsTeachHospTrust and NorthBristol.

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. In total, we have now collected 65 longitudinal samples across 8 clinical sites!

## HDClarity Longitudinal Recruitment

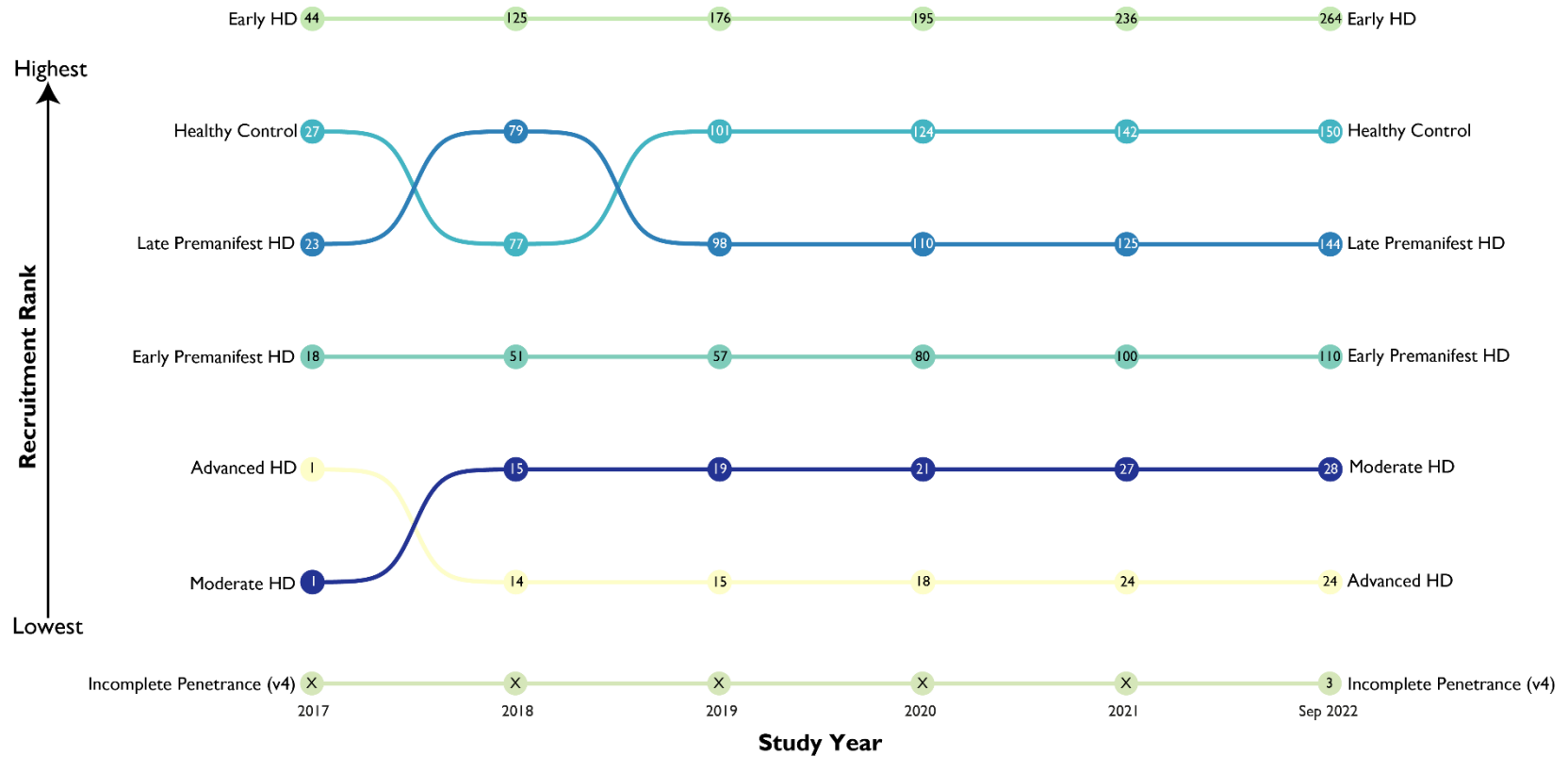


Baseline and Longitudinal Data Included.  
Data Obtained from Export on 3rd October, 2022

When we look at HDClarity recruitment across participant categories, we can see that the highest recruiting category has been 'Early HD' since the study began. 'Healthy Controls', 'Late Premanifest' and 'Early Premanifest' also having higher recruitment numbers compared to the later disease stage categories. The ordering is to be expected, with lumbar punctures becoming more challenging in individuals with advanced disease. However, our fantastic coverage across the premanifest and early stages of the disease will provide researchers with a great opportunity for biomarker development, and it is now widely thought that we need to target early stages of the disease to maximise therapeutic efficacy of experimental compounds.

## HDClarity Recruitment Rank Across Participant Categories

① Represents cumulative number of successful lumbar punctures (Sampling + RPT Sampling visits) per year.



Baseline and Longitudinal Data Included.  
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## REMINDERS

- Please ensure that all EDC data queries are answered before shipping samples to Biorep. Once samples have arrived at storage, the EDC locks which will prevent any further updates being made to the relevant forms.
- 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 CSF collection 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.