



HDClarity

Investigator Meeting

Nashville, October 2025



Accelerating therapeutic
development for
Huntington's disease



Start time	Duration (min)	Presenter	Title
13:00	60	HDClarity Study Team	Pre-meeting reception and opportunity for site-specific questions (with refreshments)
14:00	5	Cristina Sampaio CHDI Chief Medical Officer	Welcome
14:05	15	Ed Wild HDClarity Chief Investigator UCL Central Coordination	HDClarity Highlights
14:20	60	HDClarity PI Panel Discussion	Site experiences of study start-up and participation, and tips for recruitment and retention
15:20	20	Break (with refreshments)	
15:40	20	Gail Owen/Kat Schubert UCL Central Coordination	HDClarity Study Update and FAQs
16:00	30	Swati Sathe CHDI Medical VP HDClarity Study Medical Monitor	HDClarity integration with Enroll 2.0 and North American ICF update
16:30	15	Hilary Wilkinson CHDI VP Fluid Biomarkers	Biomarker discovery using HDClarity samples
	15	Ed Wild HDClarity Chief Investigator UCL Central Coordination	Analysis of the kynurenine pathway in HD using HDClarity data
	15	Doug Langbehn University of Iowa	Combining HDClarity data into statistical HD model
17:15	5	Closing remarks and questions	
17:20		The Iberian Pig (Nashville — The Iberian Pig)	Walk (~13 min) for dinner at 6pm

Introductions



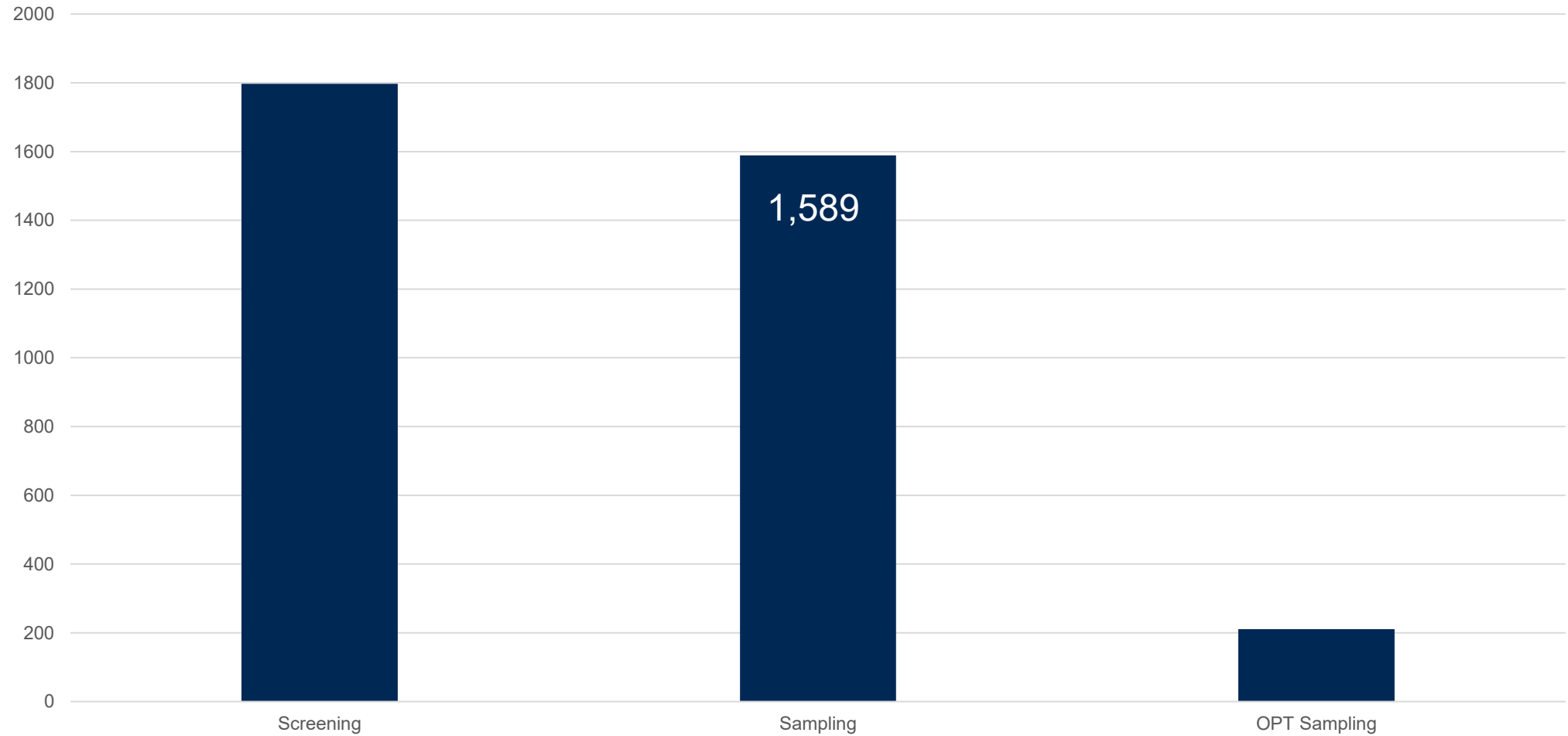
Aims

- Celebrate successes
- Learn about new developments
- Connect to science
- Share expertise
- Solve problems

Recent successes

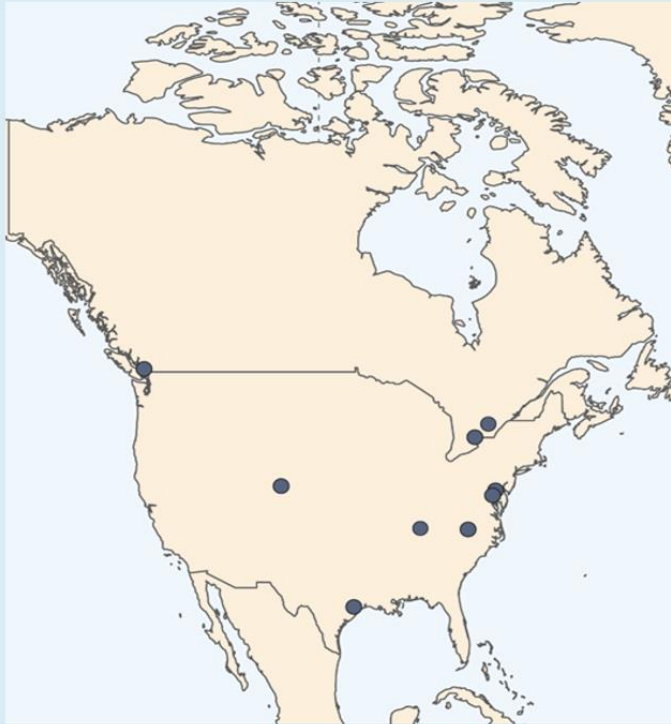


Total visits

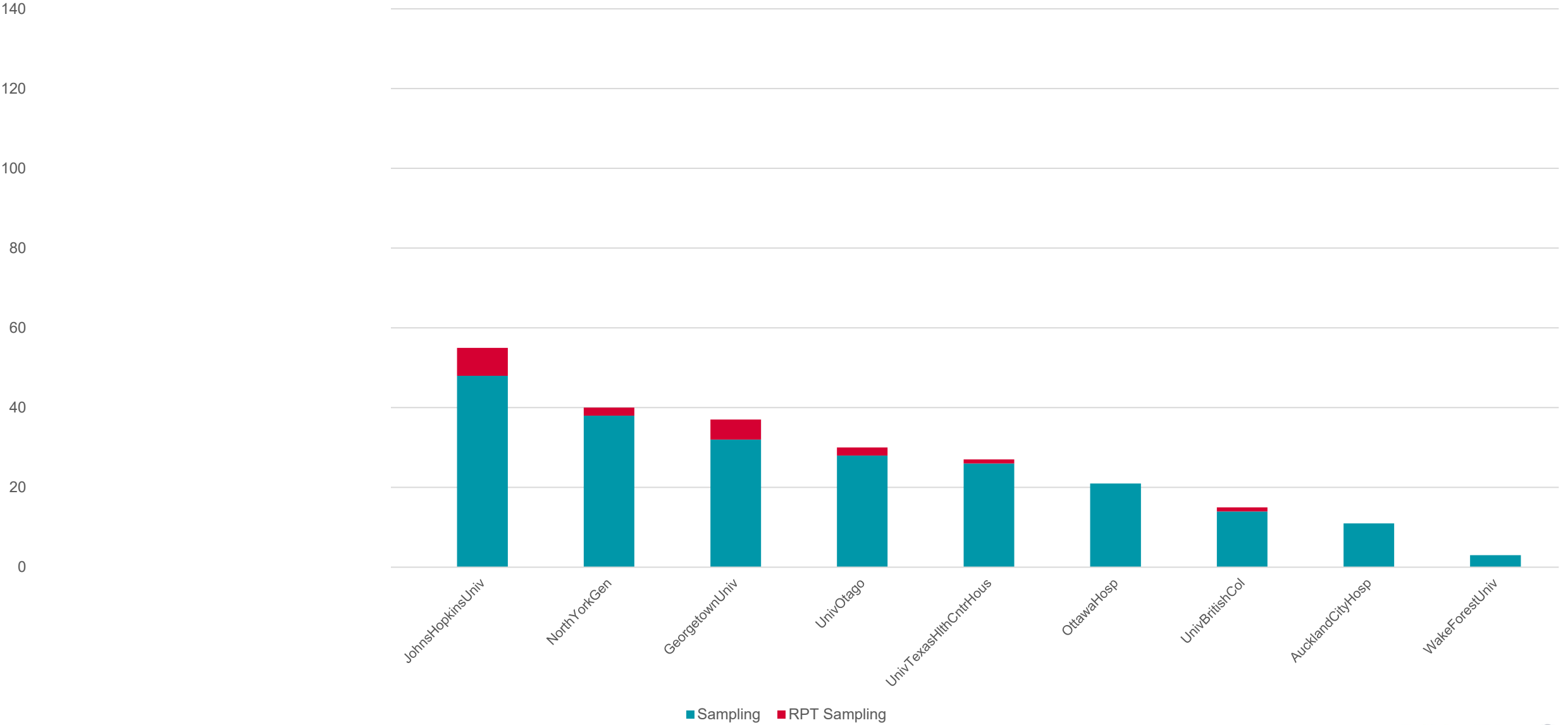


Where Are HDClarity Sites Located?

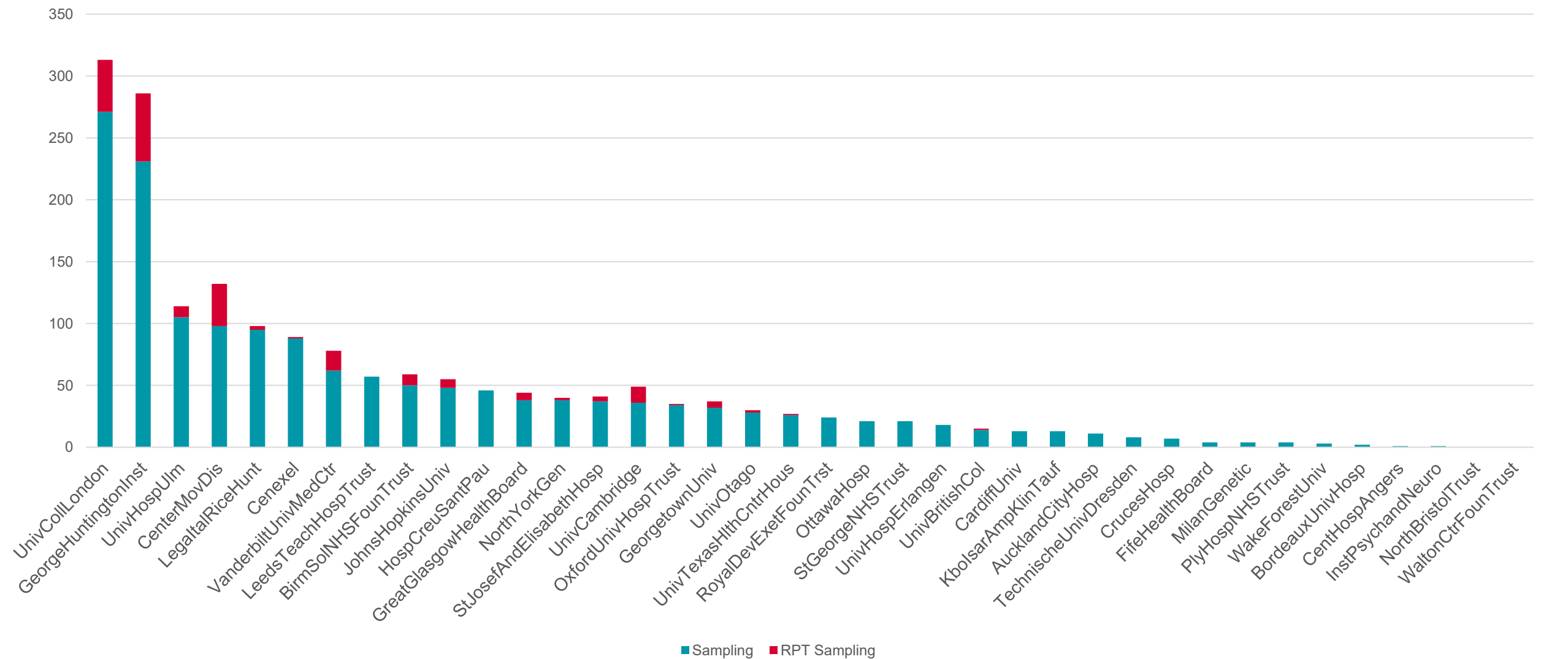
HDClarity has continued to expand and is now active at **37** clinical sites across **9** nations worldwide.



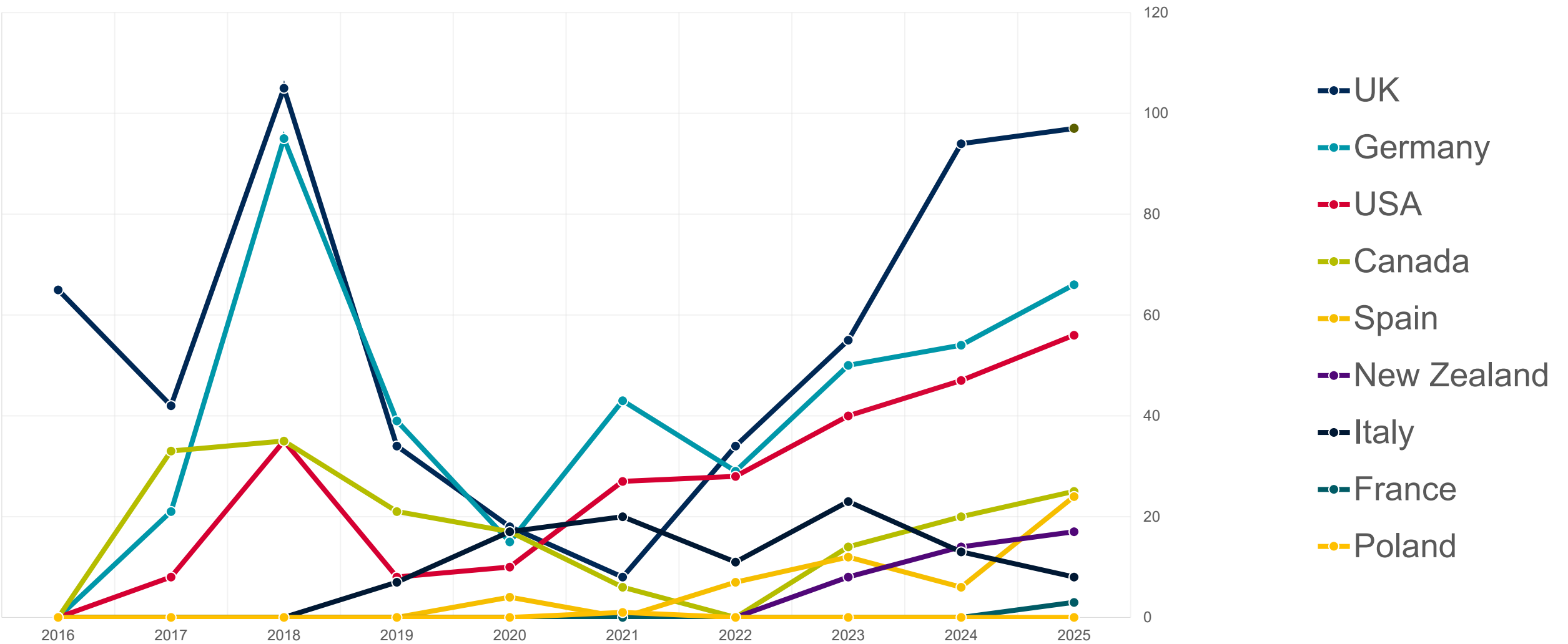
Total Sampling per Site (North America and New Zealand)



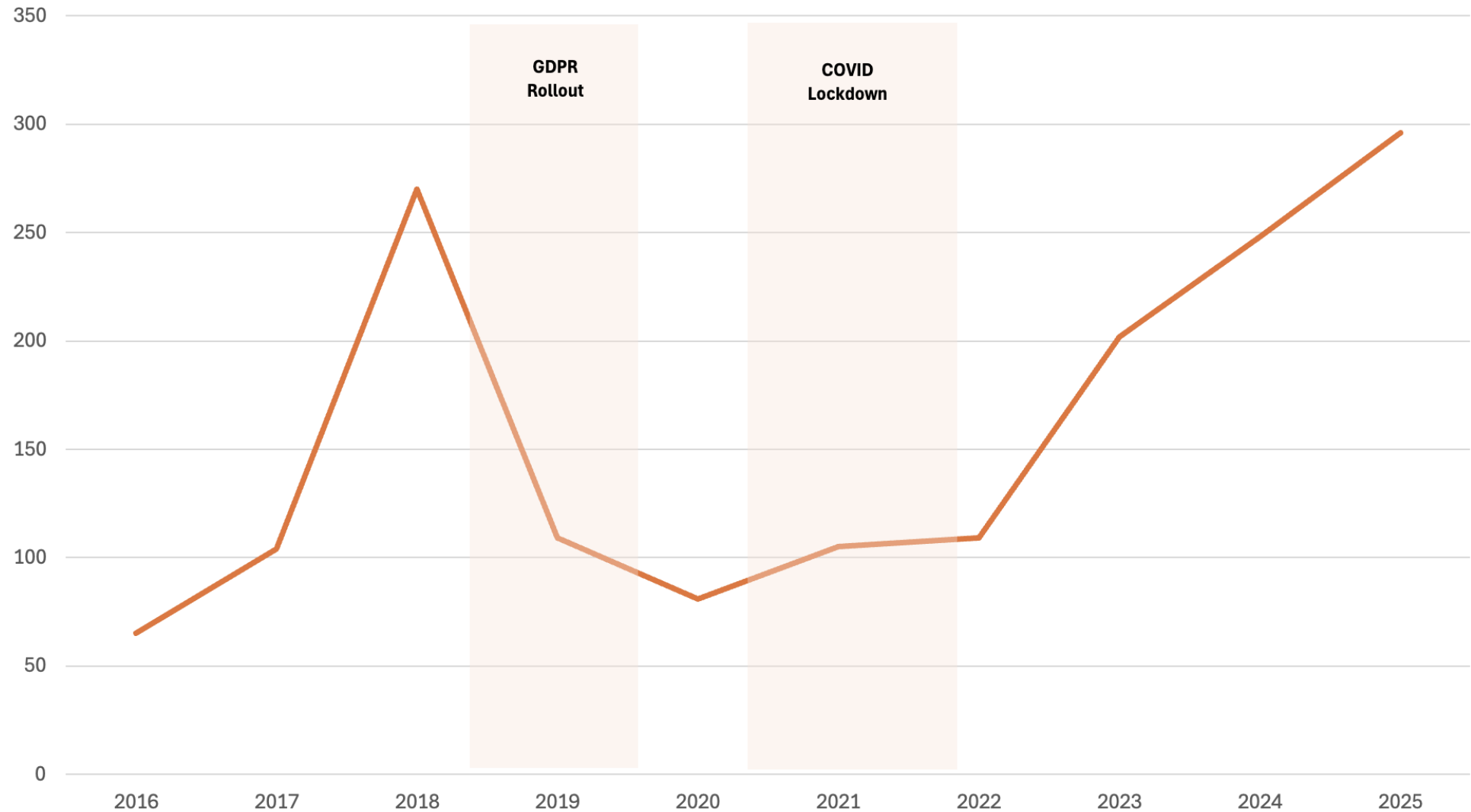
Sampling per Site



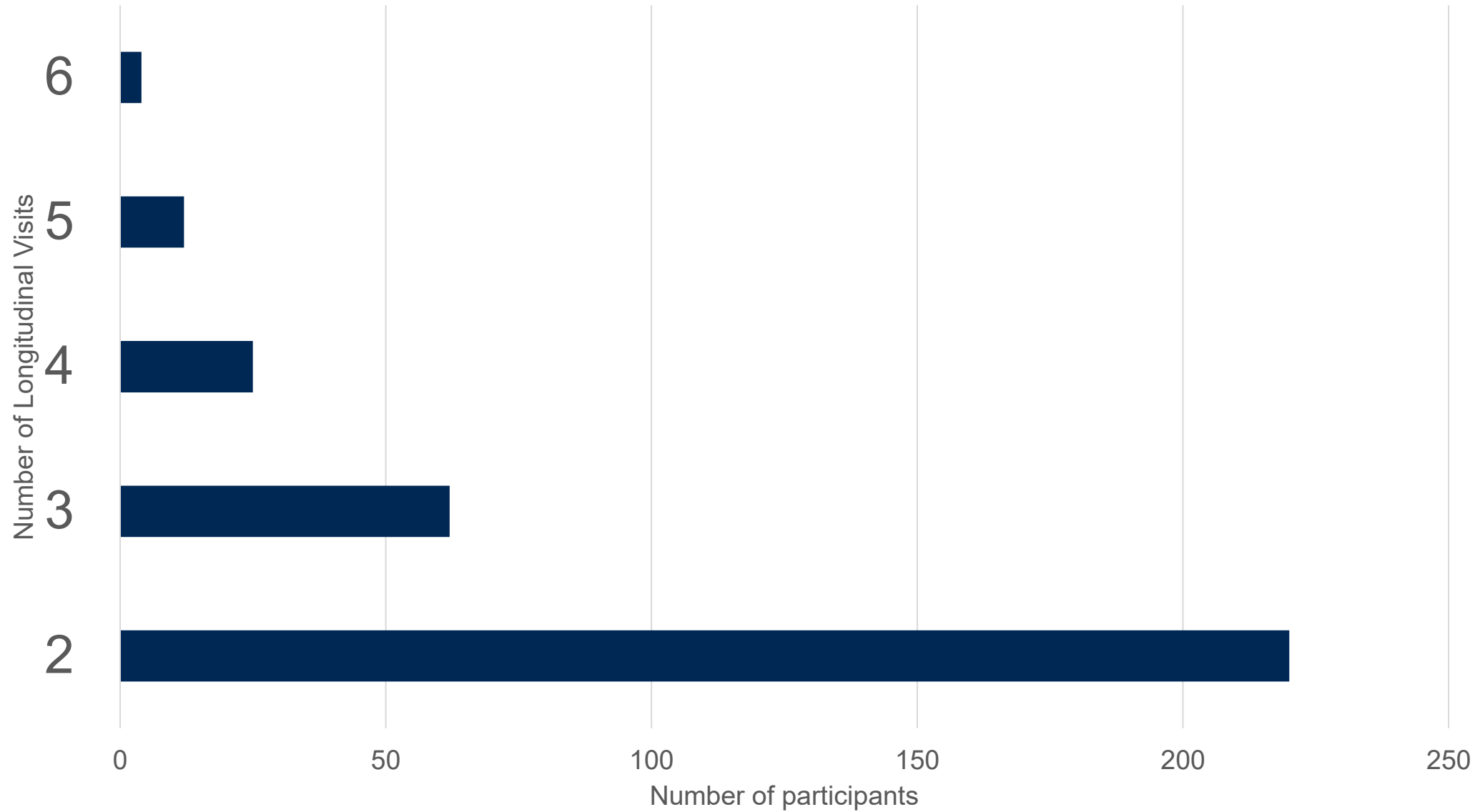
RECRUITMENT BY COUNTRY



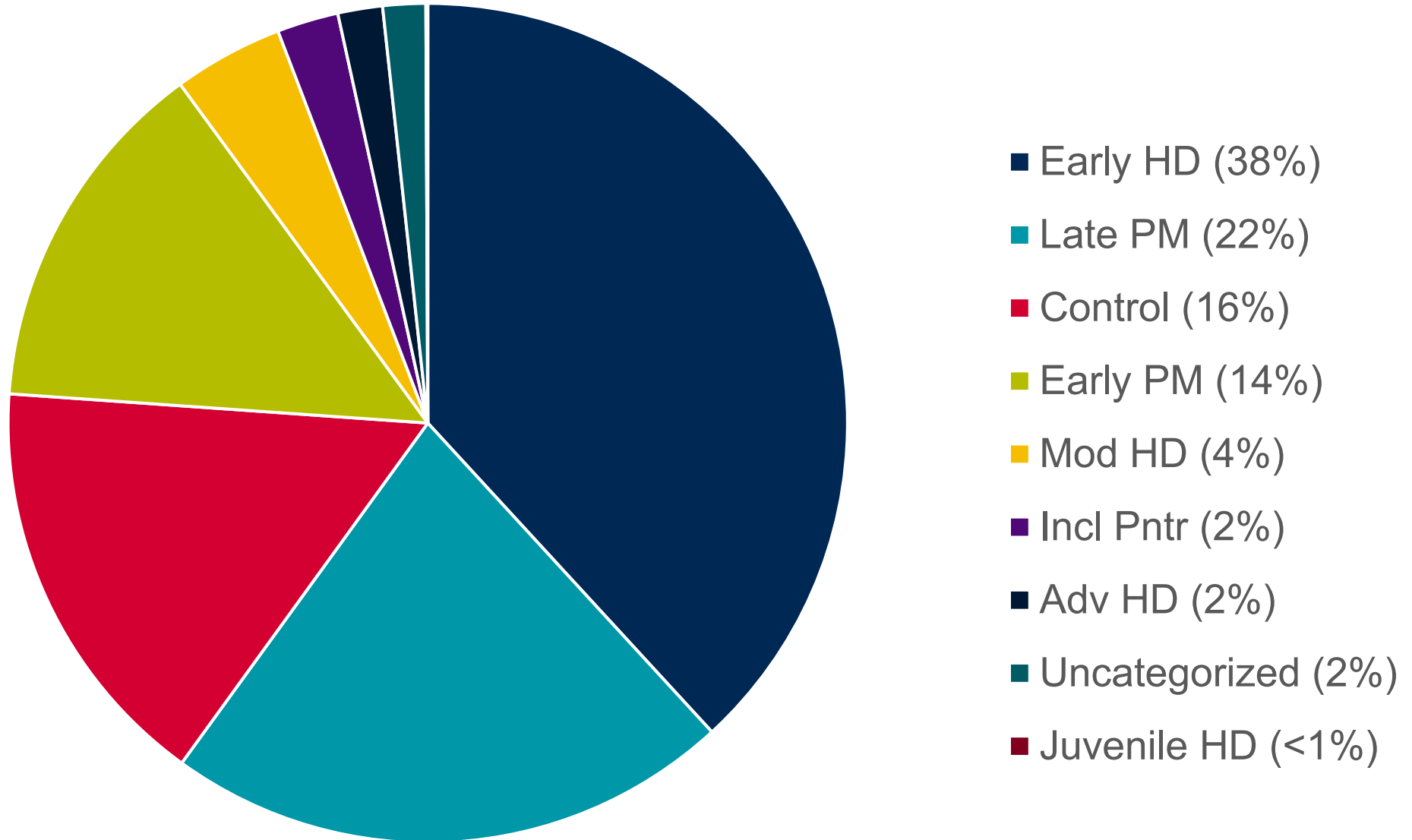
Sampling Visits per Year



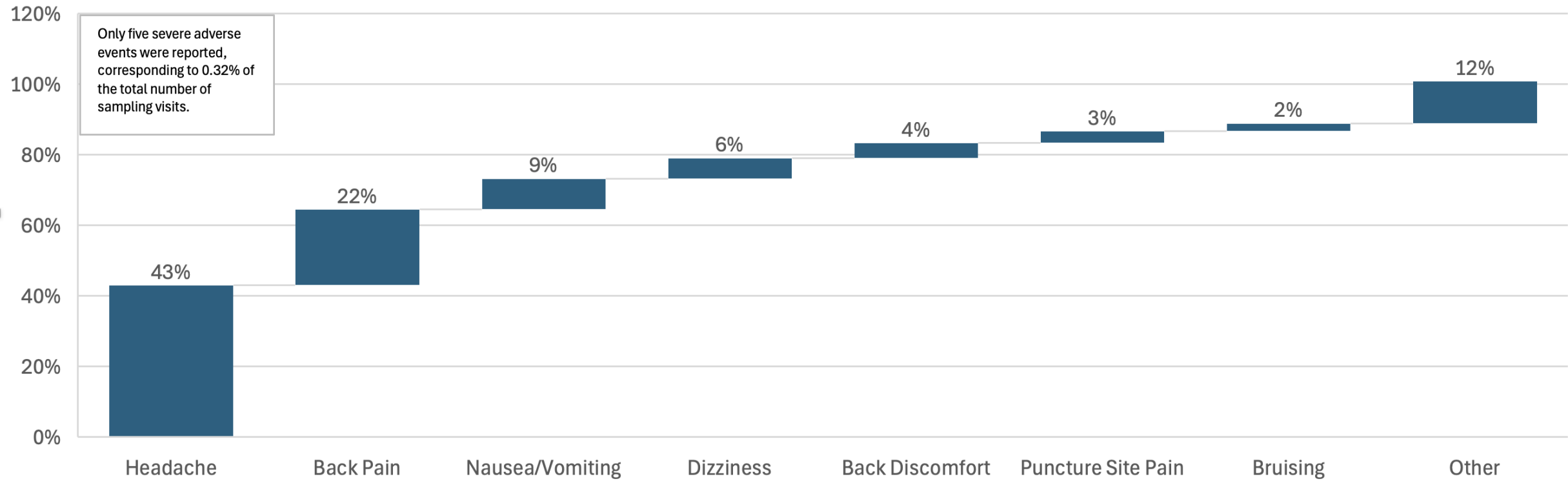
Longitudinal visits



Recruitment per Category



AEs



HD-Clarity TOTAL SPECIMEN STORAGE SERVICE (#vials)	
Plasma	64180
CSF	76016
Serum	5039
Cells from CSF	1606

HD-Clarity DISTRIBUTION SERVICE {#vials}	
Plasma	7015
CSF	12357
Serum	3226
Cells from CSF	0

So far, we have distributed HDClarity samples for **36** projects and we have **9** ongoing applications at various stages.

Total volume of CSF is 22.8 litres



Recent successes

New sites this year

- Bordeaux FR
- Madrid FR
- Lisbon PT

First participants sampled this year

- Angers FR
- Bordeaux FR
- Madrid ES

These meetings work!

After feedback received in 2024 we are implementing

- Repeater pipettes
- Reimbursement uplift
- Relaxation on cell counts
- Central supply of long needles

And progress has been made on N. American legal / ICF issues



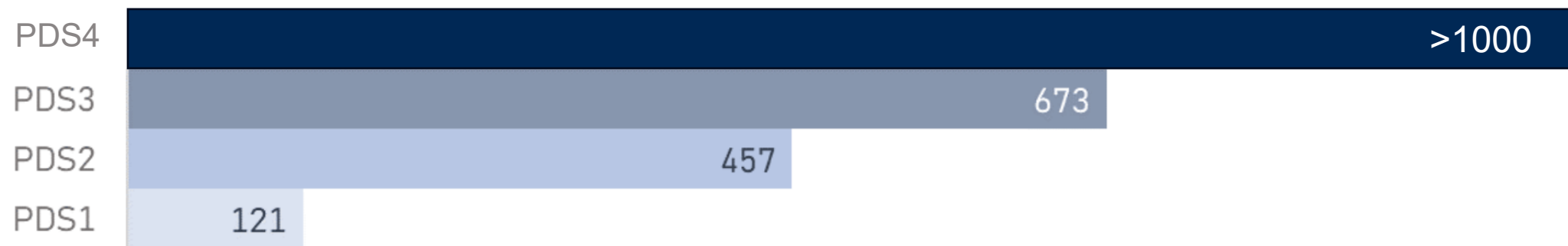


Accelerating therapeutic
development for
Huntington's disease



Metabolon 
SMALL MOLECULES, BIG INSIGHTS™

HDClarity 





HDClarity^{v5}



Accelerating therapeutic
development for
Huntington's disease



HDClarity - Study Update

HDClarity Central Coordinaton Team

Gail Owen – HDClarity Study Manager

Kat Schubert – HDClarity Study Coordinator

HDClarity

HSG meeting - Nashville
14th October 2025

Site FAQs

Why Can't I Enter My CLR4 Visit/Data?

- Participant is not eligible
- Participant is still enrolled in HDClarity 2/3
 - ▷ If enrollment is not complete, e.g. participant did not come in for sampling, you need to enter premature end form
- Optional repeat sampling visit is not available
 - ▷ Only available at baseline (Y0)
 - ▷ Participant has already had an optional repeat visit
- Enroll-HD and/or HDClarity visit window is not open
- If the EDC won't let you do it, it's probably not allowed!

Visit Scheduling – Aligning Visit Windows

Enroll-HD FUP Visit	HDClarity Screening/Sampling		Enroll-HD FUP Visit	
				HDClarity Screening/Sampling
Enroll-HD Visit Window	HDClarity Visit Window		Enroll-HD Visit Window	
				HDClarity Visit Window

Waivers, Repeat Measures and Rescreening

■ Waiver allows you to continue with sampling although there are minor deviations in inclusion/exclusion criteria

- ▶ E.g. one of the safety bloods is minimally out of range and not considered clinically relevant
- ▶ Waiver is entered in the Enrollment form

■ Repeated single measures within the 30-day screening window

- ▶ E.g. one of the safety bloods is out of range and but is expected to resolve quickly
- ▶ Additional blood draw data is entered in Safety Blood form

■ Rescreening by repeating all screening >30 days

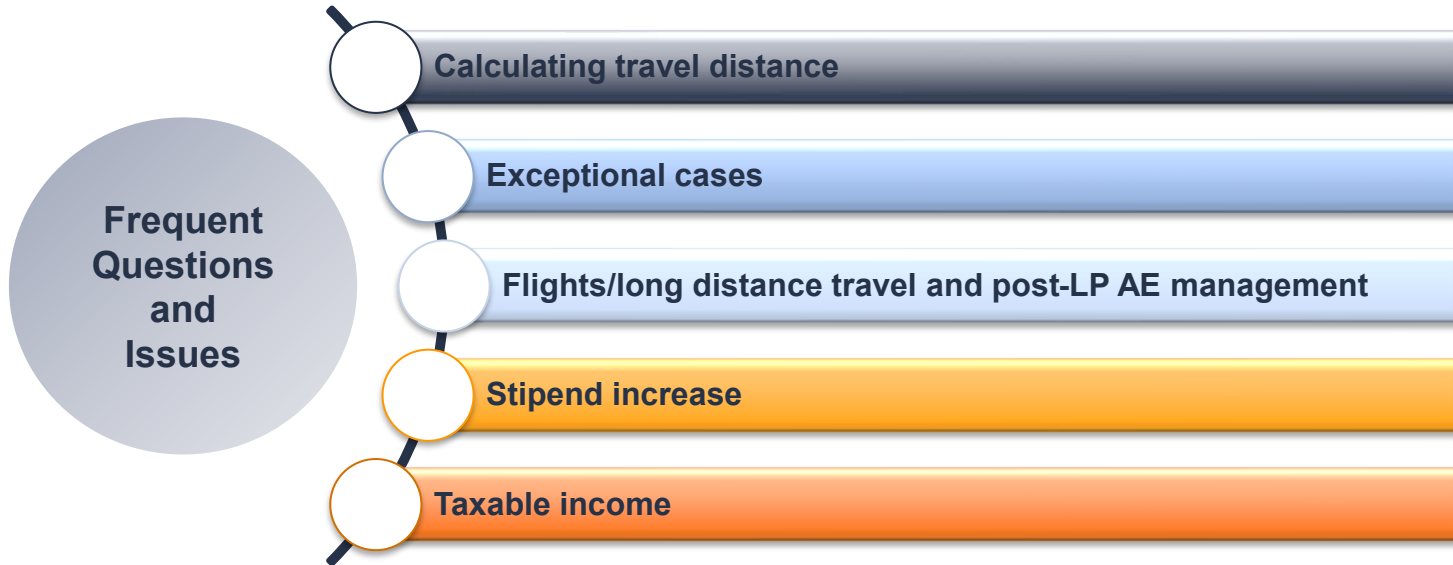
- ▶ E.g. participant passed screening but could not return within 30 days for sampling
- ▶ Original screening data is replaced with new data

■ All need prior approval

Participant Travel



Frequent Questions and Issues



Travel Allowances



Increased Travel Allowances

Transportation Allowance (Maximum Eligible Reimbursement Amount per Distance Travelled)

	< 25 mi (< 40 km)	25-50 mi (40-80 km)	> 50 mi (> 80 km)
Screening Visit/Rescreening	USD 25/ 40	USD 50/ 80	USD 75/ 120
Sampling Visit/Optional Repeat Sampling Visit	USD 30/ 50	USD 70/ 115	USD 115/ 175

Research Participant and One Companion Meal Allowance (Maximum Eligible Reimbursement Amount per Night at Hotel per Person)

Sampling Visit/Optional Repeat Sampling Visit	USD 65/ 95
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Sampling Visit/Optional Repeat Sampling Visit Lodging Allowance (Payment Amount per Night at Hotel)

Sampling Visit/Optional Repeat Sampling Visit	USD 200/ 285
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Travel Scenarios

☐ **Enroll FU**
 ☐ **HDClarity Screening**
 ☐ **HDClarity Sampling**

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

Scenario 1:

- Enroll-HD FU on the same day as HDClarity Screening -
 > **Travel paid by HDClarity**
- HDClarity Sampling not on the consecutive day to
 HDClarity Screening -> **Travel paid by HDClarity**



Travel Scenarios

○ Enroll FU ○ HDClarity Screening ○ HDClarity Sampling

S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

Scenario 2:

- Enroll-HD FU -> **Travel paid by Enroll-HD**
- HDClarity Screening on a different day as Enroll-HD FU -> **Travel paid by HDClarity**
- HDClarity Sampling not on the consecutive day to HDClarity Screening -> **Travel paid by HDClarity**



Travel Scenarios

 **Enroll FU**  **HDClarity Screening**  **HDClarity Sampling**

Scenario 3:

- Enroll-HD FU -> **Travel paid by Enroll-HD**
- HDClarity Screening on a different day as Enroll-HD FU **and**
- HDClarity Sampling on the consecutive day to HDClarity Screening -> **Travel paid by HDClarity + Lodging and Meal allowance**

S	M	T	W	T	F	S
 1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
 22	 23	24	25	26	27	28
29	30					



Travel Scenarios

 **Enroll FU**  **HDClarity Screening**  **HDClarity Sampling**

S	M	T	W	T	F	S
 1	 2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

Scenario 4:

- Enroll-HD FU on the same day as HDClarity Screening **and**
- HDClarity Sampling on the consecutive day to HDClarity Screening -> **Travel allowance paid by HDClarity + Lodging and Meal allowance**

Exceptional cases

- The most important consideration is that the participant should not be out of pocket
- Please always contact us **in advance** of a visit if:
 - ▷ the allowances will not cover the participant's costs
 - ▷ there are extra requirements, e.g. additional hotel night for participant travelling long distance
- There may be occasions when it's not possible to ask in advance, e.g. if a clinical issue arises and the PI prefers the participant to stay near the site for an extra night

Future Changes

HDClarity Protocol V5

- Alignment with Enroll 2.0
- Same day screening/sampling visits
 - ▶ Possible now that overnight fast is not required
 - ▶ Less burden to the participant



Changes to Sample Processing

Serum sample requests

Changes to serum aliquoting process

Changes to biokit components and shipment process

UCL pilot study



Central Coordination Team

THANK YOU!

Edward Wild – Chief Investigator

Gail Owen – Study Manager

Kat Schubert – Study Coordinator

Fiona Kinsella - Study Research Officer

Opeyemi Kinyomi – Study Physician/ Sub-Investigator

Chloe Young – Study Research Assistant

Mara Terres Rodriguez – Study Administrator

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