

Start time	Duration (min)	Presenter	Title
13:45	15	NA	Rendezvous and refreshments
14:00	15	HDClarity CI Ed Wild UCL	Welcome and HDClarity highlights
14:15	15	Kat Schubert UCL	Study update, frequently asked questions and issues
14:30	15	Hilary Wilkinson CHDI	Biomarkers using <u>HDClarity</u> samples
14:45	15	Ramee Lee CHDI	Cholesterol Metabolites in Huntington's Disease
15:00	15	Jim Rosinski CHDI	Proteomics using <u>HDClarity</u> samples
15:15	15	Break with tea & coffee	
15:30	30	David Rankin, CHDI Gail Owen, UCL Hilary Wilkinson, CHDI Elena Pak, CHDI	CHDI study documents: <ul style="list-style-type: none"> • ICFs and site agreements • PI role in start-up • Generic and regional issues
16:00	15	Break with cheese & wine (available through to 17:30)	
16:15	90	Ed Wild and PI panel	Site-specific experience: <ul style="list-style-type: none"> • Study start-up and participation • Sharing tips and site experiences • Recruitment and retention
17:45			Walk to dinner at Café Library for 6pm start

HD Clarity

Investigator Meeting
EHDN ♥ ENROLL-HD Congress, Strasbourg 2024



Accelerating therapeutic
development for
Huntington's disease



Start time	Duration (min)	Presenter	Title
13:45	15	NA	Rendezvous and refreshments
14:00	15	HDClarity CI Ed Wild UCL	Welcome and HDClarity highlights
14:15	15	Kat Schubert UCL	Study update, frequently asked questions and issues
14:30	15	Hilary Wilkinson CHDI	Biomarkers using <u>HDClarity</u> samples
14:45	15	Ramee Lee CHDI	Cholesterol Metabolites in Huntington's Disease
15:00	15	Jim Rosinski CHDI	Proteomics using <u>HDClarity</u> samples
15:15	15	Break with tea & coffee	
15:30	30	David Rankin, CHDI Gail Owen, UCL Hilary Wilkinson, CHDI Elena Pak, CHDI	CHDI study documents: <ul style="list-style-type: none"> • ICFs and site agreements • PI role in start-up • Generic and regional issues
16:00	15	Break with cheese & wine (available through to 17:30)	
16:15	90	Ed Wild and PI panel	Site-specific experience: <ul style="list-style-type: none"> • Study start-up and participation • Sharing tips and site experiences • Recruitment and retention
17:45			Walk to dinner at Café Library for 6pm start

Aims of the day

1. Get to know Team Clarity
2. Celebrate success
3. Discuss challenges
4. Share expertise
5. Absorb science
6. Eat and drink
7. Be merry

Introductions

First CSF: January 2017, Toronto



Successes since 2022



Now: 36 sites in 9 countries 🔥

Successes since 2022: New sites

CA North York (Alan Fung)

CA Ottawa (Tiago Mestre)

NZ Auckland (Richard Roxburgh)

NZ Otago (Tim Anderson)

DE Taufkirchen (Alzbeta Mühlbäck)

ES Cruces (Juan Carlos Gómez Esteban)

FR Angers (Christophe Verny)

Successes since 2022

- July 2024 – our best month ever, with 32 samplings
- 200+ longitudinal pairs
- 19 participants have done 4 or 5 visits 🌟
- 28/36 sites have rolled over to protocol V4 (78%)

Successes since 2022

	2022-24	2017-2021
Requests	20	19
Approved	14	18
In progress	6	
Shipped	7	17

	Cryovials Shipped
CSF	5799
Plasma	3512
Serum	1185

Successes since 2022

- PDS3



- Core biomarker data from 220

- Somalogic proteomics (7600+ proteins) from 579

- Publications and presentations

Pfalzer et al. "Alterations in metal homeostasis occur prior to canonical markers in Huntington disease." *Scientific Reports* 12.1 (2022): 10373.

Rodrigues et al. "Safety and feasibility of research lumbar puncture in Huntington's disease: The HDClarity cohort and bioresource." *Journal of Huntington's Disease* 11.1 (2022): 59-69.

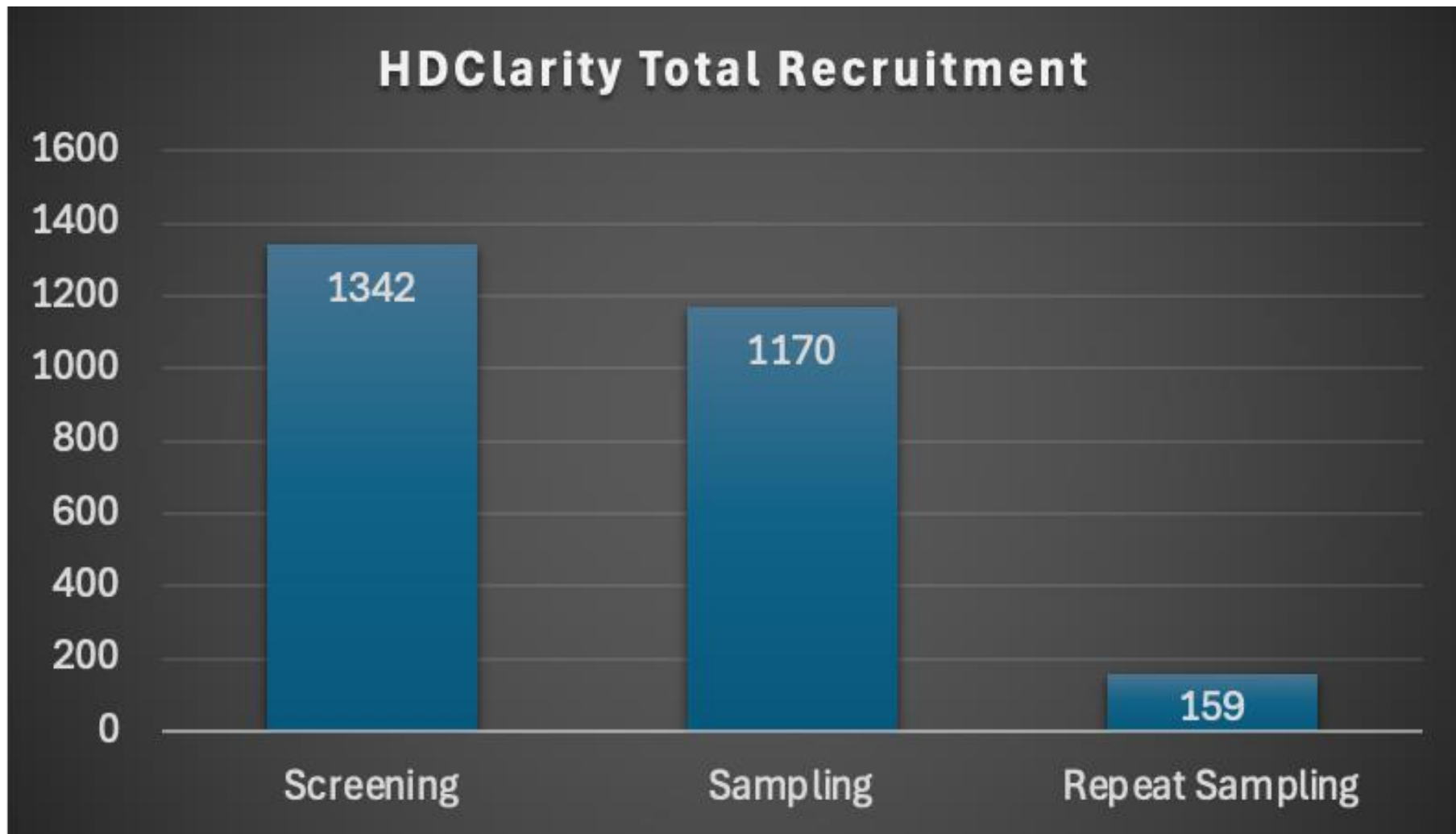
Hassan et al. "Lumbar puncture safety and tolerability in premanifest and manifest Huntington's disease: a multi-analysis cross-sectional study." *Scientific Reports* 12.1 (2022): 18377.

Niels Skotte. "Biofluid biomarker discovery in HD –Current possibilities and limitations" – HD Therapeutics Conference 2023

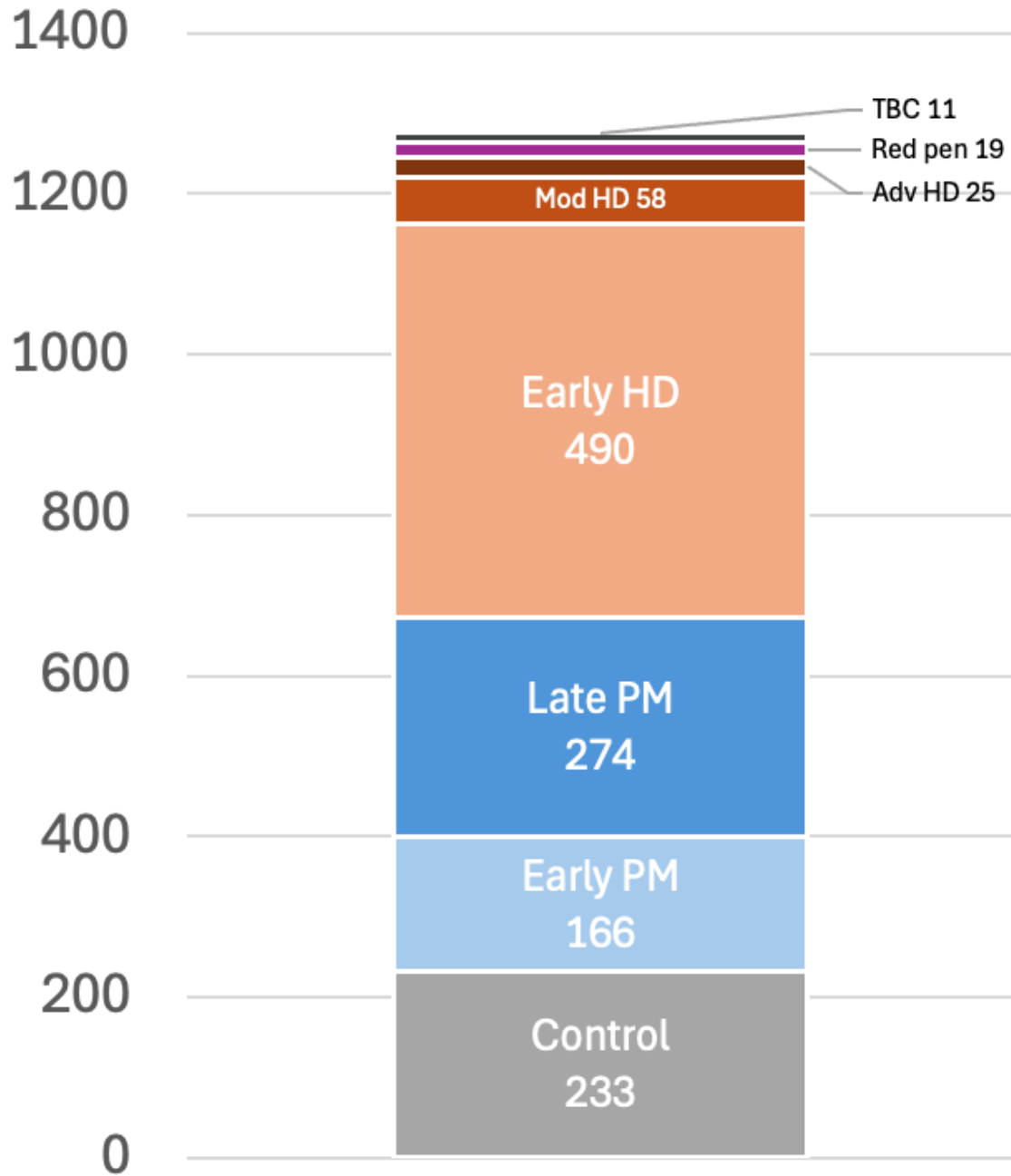
William Griffiths. "Cholesterol and oxysterols as biomarkers for Huntington's disease?" – HD Therapeutics Conference 2023

Natallia Kalinava. "Optimizing assays for accurate reliable measurement of NfL and clinical validation of the measurements" – HDTC 2023

Jim Rosinsky. "Multi-omic profiling of people with Huntington's disease (PwHD) for biomarker discovery: The future is bright!" – HDTC 2022



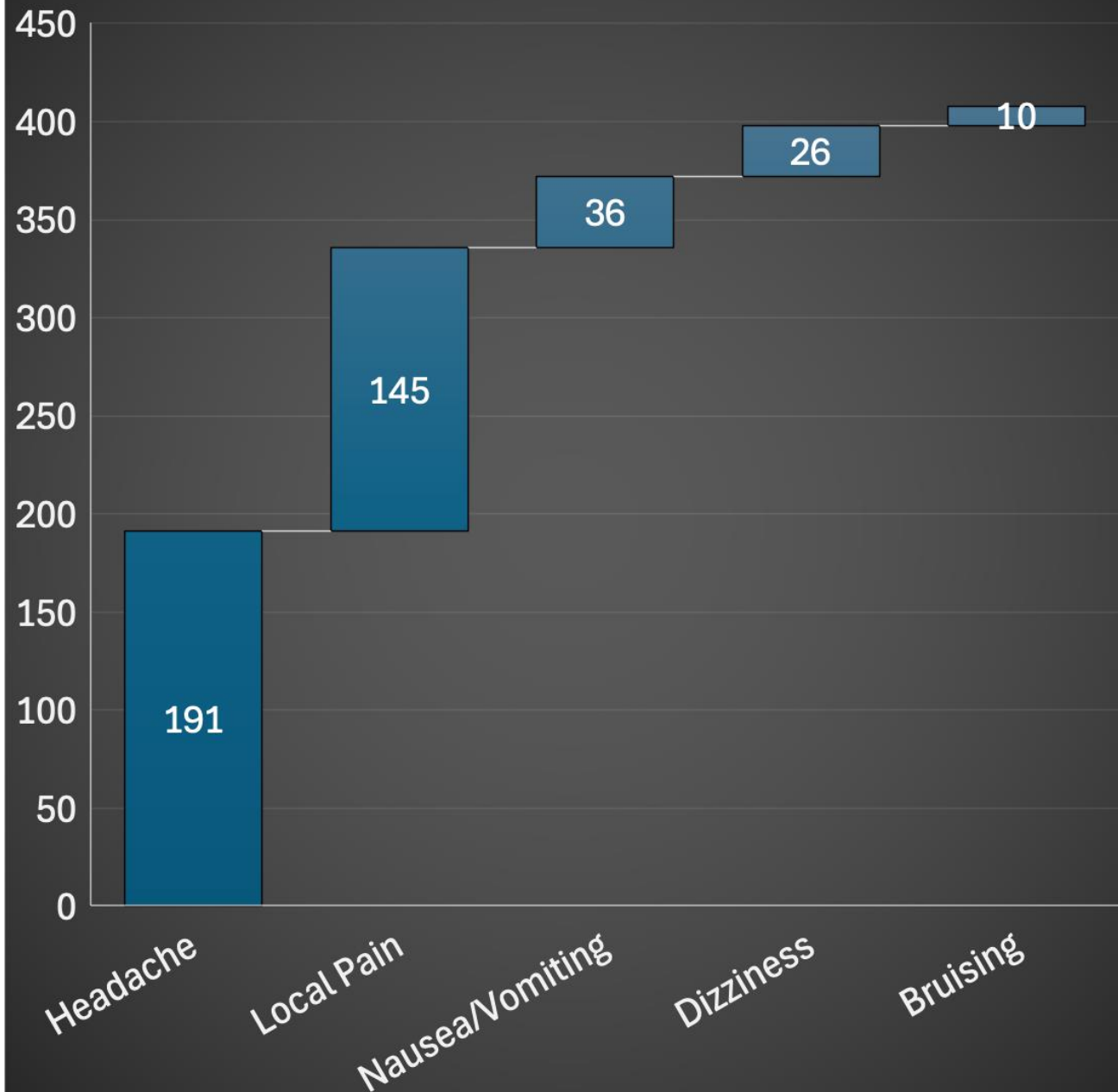
- ~ 26 litres of CSF
- ~ 88,000 CSF aliquots



All manifest 573

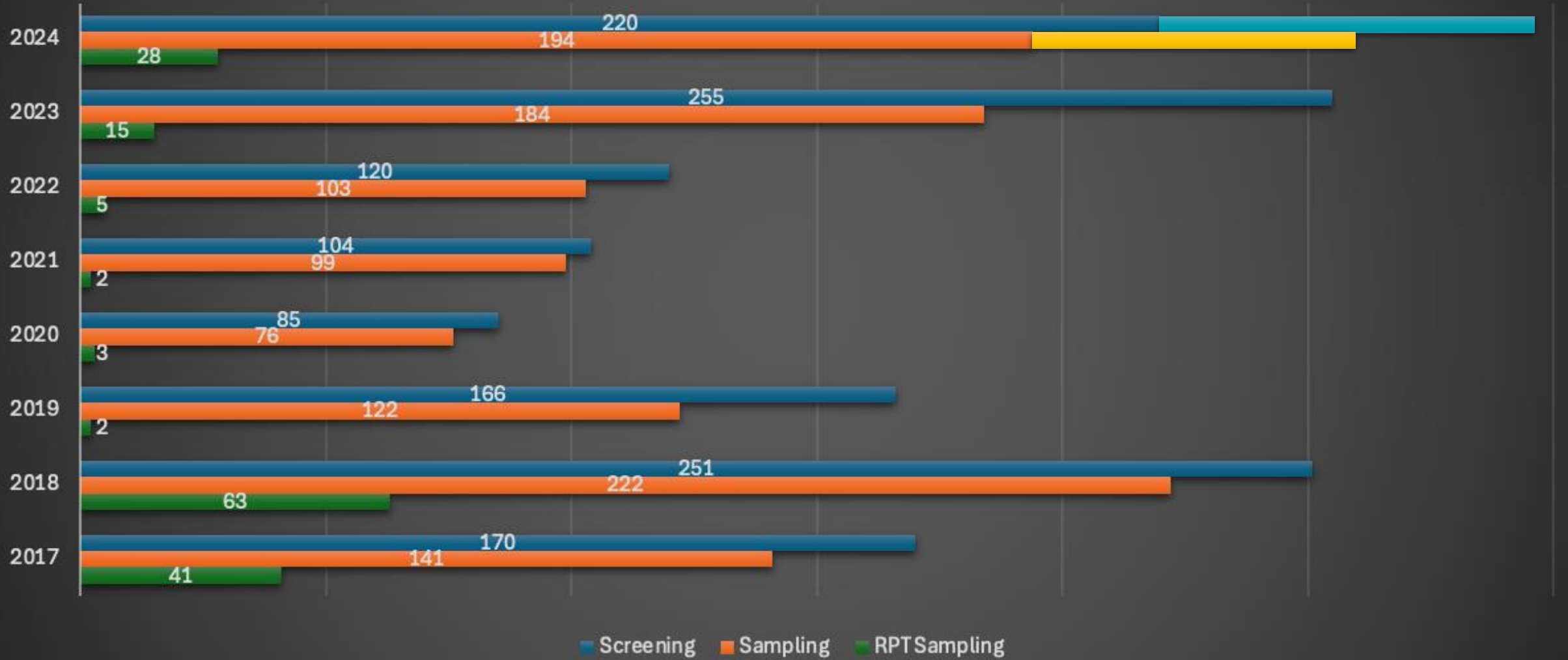
All PM 440

HDClarity AEs

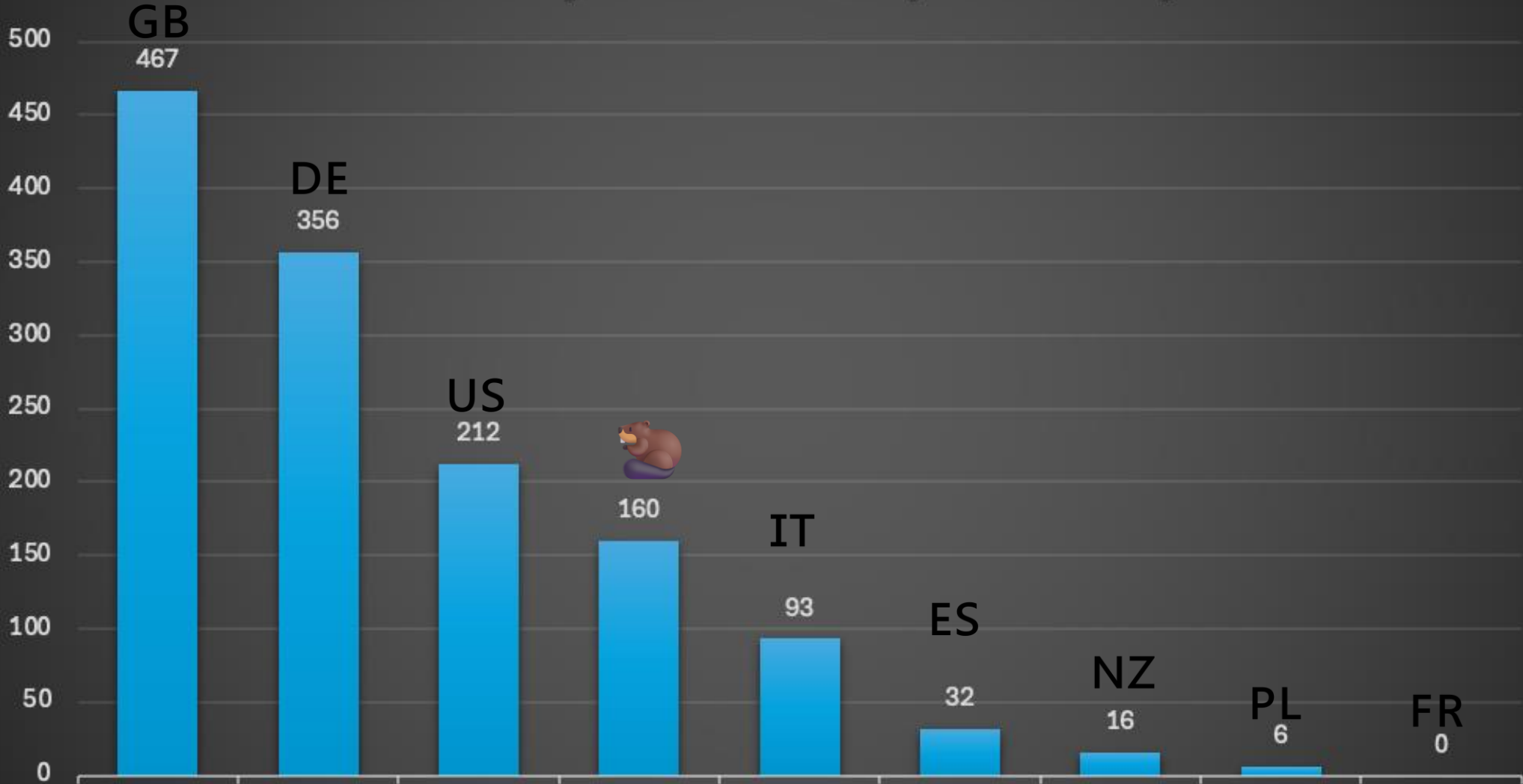


- 14% headache of any severity
- Only 2 SAEs – both headaches leading to blood patch

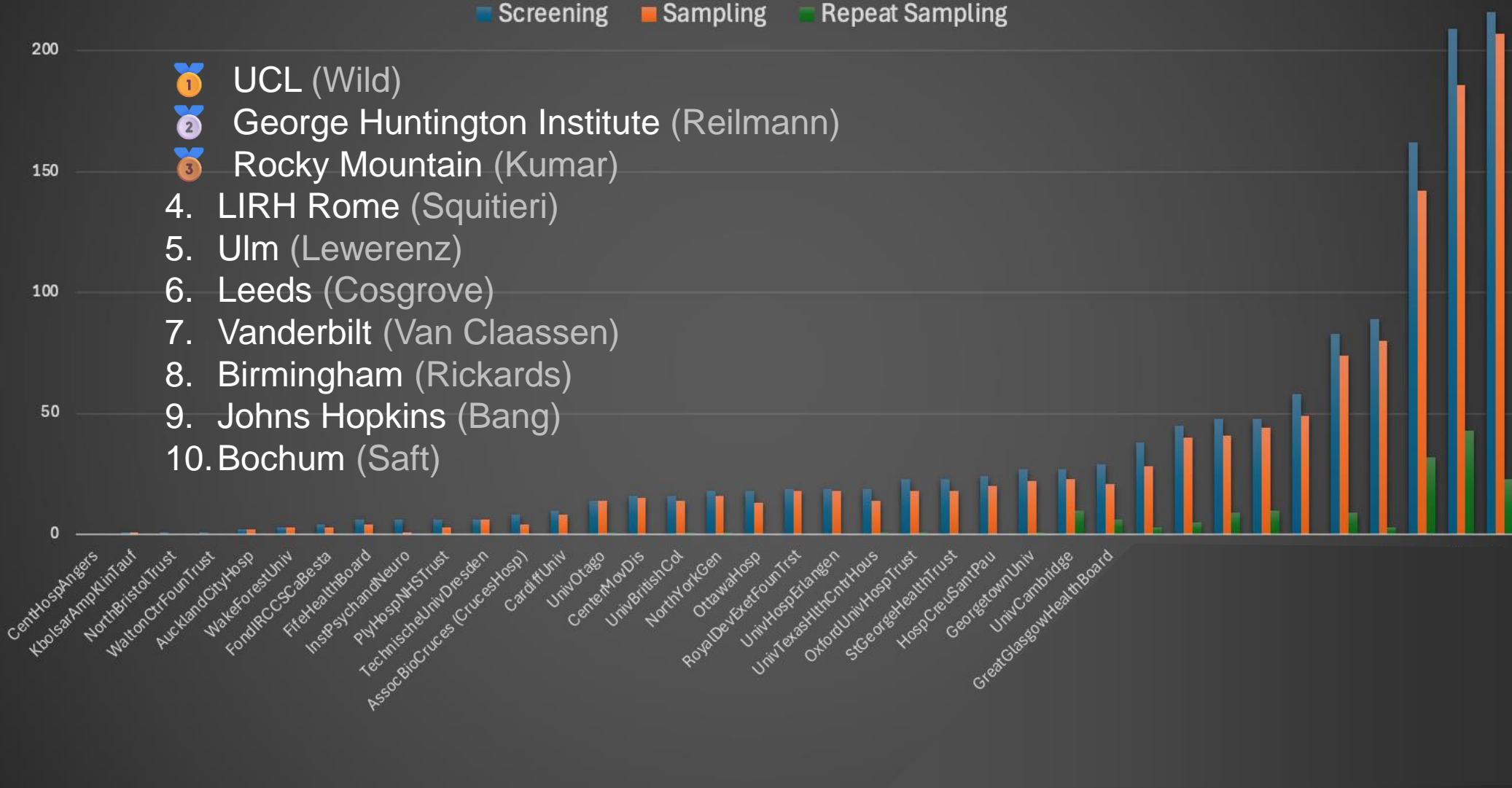
HDClarity Recruitment per Year



HDClarity Recruitment per Country



HDClarity Recruitment per Site



Speedbumps and opportunities

- GDPR 2016-2019
- Covid 2020 – ?
- us HIPPA / indemnity language
- Enroll-HD 2.0
- Remuneration conversations



Aux armes, citoyens!

- Get onto V4 (💰)
- Pls, please remain closely involved in startup activities
- Try to focus on ISS 0-1
- Nail the longitudinal followups
- What small things would make a big difference?
- Beat Ralf



Start time	Duration (min)	Presenter	Title
13:45	15	NA	Rendezvous and refreshments
14:00	15	HDClarity CI Ed Wild UCL	Welcome and HDClarity highlights
14:15	15	Kat Schubert UCL	Study update, frequently asked questions and issues
14:30	15	Hilary Wilkinson CHDI	Biomarkers using <u>HDClarity</u> samples
14:45	15	Ramee Lee CHDI	Cholesterol Metabolites in Huntington's Disease
15:00	15	Jim Rosinski CHDI	Proteomics using <u>HDClarity</u> samples
15:15	15	Break with tea & coffee	
15:30	30	David Rankin, CHDI Gail Owen, UCL Hilary Wilkinson, CHDI Elena Pak, CHDI	CHDI study documents: <ul style="list-style-type: none"> • ICFs and site agreements • PI role in start-up • Generic and regional issues
16:00	15	Break with cheese & wine (available through to 17:30)	
16:15	90	Ed Wild and PI panel	Site-specific experience: <ul style="list-style-type: none"> • Study start-up and participation • Sharing tips and site experiences • Recruitment and retention
17:45			Walk to dinner at Café Library for 6pm start