Validating Patient-Centric Microsampling in Colorectal Cancer

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FACTS & FIGURES

Start date:	November 2024
End date:	April 2028
IHI funding:	3 038 705 €
Industry contribution:	3 477 041 €
Contributing Partners:	300 000 €
Total Cost:	6 815 746 €
Project website:	www.ihi-project-comfort.com
Social media:	LinkedIn @project-comfort ·

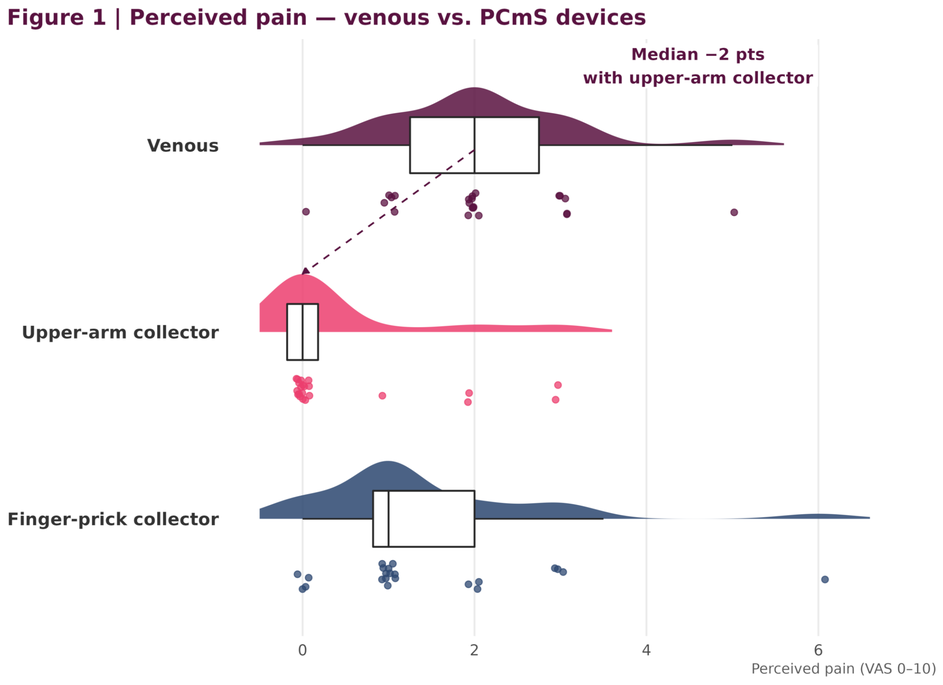
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CHALLENGE

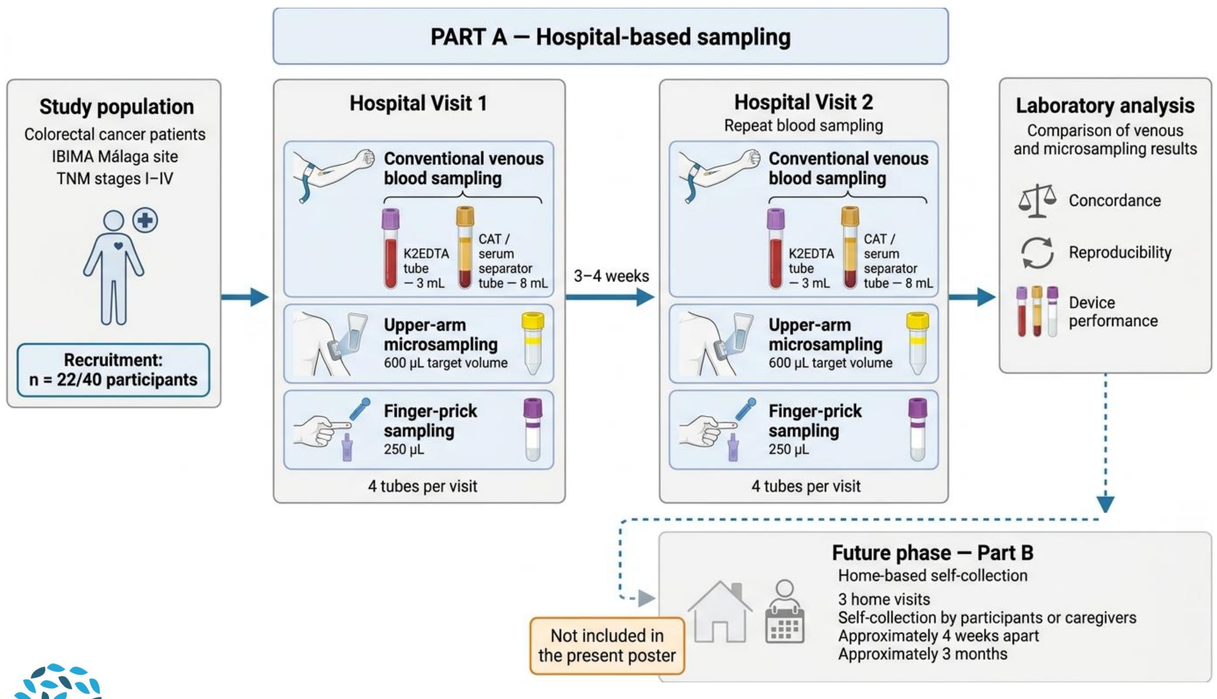
Routine blood testing relies on venipuncture, which can be burdensome for patients with chronic disease, reduced mobility or limited access to healthcare, particularly in oncology. Although patient-centric microsampling (PCmS) offers a less invasive alternative, its reliability in real-world settings remains uncertain.

Our challenge was to test this PCmS approach using two representative devices: an upper-arm collector and a finger-prick collector, in colorectal cancer patients (TNM I–IV), evaluating whether capillary results are equivalent to venous blood and whether patients accept this method as a comfortable alternative to venipuncture.

Figure 1 | Perceived pain — venous vs. PCmS devices



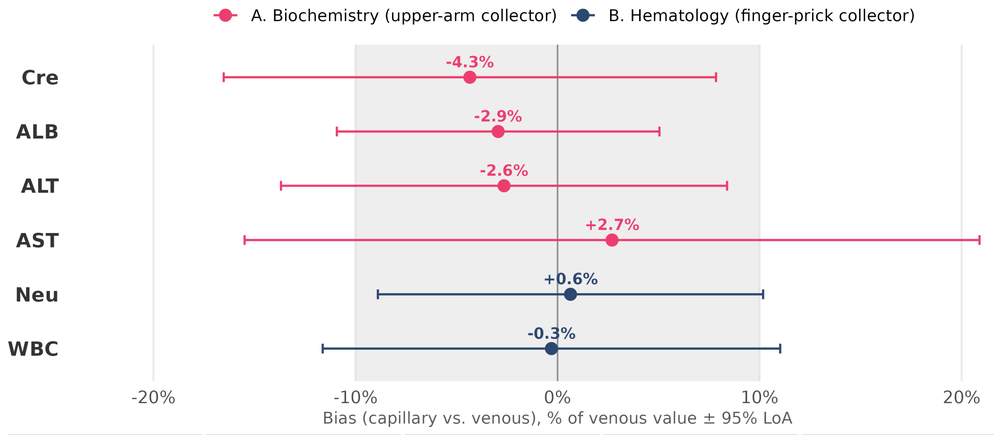
APPROACH & METHODOLOGY



PRELIMINARY RESULTS — PART A ONGOING

Figure 2 | Analytical Concordance

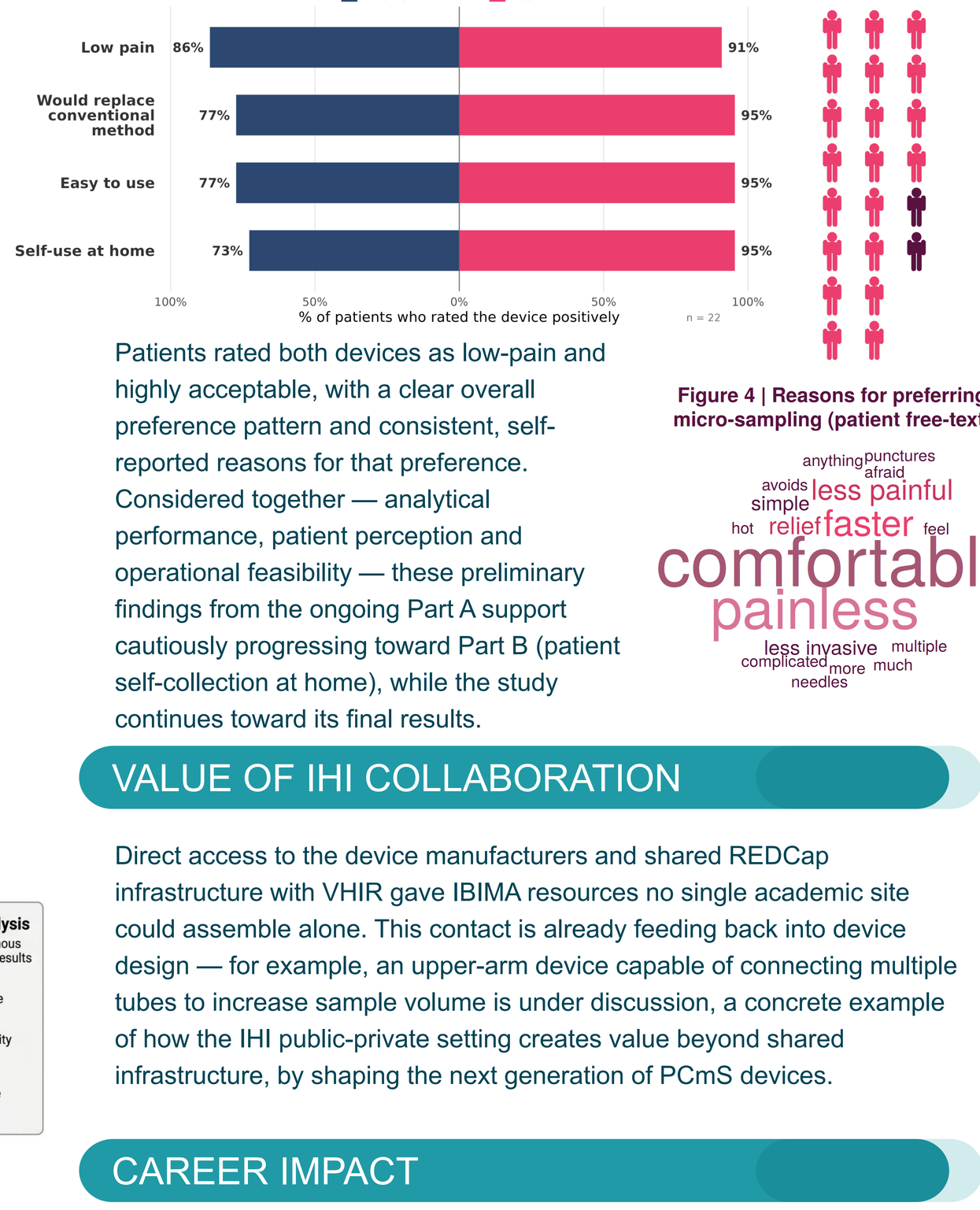
Between-patient and within-patient variance components estimated using Bland–Altman analysis for repeated measurements



Parameter	n	Bias	95% LoA	Bias %
Cre (µmol/L)	22 patients 44 visits	-3.68	[-14.00, 6.64]	-4.3%
ALB (g/L)	22 patients 44 visits	-1.05	[-3.89, 1.80]	-2.9%
ALT (U/L)	22 patients 44 visits	-0.89	[-4.58, 2.81]	-2.6%
AST (U/L)	22 patients 44 visits	0.91	[-5.22, 7.04]	+2.7%
Neu (10^9/L)	21 patients 36 visits	0.03	[-0.36, 0.41]	+0.6%
WBC (10^9/L)	21 patients 36 visits	-0.02	[-0.74, 0.70]	-0.3%

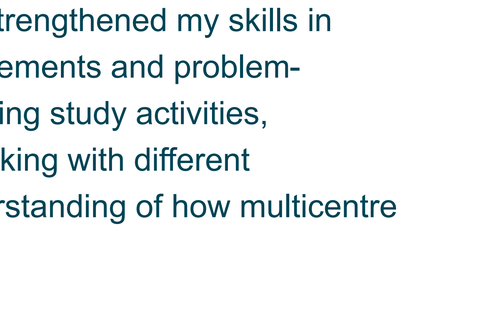
Preliminary data show that concordance between capillary and venous samples was excellent for haematology and acceptable for biochemistry, suggesting PCmS may be a viable alternative for these routine parameters, pending completion of the full study.

Figure 3 | Device acceptability — patient-reported



Patients rated both devices as low-pain and highly acceptable, with a clear overall preference pattern and consistent, self-reported reasons for that preference. Considered together — analytical performance, patient perception and operational feasibility — these preliminary findings from the ongoing Part A support cautiously progressing toward Part B (patient self-collection at home), while the study continues toward its final results.

Figure 4 | Reasons for preferring micro-sampling (patient free-text)



VALUE OF IHI COLLABORATION

Direct access to the device manufacturers and shared REDCap infrastructure with VHIR gave IBIMA resources no single academic site could assemble alone. This contact is already feeding back into device design — for example, an upper-arm device capable of connecting multiple tubes to increase sample volume is under discussion, a concrete example of how the IHI public-private setting creates value beyond shared infrastructure, by shaping the next generation of PCmS devices.

CAREER IMPACT

Working within this public–private consortium strengthened my skills in clinical research organisation, regulatory requirements and problem-solving. I gained practical experience coordinating study activities, addressing implementation challenges and working with different stakeholders, while developing a broader understanding of how multicentre research is organised and delivered.

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