

Integrating trials into routine healthcare: Decision Architecture Randomised Trials (DARTs)

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The problems

Patients and clinicians need to choose between different standard-of-care treatments for the same disease. However, evidence on which is more effective is often lacking.



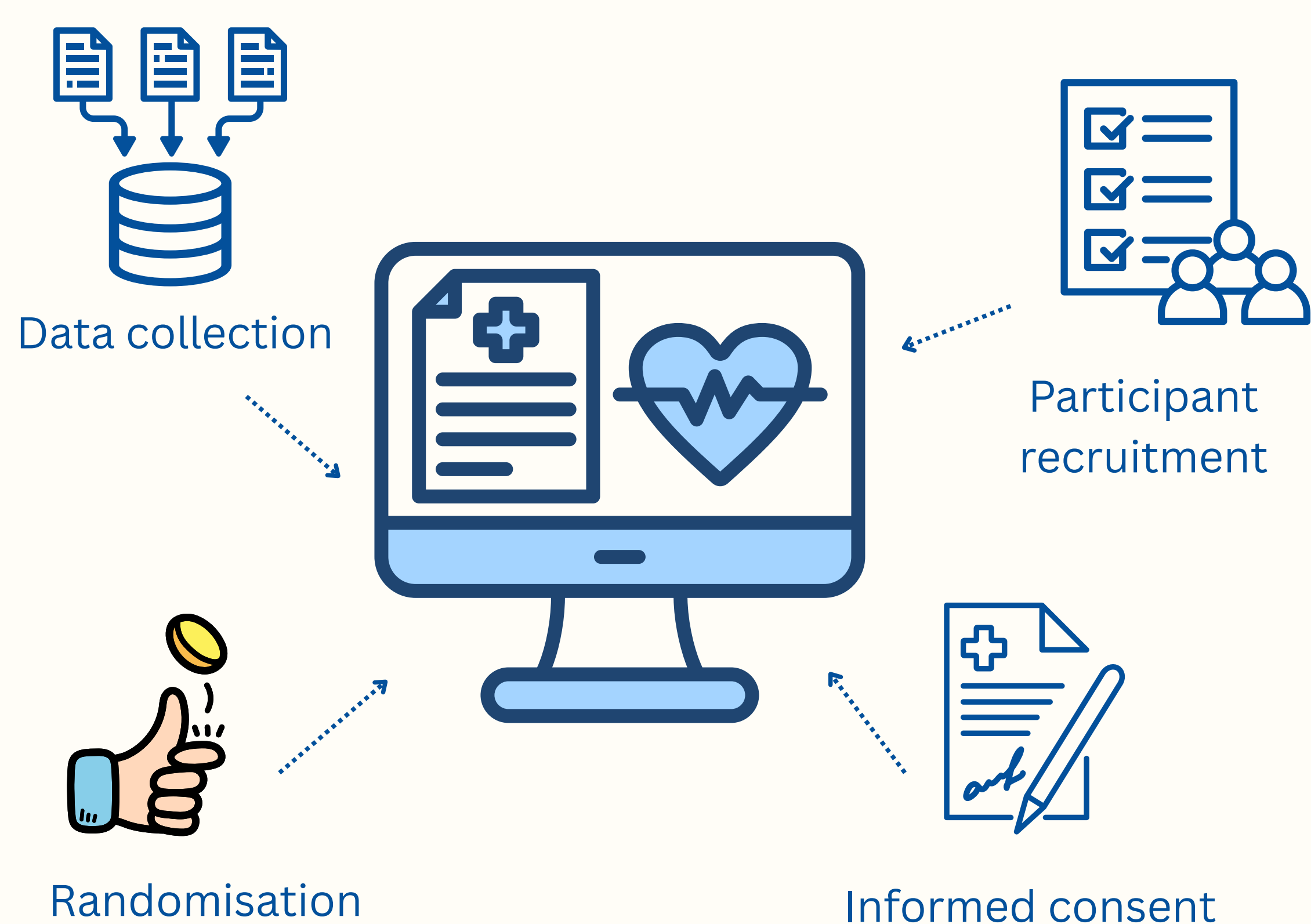
This uncertainty affects patient outcomes, drives variation in practice and reduces cost-effectiveness for health systems.



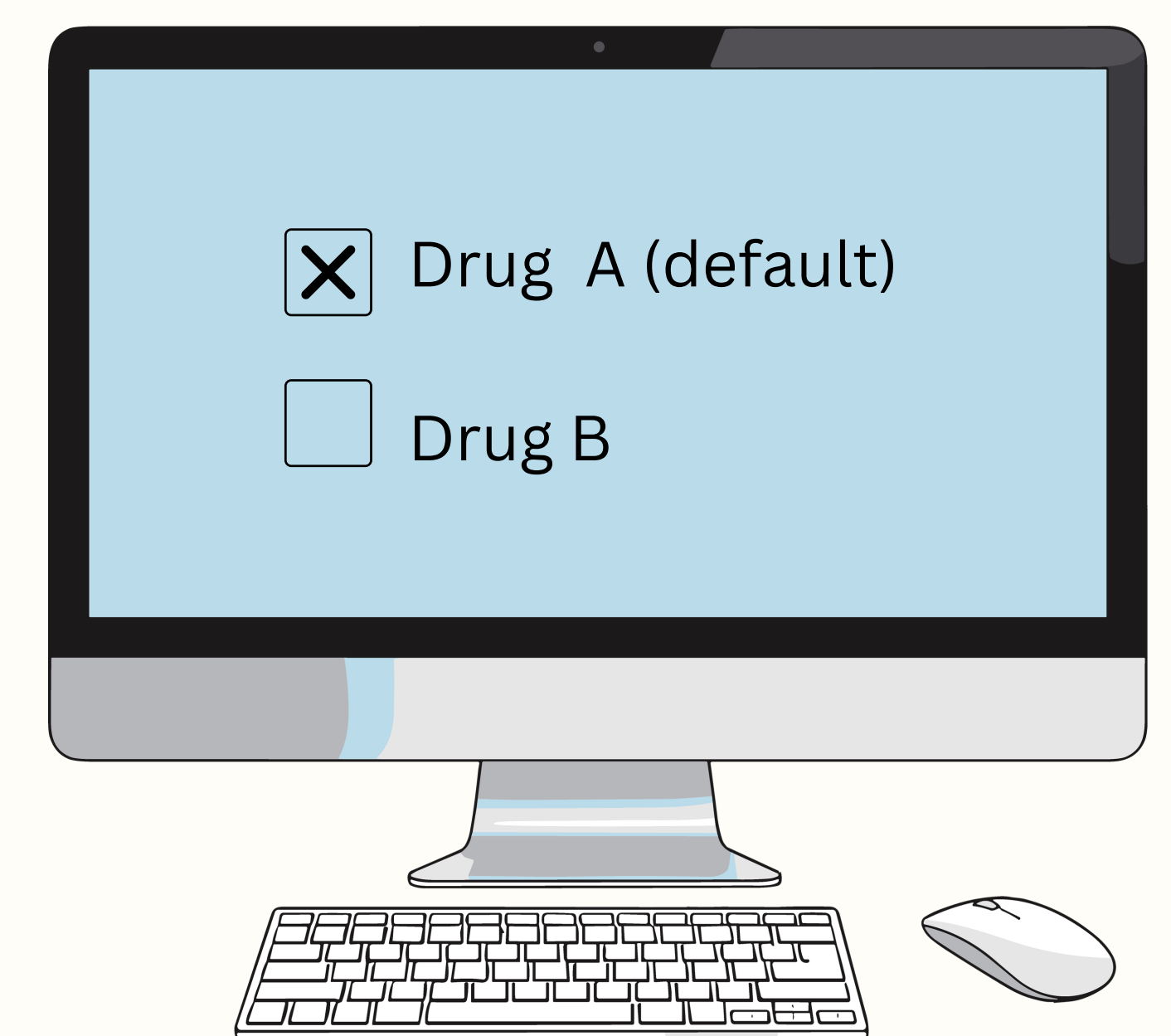
Traditional RCTs provide robust evidence, but are costly, time-consuming, and often disruptive to routine care.



Could the solution be integrating pragmatic trials into Electronic Health Record (EHR) Systems?
Decision Architecture Randomised Trials as the answer?

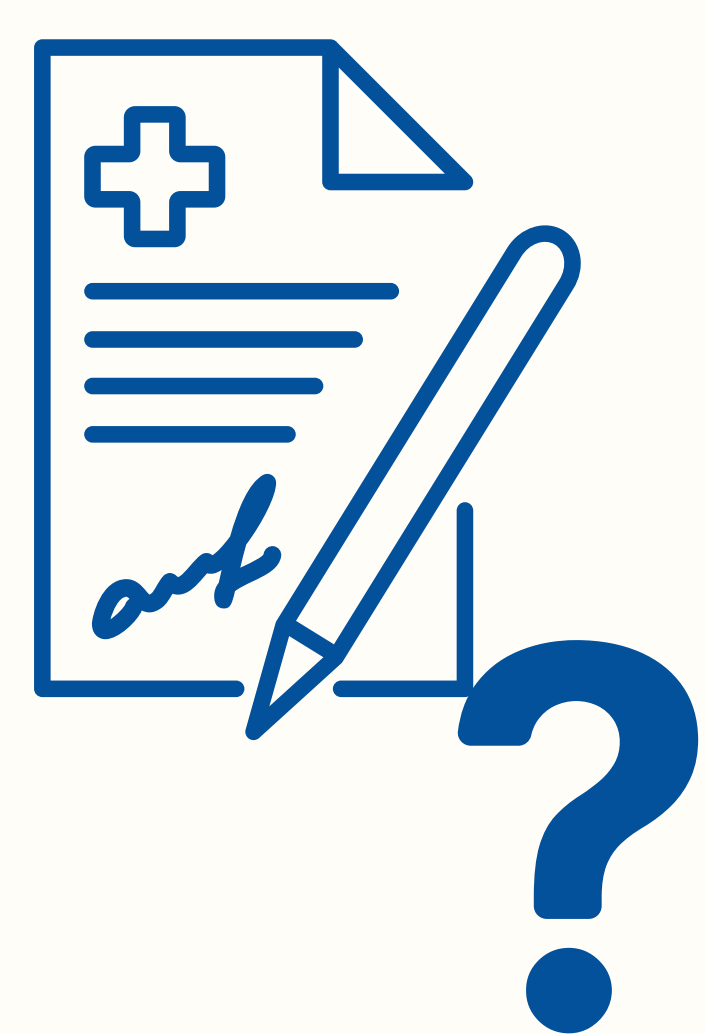


- EHRs have a decision architecture that presents prescribing choices.
- Clinicians often choose the first option (default) that appears on the screen.
- In DARTs, the default option is set randomly.
- This nudges clinicians towards one option, but they can override this default option at any time, preserving clinician and patient autonomy (Flory et al., 2024).



DARTs - highly efficient, technology-enabled trial (Chapman et al., 2026)

DARTs and informed consent?

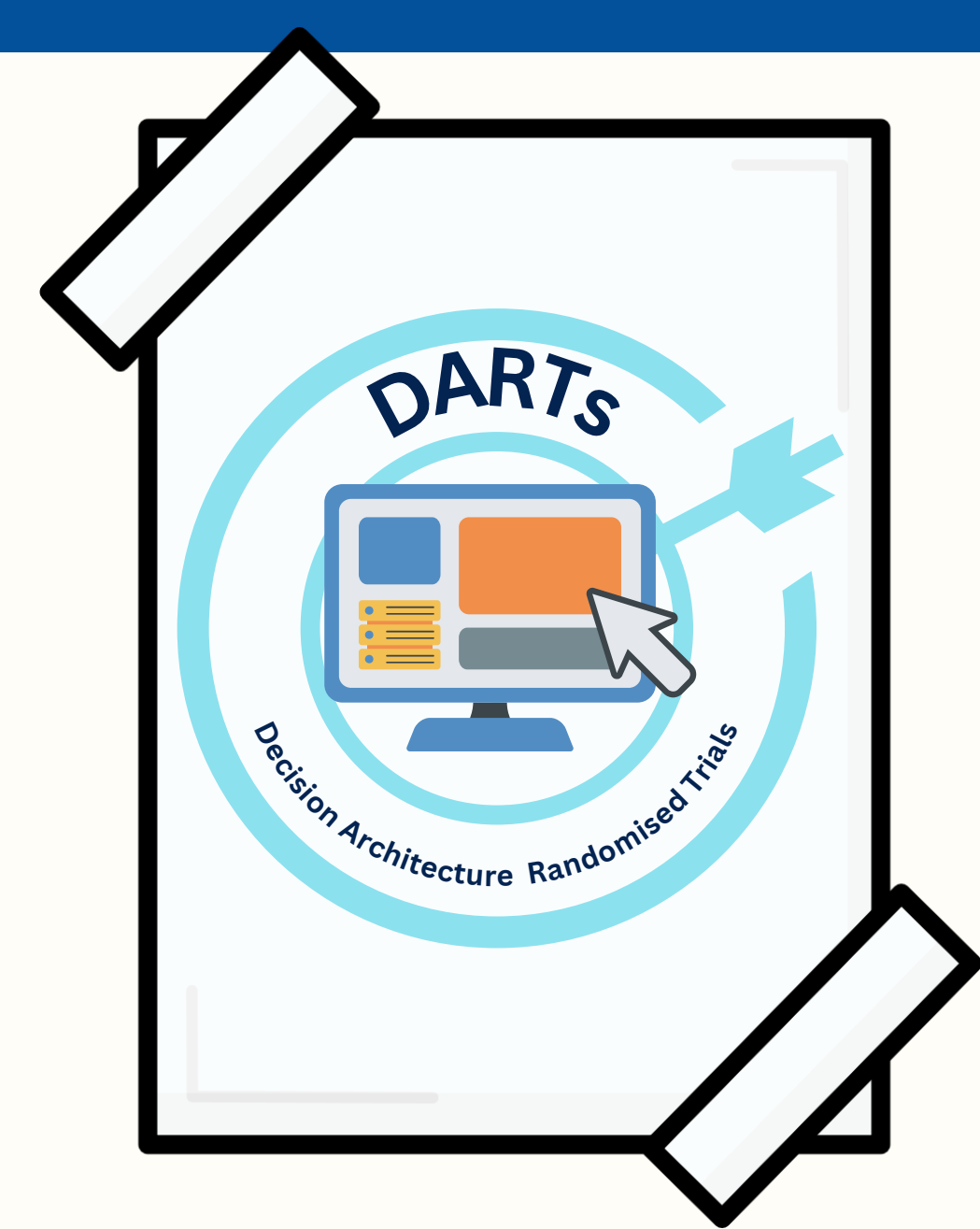


Embedding DARTs within EHR systems makes traditional informed consent impractical (Flory et al., 2024).

Waiver of informed consent has been proposed...



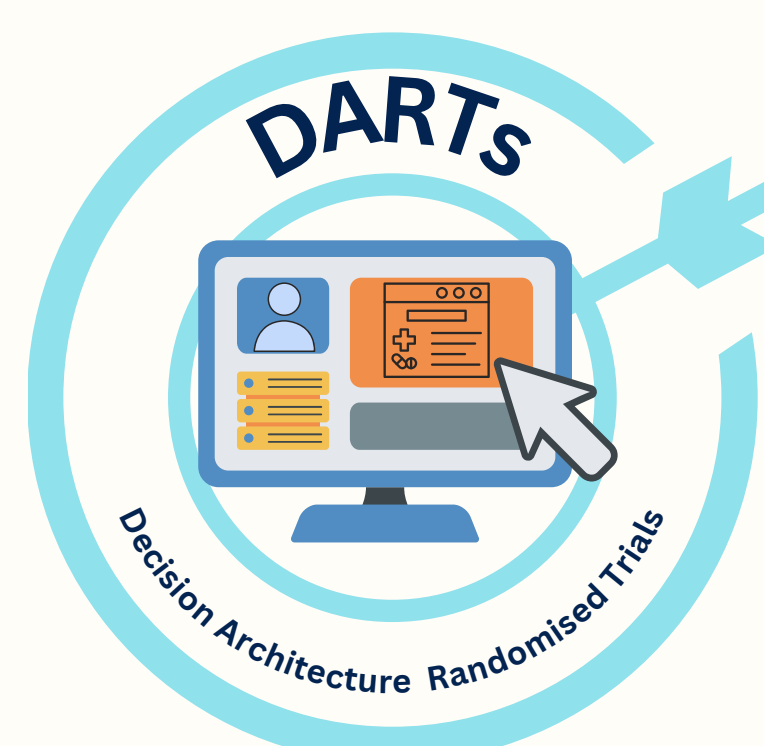
...but deliberative workshops with the public suggests broad notification may be more acceptable



Ongoing DARTs work

- The first DART evaluating peri-operative pain management in mastectomy patients (NCT07308717) **(USA)**.
- A feasibility study is exploring the acceptability and implementation of DARTs in NHS settings **(UK)**.
- A PhD project is exploring publicly legitimate approaches to informed consent using deliberative democracy methods **(UK)**.

Follow our work and latest updates:



We are undertaking interviews to gather perspectives about DARTs. If interested, contact Steve Chapman: s.chapman@leeds.ac.uk for more information.

References:

Chapman SJ, Bisset C, Fowler H, Murray A, Banks J, Kovacs J, et al. (2026). Addressing 'hard-to-fund' research questions in bowel research: Exploring the role of decision architecture randomised trials. Colorectal Dis. <https://doi.org/10.1111/codi.70589>
Flory, J., Ancker, J. S., Kim, S. Y. H., Kuperman, G., & Vickers, A. (2024). Decision architecture randomisation: extremely efficient clinical trials that preserve clinician and patient choice? BMJ Evidence-Based Medicine, 29(2), 71-74. <https://doi.org/10.1136/bmjebm-2023-112386>
Flory, J. et al. (2025). Decision architecture randomization trial of gabapentin for postoperative pain management (NCT07308717).