

Square pegs and round holes!

Overcoming the governance challenges of conducting a cluster-randomised implementation trial in UK-wide general practice

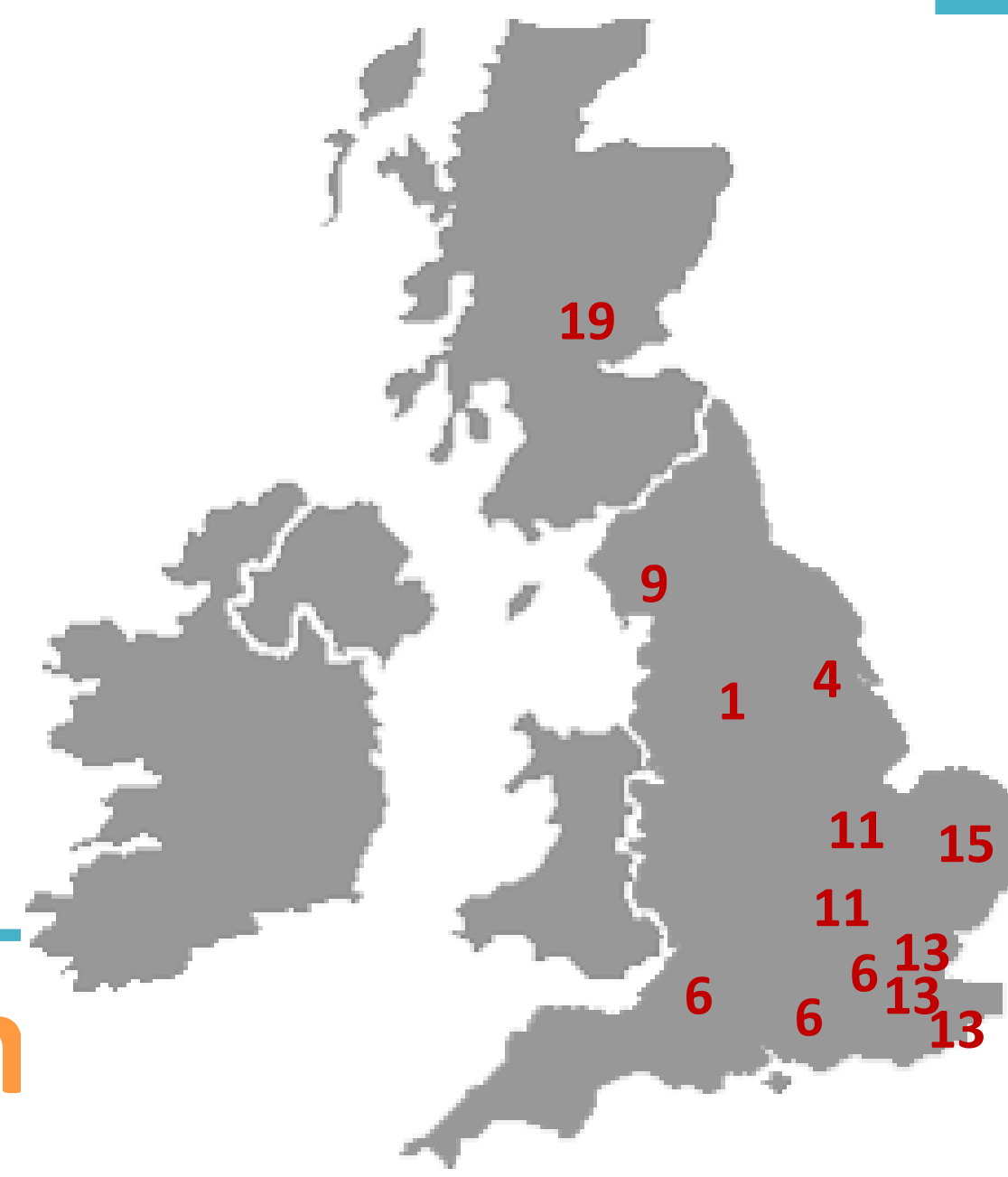
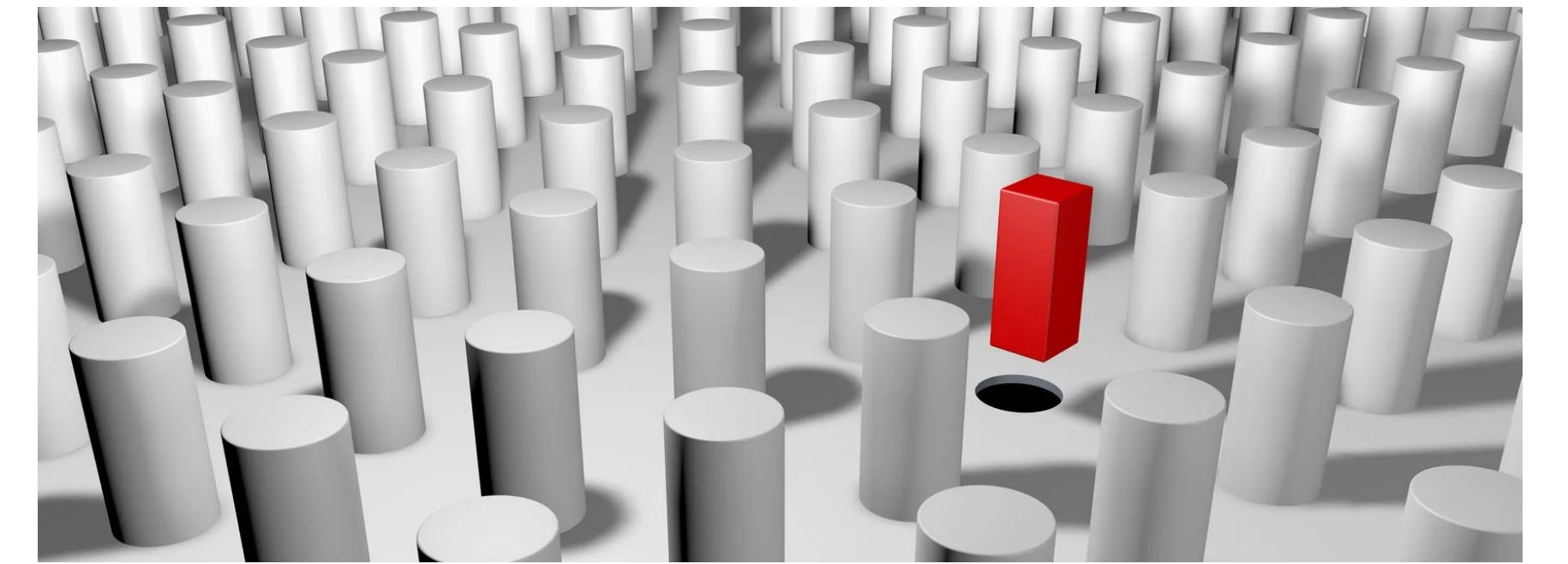
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Aim

To describe the governance challenges of delivering the UK-wide cluster-randomised IMP²ART implementation trial that has ethical and national level governance approval.

Participating general practices in the implementation arm are supported to deliver a multidisciplinary and theoretically-informed strategy to improve implementation of supported self-management. Outcomes are measured using routine data.

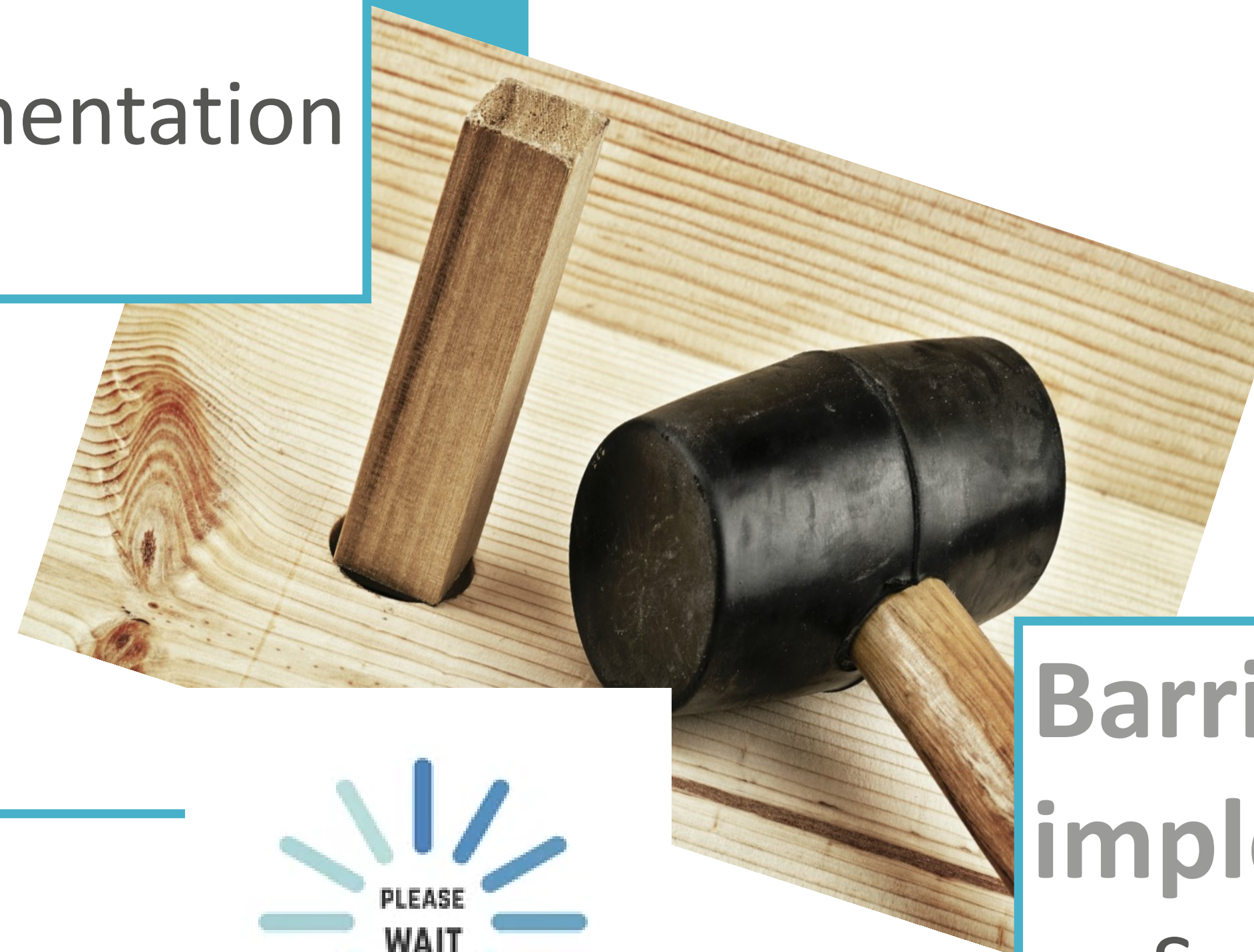


Multiplicity of local govern requirements

- Each local trust had their own, different requirements necessitating customised provision of information
- This duplicated centrally provided documentation which they seemed unable to access.

Is the GP practice a site or a participant?

- National governance (NRS/HRA) classified practices as sites not participants.
- The local information pack required by Trusts to assess 'capacity and capability' of 'sites' was not appropriate necessitating repeated explanations



Diverse interpretation of data protection implications.

- Optimum Patient Care prepared detailed, approved, Data Protection Impact Assessments for secure anonymised data transfers
- Local Health Boards and Data Protection Officers scrutinised, raised queries, and required individual edits
- This delayed (or blocked) practice participation.



Barriers to implementing IT

- Scottish Health Boards manage IT centrally, delaying scheduling set-up until two practices are recruited in their area

Delays risk practice withdrawal.

- These research-related delays add to the challenge of retaining practices' interest in IMP²ART

Recruitment goal: 144 practices across Scotland and England by June 2022

There is a need to recognise research methodologies that do not fit established processes, and develop streamlined, nationally-agreed processes to reduce the current delays and substantial burden in conducting implementation research.



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