



Australian Healthcare and Hospitals Association

ClinTrial Refer Roundtable Report



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Key Messages

Automate

Embed the functionality of ClinTrial Refer in existing general practice software and automate the identification of potential clinical trials.

Engage

Patients need to have greater awareness of the value and purpose of clinical trials and the benefit to them individually of trial participation.

Engagement with general practitioners is required to raise awareness of trial activity, build relationships and demonstrate a value proposition for participation.

Elevate

General practice involvement in research and clinical trials in particular needs a higher profile and higher prestige. It is currently under-valued which is a significant barrier to participation.

Extrapolate

To develop best practice recommendations for embedding clinical trials in the primary healthcare setting, existing success stories should be examined to identify the enablers of success.

Communicate

The practice-based conversation about clinical trials can be initiated by the patient or any member of the team. The conversation needs to be informative, accurate and engaging. The language is critically important.

Australian Clinical Trial Context

Clinical trials provide a range of benefits to the community including:

- Early access to innovative therapy
- Improved overall standards of care
- Improved patient outcomes (treatment and surveillance)
- Clinician retention

Australia, as a clinical trial site, has a number of limitations, some actual and some perceived, including:

- A small and dispersed population
- Dis-economies of scale and administrative inefficiency
- Perception of reducing volume of trials (commercially sponsored)
- Competing trials
- Limited avenues for clinician referral
- Unpredictable participation rates
- More expensive Phase II and III trials

The Australian Commission on Safety and Quality in Health Care has been tasked with developing the National Clinical Trials Governance Framework.

The Australian Government 2017-18 Budget included \$1.3 billion over ten years for a National Health and Medical Industry Growth Plan to improve health outcomes and develop Australia as a global destination for medical sector jobs, research and clinical trials including:

- a \$206M program extension for the Rare Cancers, Rare Disease and Unmet Need program
- \$42M for the International Clinical Trials Collaborations program
- \$7 million Encouraging More Clinical Trials in Australia budget measure over four years to incentivise jurisdictional activities to improve local clinical trial environments

In May 2019, the Australian Healthcare and Hospitals Association's Deeble Institute for Health Policy Research hosted a roundtable discussion with ClinTrialRefer (<https://clintrial.org.au/>), an organisation which aims to connect patients, clinicians and researchers to increase participation in clinical trials research. The roundtable aimed to explore an improved role for general practitioners in clinical trial recruitment and participants included researchers, general practitioners, Primary Health Network leaders and consumers.

World Cafe

Attendees participated in guided discussions using the World Café methodology. This involves participants circulating through a series of facilitated discussions addressing specific questions, each time reviewing and building on the work of the previous group.

The discussions were generally broad ranging and there was overlap in the strategies and opportunities identified at each discussion station.

For simplicity of presentation, where similar strategies were reported at multiple stations these have generally been reported against the question where the discussion was most prominent.

Discussion points have been grouped in three categories:

- Culture – organisational and individual attitudes and behaviours
- Politics – Policy and funding levers that can influence change
- Technology – opportunities to use technology to facilitate better outcomes

Q1: What strategies (technology or organisational) can we implement to support referrals from the GP community to clinical trials?

Technology

The potential for IT solutions to address existing barriers (awareness/time) to GP referrals was a common theme across all discussions.

A series of options/stages to optimise referrals were identified though it was noted that most were dependent on the reliability of data in practice software. However, given the current low referral base, efforts to identify potential participants and trigger conversations between the GP and patient would be beneficial.

Practice targeting

Existing data sets could be data-mined to identify potential research opportunities and determine areas where there are patients either known to, or more likely to, meet trial eligibility criteria. Target trial promotion and education could then be directed to those areas.

Automated screening

Existing practice software system could be enhanced to incorporate clinical trial eligibility screening. Aligning the data fields of practice software with the data fields of ClinTrial Refer would enable automated screening and generation of eligibility alerts in real-time during the consultation.

Retrospective screening

Using the above technology solution would also provide capacity to automatically bulk screen existing patients when a new trial was added to the system. Trial information could be automatically provided to the GP and/or the patient.

Self-screening

Patient generated screening/referral could be achieved through a “patient” version of ClinTrial Refer via an app or via an i-Pad set up in the practice waiting room. The patient could print information about the trial and/or a flag generated in the practice software enabling a conversation during the subsequent appointment.

App amalgamation

Currently the ClinTrial refer app has multiple versions reflecting different disease groups and locations. ClinTrial Refer is releasing a single app with a more robust search/filter function that will enable comprehensive global searching.

Politics

The Practice Incentive Program was identified as a lever to increase referral rates. While PIPs have generally been disease based, the concept is easily adapted to incentivise other activities.

The use of an MBS item number for trial referral was considered somewhat blunt and out-dated by some participants; however others felt that there was merit in supporting research participation via an MBS item.

There is potential for Pharma and Trial sponsors to provide payments/incentives for referrals, however this may be cost-prohibitive for smaller scale trials and could generate conflict of interest concerns.

Culture

There is significant opportunity to increase awareness of the ClinTrial refer app to both GPs, researchers and the community – either through direct promotion or as part of existing CPD programs.

Promotion of CT participation to patients appears very limited currently despite the reliance on clinical trials to develop the medications and treatments that GPs routinely prescribe for their patients. Promotion could range from small scale waiting room posters to large-scale high-profile marketing campaigns funded by a big pharma coalition.

The role of PHNs in data collection and reporting, and supporting practice improvement positions them to influence and encourage clinical trial referral.

Examples were given of regionalised support mechanisms to engage GPs and encourage referrals. There is potential for PHNs to leverage their existing access to practice data, links with the acute sector and general practice to identify clinical trials relevant to the needs of their communities and engage and connect GPs with this information. Opportunities for GP-led clinical trials should also be considered.

The capacity to enhance coverage of research processes and trial activity in the medical and GP curriculum was considered but the already crowded curriculum was acknowledged.

Generating additional recognition and acknowledgement of clinical trial participation and referral in the practice accreditation system may be beneficial and relatively straightforward.

There was a view that clinical trials could be a threat to the general practice, in that patients that were referred to a clinical trial would be lost to the practice. It needs to be determined to what extent this occurs and an appropriate response developed. If patients continue to receive care from the general practice this should be communicated. If this is not the case an alternate value proposition should be communicated e.g similar to referral to a specialist.

Q2: How can ClinTrial Refer be integrated into the primary health care setting to support GPs and their patients with access to current clinical trials?

Culture

Discussion was primarily focused on actions that would support an increased culture of support and involvement in clinical trials.

While not specifically defined, the importance of formulating a coherent and communicable value proposition was discussed.

In order for ClinTrial Refer to be seen as a valuable tool, there needs to be a stronger recognition of the value of participation in clinical trials. The efficacy of ClinTrial Refer as a tool is of little relevance if the output of the tool (referral to a clinical trial) is not valued.

To this end, GP participation in clinical trials needs to be elevated in importance, impact and prestige. Multi-centre randomised control trials at high-profile hospitals, universities and research centres grab the headlines but the contribution of general practice to these programs and research conducted in the primary health setting is rarely visible.

Involving GPs as Co-Investigators, engaged in the codesign of research, should be prioritised.

The establishment of general practice research centres was proposed with the potential to engage Advanced Health Research and Translation Centres.

The existing PHN structure has potential to support an increased focus and engagement of general practice in research activities including clinical trials. The establishment of research coordination and support positions at the PHN level would complement existing practice support structures.

Further encouragement for general practice involvement could be achieved through the development of CPD programs to educate GPs and demystify the clinical trial process. The awarding of CPD points for referral of patients to clinical trials could be a powerful incentive.

Technology

Again the integration of clinical trial opportunities within existing practice software was considered both an imperative and also a relatively straightforward step.

Q3: What are the best practice recommendations for embedding clinical trials in the primary healthcare setting to facilitate referral, recruitment and awareness?

Before best practice recommendations can be made, there is a need to further explore the barriers and enablers to greater participation by general practice in clinical trials

Enablers could be identified by reviewing existing exemplar programs and projects identified by participants.

These included:

- ASPREE (ASpirin in Reducing Events in the Elderly) study which ran over 8 years and recruited around 18,000 community living people primarily through general practice.
- University of the Sunshine Coast Clinical Trials Centre which includes study coordinators supporting primary care researchers and provide training and certification
- AusTrials which provides a study coordinator and training for GPs working in 12 corporate general practices across Australia.

Reviewing other current or recent clinical trials which have been successful in recruiting large numbers of participants and/or receiving referrals from a broad range of sources would provide further insights to support the development of best practice guidelines.

There is further potential to engage with untapped or under-represented areas of general practice including regional and rural areas.

Q4: How does/should the conversation start about clinical trials in general practice?

Culture

The conversation regarding participation in clinical trials can be initiated by the patient or any member of the practice team.

There was a strong push for greater involvement of the patient (and their family/carers) in the conversation. The ability for the patient to access information about relevant trials would support the patient initiating the conversation or being better prepared if the conversation is initiated by someone else.

Regardless of who initiates the conversation it must be a collaborative partnership.

The value for the individual patient and the community should be the focus of the conversation.

There were concerns that clinical trials can be viewed as a last resort option. The use of positive patient stories could both reduce this perception and be a more relatable medium for patients.

For the conversations to be effective and informative, clinicians need to be well informed about the trial. While documentation providing plain English explanations are now more routine there is still room for improvement and could be expanded to include plain English conversation starters.

The term Clinical Trial also has connotations of risk that may not be commensurate with the actual risk. Offering the patient the opportunity to participate in a Research Project may be less intimidating than a Clinical Trial.

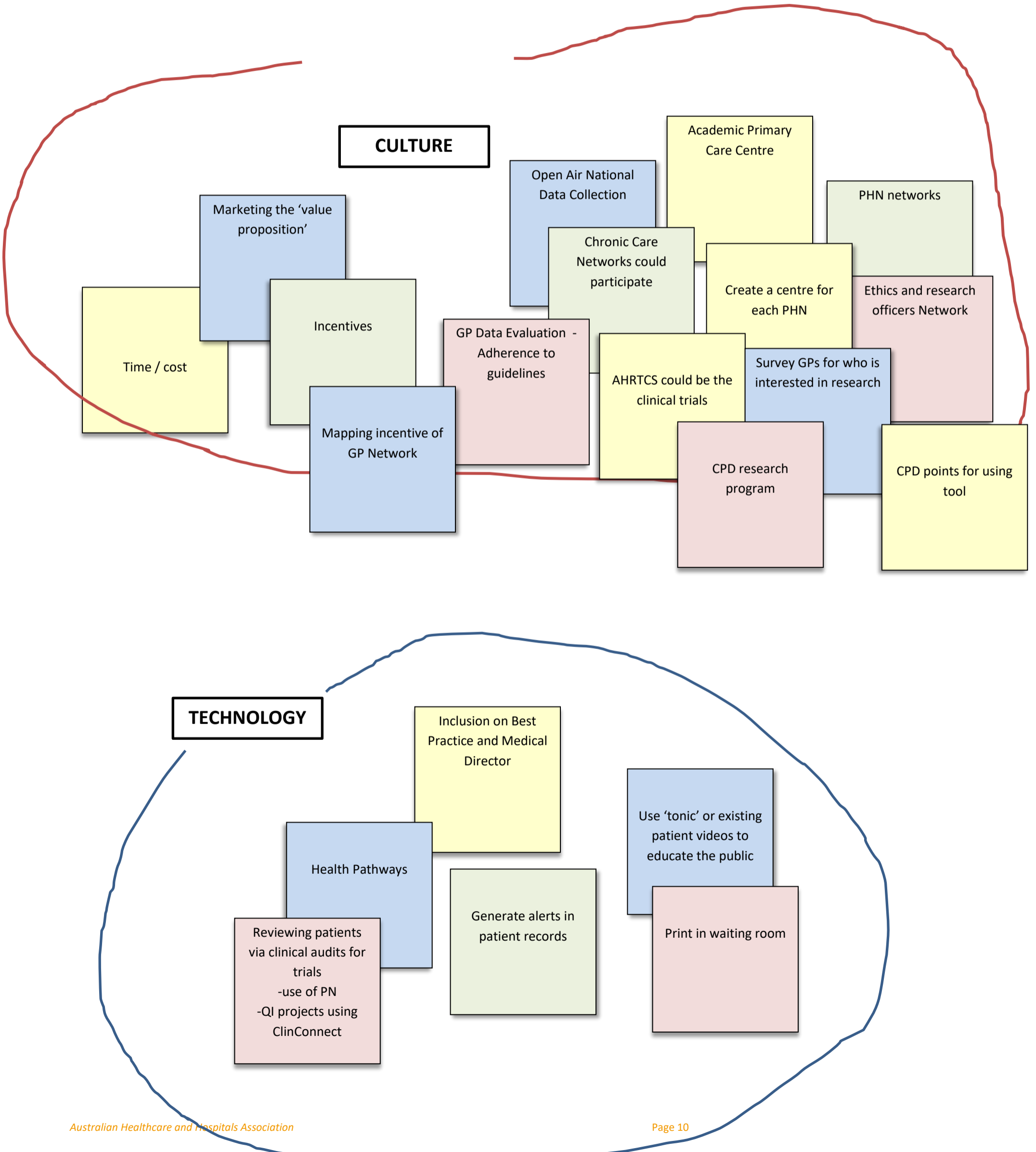
Advocacy groups and peak bodies should be engaged to raise awareness about participation in research trials. A coordinated effort to highlight the role of trial participants could be undertaken as part of National Volunteers Day.

World Café Virtual Post-its

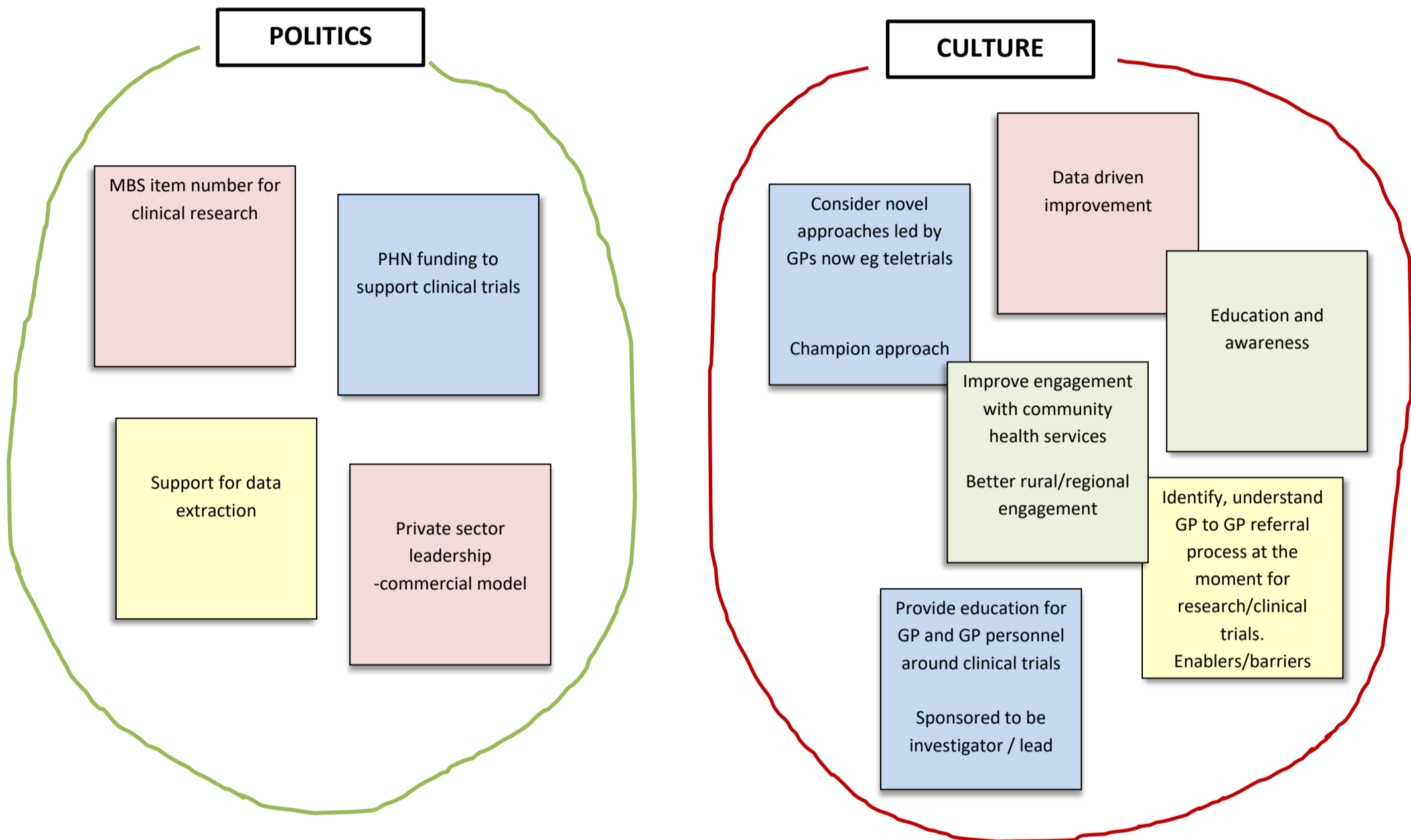
What strategies (technology or organisational) can we implement to support referrals from the GP community to clinical trials?



How can ClinTrial Refer be integrated into the Primary healthcare setting to support GPs and the patients with access to current clinical trials?



What are the best practice recommendations for embedding clinical trials in the primary healthcare setting facilitate referral, recruitment and awareness?



How does/should the conversation start about clinical trials in general practice?

