GREET PROJECT

Guidance to Recruitment: Examining Experiences at clinical Trial sites

Clinical Trial Site Recruitment Survey Report for
Site Staff and Sponsors

February 2020

Introduction

Research sites across Australia often experience difficulties in meeting study recruitment targets in terms of participant numbers and/or time frames. This is a common problem across all research sites. Inadequate clinical trial recruitment increases the cost of conducting clinical trials as more time is required to meet recruitment targets. There are delays in the development of new therapies or worse trials do not meet required targets and therefore strong conclusions are unable to be drawn due to a lack of statistical power.

An increase in participation rates in clinical trials coupled with a reduction in recruitment periods will ensure studies are completed as planned, on time and on budget and that Australia remains a competitive partner on the international stage.

This project, **G**uidance to **R**ecruitment: **E**xamining **E**xperiences at clinical **T**rial sites (**GREET**), is an initiative of CT:IQ (Clinical Trials: Impact & Quality). CT:IQ is a collaborative group of stakeholders from across the clinical trials sector, with a mission to develop and implement recommendations that will improve the impact, quality and efficiency of clinical trials, leading to more rapid, lower cost and higher quality evaluation of healthcare interventions in Australia. CT:IQ aims to act as a platform for all stakeholder voices to come together and continually improve the clinical trials field in Australia, enabling efficient and effective, participant-centred, clinical trials.

The GREET project was conducted to understand the barriers to clinical trial recruitment at the site level and issue recommendations for optimising recruitment which are broadly applicable and translational at the site level, leading to increased/optimised recruitment. Two surveys were developed, one for sites/sponsors and one for consumers. This report looks at the sites/sponsor survey. There is a separate report that looks at the consumer/community survey.

The aims of the surveys were to:

1. Identify the perceptions of barriers and solutions to clinical trial site recruitment among research sites/sponsors/CROs.
2. Identify the perceptions of barriers and solutions to clinical trial recruitment in consumers and participants.
3. Provide quantitative and qualitative data to inform the development of best practice recommendations and tools to assist sites/sponsors in clinical trial recruitment.

Methods

An online survey was developed by the CT:IQ GREET working group to explore the barriers and enablers to recruitment from the perspective of staff that work at research sites and sponsor organisations.

The survey was ethically approved by the Macquarie University Medical and Health Sciences Subcommittee, Ethics Approval Reference No: 52019576410973, Project ID: 5764.

The survey was distributed via industry groups/associations as well as through the networks of the project team and via social media. Examples of some of the groups the survey was sent to with a request to distribute include:

- Medicines Australia
- MTAA (Medical Technology Association of Australia)
- ACTA
- Bellberry
- SCRS
- ARCS
- WAHTN (West Australian Health Translation Network)
- ANGGOG (ANZ Gynaecological Oncology Group)
- ClinTrial Refer via newsletter

The survey was conducted using REDCap, a secure web application for building and managing online surveys and databases. Respondents were invited to complete a short online survey about their experience and views of clinical trial recruitment. The first page of the survey contained details of the study, privacy and confidentiality; a copy of this page can be found in Appendix 1. A PDF copy of the full survey is available to download.

The survey took approximately 10-20 minutes to complete. The online survey was open for a three-week period during November 2019.

SAS version 9.4, a powerful statistical software package, was used to retrieve, report and analyse survey data. Qualitative data was summarised by identifying themes from the free text fields. Quantitative data was summarised as frequencies and percentages, the denominators were defined as the number of responders who answered the question. Missing data were assumed to be missing at random and no methods to adjust for missingness due to survey attrition were applied.

This report provides the data, results and any free text comments from the sites/sponsor survey. This survey report was used to help inform the recommendations produced from the GREET project.

Results

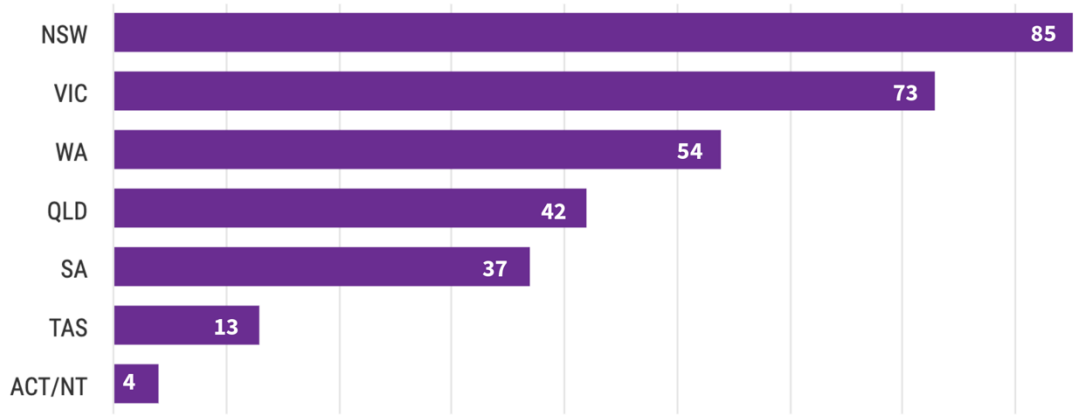
Number of responses

There were 343 respondents that consented and commenced the survey however this denominator changed as not all respondents provided responses to all questions asked.

The target number of responses for the survey was 200 respondents to enable a representative sample. The survey response numbers achieved were 171% of the target.

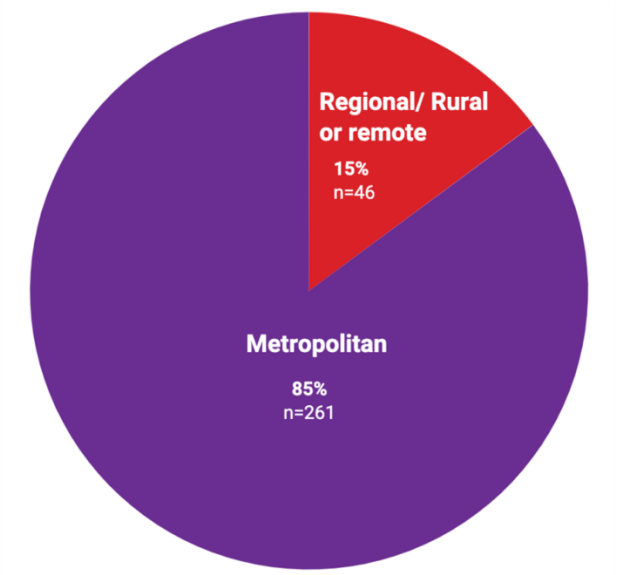
Demographics – who responded?

1. In which state of Australia do you mostly work? n=308



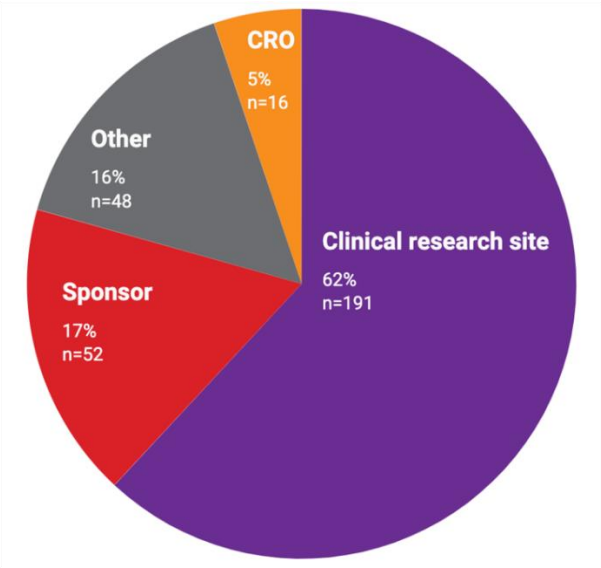
All states and territories were represented in the survey. Over half of the respondents (51.29%, n=158) were from New South Wales (27.59%, n=85) and Victoria (23.70%, n=73).

2. Do you live in a metropolitan, regional, rural or remote area? n = 307



The majority of respondents (85.01%, n= 261) worked in the metropolitan setting.

3. Which of the following best describes your organisation? n=307



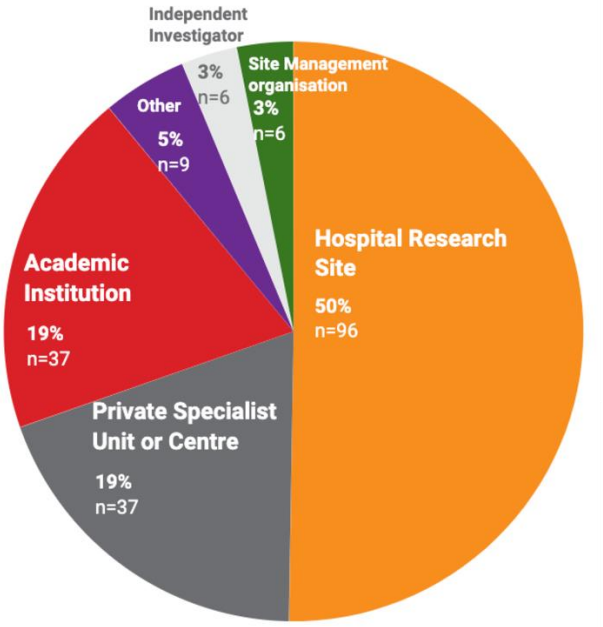
Nearly two thirds of respondents worked at clinical research sites (62.22%, n=191).

There were 48 responses provided in response to "Other", these verbatim responses can be found in Appendix 2. These "Other" responses can be themed under the following headings:

- Health Service
- GP
- Consumer Groups
- Tertiary Centres
- HREC Committee
- Government Department
- Research Organisation

The next 3 questions further break down the responses from the Clinical Research Site, Sponsor and Other groups.

4. Classify what best describes the type of clinical research recruitment site you represent? n=191



The three main clinical research sites that were represented are hospital research sites (50.26%, n=96); private specialist units (19.37%, n=37) and academic institutions (19.37%, n=37). There were eight free text responses provided in response to "Other". These are not included in this report as they are potentially identifiable.

5. What best describes your role within your organisation at your clinical research site? n=191

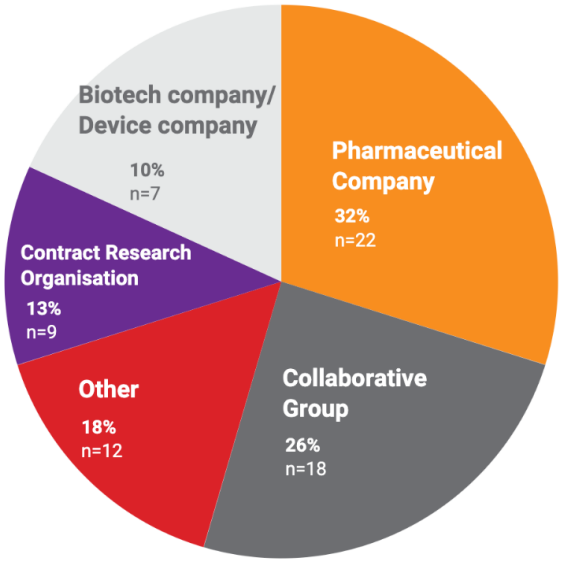
The main roles performed within the clinical research sites include Clinical Trial Co-coordinator (n=70, 36.65%); Investigator or Sub Investigator (n=41, 21.47%) and Clinical Trial Manager (n=40, 20.94%).

In response to "Other" 11 respondents provided a free text response. These included:

- Clinical Research Coordinator
- Ethics
- Laboratory Manager
- Research Data Manager
- Research Nurse

- Research Development
- Start-up Lead
- Pharmacist
- Administration

6. Classify what type of sponsor group you represent n=68

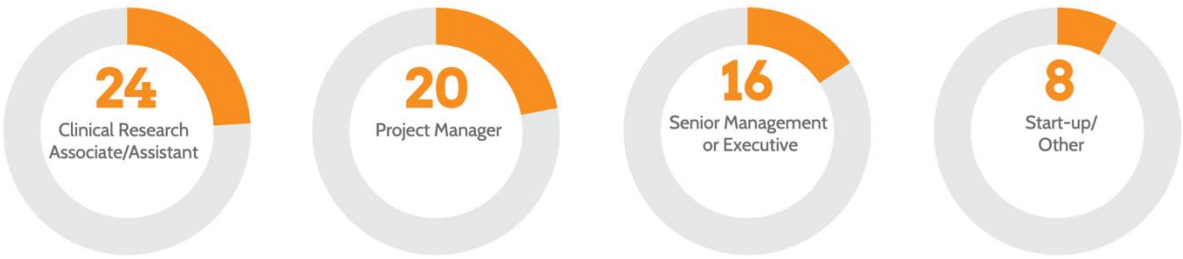


The main sponsor groups represented include pharmaceutical companies (n= 22, 32.35%); collaborative groups (n=18, 26.47%) and other (n=12, 17.64%).

In response to "Other", 12 respondents provided a free text response. These included:

- Not for profit
- Research/Academic Institute
- University
- ARO
- Not for profit organisation
- Non-pharma companies
- Nutraceutical

7. What best describes your role in your Sponsor/CRO organisation? n=68



The roles within sponsor organisations include clinical research associate (n=24, 35.29%); project management (n=20, 29.41%) and senior management (23.53%, n=16).

8. What best describes your role in your "Other" organisation. n = 48

For those that selected "Other" as their type of organisation (not a clinical research site, CRO or sponsor) in response to the question "What is your role in your organisation?", the top three responses for their role in their organisation were:

- Project Manager (n=13);
- Trials Coordinator (n=10) and
- Academic (n=5).

There were 48 responses provided in response to this question, these verbatim responses can be found in Appendix 3.

Demographic Information Summary

The above demographic questions show that the survey was representative across the different demographic groups. The survey results in the following sections represent responses from all survey respondents. The analysis has not been conducted by demographic subgroup.

9. BARRIERS to site recruitment (n=280)

The survey listed 24 identified barriers to site recruitment.

280 respondents entered the barriers section of the survey, ranking the following identified barriers from "Very Significant Barrier", "Moderate Barrier", "Minor Barrier" to "Not a Barrier at All" or "Not Applicable for me to respond" on a Likert scale.

The following table ranks the barriers based on the % or respondents that rated the barrier as either "Very Significant" or "Moderately Significant".

9a. Have we missed any barriers? n=70

Seventy respondents provided a free text response. The majority of these responses were compatible with the 24 barriers to site recruitment provided as part of the survey. The verbatim responses can be found in Appendix 4. In addition to the predetermined barriers the following additional barriers were identified from theming the free text responses provided:

- Culture of research within an organisation (n=8)
- Sponsor related barriers (n=6)
- Advertising (n=4)
- Language other than English (n=4)
- Participant experience (n=3)
- Site related barriers (n=3)

10. ENABLERS to site recruitment (n=255)

The survey listed 12 potential enablers to site recruitment.

255 respondents entered the enablers section of the survey, ranking the following identified enablers from "Very Important", "Moderately Important", "Somewhat Important", "Not Important" or "Not Applicable for me to respond" on a Likert scale.

The following table ranks the enablers based on the % or respondents that rated the enabler as either "Very Important" or "Moderately Important".

10a. Have we missed any enablers? n=43

Forty-three respondents provided a free text response in relation to this question. All the responses are contained in Appendix 5.

In addition to the twelve predetermined enablers that were provided as part of the survey the following enablers were identified from theming the free text responses provided:

- Sponsor (n=8)
- Increased awareness (n=7)
- Site Resources (n=6)
- Consumer engagement and support (n=3)

11. What site recruitment initiatives have worked well for you?

There were 168 free text responses provided in response to this question, these can be found in Appendix 6. These responses were themed under the following headings:

The following provides a little more detail of each of these key themes, with the full comments available in Appendix 6:

- Accurate Feasibilities - conducted before accepting the trial.
- Having Good Recruitment Strategies in place – that are resourced/funded, including things such as GP involvement, Multi-Disciplinary Team meeting attendance, use of professional recruitment services, daily pre-screening/screening of potential participants, patient registry, incentives, dedicated team member responsible for recruitment.
- Good Communication – within sites, with CRO and sponsor. Suggestions include weekly meetings, use of apps, proactive investigators (the engagement and active involvement of the PI was a key theme throughout the feedback).
- Successful Education/Engagement - with consumers and community.
- Effective Targeted Advertising – social media; TV; radio, blogs, Facebook.
- Participant Focussed – considering things such as home visits, adequate reimbursement, medical follow up, simpler participant information and consent forms, waiver of consent, language other than English, absence of placebo, flexible protocol.
- Ethics – quick turnaround and getting more assistance.

12. What site recruitment initiatives have not worked well for you (through personal experience or you have seen/heard about)?

There were 143 free text responses received in response to this question, these can be found in Appendix 7. These responses were themed under the following headings:

The following provides a little more detail of each of these key themes, with the full comments available in Appendix 7:

- Inadequate Staff Resourcing – staff overwhelmed by their clinical workload, staff not engaged with the trial, inexperienced site, investigators not engaged, relying on investigators to do all the recruitment activity.
- Inflexible protocol – very tight inclusion/exclusion criteria.
- Inefficient Ethics Processes delay recruitment - excessive length of time, number of amendments.
- Poor Recruitment strategies – including things such as impersonal approaches, not having effective pre-screening processes, ineffective use of databases, external recruitment agencies hadn't worked.
- Ineffective Advertising – social media, TV, radio, paper, blogs, flyers and third party vendors all have varying degrees of success, often advertising is not targeted effectively so get either no leads or too many, most of which don't meet inclusion/exclusion criteria and therefore just cause a drain on staff resources.
- Relying Solely on Clinician Referral without being proactive in other recruitment methods. Clinicians often are too busy, too protective, too slow or don't see clinical trials as a treatment option for their patients.

13. What other ideas do you have as to how sites could improve recruitment into clinical trials that haven't already been mentioned?

There were 96 free text responses received in response to this question, these can be found in Appendix 8. These responses were themed under the following headings:

Some examples within each of these themes are:

- Advertising – using social media; TV; radio, blogs, Facebook.
- Better collaboration – between health services, trial sites, GP Networks.
- Focusing on consumer engagement – trial awareness, protocol development, recruitment strategy.
- Improving the Consent process – e-consent, shorter PICF.
- More effective ethics and governance – improved processes.
- Having accurate data – better completion of feasibilities.
- Getting better site support – financial, engaged staff.
- Participant focused strategies – parking, home visits, flexible eligibility.

Summary

The top five barriers to recruitment as identified from the survey were:

1. Finding eligible participants that meet study inclusion/exclusion criteria
2. Onerous visit schedules for participants
3. Insufficient resources at site for recruitment activities
4. Time taken for governance/site review
5. Time taken for ethics submission and review, including amendments.

The top five enablers to recruitment as identified from the survey were:

1. Adequate site staff resources to perform recruitment activities
2. Adequate budget for recruitment activities
3. Active investigator in the recruitment process
4. Having a good referral network at site level, clinician level and or institution level
5. Access to a quality database or searchable electronic health records.

The free text responses provided by respondents also reflected the barriers and enablers previously identified with no significant omissions.

The key success factors to improve site recruitment were themed as:

- Undertaking accurate feasibilities before the trial starts
- Opportunity to review appropriate inclusion/exclusion criteria
- Efficient ethics processes that don't delay recruitment
- Having adequate staff resources to manage recruitment
- Successful education/engagement of consumers
- Having good recruitment strategies in place
- Effective targeted advertising
- Not relying solely on clinician referrals
- Good communication
- Being participant focused

Recommendations

The survey reinforced the view that recruitment into clinical trials is a common and significant issue at clinical trial sites. The survey captured and prioritised the key factors that impact recruitment, providing rich quantitative and qualitative data.

Findings from the survey were used in the development of the GREET Project recommendations, producing a practical Clinical Trial Site Recruitment Guide to help site staff with the challenges of clinical trial recruitment.

The GREET project recommendations come under four key themes:

1. Accurate **STUDY FEASIBILITY** before taking on the trial is essential
2. Upfront **STUDY START UP** and planning is key before recruitment starts
3. Understanding and selecting the most suitable **RECRUITMENT METHODS** will improve success rates
4. Always having the **PARTICIPANT** top of mind maximises recruitment outcomes

The GREET project recommends that to improve recruitment, recruitment needs to be considered upfront and not just when participants need to be enrolled. Undertaking accurate study feasibilities to determine whether the site has the capacity and capability to conduct the trial is key, in some cases the site should not have accepted the trial in the first place and recruitment was always going to be difficult.

Once it is determined that it is feasible to conduct the trial, doing essential planning and preparation before the study starts is crucial to give recruitment the best chance of success. Too often people jump straight into trying to recruit without undertaking feasibility and start up and planning first.

There are many different recruitment methods and there is not a one size fits all approach, so for each site and each trial, the most appropriate recruitment methods need to be determined.

Finally, and perhaps most importantly, taking into account the needs of the potential participants is crucial to engaging them to take part in the trial. Without participants a trial cannot go ahead.

A full copy of the GREET recommendations can be found on the CTIQ GREET project webpage

APPENDIX 1: Introduction page of GREET Sites/Sponsor survey

Research sites often experience difficulties in meeting study recruitment targets in terms of participant numbers and/or time frames. This is a common problem in Australia.

CT:IQ (which stands for Clinical Trials: Impact & Quality) is a collaborative group of stakeholders from across the clinical trials sector, all interested and involved in clinical trials in different ways, with a common aim to get Australia thinking smarter about the design and conduct of clinical trials.

CT:IQ are currently undertaking an industry wide collaborative project called the GREET Project - a Guideline to Recruitment: Examining Experiences at clinical Trial sites.

This project aims to better understand the barriers to clinical trial recruitment at the site level with the objective of producing recommendations for optimising recruitment that are broadly applicable and translational across research sites in Australia.

CT:IQ are contacting you and other important stakeholders to ask about your opinions and experience with site recruitment barriers, and strategies for overcoming those barriers. This survey is aimed at clinical research sites and sponsors/CRO's in Australia. If you are not part of one of these groups, this survey does not apply to you.

This survey will take approximately 10-20 minutes to complete. Your participation is entirely voluntary. We will assume that you have consented to participate if you chose to answer the questions below and on the following pages. It will not be possible to withdraw your responses from completed or partially completed surveys because we are unable to link survey responses to you as an individual. All survey responses are confidential.

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics & Integrity (telephone (02) 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

The Principal Investigator for this study is Radhika Butala from Macquarie University. For queries about this project please contact Sonia Harvey, CTIQ Project Manager, at soniaharvey@ctiq.com.au.

If you have any distress or concerns arising from this survey, please contact your human resources consultant at your place of employment who will put you in contact with your organisations employee assistance program. Alternately you may also contact the Principal Investigator for this study, Radhika Butala via the project manager at soniaharvey@ctiq.com.au.

The summary of the findings from this survey and the recommendations from this GREET project will be published on the CT:IQ website at the end of 2019.

For more information on CT:IQ please visit ctiq.com.au. Details of CT:IQ's Privacy Policy can be found at https://ctiq.com.au/disclaimer/#Privacy-Policy

---

Do you consent to participate in this survey? Yes ○ No ○

APPENDIX 2: For those that responded as “Other” for the question: Which of the following best describes your organisation?

1. Research Organisation
2. Social Impact evaluation
3. Sponsor Investigator
4. Academic Clinical Research Organisation
5. Academic Research Institute
6. Consumer and community involvement
7. Consumer organisation
8. Ethics
9. General Practice
10. Government
11. Hospital
12. Medical Research Institute
13. Public Health Service
14. Medical Research Institute
15. CAMHS clinical service
16. Cancer centre
17. Child and adolescent mental health service
18. Clinical Trials
19. GP Practice
20. GenesisCare
21. Government
22. HREC Committee
23. Health Department
24. Hospital
25. Medical Research Organisation
26. Not for profit research institute
27. Patient organisation
28. Patient recruitment
29. Patient recruitment vendor
30. Public Hospital
31. Regional Trials Network x 3
32. Research Organisation
33. Social Impact evaluation

34. Sponsor Investigator
35. Tertiary Institution
36. University x 3
37. Academic Clinical Research Organisation
38. Academic Research Institute
39. Consumer and community involvement
40. Consumer organisation
41. Ethics
42. General Practice
43. Government
44. Hospital
45. Medical Research Institute
46. Public Health Service

APPENDIX 3: For those that responded as “Other” to the Question: What is your role in your organisation?

1. CEO
2. Project Coordinator
3. Cardiologist
4. Professor
5. Senior consultant
6. Member
7. Academic
8. Clinical trials coordinator
9. Program manager
10. Program manager
11. Sessional academic
12. Research coordinator
13. Manager
14. Senior clinical coordinator
15. Program Manager
16. Program Manager
17. Mental health worker
18. Practice manager
19. Subcontractor
20. Project Officer
21. Program Manager
22. Medical Practitioner
23. Program manager
24. Academic
25. Nurse
26. Director
27. Trial coordinator
28. Allied health research coordinator
29. Research coordinator
30. Lecturer
31. Project manager/researcher
32. Project manager
33. Research assistant
34. CEO
35. Program manager

36. Administration
37. Research officer
38. Senior development officer
39. Manager
40. Clinical research advisor
41. Academic
42. Project manager

APPENDIX 4: Have we missed any barriers?

1. As a private site, our inability to access patients within the public health system is our biggest barrier to patient recruitment (not healthy volunteer trials).
2. Each trial is managed separately. Maybe if there was an overall view of the entire trials program at each site, synergies etc may be able to be identified.
3. Not being able to see trial participants outside business / school hours.
4. Low awareness of information on recruiting trials by doctors who have the potential to refer.
5. Belief that clinical trials are only a 'last resort' to be investigated when there are no alternative options available.
6. Doctors not being constantly reminded of trials that are ongoing - need to be front of mind to improve engagement.
7. Increasing concern of GPs regarding third party access to database/making contact with their patients.
8. Resources - either experienced staff, recognised need for expertise in clinical trials and hospitals having little or no KPI's around research activity that enforces hospital support for clinical trial activity.
9. High rates of staff turn-over in Research Assistant positions due to mismanagement and lack of progression opportunities.
10. Clinical practice either being ahead of research and so things that we would like to test and for which there is no evidence are being done, or clinical opinion being that what we would like to test is interesting and important but not for their patients.
11. The biggest issue for a multisite trial is when sponsors expect each site to do their advertising and are inadequately reimbursed which would be best done on a national level.
12. Funding for researchers and time.
13. The main barrier is that public hospitals do not financially contribute to the employment of PI's to take on clinical trials above their clinic work load, or contribute to the employment of study staff. Also recruitment to clinical trials is not a KPI for CEO's - so no department accountability. All clinical trial units are mostly self funded and the sponsor dictates the trials, not the hospital - so the hospital takes what it is given and is paid to do by the sponsor.
14. Issues of playing "phone tag" with potential recruits.
15. Not able to find parking at site.
16. The possibility of not being able to be prescribed the IP after the trial.
17. In reference to 7 - adequate reimbursement for rural patients is often not permitted so we miss patients who are enthusiastic but can't afford to pay for their travel to site for visits.
18. Negotiation of Contractual and financial arrangements between sponsor and sites No backup for researchers during holidays causing problems with trial compliance.
19. Language barriers. Effective translators.

20. In relation to advertising, we are often unable to advertise anything without ethical approval and this can delay the start of trials. Advertising locally would help with recruitment. Most of our population are progressive neurological disease often where there are few treatment options (MND, Huntington's Disease) therefore the risk of receiving a placebo is a risk they are often willing to take
21. Hospital administrators seeing trials as revenue raising opportunities and charging excessively for facilities and services.
22. Limited operating theatre time. Limited availability of PI for recruitment, consenting and screening procedures. Limited availability of interested and engaged site coordinators.
23. Consent forms not in their primary language.
24. No
25. No
26. Staff resources for specialised components of a clinical trial. For example in a tertiary public hospital radiation oncology department we lack physicists to do essential start up work (QA/Credentialing) for a trial to open due to lack of staff and government cut backs. Also in Radiation Oncology, if we do receive capitation to help offset some of the costs, it is normally very minimal as we aren't involved in pharma trials.
27. We currently do not have a gynae trial open to recruitment.
28. Time taken for budget negotiations.
29. Inclusion/exclusion criteria change between feasibility and trial commencement. Sponsors unwilling to pay for pre-recruitment screening of medical records/databases.
30. One person having a bad experience in research and spreading it on social media.
31. Clinical trials are not a KPI for hospitals or clinicians. Culture of 'we are too busy for research' which is an 'added workload'.
32. Collaboration in multi multidisciplinary teams, e.g. not educated for the trial and therefore not referring patients.
33. Significance of the trial to potential participants.
34. Competitive clinical trials I.e. Investigator Initiated vs Sponsor Initiated trials.
35. For adjuvant trials in the cancer setting, often patients do not want to have another treatment and have had enough of being in the cancer unit, so turn down a clinical trial.
36. A Major barrier at regional sites is public health staff freezes. This prevents research units from growing, preventing them from increasing their capacity and in the process reducing the numbers of both trials and participants they can accommodate.
37. Time for Research Governance, Universities/Hospitals and coordinating centre (usually associated with a University) to review and sign-off on Clinical Research Agreements. Very time consuming. ii) Making site payments through the hospital or university is time consuming due to the lengthy process of completing vendor and PO forms.
38. Competition between pharma and investigator initiated trials.

39. Inability to understand the different types of research. Patients need to be well enough to have capacity to understand. Patients often only want to consent once they are well again. Misconception that research does not provide the best treatment options.
40. Delays caused by sponsor to provide study documentation required for budget, and HREC/RGO submission. Delays in receiving quotes from inter hospital departments.
41. The barriers created with regards to advertising (regardless of how it is done) is onerous. The advertising questionnaires do not drill down enough to get the correct patient. For example a Facebook advertising for a cholesterol drug costs us $33,000 in extra study coordinator time in order to get 5 patients out of 137 responders. Company reimbursement was on $5,284.00. Of the responders - 28% misinterpreted the inclusion criteria, 17% did not meet the inclusion criteria, 16% were not interested in participating, 9% said it was too far to travel, *% were uncountable, 3% had mental health issues, 3% had other comorbidities, remaining 7% never turned up at clinic or faked contact details, were not an Aust citizen, or were working full time & could not attend appts. Likewise in another advertising campaign the call centre decided they could not cope with the amount of calls so the patients were pushed back onto the site. During that time we had over 300 calls in a 2 weeks period which we were required to respond to within 24 hrs - that was absolutely impossible. Of those 300 patients we got only 1 person to screen who screen failed. We were not reimbursed for the extra work required. There is a new advertising campaign at present for people who have disturbed sleep - imagine the number of calls to this. The issue here is that adequate reimbursement to sites have to be considered and most importantly these people need a sleep study to enter the trial. As a hospital who must treat all patients the wait list for a sleep study is more than 2 years - so ethically and morally how is the hospital supposed to juggle the needs of clinically ill patients who have been waiting so long for a sleep study to then have their study further delayed because of clinical trial patients who do not have an urgent clinical need for a sleep study. This issue has not been considered by the sponsor or the advertiser. Furthermore, the recruitment issues we face today are being compared to the literature which is now old and has not kept pace with the changing world. Fifteen years ago, most patients retired between 60-65 and as I work in cardiology most myocardial infarctions occurred in patients over the age 55-60. Now days myocardial infarctions now occur from 40 yrs onwards, most patients now work & all are internet savvy. So, when you go to discuss a trial it is very difficult to get someone to agree & consent as work interferes with the numerous visits now required in trials, they get onto their smart phones immediately & look up all the info on the study drug or on clinical trials (all negative), and the number of procedures now required in a clinical trial visit has pushed the visit from 30 mins 15 yrs ago out to about 2 hours in current times. So, the demography of the current patient cannot translate to the recruitment literature - new research is needed to pick up these issues. Fifteen years ago our usual recruitment into myocardial infarction trials was usually about 40 patients; today we are lucky to get 5-10 patients. Unfortunately when I raise

this a research forums or meetings this view is not accepted as no-one is listening to what is actually happening on the ground.

43. Some of the issues raised are more due to lack of prioritization and training in research generally eg it may not be lack of access to useful data system, but lack of training in how to effectively use these resources for research processes that is the problem. Also lack of ensuring clinicians, who may have dedicated research hours built into their contracts, actually use those hours for research. So accountability for clinicians supporting research activities at the operational level.
44. Insufficient Investigator lead funding for trial overall leading to disincentive for site to recruit.
45. (Public hospital) No funding for interpreters to be used for research when many of the patients do not speak/understand English at all or well enough to be able to recruit/consent them.
46. I have had several discussions with colleagues who have different training and experience to me (e.g., media and communications). You don't know what you don't know. By talking to these colleagues, they've shared unique insights and perspectives on how to engage people in tasks, how to clearly communicate a call for action. Sometimes they say they wish they'd been included in the study design as they have a different perspective on what is feasible to ask someone to do as a participant that we as researchers can lose sight of in wanting lots of data and information. I think creative and multidisciplinary collaboration is needed and silos are a barrier.
47. Complexity of having multiple teams involved in the trial.
48. New trials in precision medicine where the participants may be n=1. There is a significant need for "off label" drugs to be given under a clinical trial umbrella and not ad hoc. Still the major problem is getting studies going due to HREC and governance red tape. There MUST be a homerisation process, and there must be a capability of an institution to have rapid review of a trial for rare diseases, where a clinical trial is being run internationally.
49. Use of the word "trial" in documentation provided to potential patient- "trial" can convey meaning of experiment and therefore trial involves recruiting "guinea pigs". All Patient information should speak of "study" and not "trial".
50. Insufficient budgets from sponsors 2. Ridiculously punitive exclusion criteria 3. Duplication of activities and data to the point of ridiculousness 4. Constant dawdling of sponsors on timelines and then expectations that sites can undertake activities miraculously overnight when the sponsor has been dawdling for months and months.
51. I think there needs to be a culture change particularly in public hospitals so that every person that enters is considered for a trial i.e. is there a suitable trial for this person. Currently potential trial participants come and go without being identified for a study. This links back to the fact that research isn't seen as a standard treatment option.
52. Healthcare systems need to prioritise funding for research coordinator roles. This is truly the only thing that will really influence recruitment. You can pretend that all the other factors you

mention in your survey matter... but really it's all dependent on an RC position that is secure and valued. A secure position for a happy Research coordinator to perform the recruitment task.

53. The perversity of host institutions seeing research as revenue generating vehicles rather than part of healthcare.
54. Engagement of other clinical staff, awareness of clinical trials and understanding clinical trials, Investigators previous experience in clinical trials.
55. N/A
56. Insufficient use of technology to better connect patients with the relevant clinical trials.
57. Head of departments or CEs approval to support sites with infrastructure and funding.
58. Overly stringent inclusion/exclusion criteria. Requirement for new biopsy tissue - patients often will not consent Need for centralised tissue sample assessment extending screening period leading to an unacceptable delay in starting treatment
59. Not that I can think of at present.
60. Use of social media networks to "advertise" a trial - insufficient information provided to potential applicants means really large numbers of responders, most of whom are inappropriate, and all of whom have to be contacted back, by someone ....
61. Departmental politics.
62. Nil
63. Several available marketed treatments using these compounds and no screening period time lost when treatment commencement is paramount. Turnaround times to have screening lab results available from lab vendors necessary for randomising a patient (lost time).
64. Flexibility of trial designs / sites time to be able to accommodate rural / regional or working participants.
65. Low resources at sites (i.e. not enough staff to support the high quality work that a clinical trial involves).
66. Insufficient coding in electronic medical records to complete potential participant searches efficiently.
67. General population information about what is a clinical trial. Basic information to inform the public so that a greater percentage understand them better.
68. The biggest one by far is the lack of any funding or support for a 'clinician scientist' role within our state health department.
69. Not being a part of NMA and SEBS.
70. General awareness at the sites of how important clinical trials are to the care of patients. For many sites there is a cultural view that clinical trials are an 'add on' to core business not a key aspect of business that is essential to drive continuous improvement in care and outcomes for patients.

71. Involvement of clinical trial participants whose first language is not English - adequate use of translators from the institution, or translation of study documents from Sponsors; for trials with a long recruitment period, changes in the treatment landscape can occur - Sponsor can consider changing the sample size and potentially shortening the recruitment period; Awareness of trials by referring specialists - more education on trials provided by Sponsors to the referring specialists; relationship between Sponsor and site personnel

APPENDIX 5: Have we missed any enablers? n =43

1. Collaboration with patient support groups; patient engagement prior to finalising protocol; treating patients as part of the clinical trial team.
2. Realistic inclusion/exclusion criteria with broad scope for inclusion where appropriate.
3. Reduce unnecessary visits and blood tests especially at entry to the trial. The bigger the initial hurdle, the less likely it is that potential participants will choose to cross it.
4. Ease of access to trial site e.g. easy to find parking, free parking, (or easy reimbursement) quick follow-up to initial expression of interest, staff with excellent communication skills/phone manner etc."
5. Better clarity and agreement between research and clinical staff about client's diagnoses - preferably as early as possible.
6. I don't think so, but shorter PICFs would be great.
7. All great enablers, plus trial recruitment needs to be a KPI.
8. Sponsor taking more time to develop protocol. Less amendments.
9. A Multimedia Participant Information process to enable understanding of the trial
10. Reducing the strict barriers to enable us to advertise more freely.
11. Recruitment should be site responsibility not sponsor or CRO - this should be made clear from the immediate start.
12. More awareness campaigns for patients to ask their clinician about clinical trial suitability. Making research a part of the job and not additional work for clinicians.
13. Peer support and referral networks; word of mouth.
14. We need to be able to pay per participant. Unfortunately, we are currently forced to promise via Agreements to pay fixed FTE salaries for research nurses and there is no stick if they under recruit.
15. Matching the correct site to the protocol. The same study can be easy for some sites to recruit and difficult for others depending upon their standard of care and routine lab tests compared to the protocol.
16. The ability for participants to participate in a trial through telehealth and thus have less trial visits at site.
17. More database support for investigator led trials. More support/training for setting up a budget and payment process.
18. Reimbursement for time spent when providing telephone interview.
19. Having an introduction 1-2 page PICF would be so good - a PICF that explains why they are being asked & what it is like to participate in a clinical trial. A pre-approved stock standard brochure would suffice. I know that Bellberry HREC was doing this about 5 years ago but nothing has come of it (PICF in 2 parts). We could discuss the study with the patient and once the patient has read that & if interested then the formal PICF could be given to them.

20. Prioritization and accountability for research activities at an operational level. Better education of the public re the benefits of participating in research to themselves and society.
21. As we are regional the only barrier would be the distance some patients live from the site.
22. The expertise (and possibly personal profile/interests) of a researcher is different to the expertise of someone who is entrepreneurial or has a background in marketing/business/effective use and development of media to promote a project. Perhaps an engagement role needs to be included in the budget and funding outline.
23. Advise that results from study will be provided to participants.
24. Clinical trials that are actually about improving patient outcomes and not just finding irrelevant points of marketing difference for your new me-too-zumab.
25. Training of clinicians to include practical clinical trial methodology - i.e. how to recruit and consent patients, overview of ethics and why adherence to protocol is important etc.
26. All that matters is a research co-ordinator is employed specifically to manage the task
27. Better use of technology to connect patients with relevant clinical trials.
28. Family care. Supporting family members to stay with patients during recruitment and study treatment.
29. Quicker screening period - not having to wait for centralised tissue assessment.
30. Results communicated to the patients in their therapeutic area. Most patients in oncology trials die prior to being able to know what the compounds that they have altruistically invested their time in could be doing (i.e. benefits, even if it is just quality of life improvement with no benefit to tumour burden).
31. Presentation of trials at hospital multidisciplinary team meetings.
32. Local operating procedures that prioritise trial participants for investigator review and with pharmacy to reduce wait times.
33. Ongoing support from sponsor/CRO/CRA to site research team including: -regular communications and study updates, - prompt replies to site emails or questions, - sponsor/CRO being knowledgeable about the protocol, study status, vendors, operational methods, etc. -Medical monitor support/information sharing with investigators and site teams -in person investigator meeting (vs webex, phone) -comprehensive SIV in which the CRA reviews all operational items including lab kits, IRT actions, and reviews shipping materials, EDC requirements and parameters (being knowledgeable about edit checks, etc).
34. Engagement and interest of the investigator and study team. All must be involved and engaged and want to be successful in the study.
35. Organisational support to offer clinical trials staff permanent positions not short term contracts, based on revenue of unit. Career progression in clinical trials and access to training and knowledge sharing with other sites. Medical FTE factor in increased contribution required for clinical trials activity.

36. Transparent and robust marketing of trials being conducted where possible to promote general awareness across the system.
37. Government campaign to raise public awareness of clinical research.

APPENDIX 6: What site recruitment initiatives have worked well for you (through personal experience or you have seen/heard about?) n=168

1. Clear and well-resourced recruitment strategies that have sufficient budget allocation and time to implement. Clear communication with the Site, CRO and Sponsor (and patient recruitment vendor if involved) around recruitment updates. Campaigns that have multiple channels e.g. Facebook, Google Ads, Blog posts on patient advocacy sites.

1. Recruitment calls and sharing global recruitment statistics.
2. Education sessions – clinical trial specific or disease group specific.
3. Engagement with community groups/presentations to relevant community and hospital groups.
4. Social media, use of 3rd party such as Galen, small payment to study coordinators for every enrolled patient ID'd by them: (such as $100)- coming from PI (not study budget) to encourage them to search database and patients attending to ID potential for study.
5. For multicentre studies, getting all sites together via ftf meetings/webinars/telecoms to discuss issues and collectively strategies.
6. Social media campaigns; patient in services; traditional media releases.
7. Social media, radio.
8. Getting the investigator on board with recruitment, developing networks and site staff having time to recruit and maintain patient buy in is key. Support from patient advocacy groups. Professional advertising – branding for studies, scripts and imagery (expensive). Embracing social media.
9. Conducting scheduled home visits.
10. Social media, friend referrals.
11. Social media, 3rd party advertising agencies specialising in trial recruitment.
12. Social media (Facebook) to target eligible participants.
13. We have recruited over 2400 people into LoDoCo2 trial in our WA practice over 18 months, but it required all the things indicated on the prior page to be in place.
14. Engaged investigators and coordinators, referral patterns and trying to reduce competing studies within a small field (multiple major hospitals in one city all doing the same clinical trial should be limited as it is a waste of resources. Overall management of clinical trial activity at an institutional level, not a clinician level should reduce duplication and competition for resources.

15. Developing relationships with the clinical team to better facilitate referrals. Making participation as easy as possible for participants e.g. by providing transport and have flexible work hours.
16. Implementation of a clear allocation process and flowchart. Better involvement of clinicians.
17. We had great success in one study using peers to recruit participants.
18. Engagement/relationship building with clinical streams.
19. Getting interviewed on national TV over the study.
20. Advertising.
21. Referrals from MDT's with the Clinical Trial Coordinator Present.
22. Local papers advertising, flyers around the hospital.
23. GP recruitment strategies.
24. Social media advertising. Radio advertising.
25. Advertising and using outreach programs.
26. Social media.
27. Multidisciplinary clinic members aware of clinical trial. Pro-active investigator.
28. Dedicated medical staff employed to focus on recruitment dedicated study staff funded by sponsor to concentrate on recruitment.
29. Professional recruitment services. With a good pre-qualifying online survey.
30. Adequate funding is essential, as well as quicker ethical review, and less complicated entry procedures (less complicated PICF).
31. Visiting referral sites to meet with potential referrers; listing the study on local clinical trial websites.
32. Daily screening of patients by research staff – but need research staff available daily to do this!
33. From patient pool because there is already a doctor/patient rapport hence patient more likely to agree to participate.
34. Referral connections, database of interested patient switch desired indication, an enthusiastic PI, presenting current trials at specially hospital meetings, use of referral apps such as ClinTrial Refer.
35. Whole team based recruitment – the whole care team has awareness and a role in promotion of studies.
36. Investigator and other specialist referrals. Experience staff who know the protocol. Good processes in place that comply with ICH-GCP.
37. Sponsor supporting education sessions for referrers, particularly GPS.
38. Radio and TV coverage.
39. Direct contact with regional doctors to refer.
40. As a research assistant, being on email lists for clinical teams so that you are informed when they have changes to clinical reviews. Our organisation is both the clinical site and the

sponsor, even here we have some barriers, however the efforts to change the culture to unify have greatly helped.

41. Data dumps from our electronic medical record.
42. Media coverage, social media, on our website.
43. TV and radio advertising.
44. Site staff training that extends beyond investigator and study coordinator e.g. Hospital booking officers, reception staff, registrars etc.
45. An experienced clinical trials nurse (CTN) working closely with the physician researcher with the CTN doing the screening and first interviews and the physician finalizing the consent process.
46. Close collaboration with clinical staff has worked well for me. Colleagues working in the field, particularly at the site location, although this is rare.
47. Monitoring clinical changes in patients who do no initially meet the criteria, so we are able to recruit once they do (for example, changes in respiratory functioning which can be assessed more frequently).
48. Continued reinforcement about the need to recruit and feedback about the accrual targets.
49. Targeted advertising social media.
50. Engaged investigator network with academic interest in the trial.
51. Senior staff taking leadership and actively encouraging all members of the team of the value of participating in good clinical trials.
52. Galen, Convenience Advertising, Newspaper and radio advertising.
53. Galen recruitment services has worked the best. Referrals from associated physicians also works well and is cost effective.
54. Direct referral from Physicians.
55. Weekly department meetings to engage/inform investigators of current clinical trials – whilst working as on onsite research manager.
56. MDMs, Coordinators identifying patients for clinicians.
57. Adequate reimbursement to patient.
58. Clinician referral.
59. Screening patients and talking to the clinician prior to seeing the patient. Being present at multi-disciplinary meetings as a trial coordinator.
60. For people with chronic illness, medical follow up.
61. The capacity to “pre-screen” clinic lists for potential trial participants using system. Having regular clinical trials team meetings where protocols are reviewed to remind investigators of the key eligibility criteria and to identify problems with recruitment that may be actively addressed. A team approach to reviewing new clinical trial proposals before agreeing to conduct the trial to ensure the site has capacity to manage the trial and all investigators are

committed to offering the trial to their patients. The use of referral tools and networks which as ClinTrials Refer App and MDT meetings.

62. Effective communication.
63. Well informed registrars and consultants about the inclusion exclusion criteria. Good communication between registrars and consultants with clinical trials staff from initially seeing patient to recruitment.
64. MDTs, breakfast meetings and staff education sessions.
65. Attending multi disciplinary meetings, email current and new trials to the specialist tumour groups. Trial information sent to relevant cancer support groups.
66. Identification of potential trial participants before trial commencement. Social media utlitlsation for advertising support for maintain patient/disease databases.
67. Treatment options for patients who have no further treatment lines, making nearby hospitals and oncologists aware of active studies, having the trials list on apps etc.
68. Clin trial refer app clinician who “sells” study to colleagues.
69. Getting clinicians on board and updating them regularly.
70. Our site uses a Sharepoint platform to share all current recruiting trials by indication.
71. Payment per patient, waived consent/opt out consent.
72. The use of a state-wide app which has publically available inclusion/exclusion criteria and site contact details.
73. PMs being empowered to set up recruitment requirements and close sites promptly if way off target. PMs being able to siphon CRA resources to sites who need additional attention and having a say in resource allocation. Site referral lunch and learns set up by sponsor with tea/coffee provided, Sponsor presentation and open discussion. Identify which inclusion / exclusion criteria is tricky and have HQ review this again patient safety and amend the protocol where there is no increased risk to the patient or the integrity of the data.
74. Screening in doctors rooms, notify Dr patients potential eligibility, go to rooms when patient has visit and wait for Dr to explain the study then recruit if patient happy.
75. Completion of a good feasibility upfront.
76. Proactive investigators working directly with patients and seeking recruitment study incentives for doctors to recruit.
77. Attending MDT and conducting active screening.
78. Databases Emails Clinician support of the studies Face to face.
79. Facebook, newspaper advertising, noticeboards, stalls at university.
80. Regular meetings with PI and Sub-I’s to discuss recruitment of trials. Reviewing all new patients to see if they fit trial criteria.
81. Utilising our electronic records to find patients. Going through the new patient list each week. Have a research nurse/study coordinator attend multidisciplinary meetings for each tumour

stream. Accessing drug ordering systems to see which patients are currently receiving a line of treatment required for eligibility.

82. Assisting sites with HREC and research governance forms. Providing promotional material for recruitment.
83. Enthusiastic staff who not only understand the trial but can explain it well to patients or healthy participants. Allowing people to walk in discuss clinical trials with someone knowledgeable on the trials process.
84. Dtp-direct to patient- clinical trials service, this is happening in the United states & Europe. This has improved recruitment & retention significantly.
85. Informing informal network of colleagues who may cross-refer from other sites.
86. Engaged Investigators.
87. Not involved in site recruitment.
88. Having caring staff. Being able to accommodate the patient's needs with regard to timing of blood test and procedures. Being available when a patient has an issue.
89. Cooperation between clinical and research team/s.
90. Media coverage of the trial.
91. Direct communication with the clinician. Daily dedicated research staff at site screening. Possibility of consenting by trained research assistants.
92. Monthly meetings with investigators to keep them informed of open trials. Creating spreadsheet with recruiting trials and basic eligibility criteria to circulate to all staff involved. Adding trials to ClinTrial refer app
93. Use of the Clinical Trial Refer App. Attendance at Multi-disciplinary Team meetings to identify potential patient.s Ensuring PI is engaged and kept updated.
94. Payment for recruitment works better than in-kind support.
95. Advertising / database of people interested in clinical trials/ initial contact about trial from treating clinician.
96. 1) Advertising in the hospital out-patient clinics worked well for me. 2) Face to face conversation is much better than a phone call or letter as first contact.
97. Maintaining a participant registry/database who have agreed to be contacted about potential opportunities.
98. We tend to now outsource our advertising to Splash Clinical, as we usually receive 500+ referrals from a single 4-week marketing campaign
99. Multi-language single page information sheets about what a clinical trial is; and why we do them. Selected languages for the most common patient population of the region. ie Dari, Mandarin, etc.
100. Clear processes, checklists for trial recruitment.
101. Choosing trials that could actually help participants.
102. Radio campaigns.

103. In newsletters of trial progress, including a bar graph with recruitment per site can ignite the competitive streak in study staff to recruit better. Prize for recruiting the Xth patient.
104. In my experience the site PI needs to be very engaged and enthusiastic about the study to motivate other team members, who have less to gain from the sites participation, eg authorship, funds.
105. GP co-investigator status.
106. Advertising (if you get it right i.e. properly targeted). Referral from other institutions for early phase therapeutic research.
107. Depending on the study and what is involved before randomisation determines level of entry to approaching patient. All study members being part of a Whatsapp group to allow a smoother flow of communication.
108. Supporting peer to peer meetings to encourage referrals; working with patient advocacy groups where possible; reimbursement of travel costs for rural patients.
109. Very much depends on the nature of the study and the participants. Radio advertisements and featuring on TV stories (as long as they put your phone number/website up on screen for a long time) worked best for us.
110. Constant re-education of site staff.
111. Frequent interaction between CRA and Clinical Trial Coordinators driving and discussing recruitment. Being clear about targets. At site level, ensuring that all investigators/doctors are aware of the trial. For example, having inclusion/exclusion cards in clinic rooms as a quick reference.
112. A research clinical nurse consultant to over- see research in the unit.
113. If there is no placebo group in the trial.
114. Community involvement, proper patient databases that allow interrogation and assessment of feasibility.
115. Contacting Allied Health professionals to refer participants to a study.
116. Being in a clinic.
117. Having a proactive Chief Investigator and site Principal Investigator, has been critical. Trained site staff.
118. Social media used to be effective but I wouldn't say that it is effective any longer.
119. Improving patients awareness about ongoing clinical trials.
120. Having a robust recruitment strategy and clear communication plan. Communicate with GP and specialists on patient updates. Keep them in the loop builds trust and provides motivation to refer. Always show appreciation to them for referring patients. Make time to explain the protocol and study assessments during consenting. Patients need to be aware of everything.
121. More money paid to sites to cover staff salaries to conduct recruitment. Academic trials are run on a shoestring and investigators have to participate for the love of it only.

122. Recruiters: Recognition of people and team and hospital in newsletters, media, by emails to staff and managers recognising work and achievements. Fruit box deliveries, other small team food rewards. Targets. Supportive phone calls and emails.
123. Alert systems when opening a patient's EMR to notify the clinician currently seeing them that they are potentially/eligible for a trial.
124. High quality trials - accessible eligibility criteria.
125. Regular catch ups between all investigators.
126. We regularly utilise and are visible on the Clintrial refer app for referrals and it has proven highly successful. We receive patients from other states due to this. We conduct a thorough feasibility review process before we agree to any study.
127. Financial incentives for patients and sites, access to drugs not on the PBS. Constantly reminding the investigators of recruitment targets.
128. Having other practitioners in the hospital assist with our referral networks/patient recruitment.
129. Engaged investigator and investigator contact/rapport with other clinicians working in the hospital can work very well.
130. Blasts on the news about upcoming trials.
131. Realistic recruitment goals set by site.
132. Attendance at MDT.
133. Depends on the demographic being targeted. eg: for the older population, large ads or articles in major newspapers have worked well. For the younger demographic, social media and the ability to register online are significant benefits.
134. Chart review of onsite patients.
135. Staff engagement using lanyard cards with inclusion exclusion, presentations to ward staff and using reporting tools effectively to screen for participants.
136. Personal relationship with cross referring sites.
137. Trial coordinator attendance at multidisciplinary team meetings. Early mention of the trial to potential participants followed by a proper introduction once eligibility is confirmed.
138. Relationships built between clinicians and researchers via frequent presentations regarding the research and the relevant literature; comprehensive training and supervision of research staff; regular meetings with investigators; researchers attending clinical review meetings to identify participants; researchers going through clinic patient lists to ensure every client has been considered for the study.
139. Adaptive protocols to allow outreach visits and/or timepoint deviations to better accommodate participants' other commitments.
140. TV ad, radio ad and a good referral system.
141. Appropriate reimbursement for participants or a monetary or voucher incentive to support the project that was felt to be generous.

142. Good rapport of investigators with site staff. Keeping trial top of mind, with regular review at weekly meetings. CT staff attendance at MDT meetings.
143. Increasing referral networks - Investigators reaching out in MDTs and with other clinicians. Promoting a culture of cross referrals in the patient interest.
144. Site's who leverage referral networks and presentation of studies at MDT.
145. Talking directly to surgeons/urologists and other key staff who may see potential patients for clinical trials and educating them on the types of clinical trials that are available.
146. A dedicated member of the clinical team (nurse) reviewing inpatient lists for eligible participants and approaching their clinician with information about the trial. Conducted in a rural hospital with no other access to interventions offered on trial.
147. A sponsor that is aware of the strategy to recruit to their trial and explains the strategy to the site. Awareness of limitations and addresses barriers to recruitment.
148. As a prior CRA, my experience is that providing to sites prompt, knowledgeable support and regular study updates (country level and global) has been the primary recruitment initiative from outside the site. Also completing a recruitment plan during SIV with site personnel is critical to established recruitment methods and contingencies. If a site is struggling with recruitment, referring to the recruitment plan has been helpful to think about contingencies/alternate methods for recruitment.
149. Using a very clear, comprehensive and engaging site feasibility assessment where there are honest and open discussions about the availability of participants at site. It is a must to review the inclusion/exclusion criteria initially and upon amendment to ensure the target numbers have not changed. Use of investigators referral channels for niche populations often works well, especially in therapeutic areas where the treatment is truly novel.
150. Having study reminders in the clinic rooms for the doctors. Making finding patients a priority and taking time to do this. Having an outreach especially to multiple GP clinics who are happy to refer. Having a good cross referral practice with other clinicians.
151. Engaging different departments i.e. OT or rehab.
152. A regional site we have a very large database and are able to approach relevant patients directly.
153. Triage all new referrals in a formal meeting and consider each referral for trials available, including lists of trials on screen at the end of MDTs.
154. Developing a relationship prior to recruitment (if time permits).
155. Introducing myself and building rapport before launching into my “do you want to be in a study?” spiel.
156. Advertising the unit – general information about clinical trials to consumers raising profile of clinical trials
157. Providing incentives to staff to remember to recruit patients to the research project. Importance benefits to patient and to staff.

158. A trials dashboard to promote the trials currently recruiting.
159. We have found differences in how best to reach people: Print media works best for older populations, Facebook is good for younger populations, but is dominated by female respondents. TV and radio segments are very variable for us. If we can get materials sent out through work networks that I usually quite good.
160. Good input and collaboration with all clinicians, Nurse and doctors in the area
161. A tailored approach for site – ask site/investigator the materials that can be provided to referring specialists to increase medical education e.g. journal article or recent trial data, referral letters for site/investigator to send out.
162. I believe more needs to be put into apps/internet/online forums. In a digital age we have the potential to let an extensive number of people know about clinical trials and the potential patient numbers limitless, but it is funding appropriate and ethical ways of getting the message out there. I think tailored advertising depending on the population you are looking for would work well.
163. Face to face meetings with key staff.
164. Having a database of people who are interested in participating in clinical trials and are willing to be contacted when a trial for which they may be eligible.
165. Newspaper, online tool.
166. Face to face recruitment with patient in clinic or over the telephone.
167. Healthshare campaign – moderately successful but expensive newspaper at times.

APPENDIX 7: What recruitment initiative have NOT worked well for you (through personal experience or you have seen/heard about)? n=143

1. Flyers with clipart text and a phone number. People are more open to websites, emails and phone numbers not just one option.
2. Recruitment calls to sites that convey a tone of urgency and pressure without considering site-related issues (staff availability, budgets etc.)
3. Varies for studies, it depends on study eligibility criteria and study indication.
4. A one-size-fits-all approach. Different disease groups require different approaches. For example, social media may work well for one trial but not necessarily for another.
5. Use of third party vendors that don't vet leads before sending them on to site. - Relying solely on referrals from PI and their colleagues for rare disease groups.
6. Large advertising campaigns for a speciality population - can create a lot of noise without conversion to recruited participants. Radio adverting as been expensive for little - no benefit.
7. Radio did not work so well, high cost for low numbers/onward suitable referrals.
8. Low funded studies of older/safe treatments should be simple but are often very difficult to undertake - despite investigator commitment, site appears to prioritise very low/maybe poor site selection (-->rural & remote).
9. Expecting the PI to find patients in the database or sitting in the waiting room.
10. Short term advertising.
11. Paper / radio advertisement.
12. Can’t think of any.
13. Impersonal approaches to recruitment often fail. Face to face communication can be helpful, particularly if the study is complex and will require a large investment by the participant. Credentials of the person approaching consent are also often valued by potential participant.
14. Weekly emails to outside referrers - tendency to delete the emails as they come so frequently.
15. If we had required participants to have a separate visit beyond the initial clinical visit - the 2 should be combined - strike when hot to trot. Recruiting Dr in one room, trial nurse in the next room.
16. Un-engaged investigators. Trials that are only being done for political reasons (part of a group, but not invested in the actual trial, or doing a trial so the PI gets offered the pipeline

drug upcoming) promotion via radio etc as the influx of patients is unmanageable for the hospitals and trials staff in anything but rare cancer types.

17. Clients are engaged in clinical services without being informed about the research aspect of the organisation. Some clinicians are tolerant but not supportive of research engagement.
18. Waiting for referrals to come without being proactive and pestering people.
19. Social media advertising can be wildly variable with some bursts of good recruitment but a lot of poor returns too.
20. Posters.
21. Print ads.
22. Referrals from GPs/Specialists.
23. Advertising through 3rd party vendors as they are not specific enough to ensure that the majority of inclusion/exclusion criteria are met. Huge waste of site resources following all the referrals up and not 1 was even remotely eligible.
24. Clinician referral. Other clinicians not willing to refer patients to trials. Some do not see clinical trials as a legitimate treatment option for patients.
25. Purely relying on clinicians for referrals.
26. Clinician referrals.
27. Advertising.
28. Radio advertising.
29. We are only a short way in, so its too soon to say that something hasn't worked.
30. More training for clinical staff who are already overwhelmed by their clinical workload is not the answer! (And is counterproductive by making them cross).
31. Advertising to colleagues.
32. Flyers.
33. Clinician-only recruitment and consenting.
34. Advertisement through central referral websites.
35. Database searches. Sites have pushed back due to privacy concerns. Also sites have expressed that it is unfair to potentially move a patient up the procedure waiting list I order to participate in an interventional device trial.
36. Adverts in social media or print press.
37. n/a.
38. Cold calling/emailing clinicians who are not invested in the research/connected to the researchers. Gatekeeping by protective clinicians is the ongoing main issue.
39. Advertisements in newspapers. Television spots - always gets cut and often company not mentioned.
40. External recruitment agencies, GP referrals.

41. Social media advertising only reaches people who are pretty active on social media platforms.
42. No CTN, inexperienced Physician Researcher without support doing research while carrying a full clinic load and no hospital support for them to run their trial.
43. None.
44. Just adding a trial to the system without continual engagement of clinicians.
45. Recruitment agencies, centralised recruitment for multisite studies.
46. Relying solely on specialist physicians to identify and recruit patients.
47. P.I not leading by example
48. Posters, adverts, Facebook advertising can be hit and miss.
49. Ads, flyers, posters.
50. Some of the advertising initiatives which lack a thorough pre-screen tool, burdens site with inappropriate patients for the sites to screen.
51. Multi departmental collaborations are difficult.
52. Facebook costly and difficult with little results.
53. Posters, recruitment cards
54. Use of Facebook advertisements - self-identification of participants on condition not reliable - this created a large workload to sort through responses for few viable participants.
55. Having clinicians sign on to be involved as an AI or PI and then once the trial is open to recruitment, they decided they don't believe in the trial anymore and don't promote it. Essentially in my experience some clinicians want their names on the papers and sign up to be involved without realizing how much work goes into a trial, and when they decide to not actively recruit it makes our site look poor and it is frustrating to see all the hard work go down the drain.
56. Leaving brochures in waiting rooms.
57. Some of the "recruitment aid" materials supplied by sponsoring companies are a waste of money, and in some cases time and have little value if the sites are well selected and have engaged investigators and well trained staff. It's the engagement of the sites and involved staff with the research and their relationships with their patients that is key to recruitment.
58. Advertising directly to patients.
59. Communication about potential patients or patients that have been seen. We are not informed in a timely manner.
60. Advertising to the general public, this leads to a lot of time wasted pre-screening very ineligible participants.
61. No.
62. Letter to area GPs.
63. We always try to avoid having competing studies no real unsuccessful initiatives.

64. News story on TV (unrealistic hopes, wrong types of subjects enquiring).
65. Blindly attending clinics hoping someone eligible will turn up. Need access to clinician lists or hospital records for the purposes of identifying those who would be eligible. Obviously this should be up front and centre at public training and research hospitals that this research and training occurs here.
66. Advertising.
67. Paying for fixed FTE research nurse time.
68. Relying solely on PIs, traditional print material in waiting rooms.
69. Using same old sites over and over. Tolerating poor performers and not closing promptly. Formulating recruitment strategies without taking site feedback into account.
70. Depending on logistics what is required with the Study, sometimes if an investigator is not cooperative nothing happens and you go around in circles trying to organise a plan to recruit successfully. That has been a problem in the past and given up on the Study.
71. An inadequate lead site who is not experienced, efficient or adequately resourced.
72. Inadequate staffing to support the study.
73. Facebook Websites (minimal returns).
74. Online recruitment agency.
75. Posters in the waiting room, never seem to work.
76. Relying on the Investigators to do all the recruitment activity.
77. Small monetary incentives do not help with patient follow up appointments.
78. Cold calling healthy volunteers who had previously joined a mailing list.
79. Pressure from sponsors does not help.
80. Not involved in site recruitment.
81. Aggressive staff.
82. Pre-screening clinic lists - very time consuming and rarely results in increased recruitment.
83. Advertising through media - often not accurate information given.
84. The ethics and governance process has been extremely lengthy, and has held up our project significantly. A more streamlined ethics/governance process would be great.
85. No buy-in from PI projects poorly on recruitment staff especially when providing services in-kind.
86. Very tight inclusion/Exclusion criteria.
87. Social media hasn't worked that well for us, though I imagine it could be successful in the right hands.
88. Posters and flyers distributed in the local area, trying to engage GPs/psychologists to refer their patients.
89. Advertising, handing out information.

90. 3rd party organisations - referral pathways already exist. Involving 3rd party people complicates the process and means more work for study coordinators.
91. Site staff not engaged in the trial. Lack of support by colleagues for the trial.
92. Constant harassment from AI robot email systems from sponsor.
93. Social Media.
94. Direct community recruitment.
95. Advertising if not targeted properly. This can result in hundreds of phone call and return 2 or 3 suitable participants.
96. Relying on staff that already have a heavy workload non research related.
97. Large vendor outreach (normally too many patients not eligible and takes a lot of time to review).
98. Attendance at street fairs, social media unless it is very targeted.
99. Protocol amendments.
100. Advertising to patients rather than clinicians as patients may be willing to participate and approach trial staff but usually do not meet eligibility criteria.
101. A research coordinator whose line manager uses them at the bedside when the unit needs more nurses. Completely unacceptable as it devalues the research coordinator role.
102. Patient having to undergo multiple biopsies. Extensive screening phase.
103. Apps and social media.
104. Radio advertising- too many people with other conditions call.
105. Being off-site - relying on busy clinic staff to inform potential participants of the trial.
106. GP mail outs.
107. Inadequate site selection plan. Just adding sites because they know the PI.
108. Relying on clinicians to refer, especially radiologists at sites outside my primary hospital.
109. Use of non-specific social media channels.
110. Online recruitment esp for older patients. Prefer word by mouth or physical ads.
111. Between hospital competitions, across state completions, across country competitions.
112. Advertising.
113. Emails out to neighbouring sites to raise awareness - rarely leads to patient referrals.
114. Nil.
115. Multi site trials, with poor engagement from AI and other sites.
116. Hard to recruit in an ICU based on pt complexities and stress of ICU admission- usually traumatic.
117. Social media as a recruitment tool. We will NEVER go down this path again...
118. Repeating ads in the local papers within the same geographical region again.
119. Advertising - cast net too wide, not specific enough to target inclusion / exclusion criteria - just creates extra work load for little benefit

120. Relying on busy clinician's to refer. Relying on one person in a unit to refer.
121. Having multiple Sub I's.
122. Giving potential patients too much time to consider participation (eg, consider a RT trial during chemo).
123. Relying on clinicians/others to make referrals to your study.
124. I think this really depends on your participant/target group and ensuring that recruitment strategies are appropriate to that group. It's not a recruitment strategy if you just cut and paste what the previous group did!
125. 3rd party vendor controlling recruit with only suitable participant names given to site.
126. Pressure from the sponsor.
127. Database reviews. For the time invested few additional potential participants are ever identified.
128. Flyers, posters, tri-fold leaflets do not seem to be very effective in Australia/NZ.
129. Social media can be effective if the correct strategies are in place, but this usually involves the use of a digital marketing company to assist as site staff are not aware of the algorithms used by social media platforms to promote their post.
130. Reviewing patient lists, leaving referrals up to clinicians alone.
131. Time constraints to get consent when the baby is in a critical condition just adds further stress to the parents.
132. Don't try and answer questions about research methods, best to give simple answers that relate to the participant, even if that means over simplifying the process.
133. Broadly advertising individual trials with very specific inc / exc criteria.
134. Time consuming preparation at the bedside by clinical staff - especially after hours when staff feel they are not supported. This is not always the case.
135. Ethics! Our Ethics process in XXXXX is APPLALLING and prohibits timely start of research especially for transitioning juniors! They have totally LOST THEIR REMIT. Their job is to oversee ETHICAL issues NOT every aspect of research methodology! It should not be taking 12 months to gain ethical approval for a retrospective cohort study! Formal complaints are close to happening.
136. Taking a single focus approach. Recruitment initiatives need to be multi-modal.
137. We would like to work more closely with local clinicians for referrals, but it has been difficult to organize a flow of information.
138. Lack of buy in by all clinicians.
139. Site/patient facing posters.
140. Very small number of people now read newspapers or leaflets. This will depend of course on your targets for recruitment.
141. Posters, brochures.

142. Social media, posters in waiting rooms.

143. Trying to conduct trials in GP practices using Medical Director as a platform to remind GPs to screen patients during consultations.

APPENDIX 8: What other ideas do you have as to how sites could improve recruitment into clinical trials that haven't already been mentioned? n=96

1. Sites should consider budgeting for advertising campaigns and contract in a digital marketing expert if the trial is open for more than 3 months. This brings knowledge in house and reduces the burden on site clinical staff to manage the admin.
2. Definitely GP networks.
3. There needs to be more collaboration with the end user (ie patients) before finalising trial design.
4. More public awareness campaigns about clinical trials. Stats I heard recently in the US is that 80% of patients have never heard about clinical trials and <2% participate. - Decentralising trials and bring trial to patient to allow access for remote people.
5. Campaigns designed for local regions. We have used central, local or central + local campaigns in a range of trials. The campaigns we design to appeal to your local audience (sunny QLD!) always do better. Real-world protocols or open-ended budgets: Sometimes the trial design and/or eligibility just won't work at all. Even where it may but just not very easily, many multiples of patients need to be pre-screened or screened to get small randomised numbers. Higher budgets to do this work and to allow for patient travel from well outside the region are essential.
6. Less red tape.
7. Use of eConsent and / or video for consent.
8. Incorporate ability to approach trial participants from one study into another via a request on the original consent so that study sites can reapproach the same client for future research.
9. Advertising campaigns should accord with the risk of the study and patient demographic. eg. Facebook advertising can be successful for youth participation in low risk trial. Face to face recruitment from doctor referrals may be more appropriate for oncology trials. Adding the study to a trial registry can go a long way to increasing the profile of the study.
10. Better understanding of researchers on the requirements of ethics & Governance applications. In IIS trials poor quality o/ or non-compliant submissions is frequently and issue leading to perceived "delays" in review process.
11. Opportunities for experienced sites/staff to share successful strategies with sites or staff new to clinical trials.
12. Engage all staff, from front reception to secretaries to support the recruitment effort. constant feedback about recruitment to referring members of staff.
13. An easy to access a local registry of trials for local GPs, they report they get a lot of info about trials but need a resource to find contacts, incl/excl criteria in a hurry.
14. Improved clear referral pathways, including a focused clinical trial referral pathway for patients to go directly to a trial inquiry patient lead referral pathways, they want a trial but their current

institution is reluctant to make the referral. key contact person at each institution to act as a clinical trial navigator for enquiries.

15. Have more sites available for participants to remove accessibility barriers.
16. In order to obtain grants, investigators need to inflate the number of participants they aim to recruit. These numbers are not realistic and they set recruitment into studies up for failure.
17. Having recruitment coordinator/s who was responsible for identifying participants and engaging people into trials.
18. More access to specialist in social media. Being able to search hospital GP records for potentially suitable participants.
19. Increase advertising budgets.
20. Poster advertising at local pharmacies.
21. Allow research sites to have relationships with external databases/medical records more easily.
22. Investigator aware and prepared for extra workload associated with trial.
23. Again trial recruitment needs to be a KPI for CEO's Hospitals need to invest in employee study coordinators and trial staff to be able to run and recruit into clinical trials.
24. We haven't begun advertising using social media and professional networks yet, but I hope this would be successful.
25. Cross checking patients from prior studies that may be eligible for new studies with the same indication.
26. Speak to subjects as well as providing written PICF. Follow subjects up to answer any questions. Respect subject choices.
27. Routine consent of all hospital patients to release information that could be used to facilitate trial recruitment.
28. Nil.
29. Increasing the engagement of the Doctor group.
30. Just a thought, if Participants should be able to provide rights to access their 'My Health Record' to determine the eligibility to participate in a clinical trial.
31. Increased use of social media.
32. Experienced CTNs available to researchers and backups for holiday periods more experienced research governance officers so site approval can be done efficiently and available dedicated site lawyers with experience in research contracts.
33. Encourage networks which enable sites to send patients with rare diseases to a single site for a clinical trial.
34. Better interaction with primary care, additional resources or technology to get through patient records.
35. The sites should be made aware that this is a site responsibility - it is what they sign up for - if they cannot provide the patients then they should not sign up for the clinical trial.
36. None.

37. More advertising about Clinical Trials, most people don't even know they exist.
38. Extra staff required as team very small and have too many competing priorities and in house research to complete.
39. Recruitment advertising to referral networks.
40. No.
41. Specific recruitment networks - enable relationships to be built between investigators and referrers.
42. Reaching out to nearby facilities for help with recruitment.
43. Social media takes time to build momentum, but after a while, peer review and support really helps reach the hard to reach.
44. Engaging consumers more effectively and reimbursement for travel.
45. Governance is now an enormous time waste and paper pushing nightmare. When HREC was supposedly streamlined/sped up several years ago - all the bureaucracy just moved to the governance and SSA process. This is HIGHLY variable between hospitals for the same research study. It is now taking us up to 12 months to get even NHMRC funded projects fully approved through governance even with investigators named on the ground who are employed within the hospital.
46. The greater issue is the time taken by sites to enter data and respond to queries. Investigators also need to understand the requirement to review the data collected and sign off the data in a timely manner. Clinical trials are only successful when the data is collected accurately and to timeline.
47. Realise that they are only as good as the recruitment of their last clinical trial and turn down studies where there is a risk of poor performance.
48. Developing good relationships within the MDT and having good communications with rural networks and physicians
49. More mainstream media on what trials are offered where and what impact they have for patients. Often people approached to be in a clinical trial, consider themselves 'guinea pigs' and don't realise the importance of clinical trials and what they offer our society as a whole. If there was wider community acceptance of trials as a whole, this would be helpful.
50. Always provide an inclusion/exclusion criteria at feasibility, this will provide more accurate estimates for recruitment. The more complex the inclusion/exclusion criteria is the more difficult it is to give an accurate recruitment number.
51. Appeal more to altruism, particularly for healthy volunteer studies. Use real life scenarios eg video showing potential pts how their participation could help others (ie. the greater good).
52. Hospitals and clinics should provide better awareness of trials. Without trials our treatments cannot move forward.
53. Australia needs the best marketers on this problem to promote clinical trials as a legitimate treatment option or in the case of Phase 1 health volunteer trials as worthwhile relatively low risk

endeavour. Most of the public/doctors either don't know about trials or think they are too scary! The other long term strategy is to improve patient experience while on trial. Word of mouth is the best advertisement for increasing awareness and interest in CTs.

54. Better site selection from sponsors. Site selection seems based on personal relationships with PI rather than strategic look at population and unit activity in a geographical region.
55. Ease of parking, maybe parking vouchers if at a major hospital. If just a blood test or paperwork is needed, going to the patient's home at times.
56. Clinicians performance need to be assessed by how many patients they screened.
57. Making GPs and consultants aware of the ClinTrial refer app.
58. Monitor research activity and incorporate as part of operational duties and activity.
59. Having more resources / staffing to assist specifically with recruitment would be helpful, as the clinical staff often do not have time to devote to study recruitment.
60. Incentives or payments for site staff and quick response by research team.
61. Appropriately budgeted. Thought about from day 1 (e.g., included in grant app).
62. N/A.
63. Making sure that every member of the team; social workers, physiotherapists, play, music therapy, nurses, junior doctors on rotation - etc, are all engaged in the idea of clinical trials. Emphasise that we are doing clinical research and that clinical research should be not only the mantra of the department, but is the right for all patients to be able to participate in.
64. Shorter succinct PICF. 2 pages max with diagrams/pictures.
65. Writing better trials that help people, not just pharma company shareholders.
66. Web-based strategies.
67. Patient education programs on clinical trials and why/how to participate; encouraging GP referrals; better partnership with patient advocacy groups; better uptake of social media and other outreach programs; more positive stories about trial participation in the general media.
68. Paying GPs or external specialists a fee per referral/ successfully recruited patient.
69. Staff not in the trial clinic being aware of clinical trials and general understanding of the trials' inclusion and exclusion criteria.
70. Organisation/Institution to regularly update website and other social media platforms is required.
71. Consider opt-out approach to researcher's initial contact with the patient/family.
72. Site support -adequate site payment (investigator initiated trials) Motivating site study promotion (via app, patient group, network).
73. Empowering patients to easily find relevant clinical trials for themselves using technology.
74. Collaboration across sites.
75. Better access and integration with primary care. Money to cover nurse salary at GP sites to review patient files to identify eligible participants.
76. Ward posters about the trial underway. Who family/patient can ask about suitable trials. Financial reimbursement for time and travel required by participants.

77. Ensure that protocol eligibility is reasonable.
78. Nil.
79. Nil.
80. Invest in software that can de-identify and filter existing hospital EMR data. Assist GPs to find suitable clinical trials quickly. Work on policies that allow for targeting eligible participants easily, but without compromising patient views of clinical trials. eg: avoiding the detrimental effects of telemarketing. Make known the national clinical trial website https://www.australianclinicaltrials.gov.au/ to the general population.
81. Utilise PowerTrials ieMR better and have more freedom with this for screening. Engaging all staff in areas to refer and in general more engagement by disciplines to be research active in hospitals. Have oncall roster for weekend recruitment.
82. We need a statewide strategic plan for studies so we can develop expert centres in certain diseases. Competition for studies means we have to go through too many SEVs.
83. Nil.
84. Involvement of consumers in developing recruitment strategy.
85. Most have been covered.
86. Awareness of Clinical Trials in adjuvant and neoadjuvant setting, so that they are aware of the next options when and if recurrence happens. We often wait to pitch patients until they are stage III/IV or end of treatment options.
87. Increased awareness of CT's with clinicians not actively involved in research. Promoting referrals onto CTs.
88. Sponsors thinking about barriers prior to initiation.
89. As above.
90. More use of social media. Basic information to the general Australian population about clinical trials - even government led.
91. Increase the time frame required wherever possible. Allow the parents to discuss and think about what is required of them eg follow up visits etc if they consent
92. Increased access to participation, we don't get offered trials they go to all of the big recruiting areas. When we do get them we recruit really well.
93. Research is embedded into clinical practice.
94. Multiple extensive advertising campaigns. So few people still know of clinical trials and the benefits it can bring. We need to utilise the digital age as i said before and get the message out there!
95. Asking patients who decline participation if they would like to be contacted in the X future in case they would like to reconsider.
96. Have a national volunteer register akin to organ donation government campaigns to raise community awareness of CTs.