Annual Progress Report

Progress Report Overview

Overview of Progress

Dependents: 6

PR.1. What is the current status of your study?

If your study is the New Zealand arm of an international study, please answer the questions below for the New Zealand arm only.

- ○ This study has been abandoned prior to commencement
- ○ This study is yet to commence
- ○ This study has commenced and is continuing
- ○ This study has concluded

Depends on PR.1. Current status of study, PR.1. Current status of study

Please submit a notification of conclusion of study form instead.

Dependents: 4 Depends on PR.1. Current status of study

PR1.1 Status of ongoing study as of time of submission:

Please check all applicable boxes below.

- ☐ Active enrollment / recruitment
- ☐ Active follow up continues but participants are not receiving study-related intervention
- ☐ Enrollment has not started
- ☐ Enrollment closed and participants are receiving study-related intervention
- ☐ Enrollment closed
- ☐ Retrospective records review only
- ☐ Other

Depends on PR1.1 Status of study.

Enrollment closed and participants receiving intervention:

- ☐ Participants receiving investigational products (medicines/devices)
- ☐ Participants receiving other study-related interventions (including protocol-specified testing)

Depends on PR1.1 Status of study.

Enrollment closed:

- ☐ Open for collection of follow-up data and data analysis
- ☐ Open for data analysis only

Dependents: 1 Depends on PR1.1 Status of study.

Retrospective Records Review Only:

- [ ] Data collection has not started
- [ ] Data collection / linking ongoing
- [ ] Data analysis only
- [ ] Other

Depends on PR1.1 Status of study., Retrospective Records Review Only:

Please explain other:

Depends on PR.1. Current status of study

PR2. HDEC approval may be withdrawn for studies that have not commenced within 12 months of approval. Please explain why your study has not commenced and when you intend to do so.

Depends on PR.1. Current status of study

PR3. On what date did this study commence?

Depends on PR.1. Current status of study

PR4 On what date do you expect this study to conclude?

Studies in Progress

Administrative Section

Dependents: 1

PR5. Are there any new study sites (localities) since the last annual progress report, or if this is the first report, since approval?

- ○ Yes
- ○ No

Depends on PR5. Are there any new study sites (localities) since the last annual progress report, or if this is the first report, since approval?

PR5.1. Please provide a brief summary of the sites added and lead investigator name at each site. Note that all sites must be authorised in online forms

Dependents: 1

PR6. Has there been any change to the Sponsor since the last annual progress report, or if this is the first, since approval? If the study is not sponsored please select 'not sponsored study'.

- Yes
- No
- Not sponsored study

Depends on PR6. Has there been any change to the Sponsor since the last annual progress report, or if this is the first, since approval? If the study is not sponsored please select 'not sponsored study'.

PR6.1. Please provide a brief summary of any changes made to the sponsorship of the study.

Dependents: 1

PR7. Does the study require registration on a clinical trials registry?

- Yes
- No
- Not applicable

Depends on PR7. Does the study require registration on a clinical trials registry?

PR7.1. Please state what registry the trial is registered with and provide a link to the study.

Dependents: 1

PR8. Funding Status/Changes: Select the appropriate box that best describes the funding status of this study.

- Not funded
- Pending
- Awarded
- Funding has ended
- New funding source

Depends on PR8. Funding Status/Changes: Select the appropriate box that best describes the funding status of this study.

PR8.1. Please explain your answer to PR8.

Dependents: 1

PR9 Since your approval, or the last progress report, has the study been audited or reviewed by a third party? For example by the sponsor, a funding agency or an external provider.

- Yes
- No

Depends on PR9 Since your approval, or the last progress report, has the study been audited or reviewed by a third party? For example by the sponsor, a funding agency or an external provider.

PR9.1. Please explain who reviewed the study and what the outcome was:

Dependents: 1

PR10 Does the study have data safety monitoring arrangements? For example an individual monitor or a data safety monitoring committee.

- Yes
- No

Depends on PR10 Does the study have data safety monitoring arrangements? For example an individual monitor or a data safety monitoring committee.

PR10.1 Please explain whether the monitor has produced any recommendations, suggested any changes to the study and indicate whether there have been any changes to the composition of the reviewing body.

Commercial Studies and Claims

Dependents: 2

PR11. Is this study a commercially sponsored intervention study?

- Yes
- No

Depends on PR11. Is this study a commercially sponsored intervention study?

Please upload evidence of up-to-date insurance (ACC equivalent) for the trial.

Upload Document

Dependents: 1 Depends on PR11. Is this study a commercially sponsored intervention study?

PR11.1. Have any compensation claims relating to injuries been made by participants OR has the sponsor and / or site made any payments to any participants as a result of injuries or adverse events?

- Yes
- No

Depends on PR11.1. Have any compensation claims relating to injuries been made by participants OR has the sponsor and / or site made any payments to any participants as a result of injuries or adverse events?

PR11.2 Please provide an overview, including dates, of the status of ongoing claims/payments and the outcomes of any completed claims or payments.

Study Conduct

Dependents: 1

PR12. Has the conduct of this study over the past year complied with all the relevant National Ethical Standards for Health and Disability Research and Quality Improvement?

- Yes
- No

Depends on PR12. Has the conduct of this study over the past year complied with all relevant ethical standards?

PR12.1 Please briefly explain your answer to PR12.

Dependents: 1

PR13. Have there been any complaints received about the study from participants, staff or members of the public?

- Yes
- No

Depends on PR13. Have there been any complaints received about the study?

PR13.1 Please describe the nature of any complaints along with steps taken to resolve them.

Non-substantial Changes Update

PR14. Please briefly describe any minor (non-substantial) amendments and protocol deviations or violations that have been made or occurred to this study since the previous progress report (or, if this is the first progress report, since the study commenced).

Please upload any new versions of documents that contain non-substantial amendments. This includes minor changes to advertising, PIS/CF etc.

Note you do not need to submit all localised versions of the PIS/CF.

PR14. Please briefly describe any minor (non-substantial) amendments **and** protocol deviations or violations that have been made or occurred to this study since the previous progress report (or, if this is the first progress report, since the study commenced).

Please upload any new versions of documents that contain non-substantial amendments. This includes minor changes to advertising, PIS/CF etc.

Note you do not need to submit all localised versions of the PIS/CF.

Upload Document

Add Another

Recruitment Update

PR15. Please indicate how many participants have been recruited to this study in New Zealand, and whether recruitment is on target.

If your study involves **health information only** please enter how many individual records have been accessed.

- Behind Target
- On Target
- Ahead of Target

PR16. Please list recruitment by site:

PR17. Have any participants voluntarily withdrawn from this study?

- Yes
- No

PR17.1 Please indicate how many participants have voluntarily withdrawn from this study in New Zealand.

Please briefly describe the reasons for voluntary withdrawal, if recorded.

Please include any complaints received about the conduct of the study.

PR18. Have any participants been withdrawn by the Investigator?

- Yes
- No

PR18.1. Please indicate how many participants have been withdrawn by the investigator.

Please briefly describe the reasons for withdrawing participants, for example failure to comply with study rules.

Consultation Update

Dependents: 2

PR19. Has Māori consultation occurred since or before initial HDEC approval?

- Yes
- No

Depends on PR19. Has Māori consultation occurred since or before initial HDEC approval?

PR19.1. Please briefly describe the Maori consultation process that has occurred for your study at each site. For instance, were any issues identified with your study? Have any changes been required of your study or patient information? Are you conducting on-going consultation?

Depends on PR19. Has Māori consultation occurred since or before initial HDEC approval?

PR19.2. Explain why no consultation has taken place.

Dependents: 1

PR20. Does the study involve other stakeholder groups that require consultation?

- Yes
- No

Depends on PR20. Does the study involve other stakeholder groups that require consultation?

PR20.1. Please describe the consultation process undertaken and any changes made to the study.

Summary of Report

Dependents: 1

PR21. Have there been any findings or observations during the last approval period that may affect the study's risks and/or benefits?

- Yes
- No

Depends on PR21. Have there been any findings or observations during the last approval period that may affect the study's risks and/or benefits?

PR21.1 Please explain these findings and how they have affected the study's risks and/or benefits.

PR22. The progress report should provide the HDEC with a description of the progress of the study over the past approval period, and the study's current status. Please provide a summary for the reviewing HDEC outlining:

- Progress towards achieving research objectives;
- Barriers to meeting research objectives, and strategies to overcome barriers;
- Your analysis of the study's adverse events and unanticipated problems and any effect on the research;
- Any scientific developments affecting the equipoise, safety, efficacy or other fundamental aspect of the study;
- For community based studies, have any findings have been shared with the local community?
- Any other relevant comments.

PR23. ***An annual safety report must be attached if your study involves a new medicine. Please upload an annual safety report if required.***

PR23. *An annual safety report must be attached if your study involves a new medicine. Please upload an annual safety report if required.*

Upload Document

Add Another