**DATA MANAGEMENT PLAN**

**Version: 1.1**

 **Date: 11/10/21**

**Protocol 21.2 PMCF Tinnitus Study**

**Sponsor:** **Oticon**

**Site: Auckland (single site)**

**Co-ordinating Investigator Grant D Searchfield**

Contents

[1 Introduction 3](#_Toc51833245)

[2 Study Structure 4](#_Toc51833246)

[3 Organisational Data Governance Oversight 4](#_Toc51833247)

[4 Consent for Data Collection and Use 4](#_Toc51833248)

[5 Data Collection 5](#_Toc51833249)

[6 Privacy and confidentiality 5](#_Toc51833250)

[6.1 Breach of Privacy / Confidentiality 5](#_Toc51833251)

[7 Forms of Data 6](#_Toc51833252)

[7.1 Identifiable Data 6](#_Toc51833253)

[7.2 De-identified Data 6](#_Toc51833254)

[7.3 Anonymous / Anonymised Data 6](#_Toc51833255)

[8 Access to and Use of Data 7](#_Toc51833256)

[8.1 Identifiable Data 7](#_Toc51833257)

[8.2 De-identified Data 7](#_Toc51833258)

[8.3 [Anonymous/Anonymised] Data 8](#_Toc51833259)

[8.4 Sending of Data Overseas 8](#_Toc51833260)

[8.5 Future Use of Data 8](#_Toc51833261)

[8.6 Commercial Use of Data 8](#_Toc51833262)

[8.7 Data Linking 8](#_Toc51833263)

[8.8 Databank / Registry 9](#_Toc51833264)

[9 Storage and Destruction of Data 10](#_Toc51833265)

[9.1 Identifiable Data and Source Documents 10](#_Toc51833266)

[9.2 De-identified Data 10](#_Toc51833267)

[10 Consultation 10](#_Toc51833268)

[10.1 Māori Data Sovereignty 11](#_Toc51833269)

[11 Return of Results 11](#_Toc51833270)

[11.1 Incidental Findings 11](#_Toc51833271)

[11.2 Results Arising from Future Research 11](#_Toc51833272)

[11.2.1 Data 11](#_Toc51833273)

[11.2.2 Databank / Registry 11](#_Toc51833274)

[12 Withdrawal of Data 11](#_Toc51833275)

# Introduction

This Data Management Guide outlines how data will be handled during the study (Protocol 21.2 PMCF Tinnitus Study) and after its completion.

# Study Structure

Sponsor will enlist the support of the named Contract Research Organisation (CRO) to co-ordinate the Study. The Sponsor is responsible for supervising any and all outsourced activities.

**TABLE 1. STUDY STRUCTURE**

|  |  |
| --- | --- |
| Sponsor | Oticon, Demant |
|  | Denmark |
| Contract Research Organisation | Audiology |
|  | The University of Auckland |
| Lead Site (New Zealand) | Audiology |
|  | The University of Auckland |
| Co-ordinating Investigator | Grant D Searchfield |
|  | The University of Auckland |

# Organisational Data Governance Oversight

The following institutional data policies apply for the Study:

Protocols and Governance Policies of Clinics, The University of Auckland

National Ethical Standards for Health and Disability Research, New Zealand

# Consent for Data Collection and Use

All participants will be informed of, and provide consent for, the collection and use of their data for the purposes of this study, and for any mandatory secondary uses.

# Data Collection

Data will be collected from the following sources:

* Direct communication with the participant
* Study assessments, including audiology test results, questionnaires, interviews, and data downloaded from hearing aids

Data will be collected primarily by the Investigator or designated study staff. All study personnel involved in data collection will be trained in GCP, study protocol, and collection requirements.

Collection of data will be limited to that necessary for the specified purposes of the study, or for additional purposes that the participant has explicitly consented to.

# Privacy and confidentiality

Participants’ privacy and confidentiality will be respected through the protection of their data as outlined in this plan. The Investigator will comply with legal and regulatory requirements regarding the privacy and confidentiality of participants’ data.

Participants have the right to access and correct personal data held by the site. Other results may be available on request, and will not result in the participant being withdrawn from the study.

## Breach of Privacy / Confidentiality

A breach of privacy means unauthorised or accidental access to, or disclosure, alteration, loss, or destruction of a participant’s information.

In the event participant privacy and confidentiality is breached during the study, the following steps will be taken:

* Action will be taken to reduce the risk of harm following the breach. Where possible, the recipient will be contacted and asked to destroy or return any electronic the disclosed material.
* The participant will be informed of the breach as soon as practicable (unless the participant is under the age of 16 and notification would be contrary to his/her interests; or notification would be likely to prejudice the health of the participant (after consultation with the participant’s health practitioner, where practicable), and provided with support as required.
* CRO and/or Sponsor quality review will be conducted to ascertain factors contributing to the breach, and any corrective action required to prevent future breaches.
* The approving HDEC will be informed.
* For notifiable privacy breaches of privacy under the Privacy Act 2020, the New Zealand Privacy Commissioner will be notified in accordance with that Act.

# Forms of Data

## Identifiable Data

Direct identifiable correspondence including consent forms will be retained. A record linking ownership to participant’s unique study code will be kept for the duration of data acquisition.

## De-identified Data

De-identified data in this study includes but is not limited to:

* Case Report Forms.
* Safety and screening results entered into the analysis data set.
* Communications from the site to the Sponsor

De-identified data will carry the participant’s unique study code The Investigator will retain a log linking participant code with identifiers. This log will not be made available to the CRO or Sponsor.

All data sent to CRO and Sponsor will be de-identified. All data generated by these parties will be in de-identified form. No attempt will be made to re-identify participants.

## Anonymous / Anonymised Data

De-identified data may be anonymised prior to being made available for future research. Anonymised data will be irreversibly stripped of the unique participant code and any other identifiers.

Participants will be informed that anonymous / anonymised data is unable to be accessed, corrected, or withdrawn; and that return of individual results will not be possible.

# Access to and Use of Data

Collected data will be used to answer the research questions and fulfil the study requirements described in the study protocol.

## Identifiable Data

Identifiable data may be accessed by the following groups during the study duration.

* The Investigator and designated study staff, to fulfil protocol requirements.
* Study monitor(s), for eligibility confirmation and source data verification purposes.
* The Health and Disability Ethics Committee, for legal and regulatory purposes.
* Health, regulatory, or government agencies, for legal and regulatory purposes.

It may be necessary, but unlikely, for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

## De-identified Data

De-identified data may be accessed and used by the following groups: The Investigator and suitably trained and experienced study staff, to conduct the study.

* Sponsor / CRO study monitor(s), for source data verification purposes.
* The CRO and Sponsor, for study conduct, data analysis and, product registration and marketing, or as otherwise permitted by applicable local and international laws and regulations.
* The Health and Disability Ethics Committee, to comply with legal and regulatory duties.
* Health, regulatory, or government authorities, to comply with legal and regulatory duties.

De-identified data may be included in published study results including, but not limited to, peer-reviewed publications, clinical trial registry websites, scientific meetings, and regulatory / marketing submissions.

##  Anonymised Data

Anonymised data may be accessed and used by the groups described in Section 8.2.

Anonymised data may also be made available to other researchers, as described in Section 8.5.

## Sending of Data Overseas

De-identified / anonymised data will be sent overseas to Denmark [to the sponsor].

Participants will be informed of this.

## Future Use of Data

De-identified [and/or anonymised] data will be used by the Sponsor for future medical or scientific research as specified below:

* unspecified purposes which are directly related to the study question(s)
* unspecified purposes which are related to the item and/or condition under study

In all cases, the Sponsor must be satisfied that appropriate Data Management Plans are in place and that ethical approval for use has been obtained in accordance with local laws and regulations.

## Commercial Use of Data

Study data analysis may lead to discoveries and inventions or development of a commercial product or producers. The rights to these will belong to the Sponsor. Participants will receive any financial benefits or compensation from, nor have any rights to, any developments, inventions, or other discoveries arising from this analysis.

## Data Linking

N/A

## Databank / Registry

NA

1. **storage and Destruction of Data**
	1. **Identifiable Data and Source Documents**

During the study, study-specific source documents will be maintained in locked file cabinets in locked rooms, and/or password protected databases via password protected computers.

Post-study, study-specific source documents will be archived in locked cabinets in locked office of the PI at the University of Auckland, and/or password protected databases via password protected computers.

Source documents will be retained for at least 6, then destroyed by disposal in confidential material bins for shredding and incineration.

* 1. **De-identified Data**

Identifiable data will be converted to a de-identified form at the study site, at which point it is entered into electronic case report forms using a secure data platform. The data platform complies with international and national regulatory requirements for electronic data capture systems in the countries where it is used. Data entry will be limited to designated study staff trained and experienced in transcribing data for this purpose.

De-identified data will carry a unique alpha-numeric code. The Investigator will retain a log linking participant code with identifiers. This log will not be made available to CRO or Sponsor.

De-identified data is stored long-term by the Sponsor in secure cloud-based server [“SMART-TRIAL”].

# Consultation

Data management has been discussed and agreed between the PI and sponsor.

## Māori Data Sovereignty

During the study, data may be collected from participants identifying as Maori.

Personal and health information is a tāonga (treasure) and will be treated accordingly.

Formal Māori consultation for this study has been completed as part of the Locality Approval Process and Policies of the section of Audiology.

# Return of Results

Screening and safety results will be provided to participants on request.

Participants have the right to request a lay summary of study results.

## Incidental Findings

In the event that a study assessment returns a result of potential clinical significance, the participant will be informed. With consent the participant’s usual doctor and / or an appropriate specialist will be notified, and follow-up will be arranged.

## Results Arising from Future Research

### Data

No future unspecified research is planned for data collected in this study.

### Databank / Registry

**N/A**

# Withdrawal of Data

Participants may withdraw consent for the collection of data at any time until 1st May 2022, without providing a reason.

Should a participant withdraw consent, no further data will be collected from the participant by study staff.

With permission data collected prior to the participant’s withdrawal will not continue to be used and analysed.