# Clinical Investigation Plan

## Investigation Title: An actual use, prospective, adaptive design, single centre, non-randomised, open-label study, assessing usability of Remote Assist when used to program cochlear implant recipients.

| | |
|---|---|
| **Short Tile:** | **RAL** |
| **CIP Number:** | **CLTD5809** |
| **Date:** | **09 Aug 2021** |
| **Sponsor** | **Cochlear Limited**<br>**1 University Avenue,**<br>**Macquarie University**<br>**NSW 2109**<br>**Phone: 02 9428 6555** |

This clinical investigation shall be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki (World Medical Association, 2013), International Standard ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice, and any regional or national regulations, as applicable.

| | |
|---|---|
| **Manufacturer** | Cochlear Limited<br>1 University Avenue,<br>Macquarie University<br>NSW 2109<br>Phone: [redacted] |
| **Principal Investigator** | [redacted]<br>Principal Research Audiologist<br>Cochlear Limited<br>1 University Avenue,<br>Macquarie University<br>NSW 2109<br>Phone: [redacted] |
| **Safety Contact** | [redacted] |

# INVESTIGATOR AGREEMENT

## Principal Investigator Approval and Declaration

By my signature below, I confirm my review and approval of this Clinical Investigational Plan (CIP).

I also confirm that I will strictly adhere to the requirements therein and undertake to ensure that all staff with delegated responsibilities in the conduct of this CIP have read, understood and will strictly adhere to the requirements therein. This CIP will not be implemented without prior written approval from the Ethics Committee, any applicable National Competent Authorities, and the Sponsor. If amendments to this plan become necessary, written approval by the Ethics Committee and any applicable National Competent Authorities will be obtained before the changes are clinically implemented per the amendment, except under emergency circumstances to protect the rights, safety, and well-being of subjects.

| **Name** | **Title** |
|---|---|
| [redacted] | Principal Investigator |
| **Signature** | **Date** |
| | |

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# 1 DEFINITIONS AND ABBREVIATIONS

| Term | Description |
|---|---|
| ABI | Auditory Brainstem Implant |
| ADE | Adverse Device Effect |
| AE | Adverse Event |
| ANZCTR | Australian New Zealand Clinical Trials Registry |
| CER | Clinical Evaluation Report |
| CI | Cochlear Implant |
| CIP | Clinical Investigation Plan |
| CIR | Clinical Investigation Report |
| CL | Current Level |
| COVID-19 | Coronavirus disease 2019 |
| CRF | Case Report Form |
| CSPro | Custom Sound Pro |
| DD | Device Deficiency |
| DMC | Data Monitoring Committee |
| EC | Ethics Committee |
| eCRF | Electronic Case Report Form |
| EDC | Electronic Data Capture |
| EOS | End of study |
| GCP | Good Clinical Practices |
| IB | Investigator's Brochure |
| ICF | Informed Consent Form |
| ICMJE | International Committee of Medical Journal Editors |
| IDMC | Independent Data Monitoring Committee |
| IFU | Instructions for use |
| IMD | Investigational Medical Device |
| ISO | International Organization for Standardization |
| MCP | My Cochlear Professional Portal |
| MVBT | Master Volume, Bass and Treble |
| NA | Not applicable |
| NRT | Neural Response Telemetry |
| NSA | Nucleus Smart App |
| NSW | New South Whales |
| PC | Personal computer |

| Term | Description |
|---|---|
| RA | Remote Assist |
| SADE | Serious Adverse Device Effect |
| SAE | Serious Adverse Event |
| SOP | Standard Operating Procedure |
| SSQ-C | Speech, Spatial and Qualities questionnaire – Comparative version |
| TGA | Therapeutic Goods Administration |
| USADE | Unanticipated Serious Adverse Device Effect |

# 2 CLINICAL INVESTIGATION SYNOPSIS

| | |
|---|---|
| **Investigation title** | An actual use, prospective, adaptive design, single centre, non-randomised, open-label study assessing usability of Remote Assist when used to program cochlear implant recipients |
| **Short title** | RAL |
| **Investigation number** | CLTD5809 |
| **Name of investigational medical device(s)** | Nucleus Smart App with Remote Assist<br>Custom Sound Pro 6.3 |
| **Intended use of investigational medical device(s)** | Regulatory status of the device: Pre-market<br>The Remote Assist (RA) System is intended to support clinicians to conduct a remote programming session with their CI recipients. RA allows the clinician to 1) provide counselling via a video call and 2) make select MAP and sound processor adjustments using CSPro via the NSA installed on the recipient's smart phone over the internet. |
| **Name and description of comparator device/product(s)** | N/a |
| **Expected recruitment period** | Up to 2 months |
| **Expected duration per subject** | Up to 6 months |
| **Number of subjects planned** | 15 |
| **Number of investigational sites planned** | One |
| **Inclusion criteria** | 1. Adults (≥18 years).<br>2. Implanted with the below cochlear implants in one or both ears.<br>CI500 series (CI512, CI513, CI522, CI532,),<br>CI600 series (CI612, CI622, CI632),<br>Freedom series (CI24RE (ST), CI24RE (CA), CI24RE (CS), CI422).<br>3. At least 3 months experience with the cochlear implant.<br>4. Willing and able to provide written informed consent. |
| **Exclusion criteria** | 1. Unable or unwilling to comply with the requirements of the clinical investigation as determined by the Investigator.<br>2. Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling.<br>3. Cochlear employees or employees of Contract Research Organizations or contractors engaged by Cochlear for the purposes of this investigation.<br>4. Currently participating or participated in another interventional clinical study/trial in the past 30 days, or if less than 30 days the prior investigation was Cochlear sponsored and determined by the investigator to not impact clinical findings of this investigation. |

| | |
|---|---|
| | 5. Prior exposure to Remote Assist concept during previous usability testing. |

| **Objectives and Outcome measures** | |
|---|---|
| **Primary Objective** | **Primary Outcome measure** |
| In real world conditions to confirm the ease of use and user experience of Remote Assist. | Proportion of subjects who, while using the final version of Remote Assist, are able to complete the primary tasks determined by an observer using a rating scale. |
| **Exploratory Objectives** | **Exploratory Outcome measures** |
| Characterise the ability of the subject to understand the clinician via the video call. | The median rating on the ability to understand the clinician via the RA video call. |
| Characterise the time taken for RA to make changes to the MAP over the internet in real world conditions | The median time taken for RA to make changes to the MAP over the internet. |

# 3 SCHEDULE OF EVENTS

**Table 1: Schedule of events**

| Visit Type | Screening | Adaptive Phase[a] | | | EOS |
|---|---|---|---|---|---|
| | | Study visit | Take Home use[b] | Follow up visit | |
| **Timing of Investigation** | **Day 0** | **Day 0 to month 6** | **Day 1 to month 6** | **Day 2 to month 6** | **Month 6** |
| **Visit window (±)** | NA | NA | NA | NA | + 6 months |
| Written informed consent | X | | | | |
| Eligibility | X | | | | |
| Demographics, Hearing history, Device history | X | | | | |
| CP1000 / CP1150 fitting | X | | | | |
| Complete Remote programming session | | X | X | | |
| Usability evaluation | | X | | | |
| Troubleshooting / issues analysis | | | | (X) | |
| Return devices | | | | | X |
| Device exposure | X | | | | X |
| Adverse Events | X | X | X | X | X |
| Device Deficiencies | X | X | X | X | X |

*Abbreviations: EOS = End of Study; X= mandatory activity; (X) = Optional activity*

*[a] The adaptive phase will be conducted according to the procedure outlined in section 7.1.1. For new iterations of the App, the at home and clinical visit sessions may be repeated to ensure the Remote Assist implementation in the Nucleus Smart App is suitable. There will be no more than 5 product iterations.*

*[b] As per the adaptive design outlined in section 7.1.1 if a new iteration is deemed to be required at the in-clinic session, then the take home session may not be conducted with that device iteration. It may be conducted with the subsequent iteration.*

# 4 BACKGROUND INFORMATION AND RATIONALE

## 4.1 Introduction

Clinical management of cochlear implant (CI) recipients involve programming, counselling, performance evaluation and habilitation. The standard practice for this management involves frequent clinical visits in the first year after implantation and annual visits for the rest of the recipient's life (Müller & Raine, 2013). The need to travel to the clinic for follow up appointments can pose significant challenges for recipients, particularly those who live far away from the clinic. There have been reports of recipients being lost to follow up due to the difficulties in travelling to the clinic (Rooth et al 2017). The inconvenience of scheduling a session and travelling to the clinic might deter recipients from seeking help for some seemingly small / less troubling issues and increase their tendency to somehow bear and live with the issues. Sometimes clinicians schedule follow-up sessions with the primary purpose of following-up on progress with strategies provided earlier to overcome real world problems. Such follow-up on progress can easily be completed via a video call as well.

Remote programming is one telehealth solution known to be successful in addressing the challenges of travelling to the clinic for appointments. During the Covid-19 pandemic there was a demonstrated increase in the uptake of remote programming when traveling to the clinic posed a health and safety risk (Kim et al 2021). Current methods of remote programming of CI requires the use of special computer and programming hardware as well as proprietary programming software to be installed on a personal computer (PC) at the remote location. Although remote programming potentially reduces the travel burden for some recipients, it involves substantial administrative effort and cost by clinics to prepare, send, retrieve back, and clean remote programming hardware and software. This also reduces the frequency with which remote programming appointments can be scheduled due to time delays in sending and retrieving equipment.

Remote Assist (RA) is a new solution that allows the clinician to make MAP and sound processor adjustments via the recipient's Nucleus Smart app (NSA) installed on their smart phone. With RA the clinician can also perform counselling using a video call directly via the NSA. As RA uses no specialised hardware and software that needs to be sent and retrieved back from the recipient, it has the potential to further improve the remote programming experience and convenience for both the recipient and the clinician.

The current study aims to assess recipients ease and experience with using Remote Assist to receive remote programming of their CI.

## 4.2 Findings of Previous Nonclinical and Clinical Studies

### 4.2.1 Nonclinical Data

The investigational device in this study is the NSA and Custom Sound Pro (CSPro) 6.3 software when used with CP1000 or CP1150 sound processors. This application is assessed for their effect on the safety and efficacy as per the Cochlear's Product Risk Management Procedure [1] and in accordance with ISO 14971, "Medical devices – Application of risk management to medical devices".

Bench verification and validation [2] and [3] has demonstrated that commercially available versions of NSA and CSPro are safe and effective and does not contribute to an unacceptable risk. The RA hazard analysis [4] concludes that the overall risks for RA fall within the low and medium regions of risk acceptability.

### 4.2.2 Clinical Data

RA uses Master Volume, Bass and Treble (MVBT) adjustments for fitting. Botros, Banna and Maruthurkkara (2013) showed that new MAPs created by adjusting the threshold of NRT profile using MVBT adjustments provided speech perception benefits that were not different from MAPs created using conventional fitting methods. Vroegop et al (2017) showed that when MAPs were adjusted by recipients in real world environments using MVBT, the patients' SSQ-C scores showed significant improvement in perceived auditory functioning, while no significant changes in speech perception or acceptable noise measures (on average) were shown.

Remote programming for CI recipients has been reported in several studies in the last decade. A literature review [5] on remote programming identified 13 high quality studies (in English) where the CI fitting software on a PC was controlled remotely via the internet in order to conduct fitting procedures similar to those carried out in a typical CI clinic.

The literature review concluded that the range of networking software packages used to control the CI fitting software remotely and the audio-visual software used for communication have proved to be reasonably reliable with only occasional loss of connection or delays encountered. The studies report that remote programming provides equivalent listening benefits as compared with in-clinic appointments. Both clinicians and recipients have provided highly positive feedback on the experience of remote programming. Twelve out of 13 studies were conducted with a local facilitator in the same room as the patient to assist the patient during the session. Only one study (Slager et al. 2019) reported remote sessions with and without use of a local facilitator.

Remote Assist however is intended for conducting remote programming sessions without the help of a local facilitator and using the patient's smartphone rather than via the software on a PC.

A second literature review [6] was completed on Remote programming where patients were not accompanied by a clinician in the same room. Seven high or medium quality publications which reported on remote services where patients were not accompanied by a clinician in the same room were identified. The seven studies reported on remote services for a total of 210 adult patients, 33 teenage patients and 13 health care professionals. Majority of the studies (6 out of 7) reported on hearing aid fitting. Only one article explicitly reported on the safety of the remote service: no device-related nor procedure-related adverse events were encountered. Six out of seven studies reported on CI or hearing aid fitting via the patient's computer, tablet or smartphone.

Venkatesan and Carr (2019) and Schnittker (2019) connected the hearing aid to a tablet PC at the patient's home to complete remote programming. They reported that the remote programming sessions could be completed successfully. Froehlich et al. (2020), Miller et al. (2020) and Sonne et al. (2019) reported that remote hearing aid fitting could be successfully conducted by connecting to the app on the patient's smartphone. Slager et al. (2019) reported on the successful use of a tablet PC connected to the recipient's sound processor for remote CI fitting.

The second literature review showed that when remote programming was conducted without a local facilitator, patients' subjective hearing abilities and the objectively measured speech perception

performance are similar between patients receiving remote versus in-office follow-up appointments. Overall, patients as well as clinicians were satisfied with remote services and feel comfortable using them. The publications highlight the importance of direct, face-to-face interaction to achieve high patient satisfaction and, in turn, successful fittings. The patient's preference of remote over in-clinic appointments is highly driven by time savings (i.e., large distances to clinic). Similarly, clinicians believe that remote services would save time for themselves (i.e., scheduling efficiency). In addition, one publication demonstrated that remote services are attractive for teenagers and might increase their engagement in audiological services.

No study was identified in both literature reviews where remote CI fitting was conducted via a smartphone App.

## 4.3 Study Rationale

RA allows the clinician to perform select remote fitting activities including MVBT adjustments via the Nucleus Smart app running on a compatible smartphone. Previous studies detailed above have demonstrated that remote programming is effective and convenient, remote fitting of hearing aids using an app via the smart phone is feasible and effective. Other studies have demonstrated that MVBT is effective for making MAP adjustments. The combination of remote fitting via an app for CI fitting as offered by RA has not been evaluated before. The present study aims to evaluate the ease of use of Remote Assist for remote programming in real world environments.

**Actual use testing:** RA allows the clinician to make select MAP and sound processor adjustments using CSPro over the internet via the NSA installed on the recipient's smart phone. Both the clinician and the recipient are users of the system. One of the users, the clinician, makes MVBT changes to a MAP based on the response from the other user, the recipient. Thus, the use of RA is a unique situation where the interaction between the users affects how the product is used. Usability testing of a recipient using the app under simulated conditions alone does not expose the complexity involved when one user adaptively changes the next step based on the other user's response. Actual use testing is particularly suited for the usability testing of systems where more than one user is involved in obtaining the desired outcome for example, programming hearing aids or cochlear implant systems. Additionally, RA is intended to be used by the clinician in the clinical environment while the recipient is in their home environment. Thus, in this case the effects of the environment add an additional layer of complexity that affects how the product would function. This study will be using an actual use testing process for usability testing of RA in real world environments.

RA will be evaluated with recipients for the first time in this clinical study, and evaluations will be undertaken on developmental versions of the app, with features and updates progressively made available throughout the study period. This study aims to investigate the ease of use of these developmental versions as per (AAMI HE75, 2018).

# 5 MEDICAL DEVICE INFORMATION

## 5.1 Identity and Description of the Investigational Medical Device (IMD)

The RA system consists of 1) a new version an update of to CSPro software (version 6.3) effected with a regional key installation 2) a new version of the NSA installed on a compatible iOS or Android smart phone operating in conjunction with 3) a CP1000 (Nucleus 7) or CP1150 (Kanso 2) Sound Processor with an updated firmware.

RA enables clinicians to conduct a remote programming session by connecting the Custom Sound Pro 6.3 fitting software to the recipient's sound processor via a smartphone app over the internet. The clinician can make select programming adjustments, enable processor settings and provide counselling via a live video session with their patient.

1) Clinician determines whether a Remote Assist session is required for a patient and schedules an agreed date and time for the support session (via the existing method for scheduling clinic appointments).
2) Clinician enables recipient access to RA functionality on myCochlear professional portal (MCP).
3) Clinician joins the RA session via Custom Sound Pro.
4) Recipient joins the RA session on NSA installed on their smart phone.
5) Recipient goes to a virtual waiting room until their clinician joins the RA session where they can prepare for the session using an in-app checklist.
6) Once the clinician joins the session, the clinician and recipient can communicate with each other via video, audio and text messaging.
7) Clinician can make the following adjustments to the MAP and change processor settings on the processor.
    a. Adjust Master Volume Bass and Treble
    b. Enable / disable ForwardFocus, MVBT, Volume, Sensitivity
    c. Save MAPs to the processor

Figure 1 shows the Clinician-view of Remote Assist screens of using Custom Sound Pro software as well as the patient view on their smartphone using and on the NSA.

**Figure 1: Remote Assist screens of Custom Sound Pro (left) and on NSA (right).**

A clinician will determine the eligibility of the recipient for RA based on their implant type, Sound Processor and MAP characteristics listed below. If a recipient is eligible, they can be enrolled for an RA Session in MCP.

The RA feature will only be available within the Nucleus Smart App for those Cochlear recipients that have been enrolled by their clinician.

The RA system is indicated for use for Cochlear™ recipients of the following compatible Cochlear™ implants using a CP1000 or CP1150 Sound Processor for

- CI600 series (CI612, CI622 and CI632)
- CI500 series (CI512, CI513, CI522 and CI532)
- Freedom series (CI24RE (ST), CI24RE (CA), CI24RE (CS), CI24RE Hybrid L24 and CI422)
- Nucleus 24 series (CI24M, CI24R (CA), CI24R (ST) and CI24R (CS))
- Nucleus 22 series
- Double array (CI24M Double Array)
- Auditory Brainstem implants (ABI24M)

MVBT adjustment (a feature contained within RA) is not supported for N22, N24, ABI or Double Array implants or for incompatible MAPs that have the following characteristics.

- Non-monopolar MAPs (bipolar, common ground, variable mode)
- No recent compliance measurement
- One or more electrodes out of compliance.
- Dynamic range of <10 CL
- Hybrid mode enabled
- Mixed pulse widths
- Double channel MAPping
- Pulse widths >100 usecs
- 10 or more electrodes turned off
- Channel or electrode reordering

The download page for the Nucleus Smart app and Custom Sound Pro 6.3 will state that the app/software is exclusively for use in a clinical investigation. The smartphones provided to the participants will be labelled with “exclusively for use in a clinical investigation”.

The instructions for use of Remote Assist on iOS devices is provided in the Nucleus Smart App User Guide.

Remote Assist is compatible with the following smart phones:

**Table 2: Compatible smart phones**

| Name of Smartphone | Manufacturer | Version |
|---|---|---|
| iPod Touch 6th Generation | Apple | iOS 12.X |
| iPod Touch 7th Generation | Apple | iOS 12.X, 13.X, 14.X |
| iPhone 6 | Apple | iOS 12.X |
| iPhone 6+ | Apple | iOS 12.X |
| iPhone 6s | Apple | iOS 12.X, 13.X, 14.X |
| iPhone 6s+ | Apple | iOS 12.X, 13.X, 14.X |
| iPhone SE (1st Gen) | Apple | iOS 12.X, 13.X, 14.X |
| iPhone SE (2nd Gen) | Apple | iOS 12.X, 13.X, 14.X |
| iPhone 7, 7+ | Apple | iOS 12.X, 13.X, 14.X |
| iPhone8, 8+ | Apple | iOS 12.X, 13.X, 14.X |
| iPhone X | Apple | iOS 12.X, 13.X, 14.X |
| iPhone Xs, Xr, Xs Max | Apple | iOS 12.X, 13.X, 14.X |
| iPhone 11, 11 Pro, 11 Pro Max | Apple | iOS 13.X, 14.X |
| iPhone 12, 12 Pro, 12 Pro Max | Apple | 14.X |
| Google Pixel | Google | Android 7.1 and above |
| Google Pixel 3 | Google | Android 9 and above |
| Google Pixel 4 | Google | Android 10 and above |
| Google Pixel 5 | Google | Android 11 and above |
| Samsung S7 | Samsung | Android 6 and above |
| Samsung S8 | Samsung | Android 7 and above |
| Samsung S10 | Samsung | Android 9 and above |
| S20 | Samsung | Android 10 and above |
| Samsung Galaxy A30S | Samsung | Android 9 and above |
| Motorola G5 | Lenovo | Android 7 and above |
| LG G6 | LG | Android 7 and above |
| HTC U11 | HTC | Android 7.1 and above |

## 5.2 Identity and Description of the Comparator

N/a

## 5.3 Accessory Device Requirements

**Table 3: List of accessory devices that will be used in this investigation**

| Device name | Purpose | Regulatory Approval status |
|---|---|---|
| CP1000 programming cable | Cable needed to program the CP1000 sound processor | Approved |
| CP1150 programming cable | Cable needed to program the CP1150 sound processor | Approved |
| Cochlear™ Wired Programming pod | Interface needed to program the sound processors | Approved |
| Cochlear™ Wireless Programming pod | Interface needed to program the sound processors | Approved |
| CP1000 (Nucleus 7) Sound processor | Used by recipient to hear the clinician and to receive select updates to their MAP or processor settings | Approved hardware and firmware |
| CP1150 (Kanso 2) Sound processor | Used by recipient to hear the clinician and to receive select updates to their MAP or processor settings | Approved hardware and firmware |
| Android / iOS smart phones | To run the Nucleus Smart app | Not a medical device |

# 6 OBJECTIVES

## 6.1 Primary Objective

To confirm the ease of use and user experience of Remote Assist when used in real world conditions.

## 6.2 Secondary Objective

There are no secondary objectives.

## 6.3 Exploratory Objectives

- Characterise the ability of the subject to understand the clinician via the video call.
- Characterise the time taken for RA to make changes to the MAP over the internet in real world conditions.

# 7 DESIGN OF THE CLINICAL INVESTIGATION

## 7.1 General

This is an actual use usability, prospective, adaptive design, single-centre, non-randomised, open-label, single arm, non-controlled, pre-market clinical investigation in adults using Nucleus cochlear implants.

The subjects include adults aged 18 years or above who are currently using a Nucleus cochlear implant. Subjects will be screened, and 15 eligible subjects will be enrolled in the clinical investigation. Eligible subjects will be asked to use the IMD with the help of the inbuilt instructions in the IMD.

After the first visit, subjects will attend scheduled study visits over a six-month study period to be assessed as described in the CIP Schedule of Events (Section 3). At study visits, subjects will undergo usability assessments and safety assessments. Participants will use the IMD only during the study sessions and will be asked to use their own devices at other times.

The primary outcome measure is to determine the proportion of subjects who, while using the final version of Remote Assist, can complete the primary tasks, as assessed by the investigator / observer using a usability rating scale. Safety will be assessed by recording and summarising all AEs/ADEs and DDs. No data monitoring committee will be used for this clinical investigation.

### 7.1.1 Design Rationale

- An actual use study design is used so that the end to end workflow and user acceptance of the product can be further evaluated in a variety of internet / device configurations under real world conditions.
- The study includes only adults so that they can provide reliable feedback as to the ease of use of the RA system.
- Only Cochlear implant recipients implanted with the CI500 series, CI600 series or Freedom series cochlear implants in one or both ears are included as the RA system only supports these cochlear implants for MVBT adjustments.
- The hearing ability and the MAPs undergo significant changes in the first three months after implantation. Thus, cochlear implants recipients with at least 3 months experience with their cochlear implant will be enrolled so that any changes in their hearing function do not act as confounding variables.
- Only subjects willing and able to provide written informed consent will be enrolled to be compliant with ISO 14155.
- Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling or Cochlear employees or employees of Contract Research Organizations or contractors engaged by Cochlear for the purposes of this investigation will be excluded to avoid enrollment of a vulnerable population.
- Since the study involves only acute testing and does not require continued use of the IDE during take home use, participation in previous acute testing studies may not impact its results.

**Adaptive procedure:**

The IMD used in the study has been fully verified by bench testing to ensure safe and effective use with cochlear implant recipients. Any new versions of the IMD will be fully verified by bench testing

prior to use in the study. This study aims to continue to gain experience in as many actual use scenarios as possible to account for possible real-world scenarios. There is a possibility that product issues that were not known to date are uncovered during the study, like usability issues or bugs. The study will use an adaptive procedure to allow the use of unplanned product optimisations. If significant issues are identified that require optimisation or correction of the IMD, then further study sessions will be suspended, and the study will resume with the new device iteration. Where optimisation is required to improve usability or performance (see Table 4), subjects will receive a new device iteration. When a new version of RA is issued participants will be asked to attend a study visit to assess the usability of the new iteration (see Figure 2), and they will be asked to re-complete the session at 'take-home use' so that the RA can be re-tested outside the clinical environment, and feedback can be received after each take-home period (see Figure 2).

While there are no expected unplanned product changes, early product can be sensitive to the low-risk issues identified in Table 4. Table 4 also identifies how issues will be investigated and retested by the research subjects. All product issues will be recorded as device deficiencies.

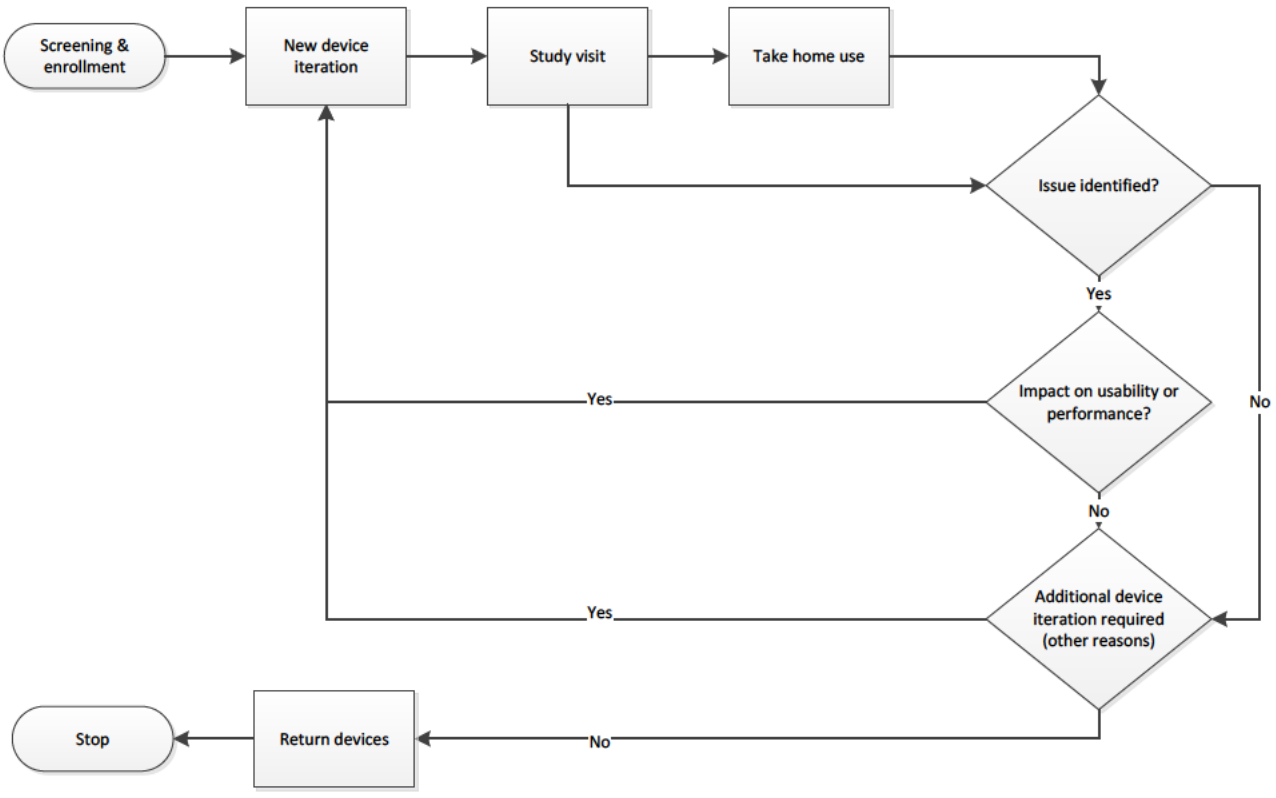


**Figure 2: Flowchart of adaptive procedure**

**Table 4. Product adaptation categories and product issue examples**

| Category | Example of a product issue | Action |
|---|---|---|
| **Connectivity** - The App will be communicating | Interruptions due to smart phone notifications (calls, messages, general | If the issue has an impact on performance or usability, the product |

| Category | Example of a product issue | Action |
|---|---|---|
| with the Sound Processor directly via Bluetooth link. | alerts etc.) that affect the app and tests within the app | will be updated and re-evaluated by subjects. |
| | Data upload issues due to unstable internet connection | If the issue has an impact on performance or usability, the product will be updated and re-evaluated by subjects. |
| | General connectivity issues between processor and smart phone | If the issue has an impact on performance or usability, the product will be updated and re-evaluated by subjects. |
| **Sound quality** – RA allows video calling between the clinician and recipient requiring audio and video signal to be of sufficient quality. | Study subjects may provide feedback on the audio and video quality experienced during the RA session. | If the issue has an impact on performance or usability, the product will be updated and re-evaluated by subjects. |
| **Product accuracy/performance** – RA allows clinician to trigger adjustment of MVBT and changes to parameters remotely. The system is expected to respond accurately and quickly. | Slow response times that result in inability to program effectively. | If the response time is considered to slow, the issue will be investigated, updated, and re-evaluated by subjects. |
| | The changes requested by the clinician are not completed by RA as expected | The product will be updated and re-evaluated by subjects. |
| **Usability and user acceptance** – The App must be easy to use and intuitive. | The user interface is unclear and leads the study subjects to use the functions incorrectly | If an identified usability issue has an impact on performance or usability, the product will be updated and re-evaluated by subjects. |
| **General bugs and product issues:** | Unforeseen issues that are exposed through usage in a subject's home environment. | General issues will be judged on a case by case basis. If it is judged that the issue has an unacceptable impact on performance or usability, the product will be updated and re-evaluated by subjects. |

## 7.2 Subjects

Written, informed consent must be obtained from each subject before any study procedures are initiated.

Eligibility of enrolled subjects must be supported by Custom Sound Pro records or device registration records that confirm the age, implant type and duration of implant use in the ear to be studied.

### 7.2.1 Inclusion Criteria

Subjects must meet all the inclusion criteria described below to be eligible for this clinical investigation.

1) Adults (≥18 years).
2) Implanted with the CI500 series (CI512, CI513, CI522, CI532,), CI600 series (CI612, CI622, CI632), Freedom series cochlear implants (CI24RE (ST), CI24RE (CA), CI24RE (CS), CI422) in one or both ears.
3) At least 3 months experience with the cochlear implant.
4) Willing and able to provide written informed consent.

### 7.2.2 Exclusion Criteria

Subjects who meet any of the exclusion criteria described below will not be eligible for this clinical investigation.

1) Unable or unwilling to comply with the requirements of the clinical investigation as determined by the Investigator.
2) Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling.
3) Cochlear employees or employees of Contract Research Organizations or contractors engaged by Cochlear for the purposes of this investigation.
4) Currently participating or participated in another interventional clinical study/trial in the past 30 days, or if less than 30 days the prior investigation was Cochlear sponsored and determined by the investigator to not impact clinical findings of this investigation.
5) Prior exposure to Remote Assist concept during previous usability testing.

### 7.2.3 Number of Subjects Required

Fifteen subjects will be enrolled in the study to meet sample size calculation requirements stated in section 9.4 with the expected dropout rate (10%).

### 7.2.4 Vulnerable Populations

Not applicable for the current clinical investigation.

### 7.2.5 Recruitment & Study Duration

The following subject status definitions apply:

- Enrolled: A subject that has a signed the Informed Consent form for the study.
- Screen Fail: An Enrolled subject that has been determined to not meet one or more eligibility criteria.
- Participated: Subjects who have met eligibility criteria and have commenced visit 1 procedures.
- Withdrawn: An Enrolled subject who withdrew or was withdrawn by the Investigator or Sponsor before the expected End of Study visit. Withdrawn subjects may still continue in safety follow up until their scheduled End of Study visit, for reasons described in section 7.2.6.

- Completed: Enrolled subjects who complete the required treatment and visit schedule.

The recruitment period for the clinical investigation is estimated to be up to 8 months from the time of first subject consent to recruitment of the last subject. This is to allow the replacement of any subjects who withdraw from the study.

The expected duration of each subject's participation in the clinical investigation is up to 6 months from the time of informed consent through to the End of Study when devices are returned. This is to allow testing of new device iterations as per the adaptive procedure described in section 7.1.1.

The anticipated total duration of the clinical investigation is therefore 8 months.

Clinical Investigation completion is last subject last visit (a take-home session is also considered as a visit).

### 7.2.6 Criteria for Subject Withdrawal

Subjects can decide to withdraw from the investigation at any time. The Investigator shall ask the reason(s), however the subject is under no obligation to give a reason for wanting to withdraw. The reason for withdrawal should be documented in the subject's source files and the case report form (CRF).

The Investigator or Sponsor may also decide to withdraw a subject from the clinical investigation if it is considered to be in the subject's best interests.

Subject withdrawal may be for any of the following reasons:

- Adverse Event (AE)
- Device Deficiency (DD)
- CIP or GCP deviation
- Subject withdrew consent
- Subject lost to follow-up
- Subject death
- Sponsor decision
- Investigator decision
- Other (specify)

If subject withdrawal is due to problems related to the IMD safety or performance, the Investigator shall ask for the subject's permission to continue in safety follow up (i.e., adverse events) until their scheduled End-of-Study visit.

If a subject is lost to follow-up, every possible effort must be made by the study site personnel to contact the subject and determine the reason for discontinuation. At least 3 separate attempts taken to contact the subject must be documented.

Participating subjects who are withdrawn/discontinued will be replaced.

### 7.2.7 Randomisation Procedures

Not applicable

#### 7.2.7.1 Blinding Procedures

As the objective of this study is to evaluate the ease of use of the IMD, blinding is not feasible for the clinical investigation and this is unlikely to affect the study results.

### 7.2.8 Post-investigation Medical Care

As this clinical investigation is non-surgical in nature, no specific medical care will be provided for the subjects after the clinical investigation has been completed. Subjects will return to their routine clinical management at their local Cochlear Implant clinic after the final study visit. Subjects will use a loan CP1000 or CP1150 sound processor for the duration of the study. All clinical study devices will be returned at the end of the study. Subjects will return to use of their own sound processor and smartphone at the end of the clinical investigation.

## 7.3 Performance Evaluations and Procedures

The following procedures will be followed in this study. Table 1 in section 3 shows the schedule of events planned in the study.

**Recruitment:** Cochlear implant recipients will be identified by review of clinic records based on the eligibility criteria in section 7.2. The potential participants will be invited to the study and will be provided the informed consent form (ICF). Potential participants who are willing to participate in the study based on reading the ICF will be invited to attend a session at the study site.

**Written informed consent:** Prior to enrolment, potential study participant will be issued an ICF and the study information will be explained in full by the investigator, after which the recipient-participant can decide whether they consent to inclusion in the study or not. Informed consent will be obtained as per section 10 in this document.

**Eligibility:** After the consent form has been signed the investigator will record the eligibility of the potential participant to confirm their enrolment to the study.

**Demographics, hearing history, device history and medical history:** After the participant has been enrolled into the study, participant demographic information, hearing history, device history will be collected from the participant. Any additional information that cannot be obtained from the participant will be obtained from the participant's CI clinic as necessary. The participants' own processor will be connected to the commercially available Custom Sound fitting software and the participants' MAP will be saved to the site's database.

**CP1000 / CP1150 fitting:** The participant will be fitted with a loaner CP1000 or CP1150 sound processor using the MAP, program and processor settings used in their own processor. Where necessary update to the MAP, programs or processor settings will be made based on feedback from the recipient. CSPro software will be used by the investigator for creating a 'soft' MAP with perceivable sound quality issues, for example, reduced overall loudness or with low or high frequency sounds. The soft MAP along with the participant's own MAPs will be loaded to a loaner sound processor prior to each remote programming session.

**Usability evaluation:** RA is designed to be easy to use for a cochlear implant recipient even if they have no prior experience in using the Nucleus Smart App. Since RA is a new feature, participants are expected to have no prior experience of using RA. No training will be provided to the participants on the use of the app; however, they will have the ability to access the guidance inbuilt in the app and user guide. The participants will be asked to complete the tasks within RA. The investigator will facilitate the session and observer(s) will record any use problems as per summative usability test methods. The observer will rate the participant's ability to complete the primary tasks in Table 6 using the rating scale in Figure 3. The participant will be interviewed at the end of the session to assess their satisfaction. The usability ratings, observations and the log files will be analysed across to assess the learnability, efficiency, memorability, use errors and satisfaction as described in Table 5.

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| Unable to complete | Completed after using help document | Completed after trying an incorrect option | Completed after some exploration | Completed in first attempt |

**Figure 3: Usability ranking scale**

**In-clinic remote programming session:** Within the clinic, the investigator will be in one room and the participant will be in another room. An Observer may be present with the participant to make observations. The investigator will present live speech using the participants own MAP through the video call function of RA to assess the ease with which participants can understand speech via the video call. The investigator will use the MVBT controls in RA to adjust the soft MAP to resolve sound quality issues. The investigator will assess the adjusted soft MAP using speech sounds and a range of real-world noise sources in the participant's environment to test the acceptability of changes to the soft MAP. The participant will be asked to provide feedback on the sound quality of the adjusted soft MAP. Video recording of the session will be done to measure the response times and any use problems.

**Custom Sound Pro:** After the in-clinic remote programming the adjusted soft MAP from the sound processor will be read and saved in CSPro. Feedback on the adjusted MAPs will be gathered.

**Table 5: Usability dimensions to be assessed**

| Dimension | Definition | Metric |
|---|---|---|
| Learnability | How easy is it for users to accomplish basic tasks the first time they encounter the design? | Task completion will be ranked, and the use errors/issues observed will be recorded when software is used by participants with no prior experience in using the app. |
| Efficiency | Once users have learned the design, how quickly can they perform tasks? | Time taken to complete the tasks in the app will be recorded when app is used by participants for the second time. |

| Dimension | Definition | Metric |
|---|---|---|
| Memorability | When users return to the design after a period of not using it, how easily can they re-establish proficiency? | Task completion will be ranked, and the use errors/issues observed will be recorded when app is used by participants for the second time. |
| Errors | How many errors do users make, how severe are these errors, and how easily can they recover from the errors? | Observation and video analysis of participants using the app. |
| Close Calls | How many cases in which a user almost commits an error, or does commit an error, but detects it and corrects it? | Observation and video analysis of participants using the app. |
| Difficulty | How many cases in which a user struggles to perform a task? | Observation and video analysis of participants using the app. |
| Satisfaction | How satisfied are users with the design? | The participant's satisfaction rating will be obtained in an interview with the participant. |

**Take-home remote programming session:** The investigator will be remote and the participant will be outside the clinic environment, such as their home environment. The investigator will present live speech using the participants own MAP through the video call function of RA to assess the ease with which participants can understand speech via the video call. The participant will be asked to use their own processor during the take home period outside the programming session. During the take home session, the study devices will be used. The investigator will use the MVBT controls in RA to adjust the soft MAP to resolve sound quality issues in the participant's soft MAP. The investigator will assess the adjusted soft MAP using speech sounds and a range of real-world noise sources in the participant's environment to test the acceptability of changes to the soft MAP. The participant will be asked to provide feedback on the sound quality of the adjusted soft MAP. Video recording of the session will be done to measure the response times and any use errors.

**Questionnaire:** Feedback will be gathered from participants about their experience of the RA session with a questionnaire.

**Troubleshooting / issues analysis:** If the participant experiences issues with the app during take home use, they will be asked to attend a follow up visit to troubleshoot issues or gather greater details of the issues.

**Adaptive Procedure:** The study will use an adaptive procedure Section 7.1.1 provides details of the adaptive procedure used.

**Return devices:** After take home RA session if no issues are identified then the study subject will be asked to return the IMD to the study site either by courier or visiting the site. The data generated in the app during take home RA session will be collected from the returned devices.

**Table 6: Primary tasks in a Remote Assist session**

| Screen | Primary Tasks | Acceptance criteria | Additional areas of interest |
|---|---|---|---|
| Burger menu | Start Remote Assist | User can start Remote Assist session | - |
| Remote Assist Start Screen | Grant Remote Assist Permissions | User successfully grants Remote Assist permissions | - |
| Connection screen | Connect to clinician | User successfully enables audio/visual connection | - |
| Video call | Position phone camera | User positions the phone optimally for the video call | Types of positions phone held during the session |
| Video call | Use reverse camera | User successfully uses reverse camera | Ability to show the sound processor using reverse camera |
| Video call | Mute microphone | User successfully mutes microphone | - |
| Video call | Turn off camera | User successfully turns off camera | Ability to understand with camera turned off |
| Chat | Use Chat | User successfully uses the chat function | Number of errors made in the chat |
| Interruption | Resume session after an interruption by a phone call | User successfully resumes session after an interruption by a phone call | - |
| Interruption | Resume session after an interruption due to processor disconnection | User successfully resumes session after an interruption due to processor disconnection | - |
| Interruption | Resume session after an interruption due to internet disconnection | User successfully resumes session after an interruption due to internet disconnection | Ability to evaluate internet connection and/or quality of internet connection |
| Fitting | Provide feedback for fitting | User is able to provide feedback to clinician for fitting. | - |
| Fitting | Test the sound with real world sounds | User is able to test the hearing with real world sounds. | - |

| Screen | Primary Tasks | Acceptance criteria | Additional areas of interest |
|---|---|---|---|
| Disconnect | Disconnect from Remote Assist Session | User successfully disconnects from Remote Assist session | - |

**Procedural mitigation relating to COVID-19**

Due to the physical distancing restrictions in place during the COVID-19 pandemic, optional device programming and procedural provisions may be introduced. These measures are to support the continuation of this project, while ensuring the safety of subjects and study staff.

- Screening and consent: See section 10 for the consent process. If COVID-19 restrictions also restrict research candidates from attending the study site, screening and consent may be performed via phone call or video conference. Paper copies of the consent form will be provided via mail/courier and subjects will be asked to use a prepaid envelope to return original signed copies.
- Study devices: Subjects may be asked to commence take-home testing through remote management. Devices, accessories, questionnaires, and instructions may be sent to subjects via courier, so that they do not need to attend the clinic. Prior to shipping, the loaner study sound processor(s) will be prepared as per the steps detailed above in “CP1000 / CP1150 fitting” section. If a subject’s most recent MAP(s) are not retrievable either from the site’s database or the subject’s clinical audiologist, remote management will not be possible until they are able to attend the site to have their own processor(s) connected to the software.
- Study procedures: Only the procedures listed under “take-home remote programming session” will be conducted. For subjects who do not wish to participate in remote study and device management, the device programming and fitting will be performed in clinic once restrictions in New South Wales allow in-clinic visits.

## 7.4 Safety Evaluations and Procedures

The risks and anticipated ADEs for the IMD, as identified in Section 8.3 of the CIP, will be assessed in the clinical investigation via reporting of all AEs/ADEs from the time of first subject first visit until last subject last visit.

Safety data adjudication may be conducted by the Sponsor’s Medical Officer in accordance with the Sponsor’s standard operating procedures.

### 7.4.1 Concomitant Medication and Therapies

Not applicable for this clinical investigation.

## 7.5 Equipment Used for Evaluation of Performance and Safety

No additional equipment apart from IMD and the accessory devices described in Section 5 will be used in this clinical investigation.

## 7.6 Sponsor Role in Conduct of the Clinical Investigation

Prior to commercially launching new technology, Cochlear conduct both pre-clinical and clinical testing to ensure the products meet quality and performance specifications. New product technology may include the implanted device, the external sound processor, fitting software, or other devices such as smart phone applications or wireless accessories that enable remote control and streaming of the sound directly to the cochlear implant. Clinical Investigations are planned when performance and/or safety evidence requirements require human use. This clinical investigation will be conducted by an internal site. Internal sites are clinical research facilities owned and operated by Cochlear. Cochlear has the following processes to mitigate the potential conflicts of interest that may arise with the use of internal sites:

- Standard Operating Procedures to manage the separation of Investigator and Sponsor activities as well as ensuring compliance with Good Clinical Practice and all applicable regulations.
- Secure separation of Investigators' trial materials and testing rooms (Audiology Suite) from Sponsor facilities and other employees. The research facility is restricted to limited personnel.
- Electronic data capture is restricted by user roles to control access to data entry/correction, source data verification, data sign off, and reporting functionalities.
- Centralised review of safety events to provide independence in oversight.
- Cochlear Investigators are qualified by education and experience in cochlear implant technology and clinical programming.
- Monitoring roles performed by individuals who are not also investigators or other delegated site personnel on the same clinical investigation.
- Joint Cochlear Site and Sponsor roles not permitted if the clinical investigation design involves double-blinding of randomised treatment or testing assignment.

Activities to be performed by sponsor representative excluding monitoring include:

1. Application of clinical quality assurance and quality control principles to the processes of the clinical investigation
    a. Implement and maintain written clinical quality procedures to ensure the clinical investigation is designed, conducted and that data generated is compliant with the ISO 14155:2011 Standard(ISO, 2011).
    b. Clinical quality assurance and quality control will be implemented according to sponsors quality system (Cochlear Quality Manual reference [7])
2. Clinical investigation planning and conduct
    a. Selection of clinical personnel for project management of the clinical investigation
    b. Preparation of documents and materials for the clinical investigation

c. Project management for the clinical investigation. i.e. accountability of investigational devices, clinical trial insurance coverage, submission of application(s) and investigation updates to the appropriate regulatory authority(ies).

3. Safety evaluation and reporting of adverse events (AE) to the TGA and ethics committee
4. Clinical investigation close-out, statistical analyses, and final report

# 8 RISKS AND BENEFITS OF THE INVESTIGATIONAL MEDICAL DEVICE AND CLINICAL INVESTIGATION

## 8.1 Anticipated Clinical Benefits

There are no additional anticipated clinical benefits to using the IMD.

This study provides subjects with the opportunity to trial a new cochlear implant CP1000 or CP1150 sound processor and related components (Nucleus 7 system) if they don't already own these features, and the new RA prior to the commercial release date. Subjects may benefit from improved usability and performance of the different components of the Nucleus 7 system, there is no expected benefit of using RA in the study environment.

## 8.2 Anticipated Adverse Device Effects

The CP1000 and CP1150 Sound Processors and Nucleus Smart App are approved products. Product specific warnings can be found in the CP1000 and CP1150 Sound Processor User Guides [8] and [9].

The Nucleus Smart app with the addition of RA allows MVBT adjustments to be done remotely. There is a low risk that participants may hear a sound that is uncomfortably loud during programming with RA.

## 8.3 Risks Associated with Participation in the Clinical Investigation

- Exposure to soft MAP temporarily during the adjustments
- Possible exposure to sound that is uncomfortable or loud during fitting of the sound processor or streaming from the smartphone.
- Possible interactions with concomitant medications and residual risks for the device are not anticipated in this clinical investigation.
- Possible increased risk of exposure to infectious diseases, for example COVID-19, due to need to visit the study site that is outside their normal routine.

## 8.4 Risk Mitigation

- The fitting and use of the sound processor will be supervised by the investigator at the start of the study. In addition, recipients will be encouraged to inform the investigator whether the

sound processor provides any physical discomfort or produces sounds that are uncomfortable. Stimulation will be immediately ceased.

- Recipients will be counselled to remove the sound processor off their head if any uncomfortable sound occurs. Subjects will maintain access to their own sound processors and programs during the course of the study.
- All reported ADEs and DDs will be regularly reviewed by the Sponsor's Clinical review Board for the duration of the study to facilitate early detection and appropriate intervention if events are unanticipated with respect to incidence, severity, or outcome.

It is expected that study participants will be taking steps to limit exposure to infectious diseases, for example, COVID-19. The site will actively follow the advice of official health authorities and governments to ensure the health and wellbeing of site employees and research subjects. These include but are not limited to:

- Cochlear headquarters has implemented procedures to enable contact tracing for all employees and visitors, as well as processes to scale up, scale down and/or deep clean should there be a confirmed positive case of coronavirus on the premises.
- The research site is separated physically, enabling separation of study participants from other employees working in the building during study sessions.
- Increased hygiene etiquette including cleaning of high-touch surfaces before and after each study visit, disinfection of any shared study devices or equipment and investigators are equipped to use gloves or wear a face mask upon request. Hygiene resources such as handwashing/rubbing stations are readily available throughout the building and research site.
- There is adequate signage to communicate onsite hygiene requirements throughout the building.
- Where possible, study participants will be encouraged to drive to Cochlear and utilize the free on-site parking instead of travelling via public transport.
- All visitors to Cochlear headquarters are to declare their health status via a written declaration on arrival at the site. The declaration must state the subject is well and COVID-19 symptom free and have not been in contact with a known or suspected case of COVID-19 in the 14 days prior to access to the building.
- Subjects will be provided with any necessary resources required to return study devices to the site, should they be unable to attend any of the scheduled visits. For example, couriers or postage may be arranged as necessary.

## 8.5 Risk-to-Benefit Rationale

The Nucleus 7 sound processor Clinical Evaluation Report (CER) [10] states that all hazards associated with the Nucleus Smart App have been classified as having "Low" or "Medium" residual risk of harm. The CER concludes that the clinical safety (risks) and performance benefit of devices relevant to anticipated performance of the Nucleus 7 sound processor including the Remote Assist

functionality on iOS devices have been evaluated, and the data demonstrate that the device has a favourable safety profile and is effective. The Cochlear-Sponsored clinical investigations and systematic literature review, coupled with the design verification/validation and post-market surveillance data, establish that the benefits of the device outweigh the risks.

Participants will only use the IMD only during the study sessions and will be asked to use their own devices at other times.

The Remote Assist system Hazards Analysis report [4] concludes that the overall risks for RA fall within the low and medium regions of risk acceptability. The post market surveillance monitoring will continue throughout the lifecycle of Remote Assist in accordance with the Product Risk Management Procedure [1]. Any new or increased risks will be managed in accordance Product Risk Management Procedure [1].

# 9 STATISTICAL CONSIDERATIONS

## 9.1 General Considerations

The summary of primary and exploratory outcome measures will be descriptive providing summary statistics reflecting the outcome measures as appropriate. Means, standard deviations, ranges will be reported for continuous variables. Numbers, percentages, and totals will be reported for binary or ordinal variables. Missing data will not be imputed. Demographic and safety data will be summarised descriptively.

**Pass / fail criteria:** The investigator or observer will rate the participant's ability to complete the primary tasks listed in Table 6 using the rating scale in Figure 3. If the participant is unable to complete the task (rating 1, unable to complete) in the final version of Remote Assist then it will be considered as a fail.

## 9.2 Outcome measures

### 9.2.1 Primary Outcome measure

Proportion of subjects who, while using the final version of Remote Assist, are able to complete the primary tasks determined by an observer using a rating scale.

### 9.2.2 Secondary Outcome measures

There is no secondary outcome measure.

### 9.2.3 Exploratory Outcome measures

- The median rating on the ability to understand the clinician via the RA video call.
- The median time taken for RA to make changes to the MAP over the internet.

## 9.3 Hypotheses

No formal testable hypotheses are applicable.

### 9.3.1 Primary Hypothesis

No formal testable hypotheses are applicable.

### 9.3.2 Secondary Hypothesis

No formal testable hypotheses are applicable.

### 9.3.3 Exploratory Hypothesis

No formal testable hypotheses are applicable.

## 9.4 Sample Size Determination

The primary outcome measure of this study is the proportion of subjects who, while using the final version of Remote Assist, are able to complete the primary tasks.

Observations will be used to determine the participant's ability to complete the tasks. Different versions of the IMD will be used in an adaptive procedure to assess the usability and to make incremental changes in the IMD. This actual use study will be conducted as per summative usability test standards.

A minimum of 15 test participants will be used for this study. As per standard HE75:2009(R2018) Human Factors Engineering – Design of Medical Devices (AAMI HE75, 2018) and Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff (UCM259760, 2016), a minimum of 15 test participants per user group is recommended for summative evaluation testing.

## 9.5 Analysis Populations

Full analysis set is generally recommended over per protocol set analysis for randomised controlled studies with multiple arms (Ranganathan, Pramesh, & Aggarwal, 2016) As this study does not involve randomisation and any subjects who withdraw will be replaced, per protocol set analysis is appropriate for this study. Primary and exploratory analysis will be completed with per protocol set data. If a participant withdraws after completion of the primary outcome measure but not the exploratory outcome measure, their data will be included in the analysis. Safety analysis will be completed with the full analysis set data to ensure that all safety issues are taken into consideration.

## 9.6 Primary Outcome measure Analyses

Proportion of subjects who, while using the final version of Remote Assist, are able to complete the primary tasks as per the pass/fail criteria will be described using descriptive statistics.

## 9.7 Secondary Outcome measure Analyses

Not applicable for this clinical investigation

## 9.8 Exploratory Outcome measure Analyses

The rating on the ability to understand the clinician via the RA video call will be described using descriptive statistics.

The time taken for RA to make changes to the MAP over the internet will be described using descriptive statistics.

## 9.9 Safety Analyses

For AE/ADEs and DDs, the percentage of subjects who experienced at least one occurrence of each, will be summarised. Any subjects who discontinued an intervention due to an AE/ADEs, or who experienced a severe or an SAE/SADEs will be summarised separately.

## 9.10 Interim Analyses

The usability observations and feedback will be analysed on an ongoing basis and these will be used to improve the product. No formal interim analysis is planned for the usability ratings.

# 10 INFORMED CONSENT PROCESS

The Investigator shall obtain written informed consent from the subject using an approved ICF prior to any clinical investigation-related examination or activity. The rationale of the clinical investigation, as well as the risks and benefits, what participation will involve, and alternatives to participation will be explained to the subject. Ample time will be provided for the subject to enquire about details of the clinical investigation and to decide whether to participate.

All questions about the clinical investigation shall be answered to the satisfaction of the subject or the subject's legally acceptable representative. Subjects shall not be coerced or unduly influenced to participate or to continue to participate in a clinical investigation.

Each subject (or their legally authorised representative) and the person who conducted the informed consent discussion, shall sign and date the Informed Consent Form (ICF). Where required, a witness shall sign and personally date the ICF. A copy of the signed ICF shall be given to the subject. The original signed ICF shall be archived in the Investigator's Site File or subject file at the investigational site.

The subject, or the subject's legally authorised representative, shall be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the clinical investigation. The communication of this information must be documented as an update to the ICF and re-consent of the subject.

# 11 ADVERSE EVENTS AND DEVICE DEFICIENCIES

## 11.1 Definitions

### 11.1.1 Adverse Event

An adverse event (AE) is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users, or other persons whether related to the medical device or the procedures required for implant or use.

NOTE 1: This definition includes events related to the medical device or the comparator device.

NOTE 2: This definition includes events related to the procedures involved.

NOTE 3: For users and other persons, this definition is restricted to events related to medical devices.

### 11.1.2 Adverse Device Effect

An adverse device effect (ADE) is an AE related to the use of a medical device.

NOTE 1: This includes any AE resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the medical device.

NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the medical device.

### 11.1.3 Serious Adverse Event

A serious adverse event (SAE) is any AE that:

1) led to a death,
2) led to a serious deterioration in the health of the subject that either resulted in:
    - a life-threatening illness or injury, or
    - a permanent impairment of, or damage to, a body structure or a body function, or
    - in-patient hospitalisation or prolonged hospitalisation, or
    - medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment or damage to a body structure or a body function, or
    - Chronic disease.
3) led to foetal distress, foetal death or a congenital physical or mental abnormality, or birth defect

NOTE: Planned hospitalisation for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a SAE.

### 11.1.4 Serious Adverse Device Effect

A serious adverse device effect (SADE) is an ADE that has resulted in any of the consequences characteristic of a SAE.

### 11.1.5 Unanticipated Serious Adverse Device Effect

An unanticipated serious adverse device effect (USADE) is a SADE, which by its nature, incidence, severity, or outcome has not been identified in the current version of the hazards analysis [4].

NOTE: An anticipated serious adverse device effect is an effect, which by its nature, incidence, severity, or outcome has been identified in the hazards analysis [4].

### 11.1.6 Adverse Events of Special Interest

Not applicable for the current clinical investigation.

### 11.1.7 Device Deficiency

A Device Deficiency (DD) is an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety, or performance.

NOTE: Device Deficiencies include malfunctions, use errors, and inadequate labelling or information supplied by the manufacturer.

## 11.2 Recording and Handling of Adverse Events

Subjects shall be carefully monitored during the clinical investigation and the investigator should enquire about AEs at investigation visits.

All *AEs* will be recorded from the time of first use of the IMD. AE recording will continue for each subject until completion of their End of Study visit. Ongoing SAEs and SADEs will be followed for 30 days, or until resolution or stabilisation of the event, whichever comes first.

Source notes should indicate the evaluation for AEs, even if none to report. All required AEs will be reported if observed, even if anticipated and/or acknowledged as a risk factor in the consent.

All AEs will have the following information documented: start and stop dates, action taken, outcome, severity, and investigators opinion on the potential relationship to the IMD and study procedures. If an AE changes in severity, the most severe (highest) grade will be captured for that event on the Adverse Events CRF.

### 11.2.1 Assessment of Severity

The Principal Investigator (or qualified delegate) will make an assessment of severity for each event based on clinical judgement. The intensity of each event recorded in the CRF should be assigned to one of the following categories:

| | |
|---|---|
| **Mild** | An event that is easily tolerated by the subject, causing minimal discomfort, and not interfering with everyday activities. |
| **Moderate** | An event that is sufficiently discomforting to interfere with normal activities |
| **Severe** | An event which is incapacitating and prevents normal everyday activities |

### 11.2.2 Assessment of Causality

The Investigator will assess the potential causal relationship of each event, using clinical judgement. Alternative causes, such as natural history of underlying diseases, other risk factors and the temporal relationship of the event to the IMD product will be considered and investigated. The causal relationship to the IMD is to be assessed by the Investigator (or medically qualified delegate) and should be assessed using the following classifications:

| | |
|---|---|
| **Not related** | Relationship to the medical device or procedures can be excluded when:<br>• the event is not a known side effect of the product category the device belongs to or of similar devices and procedures;<br>• the event has no temporal relationship with the use of the device or the procedures;<br>• the event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible;<br>• the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the event;<br>• the event involves a body-site or an organ not expected to be affected by the device or procedure;<br>• the event can be attributed to another cause (for example, an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors);<br>• the event does not depend on a false result given by the investigational medical device used for diagnosis, when applicable;<br>• harms to the subject are not clearly due to use error;<br>In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the event. |
| **Unlikely related** | The relationship with the use of the medical device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained. |
| **Possibly related** | The relationship with the use of the medical device is weak but cannot be ruled out completely. Alternative causes are also possible (for example, an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possibly related. |
| **Probably related** | The relationship with the use of the medical device seems relevant and/or the event cannot be reasonably explained by another cause, but additional information may be obtained. |

| | |
|---|---|
| **Definitely related** | The event is associated with the medical device or with procedures beyond reasonable doubt when:<br>• the event is a known side effect of the product category the device belongs to or of similar devices and procedures;<br>• the event has a temporal relationship with the medical device use/application or procedures;<br>• the event involves a body-site or organ that<br>– the medical device or procedures are applied to<br>– the medical device or procedures have an effect on;<br>• the event follows a known response pattern to the medical device (if the response pattern is previously known);<br>• the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the event (when clinically feasible);<br>• other possible causes (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out;<br>• harm to the subject is due to error in use;<br>• the event depends on a false result given by the medical device used for diagnosis, when applicable;<br>In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the event. |

### 11.2.3 Assessment of Seriousness

The Investigator will assess the seriousness of each event according to clinical judgement and the definition provided in section 11.1.3.

### 11.2.4 Assessment of Expectedness

An event should be considered unanticipated if the nature, severity, or frequency of that event is not consistent with the applicable safety reference information, such as the risk analysis report, hazards analysis, IB, or Product Information/IFU if the product is approved for marketing.

For this clinical investigation the listed items in Section 8.2 and 8.3 of this CIP are anticipated ADEs.

| | |
|---|---|
| **Anticipated** | An adverse device effect (ADE) which by its nature, incidence, severity, or outcome is consistent with the applicable safety reference information (e.g., IB, IFU). |
| **Unanticipated** | An adverse device effect (ADE) which by its nature, incidence, severity, or outcome is not consistent with, or has not been identified in the applicable safety reference information (for example, IB, IFU). |

## 11.3 Recording and Handling of Device Deficiencies

Subjects shall be carefully monitored during the clinical investigation and routinely questioned about DDs at investigation visits. Source notes should indicate the evaluation for DDs, even if none to report.

The Investigator shall assess if the DD led to an AE or could have led to a serious medical occurrence (serious adverse device effect) if;

a) suitable action had not been taken,

b) intervention had not been made, or,

c) circumstances had been less fortunate

All DDs will be documented in the source notes and the DD page of the CRF.

## 11.4 Reporting Responsibilities

The Investigator is responsible for reporting all AEs and DDs in the CRF.

### 11.4.1 Investigator Reporting of Serious Adverse Events

All AEs meeting the criteria for an SAE, or DD that could have led to an SADE, must be reported to the Sponsor by five working days.

Reporting is achieved through completion of the events details in the Adverse Event page of the eCRF

The Investigator shall always provide an assessment of causality at the time of the initial report, as described in section 11.2.2 ‘Assessment of Causality’. If data obtained after reporting indicates that the assessment of causality is incorrect, then the SAE form may be appropriately amended, signed, dated, and resubmitted to the Sponsor.

If the Investigator does not have all other information regarding an SAE, he/she will not wait to receive additional information before reporting the event. The reporting forms shall be updated when additional information is received.

The Investigator is responsible for reporting of safety events to their local EC using the applicable report form, in accordance with local regulations.

### 11.4.2 Sponsor Notification of Events

The Sponsor is responsible for reviewing all safety data to evaluate potential causality and anticipation of all ADEs.

The Sponsor is also responsible for reporting all reportable events according to the requirements and timelines of the regulatory authorities relevant to this clinical investigation, and shall conduct an expedited assessment of all SAEs, unanticipated ADEs, DDs that could have led to an SADE.

The Safety Monitor for AE/DD assessment and any AE/DD related queries is:

| | |
|---|---|
| **Name of contact person of the Sponsor:** | [redacted] |
| **Country and time zone:** | Australia, Australian [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |

## 11.5 Independent Data Monitoring Committee

The decision of whether to establish a Data Monitoring Committee (DMC) is guided by the risk analysis, considering both the risks associated with the use of the investigational device and the risks associated with subject's participation in the clinical investigation.

The risks associated with the use of the investigational device and the subject's participation in the clinical investigation is described in Section 8 of this document. The subjects in the proposed clinical investigation will be able to revert to their own processor if there are sound quality issues or dissatisfaction with the CP1000 sound processor. As a result, no Data Monitoring Committee (DMC) has been established for this clinical investigation.

# 12 Device Accountability

Supply of investigational medical devices will be recorded using the Sponsor Device Tracking Form [11] and Software Tracking Form [12] by the sponsor representative. Investigational medical device(s) will be quarantined at the investigational site and clearly labelled to identify exclusively for use in a clinical investigation.

Subject level device supply will be tracked using the Sponsor's Individual Subject Accountability Log Form [13] by the principal investigator.

All device(s) that have been identified with Device Deficiencies will be returned to Device Analysis for analysis and archiving.

Contact information regarding the IMD is provided below.

| | |
|---|---|
| **Name of contact person of the Sponsor:** | [redacted] |
| **Country and time zone:** | Australia, Australian Eastern Standard Time |
| **Phone number:** | [redacted] |
| **Email:** | [redacted] |

# 13 Deviations from the Clinical Investigation Plan

The Investigator(s) must not deviate from the CIP, except in case of an emergency to protect the safety and well-being of the subject(s). Such deviations will be documented by the site personnel in the source documentation for the subject and reported to the relevant EC as per institutional requirements and to the Sponsor as soon as possible, but not later than five working days from the date of the emergency.

If there is a deviation from CIP-defined assessments or parts thereof are omitted or completed incorrectly, the deviation will also be documented by the site personnel in the source documentation for the subject. Depending on the type or severity of the deviation the Investigator may be required to notify the EC, particularly if the deviation potentially impacts subject safety, performance of IMD, or data integrity.

All CIP deviations will be documented in the eCRF to enable analysis and reporting by the Sponsor in the Clinical Investigation Report (CIR), or to the relevant regulatory authority(s), if applicable.

Gross misconduct on behalf of an Investigator, such as intentional non-compliance with CIP or GCP requirements or fraud, will result in disqualification of the Principal Investigator and/or Investigational Site from participation in the investigation. Data provided by the Principal Investigator or Investigational Site will be excluded from the per-protocol analysis group.

# 14 DATA MANAGEMENT

The CRF will capture the datapoints necessary to determine the subject status according to the criteria described in section 7.2.5.

Source data will be captured in clinic notes, paper-based source data worksheets, or printed directly from testing software. If electronic medical records do not permit read only access for monitoring purposes, a certified printout must be provided.

Data collection for demographics, device exposure, adverse events, device deficiencies, protocol deviations and completion will be performed using Medidata Rave for electronic data capture (EDC) on electronic Case Report Forms (Medidata Safety eCRF), to support safety analysis and reporting. All other data will be collected from clinical fitting software, and captured into Nucleus Smart App. Unamended data files shall be regarded as the source.

Site personnel will be trained on the completion of the Medidata Safety eCRF prior to obtaining access to the system, and will have their own Login/Password. Access to clinical study information will be based on an individual's role and responsibilities.

Medidata Rave uses role-based user permissions for data entry, viewing, and reporting options. All communications between users and the EDC server are encrypted. Web servers are protected by a managed firewall. This application is designed to be in compliance with applicable regulations including 21 CFR Part 11.

The application will include programmed data consistency checks and supports manual generation of data clarifications/queries, including documentation of site responses. The application maintains a comprehensive audit trail for all data entered, including updates and queries, and documents the time that each entry occurred and who made the entry.

Principal Investigators will affirm that the data for each subject at their site is accurate and complete by way of an electronic signature.

# 15 CONFIDENTIALITY

The investigator and site staff will collect and process personal data of the subjects in accordance with governing data privacy regulations.

Data will be reported to the Sponsor on CRFs or related documents (for example, questionnaires). Subjects will be identified on CRFs and other related documents only by a unique subject identification code and shall not include the subject's name or other personal identifiable information. Completed CRFs or related documents are confidential and will only be available to the Investigator and site staff, the Sponsor and their representatives, and if requested to the Ethics Committee and national regulatory authorities. Publications or submission to a regulatory authority shall not disclose the identity of any subject.

# 16 ETHICS COMMITTEE AND REGULATORY AUTHORITY APPROVAL

The clinical investigation will not commence prior to the written favourable opinion or approval from the EC and or regulatory authority (if appropriate) is obtained.

The final Sponsor-approved version of the CIP, Informed Consent Form, and other necessary documents shall be submitted to the EC. A copy of the EC opinion/approval shall be provided to the Sponsor.

The Investigator shall forward to the Sponsor, for review and approval, any amendment made to the approved ICF and any other written information to be provided to the subject prior to submission to the EC.

The Sponsor and Principal Investigator will continue communications with the EC, as required by national regulations, the clinical investigational plan, or the responsible regulatory authority.

Any additional requirements imposed by the EC or regulatory authority will be implemented by the Sponsor.

The Investigator shall submit the appropriate documentation if any extension or renewal of the EC approval is required. In particular, substantial amendments to the CIP, the ICF, or other written information provided to subjects will be approved in writing by the EC.

The Investigator shall report to the EC any new information that may affect the safety of the subjects or the conduct of the clinical investigation. The Investigator will send written status summaries of the investigation to the EC regularly, as per local EC requirements.

Upon completion of the clinical investigation, the Investigator shall provide the EC with a brief report of the outcome of the clinical investigation, as per local EC requirements.

The clinical investigation is covered by clinical trial insurance, meeting the requirements of the participating countries.

# 17 SUSPENSION OR PREMATURE TERMINATION

The Sponsor will discontinue the clinical investigation site if:

1) major non-adherence to the CIP or GCP principles is occurring

2) it is anticipated that the subject recruitment will not be adequate to meet the objectives of the clinical investigation

An ongoing clinical investigation may be discontinued in case of:

1) device failure
2) serious or intolerable ADE, leading to the explant or discontinued use of the device
3) subject's death

# 18 AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN

No changes in the CIP or investigation procedures shall be made without mutual agreement of the Principal Investigator and the Sponsor. This agreement will be documented as a CIP amendment. Amendments will require notification to the Ethics Committees (ECs) by the Principal Investigators (and to the relevant regulatory authority(s) by the Sponsor, if applicable).

# 19 RECORD KEEPING AND RETENTION

Data generated from the clinical investigation will be stored in a limited-access file area and be accessible only to representatives of the study site, the Sponsor and its representatives, and relevant health authorities/regulatory agencies. All reports and communications relating to study subjects will identify subjects only by subject unique identification code. Complete subject identification will be maintained by the Investigator. This information will be treated with strict adherence to professional standards of confidentiality.

The investigator must retain study-related records for a period of at least 15 years after completion of the investigation or after the last device was placed on the market, if the IMD has market authorisation.

The Sponsor will notify the Principal Investigator when records are no longer needed. The Investigator will not discard any records without notifying the Sponsor. If the Principal Investigator moves from the current investigational site, the Sponsor should be notified of the name of the person who will assume responsibility for maintenance of the records at the investigational site or the new address at which the records will be stored. The Investigator will notify the Sponsor as soon as possible in the event of accidental loss or destruction of any study documentation.

# 20 PUBLICATION POLICY

This clinical investigation will be prospectively registered at a public clinical trial registry ClinicalTrials.gov.

A joint peer-reviewed publication authored by the clinical investigator(s) and Sponsor will be prepared. In addition, the results of the clinical investigation may also be disseminated as conference presentations (for example, abstract and poster session). Manuscript authorship and responsibilities will be discussed and agreed upon prior to investigation start and in accordance with guidelines and recommendations provided by the International Committee of Medical Journal Editors (ICMJE) to enable communication in a timely manner. All contributors who do not meet the criteria for authorship will be listed in an acknowledgments section of the publication.

# 21 STATEMENTS OF COMPLIANCE

This clinical investigation shall be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki, International Standard ISO 14155 Clinical investigation of medical devices for human subjects - Good Clinical Practice, and any regional or national regulations, as applicable.

# 22 QUALITY CONTROL AND ASSURANCE

In accordance with Cochlear's Quality Management System, all clinical investigations shall be conducted according to internationally recognised ethical principles for the purposes of obtaining clinical safety and performance data about medical devices.

The Sponsor employees (or designee) shall use standard operating procedures (SOP) to ensure that clinical study procedures and documentation are consistently conducted and compliant with the ISO 14155 Standard, Good Clinical Practice (GCP), and applicable local regulations.

## 22.1 Monitoring

The Sponsor will perform on-site and remote monitoring visits as frequently as necessary to oversee conduct, data collection and record keeping by sites. The clinical investigation monitoring plan is a separate document describing all the activities performed during site initiation, monitoring, and close out.

## 22.2 Audits

An Investigator must, in reasonable time, upon request from a relevant health authority or regulatory agency, permit access to requested records and reports, and copy and verify any records or reports made by the Investigator. Upon notification of a visit by a regulatory authority, the Investigator will contact the Sponsor immediately.

The Investigator will grant the Sponsor representatives the same access privileges offered to relevant health authority or regulatory agents, officers, and employees.

# 23 TRADEMARKS AND COPYRIGHT

# 24 REFERENCES

## 24.1 Internal References

| ID | Document Title | Number |
|---|---|---|
| [1]. | Product Risk Management Procedure | 1143376 |
| [2]. | Custom Sound Pro 6.2 verification and validation Summary Report | D1792946 |
| [3]. | Recipient App Risk Management Summary Report | D980355 |
| [4]. | Remote Assist Hazards Analysis Report | D1795601 |
| [5]. | Literature review report - clinical outcomes from remote programming of cochlear implants | D1748085 |
| [6]. | Goossens T. Literature Search Report: Safety and Benefits of "Remote Live Assist" Services. Cochlear Bone Anchored Solutions AB, Sweden. 2021 | D1811907 |
| [7]. | Cochlear Limited Quality manual | 1141823 |
| [8]. | CP1000 SP User Guide ENGLISH | 592753 |
| [9]. | CP1150 SP User Guide ENGLISH | D1608850 |
| [10]. | The Nucleus 7 sound processor Clinical Evaluation Report | 556314 |
| [11]. | Sponsor Device Tracking Form | 1295388 |
| [12]. | Software Tracking form | 1302326 |
| [13]. | Individual Subject Device Accountability Log Form | 1295295 |

## 24.2 External References

21 CFR Part 11. FDA Regulation Code of Federal Regulations Title 21 Part 11 - Electronic Records; Electronic Signatures.

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AAMI HE75. (2018). Human Factors Engineering – Design of Medical Devices (Vol. 2009).

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Ranganathan, P., Pramesh, C., & Aggarwal, R. (2016). Common pitfalls in statistical analysis: Intention-to-treat versus per-protocol analysis. Perspectives in Clinical Research, 7(3), 144. https://doi.org/10.4103/2229-3485.184823

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Slager et al. (2019) Remote Programming of Cochlear Implants.Otol Neurotol. 40(3):e260-e266.

Sonne et al. (2019). Right at Home: Remote Care in Real Life. Hearing Review.

Venkatesan et al. (2019). Could teleaudiology be the answer for teens? Phonak Field Study New.

Vroegop JL, Dingemanse JG, van der Schroeff MP, Metselaar RM, Goedegebure A. Self-adjustment of upper electrical stimulation levels in CI programming and the effect on auditory functioning. Ear and Hearing. 2017 Jul 1;38(4):e232-40.

World Medical Association. (2013). World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA, 310(20), 2191–2194. https://doi.org/10.1001/jama.2013.281053

# 25 CHANGE HISTORY

| Version | Change | Rationale |
|---|---|---|
| 1 | 1) Introduction of the document<br>2) Boiler plate wording for exclusion criteria has been changed to "Currently participating or participated in another interventional clinical study/trial in the past 30 days, or if less than 30 days the prior investigation was Cochlear sponsored and determined by the investigator to not impact clinical findings of this investigation" | 1) N/a<br>2) Since the study involves only acute testing and does not require continued use of the IDE during take home use, participation in previous acute testing studies may not impact its results. |
| 2 | Section 7.1.1 Clarified that IMD has been fully verified on the bench and that any new versions of the IMD will be fully verified prior to use in the study.<br>Section 7.2.6 Clarified that if a subject withdraws, they are under no obligation to give a reason for wanting to withdraw<br>Section 7.3 Added procedural mitigation relating to COVID-19. The procedures allow for conducting the study remotely to minimise the risk of exposure to COVID-19 due to the participants and investigators travelling to the study site. | Clarifications added as requested by the Ethics committee.<br>Additional procedural mitigation relating to COVID-19 added in view of travel restrictions in NSW. |

Signature Page for VV-TMF-06169 v2.0

| | |
|---|---|
| Reason for signing: Approved | Name: [redacted]<br>Role: A<br>Date of signature: 10-Aug-2021 02:02:25 GMT+0000 |

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