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Clinical Studies Ops Manager

Name/Signature	Title	Date	Meaning/Reason
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PROTOCOL

An Evidence Based Delivery Model of Care for Newly Implanted Adult CI Recipients

Investigation Number: 5753

Clinical Study

Version 6.2

April 24, 2019

Study Sponsor:

Cochlear Americas

13059 E. Peakview Avenue,

Centennial, CO 80111

5753

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Investigator Responsibilities

I, the undersigned, am responsible for the conduct of the study at the site below and by my signature below, I confirm that I have read, understand and will strictly adhere to the study protocol, Clinical Evaluation of an Evidence Based Adult Delivery Model in a Newly Implanted Nucleus CI Population.

Clinical Investigational Site

Principal Investigator's Name (print)

Title

Signature

Sponsor Representative

Title

Signature

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Table of Contents

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1. Clinical Investigational Synopsis

Title	An Evidence Based Delivery Model of Care for Adult CI Recipients
Study Sites	Up to 5 sites
Study Duration per subject	Up to 12 months
Study Population	Minimum of 35 and up to 50 Newly implanted postlingually hearing-impaired patients, aged 18 years and older.
Study Overview	The clinical investigation is evaluating a new clinical model in a group of newly implanted subjects who have already been consented to CI surgery. This randomized multi-center study will investigate a new model (Group A) based on outcome evidence, a standardized programming and testing method that utilizes artificial intelligence and will be compared to a traditional clinical model (Group B).
Primary Objective	To evaluate the total amount of clinical time as defined by number and duration of visits in a new model (Group A) compared to a traditional clinical care schedule (Group B)
Secondary Objectives	1. To compare speech perception in quiet as measured on CNC words in the implanted ear. 2. To compare subject hearing outcome satisfaction on the SSQ-12 between the two models. 3. To compare device and accessory use of subjects as measured by a device use questionnaire and datalogging between the two models. 4. To compare clinician satisfaction between the models through a questionnaire. 5. To compare speech perception in noise as measured on AzBio +10 S/N in their everyday listening situation using

	the subjects preferred noise program and accessory if appropriate.
Primary Endpoint	Reduction in the overall number of minutes of cochlear implant appointments over the first 6 months post activation in the new model (Group A) compared to the traditional model (Group B).
Secondary Endpoints	1. Speech perception on CNC at 3 and 6 months post activation will be the same or better in the new model group compared to the traditional model. 2. Subjective hearing outcome satisfaction on the SSQ-12 at 6 months post activation will be the same or better in the new model group compared to the traditional model. 3. Device and accessory use will be the same or better at 6 months of device use with the new model compared to the traditional model as measured by a device use questionnaire and datalogging. 4. Clinician satisfaction will be the same or better with the new model when compared to the traditional model at the 6-month interval. 5. Speech perception on Az-Bio +10 S/N at 6 months post activation in the subjects everyday listening condition will be better than the pre-operative score.
Study Inclusion Criteria	• Patients who are receiving a commercially approved Nucleus® electrode • 18 years and older • Postlingual onset of hearing loss (onset of hearing loss >two years of age) • Individuals who qualify for cochlear implantation using the clinics current CI candidacy criteria • Individuals who have recently been implanted but not yet had their external device activated

	• Willingness to participate in a study and comply with all study requirements • Fluent in spoken English
Study Exclusion Criteria	• Ossification or any other cochlear anomaly that might prevent insertion of less than 10 electrodes of the electrode array • Diagnosis of retro-cochlear pathology • Diagnosis of auditory neuropathy • Subject considering an acoustic component in the implanted ear • Unrealistic expectations on the part of the subject regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure and use of the prosthetic device • Unwillingness or inability to comply with all investigational requirements • Severe-profound sensorineural hearing loss >30 years • Previous cochlear implant in the contralateral ear. Additional cognitive, medical or social handicaps that would prevent completion of all study requirements as determined by the investigator
Study Intervals	New Model (Group A): Pre-operative, switch-on,1-month, 3 month and 6 months Traditional Model (Group B): Pre-operative, switch-on, 1-month, 3 month and 6 months with time measurements for any additional visits included within their typical clinical care schedule.

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2. Glossary

Term	Definition
CI	Cochlear Implant
IA	Initial Activation
AE	Adverse Event
IRB	Institutional Review Board
CRF	Case Report Form
SAE	Serious Adverse Event
Direct Connect	Subject evaluation including the Personal Audio Cable or mini-mic outside of the soundfield. Also referred to in separate documents as CoalaLink.
MAP	Individualized listening program created for cochlear implant recipients
AI	Artificial Intelligence: behaves similar to car navigation. Logic based in knowledge, decision making and learning capacity.
Artificial Intelligence (AI) MAP	Map created with AI
AutoMAP	Standardized set of MAPs that are based on averaged proven final maps of CI users at that time the fitting process is finished, and all metrics are met, i.e. tonal audiometry, phoneme discrimination, loudness normality and speech audiometry are on target.
Auditory hierarchy skills	Skills to determine auditory processing ability—or listening success. They develop in a general four-step hierarchy, but all work together and are essential for daily listening. These include detection, discrimination, identification and comprehension.

Psychoacoustic tests	This term is an overarching name for the Speech audiometry, phoneme discrimination, loudness scaling, and audiometry collected via Direct Connect. These tests collect data regarding the auditory hierarchy skills through the cochlear implant. Results from these tests are incorporated into recommendations for the AI MAP.
Pending Outcome Requests (POR)	Additional Psychoacoustic tests recommended by the AI engine to be completed by the audiologist at the next clinical visit.
Usage Data	Custom Sound comes with a wireless data logging capability where key usage information is displayed to track recipients' hearing progress. The collected data will provide insights on user compliance and information to assist in managing programs, sound processor and accessory usage.

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3. Introduction

Cochlear implant technology has improved immensely since its inception with significant improvements in hearing abilities, smaller sound processors and opportunities for wireless connectivity. One component of care that has not seen the same amount of change is the aftercare of the cochlear implant (CI) recipient. "Aftercare" includes all clinical care delivered from the switch-on up until the recipient has their annual visit.

Based on data collected through survey's, focus groups and clinical observations, there is no standardized approach to the number of clinical visits, programming methodology or tools and materials used in the aftercare treatment of the Adult CI recipient (Dunn 2018, Global Audiology Focus Group 2018). Patients are typically seen 7-10 times in the first-year post CI surgery regardless of their performance. Changes to the recipient's MAP, usually T and C levels, are typically based only on subjective feedback from the recipient and not based on data. This may be due to several reasons including: inconsistent collection of outcome data due to limited sound booth access, lack of benchmark milestones for performance, uncertainty of what parameters to change based on the data they have obtained or clinician preference. This has resulted in a complex and inefficient delivery model. It is unclear the impact this has on the variability seen in patient outcome and hearing satisfaction. In summary there is no standardization to the traditional model and the model can therefore vary from clinic to clinic.

A standardized evidence based adult delivery model has been created using clinical and recipient milestones, clinical outcomes, an AI based programming tool, standardized test paradigm and defined materials and tools to help guide the professional through the clinical aftercare process.

The clinician milestones were created using global data which includes impedance stabilization within the first 60 days, T and C levels by 3 months and data from the Nucleus® CI532 Cochlear Implant in Adults study which suggests pre-post CNC performance for 80% of the study group was ≥20 % at 3 months and ≥30 at 6 months (M. Bewley, Mining clinical databases: Post-Hoc study 2013; Nucleus CI532 Cochlear Implant in Adults study, Preliminary data 2018) .

A clinical decision support tool using AI and evidence (performance tests) collected through a direct connect system is also used in the model. The recommendations by the AI agent is outcome driven based on data from psychoacoustic tests (Bermejo et al, 2013, Varenberg et al 2011, Govaerts et al 2010). The

psychoacoustic tests represent the auditory hierarchy skills. These include detection, discrimination, identification and comprehension of auditory stimulus. This technique can be utilized as a clinical tool for the audiologist to use in modifying programming parameters for both existing and newly implanted cochlear implant recipients. The AI technology is a tool used by an audiologist to provide programming modifications in a more consistent manner.

The AI system provides several recommendations to potentially improve outcomes, based on data across major cochlear implant systems and individual psychoacoustic data. These Artificial Intelligent recommendations can substantially reduce programming time, by reducing the overall number of programming visits, time taken within the visit, as well as assist the audiologist in implementing changes to the MAP based on evidence to a variety of parameters within the programming software for the average cochlear implant recipient (Battmer et al, 2015).

This system allows for test measures to be presented in a calibrated manner outside of the soundfield through the commercially available wired and wireless programming pods as compared to the traditional sound booth set-up which can be costly. There are several configurations which can be utilized based on clinician and patient preference as well as the sound processor type. One of these configurations is via the commercially available CP910 sound processor, Personal Audio Cable, and standard of care Cochlear Nucleus Programming Pod as shown in Figure 1 below. The software test module may allow for improved clinician and recipient experience by allowing the testing to be delivered directly to the recipient's sound processor outside of a sound booth.

Figure 1. Personal Audio Cable connection

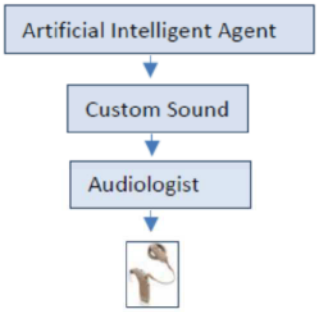

Figure 2. AI system interaction

In addition, the evidence-based model provides recipient milestones based on a subjective outcome measure, Client Oriented Scale of Improvement (COSI). This enables the clinician to provide guidance and ways to track their progress during the aftercare process. The final component to the model is the structured use of materials and tools used to support the recipient in successfully using their device and related equipment. The model utilizes self-guided patient materials for device and accessory use.

4. Study Design Overview

The clinical investigation is evaluating a new clinical process in a group of newly implanted subjects.

The new model (Group A) that uses a prescriptive method to deliver CI care in newly implanted adults will be compared to a control method defined as the clinics existing or (Group B) traditional model (i.e. programming, outcome testing completed in a sound booth and materials used for device counseling). The new clinical process standardizes the care model through clinical outcomes, AI based programming, test battery completed through direct connect and tools and materials used for counselling. The goal is to reduce the total amount of clinical time as defined by number and duration of visits compared to the clinics traditional model without compromising clinical outcomes or patient satisfaction.

Group A Study participants will be evaluated during the switch on ,1-month, 3-month and 6-month post op visit. In addition, sound processor and accessory usage data will be collected as well as psychophysical tests completed as part of the clinical decision support tool. Outcome measures will be collected at 3 and 6 months post activation. Total time of the appointment will be collected for each visit using a timer. Programming will be calculated from the CDX file which includes a time stamp. Other activities (accessories, device use, counseling etc.) will be estimated based on subtracting programming time from the total time of the sessions.

- Total time of appointment:
    - Timer will be started when the professional and subject are seated in the consultation room to end the session.
- Programming time
    - Will be extracted from the CDX file based on the time stamps within the session file.

- Other activities (accessories, device use, counseling etc.)
    - Will be estimated based on subtracting programming time from the total time of the sessions.
    - Note: Data entry or forms associated with data collection are not included in the total time of the appointment

Group B subjects will be evaluated at each clinic visit as part of the clinics traditional model on sound processor and accessory usage data. The same three-time measurements will be collected for each visit as Group A. Outcome measures will be collected at 3 and 6 months post activation. Total time of the appointment will be collected for each visit using a timer. Programming will be calculated from the CDX file which includes a time stamp. Other activities (accessories, device use, counseling etc.) will be estimated based on subtracting programming time from the total time of the sessions.

- Total time of appointment:
    - Timer will be started when the professional and subject are seated in the consultation room to end the session.
- Programming time
    - Will be extracted from the CDX file based on the time stamps within the session file.
- Other activities (accessories, device use, counseling etc.)
    - Will be estimated based on subtracting programming time from the total time of the sessions.
    - Note: Data entry or forms associated with data collection are not included in the total time of the appointment

4.1 Device description

Cochlear implant sound processors to be used in this study may include commercially available Nucleus sound processor systems.

4.2 Programming Software Description

4.2.1 Custom Sound 5.1

Programming of the sound processor is achieved via the commercially available and FDA approved Cochlear Nucleus Custom Sound (CS) software. In addition, the psychoacoustic tests will be used to assess performance of the subject and provide

the audiologist with programming parameter suggestions. Each clinical site will be provided a laptop which includes software to complete psychoacoustic testing, advice provided through Artificial Intelligence in addition to CS for use in the study.

4.3 Subject Population

Study sites will enroll up to 50 adult cochlear implant candidates at up to 5 North American cochlear implant centers.

Subjects must meet the following inclusion and exclusion criteria (Group A and B):

4.3.1 Inclusion Criteria

1. Patients who are receiving a commercially available Nucleus® electrode
2. 18 years and older
3. Postlingual onset of hearing loss (onset of hearing loss >2 years of age)
4. Individuals who qualify for cochlear implantation using the clinics current CI candidacy criteria
5. Individuals who have recently been implanted but not yet had their external device activated
6. Willingness to participate in a study and comply with all study requirements
7. Fluent in spoken English

4.4 Exclusion Criteria

1. Ossification or any other cochlear anomaly that might prevent insertion of less than 10 electrodes of the electrode array
2. Diagnosis of retro-cochlear pathology
3. Diagnosis of auditory neuropathy
4. Acoustic component in the implanted ear
5. Severe-profound sensorineural hearing loss >30 years
6. Previous cochlear implantation in either ear
7. Unrealistic expectations on the part of the subject regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure and use of the prosthetic device

8. Unwillingness or inability to comply with all investigational requirements
9. Additional cognitive, medical or social handicaps that would prevent completion of all study requirements as determined by the investigator

4.5 Study Objective

4.5.1 Primary Objectives

Primary Objective

To evaluate the total amount of clinical time as defined by number and duration of visits in a new model (Group A) compared to a traditional clinical care schedule (Group B).

Secondary Objectives

1. To compare speech perception in quiet as measured on CNC words in the implanted ear.
2. To compare subject hearing outcome satisfaction on the SSQ-12 between the two models.
3. To compare device and accessory use of subjects as measured by a device use questionnaire and datalogging between the two models.
4. To compare clinician satisfaction between the models through a questionnaire.
5. To compare speech perception in noise as measured on AzBio +10 S/N in their everyday listening situation using the subjects preferred noise program and accessory if appropriate.

5. Investigational Procedures

5.1 Subject Identification

All individuals who provide informed consent (sign the informed consent form) are considered enrolled into the study and will be assigned a unique identifier. A unique alphanumeric code will identify each subject throughout the course of the study. For example, US01-SOC-0000, where:

- US = United States,

- 01 = a sequential numeral corresponding the order in which a subject is enrolled into the study for a given study site, in this case this would correspond to the first subject recruited into the study for a particular site,
- SOC=an abbreviation for the study,
- 0000 = a unique, numeric study site identification.

5.2 Release of Medical Information

Subjects will be required to release the exchange of medical information between the Investigator(s) and the Sponsor. This requirement will be clearly identified in the Informed Consent form.

5.3 Description of Study Measures

5.3.1 Patient Outcome Measures

Psychophysical Tests

This term is an overarching name for the following tests: Speech audiometry, phoneme discrimination, loudness scaling, and audiometry. All tests are completed via a direct connect system and collect data regarding detection, discrimination and identification of sound through the cochlear implant. Results from these tests are incorporated into recommendations for the AI MAP. Specific tests within the psychoacoustic test battery to be completed at each study visit are based on recommendations through the AI.

The following psychoacoustic tests will be completed through a direct connect system for the new model group (Group A):

- Speech audiometry

  For this study, 25 CNC words randomly selected from each list will be administered in quiet at each level equal to 40, 55, 70 and 85dB SPL for speech audiometry. Testing will be completed and scored as the percentage of correctly repeated phonemes. An average phoneme score will be calculated within the test module, across the four presentation levels.

- Phoneme discrimination

  The phoneme discrimination test is performed using up to 20 pre-defined speech sound contrasting pairs (a-r, u-ʃ, u-a, u-i, i-a, o-a, i-e, m-z, s-ʃ, e-a, u-o, ə-a, ə-o, ə-e, ə-i, z-s, v-z, ə-u, u-y, y-i). Phoneme pairs have been

established as linguistically representative and are tested at 70 dB HL in an oddity paradigm (Govaerts et al., 2006). Subjects will provide a behavioral response (e.g., hand raise or verbal response) if a discrimination is recorded for the phoneme contrast. Two correct responses are required to be considered as correct identification as scored by the Investigator. Training for at least one phoneme pair will be completed for each study visit to ensure familiarity with the test.

- Loudness scaling

  Loudness scaling testing is completed by presentation of one-third octave narrow band noises centered at 250, 1000, and 4000 Hz. A 1876 ms duration stimulus will be presented randomly twice at 5dB increments between 30 and 80dB HL. Loudness will be scored on a visual analogue scale ranging from 0 (inaudible) to 6 (too loud) by the subject. (Varenburg et al. 2011, Govaerts et. al, 2006, Hereen et al., 2012).

- Audiometry

  Aided audiometric thresholds will be obtained using narrow band noise and the standard audiometric technique at the following frequencies 250, 500, 1000, 2000, 3000, 4000, 6000, Hz.

In addition, one list of AzBio +10 S/N at S0N0 in the sound field in the two-ear listening condition using the subjects preferred noise program and accessory if appropriate will be completed in a calibrated sound booth.

Two lists of CNC words of 50 monosyllabic words in CD format will be administered in quiet at a level equal to 60dBA in the soundfield and scored as total number of words correct, which will be expressed as a percentage correct for this study. Subjects will be tested in the unilateral condition using a configuration of speech at 0º azimuth in quiet in a calibrated sound booth.

The following speech perception tests will be administered to the traditional model group (Group B):

- One list of AzBio +10 S/N at S0N0 in the sound field in the two-ear listening condition using the subjects preferred noise program.
- Two lists of CNC words of 50 monosyllabic words in CD format will be administered in quiet at a level equal to 60dBA in the soundfield and scored as total number of words correct, which will be expressed as a percentage

correct for this study. Subjects will be tested in the unilateral condition using a configuration of speech at 0° azimuth in quiet in a calibrated sound booth.

5.3.1.1 Clinician Based Survey

This questionnaire developed by Cochlear focuses on the current clinical model and practices that are clinic centric and variable.

5.3.1.2 Speech, Spatial, Qualities (SSQ-12)

The SSQ-12 (Gatehouse & Noble, 2013) will be used as a subject self-assessment in three categories (speech hearing rating scale, spatial rating scale, and sound qualities rating scale) for both Group A and B.

5.3.1.3 Client Oriented Scale of Improvement (COSI)

The COSI™, developed by the National Acoustic Laboratories, is a subjective outcome measure completed by the audiologist with input from the patient across 2 appointments. However, can be repeated as the patient gets more experience with their device and continues to improve in their listening abilities. At the first appointment the patient should identify specific situations where they currently struggle and would like to see improvement with an implantable hearing solution. After the implantable hearing solution has been fit, the recipient is asked to record the change in hearing function in those same situations. The five choices of response vary from "worse" to "much better." The patient is also asked to report their final hearing ability from "hardly ever" to "almost always." Some patients may prefer to describe their improvement and hearing abilities. This will be completed for Group B as part of the new model.

5.3.1.4 Unscheduled Visit Form

If the subject requires an interim clinical visit for programming, counselling, troubleshooting or any other clinical reason, an Unscheduled Visit Form will be completed (Group A and B). Information collected will include the date of the visit, reason for the visit, and activities completed.

5.3.1.5 Communication Documentation form

The form will be completed by the clinician at each visit to document any communication by the subject (Group A and B) to the clinic or the manufacturer. Information collected will include the purpose of the communication and outcome.

5.3.1.6 Subject Service Satisfaction Survey

The in-house questionnaire will be completed by the subject to rate the service they have received by their provider at switch-on and 6 months (Group A and B).

Recipient Services post-call survey will be completed by subject to rate their experience with the video call (Group A).

5.3.1.7 Rehabilitation Screener

The clinician will use the screening tool based on the auditory hierarchy to evaluate Group A subject progress in the detection, identification, discrimination and comprehension of auditory stimuli. A list of resources will be provided to the subject for take home use.

5.3.1.8 Materials/Tools Questionnaire

The in-house questionnaire will be completed by the professional to evaluate the subject's ability to complete basic device use and accessory use tasks at switch-on, 3 months and 6 months (Group A and B).

5.4 Pre-operative Procedure

5.4.1 Preoperative Candidacy Evaluation

5.4.2 Informed Consent

A preoperative interview (as part of the informed consent process) will be conducted by the surgeon and/or audiologist to inform the candidate about all aspects of implantation with a cochlear implant, study goals and requirements, as well as the evaluation schedule. The potential limitations and advantages of cochlear implantation shall also be explained.

After reviewing the Informed Consent Form, the candidate will be given the opportunity to review and ask questions about the Informed Consent Form and/or the study prior to signing the Informed Consent Form. The candidate will be offered the opportunity to take the form home to discuss with family members should they choose to do so. If they sign the Informed Consent Form, the candidate will then be given a copy of the signed Informed Consent Form to take home.

A candidate is not considered enrolled until a properly executed Informed Consent Form has been obtained along with the results of the preoperative candidacy evaluation. CNC, AzBio at + 10 SNR, SSQ-12 and COSI completed prior to consent within 90 days will be accepted as part of the pre-op candidacy evaluation.

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5.4.3 Candidacy Baseline Assessment

The clinic will administer their typical candidacy baseline assessment for patients receiving a cochlear implant as standard of care. In addition, they will administer the following, if not part of the standard battery:

- New Model (Group A) and Traditional Model (Group B)
    - CNC Words: Two lists at 60 dBA with an appropriately fit hearing aid in the unilateral condition (contralateral ear plugged)
    - AzBio Sentences in Noise at 60 dBA at +10 dB S0N0 presented in the sound field for the everyday listening condition.
    - Patient reported outcomes:
        - SSQ-12
        - COSI
    - Hearing History: Information collected from the subject regarding the type and duration of their hearing loss.
    - Demographics: Characteristics of the subject population to include race, ethnicity and gender etc.
    - Device History: Current and previous use of hearing aids
    - Medical History: current or past medical conditions or surgical history relevant to the conduct of the study
- Eligibility: confirmation subject meets inclusion and exclusion criteria
- Randomization: Upon randomization, Group A subjects will receive the following:
    - A take home packet (at the candidacy evaluation or post-surgery) prior to the switch-on to provide them with information they will review as part of the self- learning.
    - Written instructions for scheduling a support call with Cochlear Recipient Services for counselling on external equipment and cochlear implant system. Call will be scheduled 2 weeks following initial activation.

5.5 Post-operative Procedure

5.5.1 Initial Activation of Sound (Switch-on)

At the initial activation appointment, the following procedures will be completed:

- New Model (Group A):
  - Creation of AutoMAPs with AI
  - Self-directed device use using study materials and video conference call with Cochlear Recipient Services
  - Clinician reported Materials/Tools questionnaire
  - An anonymized .cdx file will be provided to the study sponsor
  - Subject Service Satisfaction Survey
- Traditional Model (Group B):
  - Programming and counselling as defined by Center
  - Complete Clinician reported Materials/Tools questionnaire
  - An anonymized .cdx file will be provided to the study sponsor
  - Subject Service Satisfaction Survey

5.5.2 1-2 weeks Post Activation

- Traditional Model (Group B)
  - Programming and/or counselling as defined by Center
  - An anonymized .cdx file will be provided to the study sponsor

5.5.3 One Month Post activation

At 1-month post activation, the following procedures will be completed:

- New Model (Group A)
  - Confirm Device use through usage data screen in Custom Sound
  - Optional: AutoNRT if not collected in the OR at the time of surgery
  - Evaluate highest tolerable AutoMAP

- Administer psychoacoustic tests using direct connect:
  - Complete Audiogram – obtain FOX (AI) advice
  - Complete phoneme discrimination and obtain FOX (AI) advice
  - Provide AI MAP to subject for take home use
- Complete Rehabilitation Screener and provide list of resources
- Provide appropriate accessory materials for self-driven learning based on goals of COSI and ability of subject
- Communication documentation form
- An anonymized .cdx file will be provided to the study sponsor

- Traditional Model (Group B)
  - Programming and/or counselling as defined by Center
  - Communication documentation form
  - An anonymized. cdx file will be provided to the study sponsor

5.5.4 Three Month Post activation

At 3 months post activation, the following procedures will be completed:

- New Model (Group A)
  - Confirm Device use through usage data screen in Custom Sound
  - Administer psychoacoustic tests to include:
    - Any pending outcomes requests from 1-month visit
    - Loudness scaling
    - Speech Audiometry
  - Obtain FOX (AI) advice
  - Review CNC performance at 70dB on speech audiometry to determine if recipient tracking to ≥20 pre-post improvement on CNC words
    - If meets above criteria and AI has no other recommendations (Green/Teal FOX): Provide AI MAP for take home use. If recommendations have been made, complete at 6 month visit

as part of Pending Outcomes. Provide the MAP with the best outcome for take home use.

- If **not** completed at 1 month, provide appropriate accessory materials for self-driven learning based on goals of COSI.
- If does **not** meet above criteria (≥20 CNC words) and/or AI has made modifications to the fitting and wants additional outcome measures, complete as requested.
    - Obtain FOX (AI) advice to see if the outcome has improved. Provide the MAP with the best outcome for take home use.
    - If **not** completed at 1 month, provide appropriate accessory materials for self-driven learning based on goals of COSI

- Complete Clinician reported Materials/Tools questionnaire
- Communication Documentation form
- Update COSI (Degree of Change)
- An anonymized .cdx file will be provided to the study sponsor
- CNC Words: Two lists of 50 monosyllabic words at 60 dBA in the soundfield using a configuration of speech at 0º azimuth in quiet for the implanted ear (contralateral ear plugged)

- Traditional Model (Group B)
    - Programming and/or counselling as defined by Center
    - Communication documentation form
    - Update COSI (Degree of Change)
    - CNC Words: Two lists of 50 monosyllabic words at 60 dBA in the soundfield using a configuration of speech at 0º azimuth in quiet for the implanted ear (contralateral ear plugged)
    - An anonymized. cdx file will be provided to the study sponsor

5.5.5 Six Months Post activation

At 6 months post activation, the following procedures will be completed:

- New Model (Group A)
    - Confirm Device use through usage data screen in Custom Sound
    - Administer psychoacoustic tests to include:
        - Any pending outcomes requests from 3-month visit
        - Speech Audiometry
    - Obtain FOX Advice
    - Review CNC performance at 70dB on speech audiometry to determine if recipient tracking to ≥30 pre-post improvement on CNC words
        - If subject meets above criteria and AI has no other recommendations (Green/Teal FOX): Provide AI MAP for take home use.
            - Complete patient reported COSI and SSQ-12
            - Complete Clinician reported Materials/Tools questionnaire
            - Complete Clinician satisfaction questionnaire
            - Complete subject Service Satisfaction Questionnaire
            - Evaluate hearing options for contralateral ear
            - CNC Words: Two lists of 50 monosyllabic words at 60 dBA in the soundfield using a configuration of speech at 0° azimuth in quiet for the implanted ear (contralateral ear plugged)
            - AzBio Sentences in Noise at 60 dBA at +10 dB S0N0 presented in the soundfield for the everyday listening condition
            - Communication Documentation form
            - An anonymized .cdx file will be provided to the study sponsor
        - If the subject does **not** meet above criteria (≥30 CNC words) and AI has made modifications to the fitting and wants additional outcome measures, complete as requested.

- Complete patient reported COSI and SSQ-12
- Complete Clinician reported Materials/Tools questionnaire
- Complete clinician satisfaction questionnaire
- Complete subject Service Satisfaction Questionnaire
- Evaluate hearing options for contralateral ear
- CNC Words: Two lists of 50 monosyllabic words at 60 dBA in the soundfield using a configuration of speech at 0º azimuth in quiet for the implanted ear (contralateral ear plugged)
- AzBio Sentences in Noise at 60 dBA at +10 dB S0N0 presented in the soundfield for the everyday listening condition
- An anonymized .cdx file will be provided to the study sponsor.

  - If CNC word score at 70 dB on speech audiometry remains less than 30% after completing the above steps, it is recommended the patient be seen in 1 month using standard clinical procedures using Custom Sound directed by CTM Cochlear staff.

- Traditional Model (Group B)
  - Programming and/or counselling as defined by Center
  - Communication documentation form
  - CNC Words: Two lists of 50 monosyllabic words at 60 dBA in the soundfield using a configuration of speech at 0º azimuth in quiet for the implanted ear
  - AzBio Sentences in Noise at 60 dBA at +10 S0N0 presented in the soundfield for the everyday listening condition with accessory is appropriate
  - Complete COSI, SSQ-12 and subject Service Satisfaction Questionnaire
  - An anonymized. cdx file will be provided to the study sponsor

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6. Data Analysis

Statistical Analysis for this study is addressed in detail in the document entitled "Statistical Analysis Plan for the Evidence Based Delivery Model of Care for Newly Implanted Adult CI Recipients".

7. Summary of Data Collection Visits

Each subject will participate in 4-6 scheduled evaluation sessions. For Group A, subjects will be seen preoperatively, at switch-on and at 1, 3, 6 post activation. Visit windows are restricted for the switch on, 1, 3 and 6 month, and deviations from these intervals by more than the windows indicated in the table below.

Unscheduled visits should be documented on the form indicated above in section 5.3.1.4.

Table 1: Data Collection Visit Schedule Group A

Measure	Pre-Op	Switch - on	Video Conference (+/- 1 week)	1 mth (+/- 3 weeks)	3 mth (+/-3 weeks)	6 mth (+/- 3 weeks)
Informed Consent	X					
Clinician Sat.						X
Hearing History	X					
Medical History	X					
Demographics	X					
Eligibility	X					
Device History	X					
Time measurement		X		X	X	X
Comm. Doc.			X	X	X	X

Form						
CNC Words	X				X	X
Az Bio +10	X					X
Usage Data				X	X	X
Service Satisfaction		X				X
SSQ	X					X
Rehab Screener				X		
COSI	X				X	X
Mat.-Tools Q.		X		X	X	X
AEs and DDs		X		X	X	X

For Group B, subjects will be seen preoperatively, at switch-on, 1-2 weeks, and at 1, 3, 6 post activation. Visit windows are restricted and deviations from these intervals by more than +/-1 week for the video conference (Group A) and 1-2 week follow-up (Group B), and +/- 3 weeks for all other visits will be reported on in the clinical investigation report.

Unscheduled visits should be documented on the form indicated above.

Table 2: Data Collection Visit Schedule Group B

Measure	Pre-Op	Switch - on	1-2 weeks (+/- 1 week)	1 mth (+/- 3 weeks)	3 mth (+/- 3 weeks)	6 mth (+/- 3 weeks)
Informed Consent	X					
Clinician Sat.						X

Medical History	X					
Device History	X					
Hearing History	X					
Demographics	X					
Eligibility	X					
Time measurement		X	X	X	X	X
Comm. Doc. Form			X	X	X	X
Service Satisfaction		X				X
CNC Words	X				X	X
AzBio +10	X					X
Usage Data			X	X	X	X
SSQ	X					X
COSI	X				X	X
Mat.-Tools Q.		X		X	X	X
AEs and DDs		X	X	X	X	X

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8. Reporting Process for Adverse Events and Device Deficiencies

8.1 Definitions

8.1.1 Adverse Event (AE)

An adverse event (AE) is defined as 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 investigational medical device or procedure.

8.1.2 Adverse device effect (ADE)

An adverse device effect is defined as an adverse event related to the use of an investigational medical device. This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device. This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

8.1.3 Serious Adverse Event (SAE)

A serious adverse event (SAE) is defined as any adverse event that

- led to death
- led to serious deterioration in the health of the subject, that either resulted in
    1) a life-threatening illness or injury, or
    2) a permanent impairment of a body structure or a body function, or
    3) in-patient or prolonged hospitalization, or
    4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- led to fetal distress, fetal death or a congenital abnormality or birth defect

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

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8.1.4 Serious adverse device effect (SADE)

8.1.5 A serious adverse device effect is defined as an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event. Unanticipated Adverse Device Effects

8.1.6 Unanticipated adverse device effects refer to any event that represents a “serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.” [FDA 21 CFR 812.3(s)] Device deficiency (DD)

A device deficiency is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Device deficiencies include malfunctions, use errors, and inadequate labelling. For the purposes of this study, the device of study is the AI software and related functions to complete testing and/or programming.

8.2 Assessment and Reporting of Adverse Events and device deficiencies

To monitor subject safety throughout this study, device deficiencies and device and/or procedure-related serious adverse events will be recorded. Information on these adverse events will be maintained by event type. The investigator will complete an Adverse Event and/or Device Deficiency form.

In accordance with 21 CFR 812.3, Investigators are required to inform their respective Institutional Review Boards (IRBs) and Cochlear Americas immediately if an unanticipated adverse device effect is suspected (no more than 10 working days after the investigator learns of the effect). If the case is determined to be an unanticipated adverse device effect, the investigator will fill out an “Unanticipated Adverse Device Effect Form.” Cochlear Americas will report the results of an evaluation of the unanticipated adverse device effect to the FDA and all other reviewing IRBs and investigators within 10 working days after first receiving notice of the event.

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The investigator shall report all serious device and procedure related adverse events and device deficiencies that could have led to a serious adverse event to the sponsor and respective IRBs per local requirements.

The Sponsor will report adverse event and device deficiency information to the respective IRBs per local requirements.

The details of the Medical Monitor responsible for the clinical investigation are:

Name of contact person of the sponsor	[redacted]
Phone number (business hours)	[redacted]
Phone number (after hours)	[redacted]
E-mail	[redacted]

8.3 Protocol Deviations

The investigator is not allowed to deviate from the protocol except under emergency circumstances to protect the rights, safety and well-being of the subjects. Such deviation shall be documented and reported to the Sponsor and the IRB as soon as possible in accordance with 21 CFR 812.150.

The procedure for recording and reporting protocol deviations shall be via a Protocol Deviation form. Analysis of protocol deviations shall be undertaken by the Sponsor and reported to the IRBs per local requirements.

9. Study Completion

9.1 Completed Subjects

Once the 6-month post-activation visit is completed, the subject will be deemed complete and will continue to receive standard clinical follow-up care at their cochlear implant facility after the study.

9.2 Discontinued Subjects

Any subject may voluntarily discontinue the study at any time without prejudice. The Investigator may discontinue a subject from the study at any time if (s)he considers that remaining in the study compromises the subject's health or the subject is not sufficiently cooperative. In either event, the reason(s) for discontinuation should be

recorded on a study withdrawal form, provided as part of the case report form packet for the study. Possible reasons for study discontinuation include the following:

- AE necessitating discontinuation from the study
- The subject is lost to follow-up
- Voluntary decision to withdraw consent made by the subject
- Investigator decision
- Other reason

In the case of a subject lost-to-follow-up, the Investigator must attempt to contact the subject (or relative/family contact) by phone, email, or letter at least three times. If attempts are unsuccessful, the 'subject withdrawal' form is to be completed in the study file and reported to the Sponsor and, as appropriate, to the IRB.

9.3 Premature Study Termination

The Sponsor may terminate the study early in the case of major non-adherence to the protocol, or if it is anticipated that recruitment will not be met for the required number of subjects to complete the study objectives. In the event of premature study termination, the subjects who are already enrolled will be sponsored through study completion.

10. Data Analyses

10.1 Additional Analyses

- Evaluation of the number and reason for unscheduled visits outside new and traditional models and comparison between the models.
- Evaluation of (COSI) Client Oriented Scale of Improvement and Speech, Spatial, Qualities of Hearing Scale (SSQ-12) and relationship between the two measures.
- Evaluation of test administration between clinics.
- Observation of the number of subjects performing ≥20% on CNC words pre to post at the 3-month interval for Group A and Group B.
- Evaluation of the communication documentation form to include comparison between Group A and Group B.

- Observation of the number of subjects performing ≥30% on CNC words pre to post at the 6-month interval for Group A and Group B.
- Evaluation of clinic site differences in subject reported service satisfaction between sites and between and within Group A and Group B subjects.
- Evaluation of clinic site differences in time and outcomes between and within Group A and Group B.
- Evaluation of the effectiveness of self-guided subject materials for Group A subjects.

10.2 Study Population

All subjects who are consented into the clinical study will constitute the intention-to-treat (ITT) population for the purposes of adverse event reporting. Only subjects who completed per the protocol will be considered as the completed cases (CC) population and per protocol (PP).

10.3 Missing Data

All efforts will be put forth to ensure near complete follow-up, with focus on the assessment of the primary outcome and occurrence of adverse events. Regular reminders of subject follow-up due dates will be provided to participating centers to facilitate scheduling of follow-up visits.

11. Risk Benefit Statement

11.1 Benefits

It is possible but not guaranteed that advances to cochlear implant technology will improve performance or increase usability of devices for future recipients. This investigation will help to inform clinical guidance when fitting new cochlear implant patients. It cannot be promised that subjects will receive any medical benefits from being in this study.

11.2 Risks

With any cochlear implant mapping, there is a very small risk of unintentional over-stimulation. Subjects may experience sounds during mapping that are uncomfortably loud. Mitigation of this risk is similar to that used during clinical cochlear implant mapping wherein the sound processor is removed from the subjects' head and/or the stimulation to the sound processor is ceased in Custom

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Sound. This is a modified clinical treatment plan and therefore the possibility of patient dissatisfaction and reduced performance.

12. Good Clinical Practices Statement

The study obligations for the Investigator(s) are outlined in guidelines for Good Clinical Practice (GCP), 21 CFR Part 812 (Code of Federal Regulations Part 812 Investigational Device Exemptions), ISO14155:2011 (Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice), and the Declaration of Helsinki.

12.1 Access to Study Documents and Study Monitoring

Investigator(s) will provide access to study documentation including source data and electronic medical records for the purposes of monitoring, audits, IRB review, and regulatory inspections. 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 qualification, initiation, monitoring, and close out and is available for review.

12.2 Quality Control and Assurance

Study sites may be subject to Quality audits at any point during the study. Regulatory agencies may conduct inspections during the course of the clinical investigation and after study completion.

12.3 Institutional Review Board

Each site will obtain approval from its designated IRB prior to commencing any study-related activities. A copy of the IRB approval will be kept in the Investigator file(s). Any additional requirements imposed by the IRB and/or regulatory authority shall be followed. The Investigator(s) will submit the appropriate documentation if any necessary extension or renewal of the IRB approval must be obtained.

12.4 Informed Consent Process

Prior to recruitment of any subjects into the study, written approval of the investigational plan including clinical protocol and informed consent form will be obtained from reviewing Institutional Review Board (IRB). An interview (as part of the informed consent process) will be conducted by the surgeon and/or delegated

staff to inform the subject about rationale for and the details, aims, objectives of the study, study expectations, evaluation schedule, and the risks and benefits of the trial treatment (and alternative treatments), and the extent of the patient's involvement. Written informed consent shall be obtained from each subject after this explanation. After reviewing the Informed Consent Form, the subject will be given the opportunity to review and ask questions about the Informed Consent Form and/or the study prior to signing the Informed Consent Form. The subject will be offered the opportunity to take the form home to discuss with family members should they choose to do so. If they sign the Informed Consent Form, the subject will then be given a copy of the signed Informed Consent Form to take home. The informed consent process is intended to be completed after standard of care surgery but may be completed pre-operatively if deemed appropriate by the Investigator.

The Investigator is responsible for ensuring that all patients give written informed consent prior to any study-related examination or activity. All patients shall sign and date the Informed Consent Form, and a copy of the Informed Consent Form shall be given to the patient. The Sponsor and the Investigator(s) shall avoid improper influence on or inducement of the subject, monitor, the Investigator(s) or other parties participating in or contributing to the clinical investigation.

12.5 Confidentiality

A Case Report Form (CRF) will be completed for each study subject, summarizing all clinical and study data. The CRF contains confidential material. Subjects will only be referred to in the CRF by their subject numbers in order to retain subject confidentiality. Specific instructions to complete the CRF shall be provided to the clinical investigation team as appropriate.

The CRFs are to be retained by the Investigator for a period of time as determined by local regulations.

12.6 Protocol Deviations and Amendments

The Investigator must receive prior approval from the Sponsor, and the IRB when necessary, to deviate from the protocol except in cases of emergency to protect the rights, safety, and well-being of the subjects. Emergency protocol deviations must be documented and reported to the Sponsor and the IRB.

No changes in the protocol or informed consent shall be effected without mutual agreement between the IRB and the Sponsor. Changes related to the scientific

intent of the study shall be documented in the protocol amendment and requires signatures from both the sponsor and the participating investigator.

12.7 Data Management

Data collection is performed using Case Report Forms (CRFs) and paper test outcome measures. Data will be stored in an electronic data capture system (EDC) maintained by the Sponsor. Site personnel will be trained on the completion of the CRFs.

12.8 Record Keeping and Retention

All source documents, CRFs, and trial documentation will be kept by the Investigator(s) for the appropriate retention period as stipulated by local regulations and ICH-GCP.

12.9 Study Report and Publication

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law.

The aggregate data resulting from this study will be the proprietary information of the Sponsor and may be made public after all data have been analyzed and the study results are available. None of the data resulting from this study will be allowed to be presented or published in any form, by the Investigator or any other person, without the prior written approval of the Sponsor. At the end of the study, a clinical study report will be written by the study Investigators or their designee and reviewed by the Sponsor.

13. References

Camille Dunn, University of Iowa presentation at ACIA Washington DC 2018

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14. Change History

Version	Change	Author	Date
1.0	Introduction of document	B Buck	10/2/2018
2.0	Rewrite of introduction and primary objective	B Buck	11/20/2018
3.0	Change to randomized study	B Buck	12/5/2018
4.0	Modification to Group A schedule	B Buck	12/13/2018
5.0	Corrections to study language	B Buck	12/18/2018
6.0	Modification to Group A and B schedule	B Buck	12/21/2018
6.1	Clarification to sites for expectation for study monitoring and data collection	B Buck	1/31/2019
6.2	Update protocol to include Recipient Services video call pilot information and materials, clarification/modification of Group A protocol	L Chenier	4/11/2019