A registry for the collection of data in cochlear implant patients

Messa a punto di un registro per la raccolta dati dei pazienti portatori di impianto cocleare

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SUMMARY

The need to optimize the use of all the information that modern technological tools have made available to the physician ENT/audiologist has increasingly emerged within the Italian scientific community. Towards this purpose, it is necessary to create a registry of the patients using cochlear implants (CIs). This registry will include a homogeneous summary of the information deriving from multiple sources related to daily clinical practice, in order to assess auditory benefits, safety and reliability in patients with cochlear implants, and organization over the national territory. The primary objectives relative to the above-mentioned analysis are to assess the impact of the use of cochlear implants on patient health, to ensure traceability of the devices currently used, monitoring their safety and reliability over time, to guarantee access of the technique in clinical and organizational conditions that can allow the best possible benefits. The aspects concerning implementation of the registry were discussed extensively during the first meetings of the Working Group (WG). In particular, owing to the complexity and high costs related mainly to the development of the technological aspects and the need to involve technological partners external to the WG, and to respect current privacy laws, the WG members decided that the project should be limited to proposal of a paper registry to be implemented at a later stage, possibly within the framework of successive research projects. During meetings, the WG members discussed various aspects of implementation of the registry, and in particular the scientific features connected to objectives, inclusion criteria, and structure of the forms needed for data collection and organizational aspects. A registry is proposed herein.

KEY WORDS: Registry • Cochlear implant • Cochlear implant recipient

RIASSUNTO

Da qualche tempo in seno alla comunità scientifica italiana sta emergendo sempre più l'esigenza di ottimizzare l'utilizzo di tutte le informazioni che gli strumenti moderni già mettono a disposizione del medico ORL/audiologo. A tale scopo è necessaria la creazione di un registro dei pazienti portatori di impianto cocleare, contenente una sintesi ragionata ed omogenea delle informazioni che scaturiscono da più fonti nell'ambito della pratica clinica quotidiana, al fine di valutare i benefici uditivi dei pazienti portatori di impianto cocleare, la sicurezza ed affidabilità dei dispositivi e l'organizzazione sul territorio nazionale del percorso implantologico del paziente.

Gli obiettivi primari funzionali alla suddetta analisi risultano essere i seguenti: valutare l'impatto dell'utilizzo degli impianti cocleari sulla salute dei pazienti, garantire la tracciabilità dei dispositivi impiantabili attualmente in uso, monitorandone la sicurezza ed affidabilità nel tempo, garantire l'accesso a questa tecnologia a tutti i cittadini in condizioni cliniche ed organizzative che rendano possibile il raggiungimento dei massimi benefici possibili.

Durante le prime riunioni dei componenti del Gruppo di Lavoro (GdL), sono stati ampiamente discussi gli aspetti relativi alla messa a punto del registro. In particolare vista la complessità e gli alti costi principalmente legati allo sviluppo della parte tecnologica e alla necessità di coinvolgere partners tecnologici esterni al GdL e data la necessità di rispettare le normative vigenti in campo di privacy, il GdL decide di limitare il presente progetto alla proposta di un registro cartaceo, che potrà essere implementato successivamente, magari nell'ambito di successivi progetti di ricerca. Durante le riunioni, i componenti del GdL hanno discusso i vari aspetti riguardanti la messa a punto del registro, soprattutto gli aspetti scientifici quali gli obiettivi, i criteri di inclusione, la struttura delle schede di raccolta dati e gli aspetti organizzativi. In appendice viene riportata la proposta di registro.

PAROLE CHIAVE: *Registro • Impianto cocleare • Portatori di impianto cocleare*

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Introduction

Rationale for a Registry. The approach and management of patients who are suitable candidates for cochlear implantation varies from one centre to another. The identification of candidate subjects, their selection and preparation for the intervention, the choice of the device and surgical techniques, as well as the management of post-operative recovery, are critical elements for recovery of auditory function. All of these successive phases should be taken into account and given their correct predictive value when evaluating the outcomes of the implant. In a scenario of this type, it is essential to have as much data as possible, collected in a standard fashion, applying the same criteria, and with the same knowledge and goals.

The need to optimize the use of all the information that modern technological tools have made available to the otolaryngologist and audiologist has increasingly emerged within the Italian scientific community. Unfortunately, despite all attempts at standardization, no uniform model for outcome assessment in this therapeutic area has been reached, representing a limit to the production of high quality methodological scientific trials. On the one hand, this drawback seems to depend on objective scientific difficulties, such as the need to represent the results from the different points of view of the specialists involved (surgeon, otolaryngologist, audiologist, speech therapist, patient), and to transpose this information in a quantitative and valid manner. On the other hand, the information systems currently available in the different structures are often incompatible with one other, making it difficult to obtain information that is essential to provide safe, high-quality care. Essential clinical and technical information, often missing in hospital discharge cards, can only be obtained by examining clinical records. Furthermore, a monitoring system following the implanted patient in the course of his life has not been developed. For an integrated and exhaustive study of the data, the specialists treating the candidate for cochlear implantation feel the need for an efficient clinical database assessing auditory benefits in cochlear implant patients.

Health technology assessment is becoming one of the most important institutional tasks falling within the competence of the Ministry of Health. The need to implement a registry for patients using cochlear implants reflects the interest of the Ministry of Health in assessing healthcare techniques [1]. The Italian financial law for 2007 [2] already planned to assign part of its funds to activities aimed at strengthening the implementation of medical devices. In particular, funds have been destined to activities of supervision of the market, control of accidents, technology assessment studies, development of registerys for diseases requiring the use of medical devices. The interest of the Health Ministry falls within the framework of cochlear implantation.

A similar national – or at least regional – initiative is designed to illustrate the state-of-the-art of the three macro areas involved in the process, namely clinical, technological and clinical governmental.

Towards this end, it is necessary to create a registry of patients using cochlear implants. This registry will include a homogeneous summary of the information deriving from multiple sources related to daily clinical practice, in order to assess the auditory benefits, safety and reliability of cochlear implants, and organization of patient travels. [3 4]. The primary objectives to the abovementioned analysis are to assess the impact of the use of cochlear implants on patient health, to ensure traceability of the devices currently used, monitoring their safety and reliability over time and to guarantee access of this technique to all citizens in clinical and organisational conditions, which can allow them to achieve the best possible benefits.

Among the benefits resulting from the creation of a registry, the possibility to obtain outcomes which are statistically comparable in the different centres is particularly interesting (increasing the robustness of statistical analyses performed on a number of cases superior to those annually available for each clinic). A registry can also help to: i) develop a methodology that is able to compare and objectively assess performance of each product both from clinical and technological points of view; ii) improve clinical practice through standardized protocols; iii) improve the quality of practice, thanks to an operative monitoring system of the results; iv) assess the appropriateness of treatment, in particular for the subject categories for which application of cochlear implants must be evaluated carefully; v) increase scientific activities (e.g. clinical studies and publications), in particular by developing – if possible – independent clinical research based on a number of statistically significant cases; and vi) create a national network of centres involved in cochlear implant procedures, in order to exchange experience, clinical advice and opinions.

Methodology: project for a registry implementation

The following project for implementation of the register was defined during the phase of definition of the *Aims*.

Study methodology

Observational, prospective, multicentre, national or regional registries.

Recruitment of participating centres

Recruitment of structures interested in joining the registry (signing a participation form).

Inclusion criteria

Patients submitted to unilateral or bilateral cochlear implantation, using simultaneous or sequential procedures.

Exclusion criteria

The following patients will be excluded: a) all retrospective patients, as fragmentation of the information and inconsistency of the definitions with respect to the terminology requested would make it difficult to complete the different registry fields; b) all patients who refuse consent to the use of data.

Observation period

A registry of cochlear implant users implies a multiyear prospective study of the collected data in order to obtain preliminary, clinically-reliable results and implant reliability outcomes. Therefore, it is necessary to have a sufficiently large number of cases. Only long-term results are possible, because failure of devices and clinical benefits can only be assessed over the long-term. These aspects often come into conflict with the needs of institutions and projects seeking short-term results.

Data analysis

In accordance with statistical analysis planning and technological platform features, the system will include different types of reports, as well as analytical and synthetic data processing related to scientific and organizational aspects.

The information obtained from this collection of data will concern: a) clinical epidemiology of implanted deaf patients; b) epidemiology of treatment; c) epidemiology of therapeutic-diagnostic protocols; d) compliance of Centres to guidelines; e) postmarketing surveillance (study of implant survival), and analysis of risk factors that may influence outcome (e.g. different lifestyles of the patient); f) direct analysis of sanitary and social costs by assessment of economic implications determined by the use of cochlear implants and recovery of auditory abilities; g) new routes/applications; h) best practices: identification and dissemination.

Logical structure of the database

In order to obtain adhesion to the registry by as many centres as possible, it is necessary to identify a minimum set of data that is both comprehensive and functional to the aims proposed.

Identification of the two data levels can be divided into: a) obligatory data, functional to the objectives of the registry, accessible to as many national centres as possible; b) large amounts of non-obligatory data, alongside a minimum group of obligatory data, but only accessible to the few reference centres able to support the collection.

The data collected can be subdivided into three principal subsets.

The *first subset* of data allows identification of the patient and his/her clinical course within the hospital structure (identifying organization indicators, e.g. separation between place of first intervention and follow-up and/or post-intervention; waiting times between diagnosis and intervention, intervention and activation, etc.).

The *second subset* of data includes technical information relative to the devices used (both implantable and external), to allow traceability of the implant during the patient's life when associated with previous data (analysis of reliability/survival curve of the implant).

The *third subset* of data concerns clinical data, or information related to anamnesis, surgical intervention, activation and follow-up. These elements are necessary to trace the clinical profile of the patient and to check the impact of cochlear implant usage on patient health, i.e. auditory benefit and improvement of quality of life.

e-CRF (electronic-Case Report Form) design and data management

Technical development of the project in terms of preparation of the registry will be assigned to one or more technological partners (clinical research organization (CRO), University, research institute or other), and will concern both the practical aspects (from design and implementation of the e-CRF, with on-line control, generation of ongoing queries, to creation of the database, including data-clearing and production of tables and statistical reports in agreement with a pre-established study plan), and the maintenance aspects (hosting server, constant back-up, connections, usage licenses).

The e-CRF will include both obligatory and optional fields that will be differentiated to obtain two possible registry levels. The system will periodically check for congruence and completion, and send warning messages aimed at correcting any input mistakes made by users. All variables introduced in the registry will be codified by standard definitions and appropriate terminology to ensure a systematic approach to collection and inclusion of the data).

The server hosting the data will be protected, validated for the purpose and submitted to rigid back-up and anti-intrusion protocols.

In the case of data collected on paper forms, further resources for data inclusion will be necessary to perform the above-mentioned activities.

Data flow recording

The mode of data inclusion suggested is through a web-interface, owing to the practical management that the information system offers with respect to traditional recording on paper forms. The data will be collected in a resident database stored on a centralized server owned by the registry group. The intervention of a technological provider will be necessary for implementation of the data collection cards. Transmission of the data, from local clinical to central registry sites, will essentially need to respond to

the following principle: the data must be transmitted safely. This includes cryptography of the information as well as possibility of access after the authentication procedure. Furthermore, it will be possible for the person responsible for each centre, using a password, to access, consult and update at any time the data of his/her own centre. Consultation of the "national" data of the registry will also be allowed, with the following rules safeguarding privacy: this collection of data will be completely anonymous, preventing identification of patient and centre.

Privacy

All possible solutions should be taken to protect patients' right to privacy and data security in compliance with "code 196 concerning personal data protection", and the more recent guidelines of July 2008 "for treatment of personal data in the field of experimental clinical experimentation" [5]. The patient should consent to treatment of his/her data, signing an informed consent form.

Conclusions and implementation of the project

The aspects concerning registry implementation were discussed extensively during the first meetings of the Working Group (WG) members. In particular, owing to the complexity and high costs related mainly to the development of the technological part and the need to involve technological partners external to the WG and to respect current privacy laws, the WG members decided that the project should be limited to the proposal of a paper registry to be implemented at a later stage, possibly within the framework of successive financed research projects.

The WG members discussed various aspects of implementation of the registry, and in particular the scientific features related to objectives, inclusion criteria and structure of the forms related to data collection and organisational aspects.

The registry proposal is reported in Appendix 1.

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Appendix I
Registry proposal for collection of patient data

Cochlear Implant Registry

Retrieval Information Card

Part 1 – Personal Details

PARTICIPATION CONSENT/DATA TREATMENT DL 196/03 ❑ YES (PATIENT)
❑ YES (PARENT/TUTOR)

1* Progressive card n° |__|__|__|__|__| **2* Clinical card n°** |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|

3* Hospital_____ **4* Ward/Division**_____

5* Surname_____ **6* Name**_____

7* Sex |__| M |__| F **8*** Date of birth ___ / ___ / _____
day month year

9* Place of birth_____ **10 Province of birth** |__|__|
or Foreign Country

11* Municipality of residence_____ **12 Province of residence** |__|__|
or Foreign Country

13 Fiscal Code |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| **14 Nationality**_____

15 Telephone number_____ **Mobile phone**_____

16 E-mail address_____

17 Civil status_____ **18 Educational qualification**_____

19 Current occupation_____

20* Admission date ___ / ___ / _____ **21* Intervention date** ___ / ___ / _____
day month year day month year

22* Discharge date ___ / ___ / _____*or* **22a Transfer date** ___ / ___ / _____
day month year day month year

23* Patient sent by:
❑ **Doctor or Family Paediatrician**
❑ **Password, Internet**
❑ **Neonatology screening**
❑ **Specialist ORL-Audiologist**
❑ **Other** (*specify*)

Part 2 – Clinical Data

24* Deafness onset time:
❑ Prelingual (< 1 yr) ❑ Perilingual (1-3 yrs) ❑ Postlingual (> 3 yrs)
❑ Late postlingual (7-18 yrs) ❑ Adult age (≥ 18 yrs)

❑ Congenital ❑ Acquired ❑ Undefinable

25* Age of hearing loss first diagnosis:_____

26* Hypoacusia trend ❑ Progressive ❑ Stable

27a* Aetiology of paediatric hypoacusia
❑ Genetic: ❑ Isolated ❑ Syndromic (*specify*_____)
(❑ recessive ❑ dominant ❑ mitochondrial ❑ other (*specify* _____)
❑ Inner ear malformations (*specify* _____)
❑ Achieved cause
❑ Prenatal-Infective ❑ CMV ❑ Toxoplasma
❑ Other (*specify* _____)
❑ Perinatal ❑ TIN
❑ Other (*specify* _____)
❑ Postnatal ❑ Meningitis
❑ Other (*specify* _____)
❑ Unknown

27b* Aetiology of adult hearing loss
❑ Genetic: ❑ Isolated ❑ Syndromic (*specify*_____)
(❑ recessive ❑ dominant ❑ mitochondrial ❑ other (*specify* _____)
❑ Inner ear malformations (*specify*_____)
❑ Otosclerosis
❑ Meningitis
❑ Other (*specify* _____)

28* Admission-associated pathologies *(more than one answer is possible)*
❑ *none*
❑ hypertension
❑ diabetes
❑ malformation syndromes (❑ middle ear ❑ external ear ❑ other)
❑ nervous system diseases
❑ cerebrovascular diseases
❑ respiratory diseases
❑ neuropsychiatric paediatric diseases_____ ❑ mental retardation
❑ acute visual deficit_____ ❑ cerebral palsy
❑ other (*specify*_____) ❑ pervasive development disorders
❑ attention deficit with/without hyperactivity
❑ other

29* Use of hearing aids/devices/Cochlear Implant
❑ NO
❑ YES (hearing aids) (age of first fitting_____ ❑ RIGHT ❑ LEFT ❑ BIL – type (*specify*____)
❑ YES: CI user: ❑ RIGHT (Brand-Model _____) – Age of CI positioning:_____
❑ LEFT (Brand-Model _____) – Age of CI positioning: _____
❑ YES (vibro-tactile stimulation)
❑ Observations-Annotations_____

30* In case of children and adults was rehabilitation treatment performed?
❑ YES (number of weekly sessions for months_____ ❑ Oralist ❑ Sign Language
❑ NO

31* Duration of hearing deprivation (months/years)
_____

32* Otoscopy
Right ❑ negative - ❑ positive (*specify*_____)
Left ❑ negative - ❑ positive (*specify*_____)

33 Tonal Audiometry without prosthesis (*adults, **children)

dB	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	8000 Hz
*R						
*L						
**F.F.						

34 Tonal Audiometry with hearing aids (*adults, **children)

dB	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz	8000 Hz
R Pr.						
L Pr.						
*, **F.F.						

35* Vocal Audiometry (*adults, **children)
% maximum verbal discrimination reached %_____ **dB** _____

36* Tympanometry
Right ❑ normal - ❑ pathological (*specify*_____)
Left ❑ normal - ❑ pathological (*specify*_____)

37* Stapedial Reflexes
Right ❑ present - ❑ absent
Left ❑ present - ❑ absent

38* A.B.R. threshold V wave: ❑ absent
❑ right threshold: (*specify*_____)
❑ left threshold: (*specify*_____)

39 Test of speech perception abilities (* adults, ** children)
** Perceptive Category of Moog & Geers_____
** Questionnaire score at MAIS _____
* % of recognition of bisyllabic words in open-set in auditory mode (also obligatory in children with sufficient lexicon for test performance) _____

40 Assessment of language development (obligatory only for patients in paediatric age)
** Questionnaire score MUSS _____
Phonetic Inventory _____
Lexical level (specify score and test used) comprehension_____ production_____
Morphosyntactic level (specify score and test used) comprehension_____ production _____

41* Diagnostic Imaging
CT of Petrous bones:
❑ YES (❑ normal ❑ alterations_____) ❑ NO
MR of the inner ear:
❑ YES (❑ normal ❑ alterations _____) ❑ NO
MR of the acoustic nerve and internal auditory canal:
❑ YES (❑ normal ❑ alterations_____) ❑ NO
MR of the brain:
❑ YES (❑ normal ❑ alterations_____) ❑ NO

Part 3 – Surgical Data

42* Surgeon **43* Date of surgery** ___ / ___ / _____
day month year

44* Side
❑ RIGHT
❑ LEFT
❑ BILATERAL (❑ simultaneous - ❑ sequential: time between 2 CI:_____

45* Duration of intervention (cutis-cutis) 1° int. |__|__| |__|__| hr min 2° int. |__|__| |__|__| hr min

46* CI brand

Right
❑ ABC – Advanced Bionics Corporation (model _____)
❑ Cochlear (model _____)
❑ Med-el (model _____)
❑ Neurelec (model _____)

Left
❑ ABC – Advanced Bionics Corporation (model _____)
❑ Cochlear (model _____)
❑ Med-el (model_____)
❑ Neurelec (model_____)

47* N° of series implant

Right _____ **Left**_____

48* Type of intervention

❑ Implant
❑ Revision
❑ Explantation (❑ RIGHT (Brand-Model_____) ❑ LEFT (Brand-Model _____)
❑ Replanting (❑ RIGHT (Brand-Model_____) ❑ LEFT (Brand-Model_____)
❑ 1. Explantation - 2. Replanting (simultaneous):
1. (❑ Right (Brand-Model _____) ❑ Left (Brand-Model _____)
2. (❑ Right (Brand-Model _____) ❑ Left (Brand-Model _____)
Ministry documentation sent on _____

49* Reason for Explantation

Medical:
❑ extrusion – infection
❑ extrusion – necrosis edge
❑ other (*specify*_____)
Techniques:
❑ Rupture
❑ Soft failure (*6,7*)
❑ technology advancements
❑ no use of implant (*specify*_____)
❑ other (*specify* _____)

50* Antibiotic prophylaxis
❑ YES
❑ NO

Surgical Technique

51* Cutaneous incision ❑ Enlarged retroauricular (inverted L) ❑ Minimum retroauricular
❑ Other (*specify* _____)

52* Particular cases:
❑ Chronic otitis media
❑ Inner ear malformation (*specify* _____)
❑ Cochlear ossification (*specify*_____)
❑ Other (*specify* _____)

53* Electrode insertion ❑ Round window ❑ Anterior Cochleostomy ❑ Perifenestral Cochleostomy
❑ Other (*specify* _____)
❑ Perimodiolar insertion technique
❑ Non-perimodiolar insertion technique

54* Cochleostomy Size _____

55* Cochleostomy closure_____

56* N° of electrodes inserted ❑ all ❑ number (*specify*_____)

57* Receptor-stimulator fixing ❑ Fissure with non-reabsorbable suture passed through osseous tunnel
❑ Seat and anterior osseous tunnel
❑ No fissure
❑ Other (*specify* _____)

58* Intraoperational measures
Neural telemetry
❑ not performed
❑ performed (❑ normal[#] ❑ pathological)
Telemetry Impedance
❑ not performed
❑ performed (❑ normal[#] ❑ pathological)
([#] normal if at least 3 electrodes are present for which action potentials are identified)

Complications

59* Intraoperative *(multiple answers possible)*
❏ *none* ❏ liquorrea ❏ gusher ❏ haemorrhage ❏ anaesthesia
❏ Difficult Insertion of electrode ❏ Other (*specify*_____)

60* Postoperative *(multiple answers possible; specify onset time after intervention and duration)*
❏ *none*
❏ haemorrhage _____ Time _____
❏ haematoma _____ Time _____
❏ liquorrea _____ Time _____
❏ infection of the flap _____ Time _____
❏ necrosis of the temporal flap_____ Time _____
❏ meningitis_____Time _____
❏ electric stimulation of facial nerve_____Time _____
❏ post-traumatic facial paralysis_____Time _____
❏ extrusion-infection_____Time _____
❏ vertigo _____Time _____
❏ disgeusia_____ Time _____
❏ xerostomy_____ Time _____
❏ tinnitus_____ Time _____
❏ electrode extrusion (specify number) _____ Time _____
❏ traumatic failure device_____ Time _____
❏ spontaneous failure device_____Time _____
❏ rupture - soft failure of inside part of the implant_____ Time _____
❏ other (*specify* _____)_____ Time_____

Part 4 – Activation and Fitting Data

61* Post-implantation X ray
❏ correct position ❏ lateral wall ❏ medial wall
❏ erroneous position (*specify*_____)

62* Activation Data _____

63* Brand/ Processor Model

Right
❏ ABC – Advanced Bionics Corporation (model_____)
❏ Cochlear (model _____)
❏ Med-el (model _____)
❏ Neurelec (model _____)

Left
❏ ABC – Advanced Bionics Corporation (model_____)
❏ Cochlear (model_____)
❏ Med-el (model_____)
❏ Neurelec (model_____)

64* Series processor n°
Right_____ **Left**_____

65* Coding strategy
SPeak (❑ RIGHT - ❑ LEFT) **CIS** (❑ RIGHT - ❑ LEFT) **ACE** (❑ RIGHT - ❑ LEFT)
CIS-RE (❑ RIGHT - ❑ LEFT) **ACE-RE** (❑ RIGHT - ❑ LEFT) **FFT** (❑ RIGHT - ❑ LEFT)
SAS (❑ RIGHT - ❑ LEFT) **Other** (❑ RIGHT - ❑ LEFT) *specify* _____

66* Use of acoustic hearing aid – Bimodal stimulation ❑ YES ❑ NO
If YES, specify type and brand of prosthesis _____
If NO, specify reason _____

67* Neural Response ❑ YES ❑ NO

68* Electrode impedance
❑ Active
❑ Presence of non-functioning electrodes (*specify* _____)

69 Audiometric Test in free field with CI

dB HL	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
R CI					
L CI					
R+L CI					

70* Pure tone audiometry of the implanted ear (obligatory only for collaborating adults and children aged > 6 yrs)

dB	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
R					
L					

71 Other (*specify* _____)

1st MONTH POST–ACTIVATION

72* Use of acoustic hearing aid– Bimodal stimulation ❑ YES ❑ NO
If YES, specify type and prosthesis brand _____
If NO, specify reason _____

73* Neural Response ❑ YES ❑ NO

74* Coding strategies

SPeak (❑ RIGHT - ❑ LEFT) **CIS** (❑ RIGHT - ❑ LEFT) **ACE** (❑ RIGHT - ❑ LEFT)
CIS-RE (❑ RIGHT - ❑ LEFT) **ACE-RE** (❑ RIGHT - ❑ LEFT) **FFT** (❑ RIGHT - ❑ LEFT)
SAS (❑ RIGHT - ❑ LEFT)
Other (❑ RIGHT - ❑ LEFT) *specify*_____

75* Electrode impedence
❑ Ok
❑ Presence of non-functioning electrodes (*specify*_____)

76* Audiometric test in free field with CI

dB HL	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
RIGHT CI					
LEFT CI					
(R+L) CI					

77* Pure tone audiometry of implanted ear (obligatory only for collaborating adults and children aged > 6 yrs)

dB	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
R					
L					

78* Test of speech perception abilities (*adults, **children)
** Perceptive categories of Moog & Geers _____
** Questionnaire score at MAIS_____
* % of recognition of disyllabic words in open-set IN auditory mode
(obligatory also in children with sufficient lexicon for test performance)_____

6TH MONTH POST–ACTIVATION

79* Use of hearing aid– Bimodal Stimulation ❑ YES ❑ NO
If YES, specify type and brand of prosthesis _____
If NO, specify why _____

80* Neural Response ❑ YES ❑ NO

81* Coding strategies

SPeak (❑ R - ❑ L) **CIS** (❑ R - ❑ L) **ACE** (❑ R - ❑L) **CIS-RE** (❑ R - ❑ L)
ACE-RE (❑ R - ❑ L) **FFT** (❑ R - ❑ L) **SAS** (❑ R - ❑ L)
Other (❑ R - ❑ L) *specify*_____

82* Electrode Impedance
❑ Ok
❑ Presence of non-working electrodes (*specify*_____)

83* Free field audiometry with CI

dB HL	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
R CI					
L CI					
(R+L) CI					

84* Pure tone audiometry of the implanted ear (only obligatory for collaborating adults and children > 6 yrs)

dB	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
R					
L					

85* Test of speech perception abilities (*adults, **children)
** Perceptive category of Moog & Geers_____
** Questionnaire score. MAIS_____
* % of recognition of disyllabic words in open-set in hearing modality
(obligatory also for children with sufficient lexicon for performance of the test)_____

86 Other (*specify*_____)

87 Assessment of language development (obligatory only for paediatric patients)
**Questionnaire score at MUSS_____
Phonetic inventory _____
Lexical level (specify score and test used) comprehension_____ production_____
Morphosyntactic level (specify score and test used) comprehension_____ production_____

Check-up 1 year (as control at 6 months post-activation)

Annual check-up (as control at 6 months post-activation)

Explicatory notes for compilation of retrieval information card (RIC)
***:** the **asterisk** indicates **obligatory** fields to be compiled (others are optional)
****:** obligatory fields only for children
For each question, unless specified, give *only one answer*
1: *card number* – assign a progressive number to the cards;
2: *progressive admission number* – the hospital assigns a progressive number to each card; It must be univocal in the year and allow rapid retrieval of the card;
4: *ward/division* – it refers to the ward/division of the intervention;
17-18: *civil status* end *qualification* – the information must come from the patient and refer to the time at which the card is compiled;
19: *current occupation* – the information is referred to patient's occupation (even if s(he) is temporarily unemployed due to illness);
33-34: F.F. = free field.