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 deritivi 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 implantabili 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 coinvolvere partner 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. The Italian financial law for 2007 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 registries 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. The primary objectives 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 and to guarantee access of this technique to all citizens in clinical and organizational 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 registry 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 cleaning 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**

| Field | Description |
|-------|-------------|
| 1* Progressive card n° |  |
| 2* Clinical card n° |  |
| 3* Hospital |  |
| 4* Ward/Division |  |
| 5* Surname |  |
| 6* Name |  |
| 7* Sex |  
| 8* Date of birth |  
| 9* Place of birth |  |
| 10 Province of birth |  |
| 11* Municipality of residence |  |
| 12 Province of residence |  |
| 13 Fiscal Code |  |
| 14 Nationality |  |
| 15 Telephone number |  |
| 16 E-mail address |  |
| 17 Civil status |  |
| 18 Educational qualification |  |
| 19 Current occupation |  |
| 20* Admission date |  
| 21* Intervention date |  |
| 22* Discharge date |  
| 22a Transfer date |  |
| 23* Patient sent by: |  |

- Doctor or Family Paediatrician
- Password, Internet
- Neonatology screening
- Specialist ORL-Audiologist
- Other *(specify)*

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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________________________)  
    (specify recessive   domiant   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_______________________)  
    (specify recessive   domiant   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______
A registry for data on cochlear implant recipients

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 1° int. [ ] [ ] [ ] 2° int. [ ] [ ] [ ]
(cutis-cutis) hr min 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 extravasion (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 impedance
☐ 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)

Explanatory 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 unem-
   ployed due to illness);
33-34: F.F. = free field.