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D1.5 – EXPLOITATION & IPR STRATEGY PLAN

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Acronyms

AIMD	Active Implanted Medical Device
ASIC	Application-Specific Integrated Circuit
CA	Consortium Agreement
CT	Clinical Trial
EEAB	External Expert Advisory Board
ES	Electrical Stimulation
FIM	First-In-Man Trial
GA	Grant Agreement
GDPR	General Data Protection Regulation
IP	Intellectual Property
IPG	Implantable Pulse Generator
IPR	Intellectual Property Rights
KER	Key Exploitable Result
PNS	Peripheral Nervous System
ROL	Result Ownership List
WP	Work Package

PUBLISHABLE SUMMARY

The AI-HAND project proposes new paradigms of electrical stimulation (ES) of the peripheral nervous system (PNS) requiring disruptive methods and technologies that will open breakthrough therapeutic perspectives. To date, patients with a complete quadriplegia has no solution to restore hand movements; they will be the first to benefit from AI-HAND new approach. Indeed, multiphasic stimulus waveforms, multiple synchronized currents sources for 3D current shaping over a multi contact neural cuff electrode and complex interleaved stimulation instead of standard rectangular single-source sequenced stimulation, are the strong breakthrough innovations proposed that allows to answer unmet needs in a wide range of medical applications.

Besides, the Active Implanted Medical Device (AIMD) research and industry are highly conservative as both innovation and regulation demand a strong effort and a long-term vision to go a step further. AI-HAND thus proposes to implement the cutting-edge findings in electrophysiology through radically innovative, fully safe and software-free implant technologies that would lead to a generic powerful new generation of AIMD.

The project is funded under the Horizon Europe Framework Programme (Horizon Europe) and started 1st August 2023 for 42 months It gathers six European partners:

- Inria, the coordinator, the French national institute in computer science and new digital technologies,
- NEURINNOV, a French private company developing advanced neurostimulation solutions,
- Rehazenter, the National Centre for Functional Re-education and Rehabilitation in Luxembourg,
- USSAP, the health and social union for support and prevention in Perpignan France,
- UFR, Albert-Ludwigs University in Freiburg in Germany,
- CorTeC GmbH as an affiliated entity, a private company, provide components, interfaces and active systems to enable the communication with the brain or other parts of the nervous system.

The project implies ethical dimensions as it involves multiple clinical and preclinical trials, including preclinical studies in pigs (WP5); two preliminary non-invasive clinical trials to validate some of the proposed approaches with non-implanted technology (WP6); and the final permanent AIMD will be validated via an invasive First in Man trial (FIM) in four persons with complete tetraplegia (WP7).

ABSTRACT

The Plan for Exploitation and Intellectual Property Rights (IPR) outlines how the AI-HAND project results will be protected, utilized and exploited during and after the conclusion of the project. This plan is the result of collaborative efforts in Work Package 1 (WP1) - Coordination & Communication, with contributions from all consortium partners. Led by Inria, WP1 spans the project's entire duration, from Month 1 to Month 42, and includes specific activities such as management, collection, sharing, and storage of project data in compliance with GDPR, coordination of result monitoring, utilization and exploitation and managing the IP of project results, including considerations for open-source licensing.

The present document, Deliverable D1.5, details the exploitation and IPR procedures applicable to all consortium members. It is based on data provided by each partner during project meetings, reporting activities, and contributions to the Data Management Plan (D1.3), the Dissemination and Communication Plan (D1.4), the Consortium Agreement, and the Grant Agreement. The project has a strong emphasis on data protection as it processes the personal and sensitive data of patients involved in multiple clinical trials, including invasive ones. The consortium is committed to applying the strictest confidentiality measures to protect the rights of the involved subjects.

Regarding intellectual property rights, this document summarizes the potential IPR agreements that may arise from the project's results, as detailed in the Consortium Agreement. It also addresses key issues related to IPR management, including ownership, protection of background and foreground knowledge, dissemination, access rights, and confidentiality.

For exploitation aspects, this plan serves as a platform for fostering new connections with industry, and academic stakeholders. It outlines the steps required to translate the project's scientific outputs into tangible results for patients, companies, and industrial players, following their IPR protection. Given the project's early stage, the initial focus is on assessing the interests, needs, and limitations of key stakeholders concerning the future AIMD and other project outcomes. These include the self-adapting multi-contact epineural cuff electrodes developed in WP2, the digital stimulation pattern generator and its core technology, Application-Specific Integrated Circuit (ASIC) developed in WP3, and the hand simulator and clinical interface for online assessment of hand gestures developed in WP6.

This plan will be updated at the end of the project if new elements that were not covered in the present version need to be considered.

1| INTRODUCTION

1.1 Definitions

"**Access Rights**" means licenses and user rights to results or background under the terms and conditions of the AI-HAND Grant Agreement and in the Consortium Agreement.

"**Background**" means all information, deliverables, materials, services and other tangible and intangible work product which are developed or controlled by a partner prior to the project (or created independently from the project) without any reference to or use of the other parties' confidential information, intellectual property rights and/or related documentation and which a partner chooses to deliver or make available for use to the other partner for the purposes hereof. a list of background is described in Attachment 1 of the Consortium Agreement.

"**Confidential Information**" means any technical, commercial and strategic information, in whatever form or mode of communication, which is disclosed between project partners in connection with the project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure[1].

"**Data**" is any scientific or technical data, including the personal data and clinical data, that is owned or stored by a partner prior to the project start or that is generated under the project. AI-HAND collects and generates different types of data, including sensitive ones:

- Research or scientific data related to the four experimental protocols;
- Technical data related to the technological developments and performances;
- Clinical and health data related to or generated during the clinical trials;
- Personal data, which falls within the scope of the GDPR.

"**Dissemination**" means public disclosure of the results by any appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium.

"**Fair and reasonable conditions**" means appropriate conditions, including financial terms conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

"**Joint Owners**" means project partners who are co-owners of results.

"**Object Code**" means software in machine-readable, compiled and/or executable form including, byte code form and in form of machine-readable libraries used for linking procedures and functions to other software.

[1] In the absence of written support, each Party agrees to expressly indicate the confidential nature of the information to the receiving Party and to confirm this confidential nature in writing, as soon as possible and no later than fifteen (15) days after its disclosure.

"**Project partners**" means members of the consortium, namely the partners listed in Grant Agreement number 101099916 (Coordinator, Beneficiaries and Affiliated Entities).

"**Results**" means any tangible or intangible effect of the project, such as data, know-how, softwares or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

"**Software**" means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression, as well as the associated documentation.

"Source Code" means software in human readable form normally used to make modifications to it including, but not limited to, comments and procedural code such as job control language and scripts to control compilation and installation.

1.2 Alignment with the legal framework

The present document has been elaborated on the basis of the information provided by each partner during project meetings, reporting activities and contributions to the project's official documents.

Intellectual property rights (IPR), background and results, access rights and rights of use and exploitation, as well as communication, dissemination and visibility of project results, follow the specific conditions on Article 16 and 17 of the AI-HAND **Grant Agreement**, as well as in the **Consortium Agreement**.

AI-HAND project partners drafted and comply with a **Data Management Plan** (deliverable 1.3, which will be update twice in the course of the project), setting out the rules relating to the collection, management, and processing of data pre-existing to the project, to the data generated within the framework of the project and to the exploitation of such data, including measures to make this data FAIR (findable, accessible, interoperable, reusable as well as the rules relating to the hosting of the project data after the end of the project.

Moreover, some indications concerning the project exploitation plan were already detailed in the **Communication and Dissemination Plan** (deliverable 1.4), whose final version will be delivered at the end of the project (month 42), including exploitation aspects.

2| OWNERSHIP OF RESULTS

The European Commission does not obtain ownership of the results produced under the action. Results are owned by the partner(s) that generate them, and the consortium must indicate the owner(s) of the results (Results Ownership List) in the final periodic report.

The sponsors (USSAP for CT1 and CT2; NEURINNOV for the FIM) are solely and exclusively responsible for the clinical data generated under each clinical trial. In the case of the FIM clinical trial, the responsibilities, data sharing and ownership will be defined in specific agreements called "sole agreement" between the sponsor (NEURINNOV) and the investigators. Data sharing in CT1 and CT2 are also defined in the specific documents submitted to National Competent Authority and Ethics Committee.

2.1 Joint ownership

Joint owners must agree on all protection measures and the division of related costs in advance. Results are jointly owned by two or more partners if they have generated them together and it is not possible to establish each partner's respective contribution or separate them for protection purposes.

Joint owners will establish a Joint Ownership Agreement as needed and before any industrial or commercial exploitation. Under this agreement – unless otherwise agreed in the Joint Ownership Agreement or in the Consortium Agreement – each joint owner has the right to freely use the jointly owned results for non-commercial research and teaching purposes without needing consent from the other joint owner(s). Additionally, each joint owner can exploit these results and grant non-exclusive licenses to third parties, provided that all joint owners receive at least 45 calendar days' notice and fair and reasonable compensation.
As joint results will be co-owned, the Joint Ownership Agreement will cover the allocation of the shares between joint owners – e.g., the choice is between equal share among partners and share proportional to their involvement in the development of the results – the conditions for exploitation and the designated entity who will act on behalf of all co-owners.

In the case of software, the basic software remains the property of the partner that holds the grandfather rights. Any adaptations, no matter who creates them, belong to the original owner as well. Extensions made by an individual partner are solely owned by that partner. Extensions developed by more than one partner are jointly owned by them. Nevertheless, the basic software to which the extensions were added remains the property of its initial owner.

2.2 Transfer of results

Each partner has the option to transfer ownership of their own results, including their share in jointly owned results, as long as this transfer does not violate their obligations under the Grant and Consortium Agreements. Partners must ensure that their responsibilities concerning their results are transferred to the new owner, who must also commit to passing these obligations along in any subsequent transfers. Furthermore, partners must notify other partners with access rights of any such transfer at least 45 days in advance (or less if mutually agreed in writing), unless agreed otherwise for specific third parties, including affiliated entities, or if prohibited by law.
The granting authority reserves the right to object to such a transfer of ownership up to four years after the project ends, following the procedures outlined in the Grant Agreement. Requests for

access rights can be submitted up to one year after the end of the project or after the requesting partner's participation in the project terminates.

3| ACCESS TO DATA AND RESULTS

During the project, AI-HAND partners will collect, exchange, generate and re-use **various types of data**, including sensitive information requiring specific handling before and after collection. Different levels of data access (e.g., read-only, read-write) will be granted to users and authorized personnel and systems by designated staff, in accordance with defined study protocols.

Project partners have identified five **main categories of data**:

- *Research or scientific data* related to the four protocols: non-invasive trials on human beings (CT1 and CT2, WP6), invasive experiments on animals (WP5) and the First In Man (FIM) clinical trial (WP7);
- *Technical data* related to the technological developments and performance;
- *Clinical data* (e.g. hospital records, laboratory notes) generated during the clinical trials, that can be shared with project partners in the form of pseudonymized data and which remains under the sole direction, custody and responsibility of the sponsor (data owner);
- *Health data*, a broader concept encompassing information indicative of a person's health status, such as patient names and hospital admission numbers;
- *Personal data* that, even when pseudonymized, can lead to the (re)identification of specific individuals, and which falls within the scope of the GDPR.

Partners must share necessary **background data** for their project tasks and for making use of their results without charge, unless specified in the Consortium Agreement. Access is provided without administrative fees and on a non-exclusive basis. Access may be conditional to ensure data use aligns with intended purposes and confidentiality requirements. Each partner retains ownership of their background data. In the Consortium Agreement, partners identified necessary background data for the project and any access restrictions. Additional background data may be added with notice and General Assembly approval.

Partners must also grant each other **access to results** essential for their project tasks without charge. Results may be shared on a royalty-free basis, limited to non-commercial and non-competitive uses, with other project partners, EU institutions, and bodies. Specifically, clinical trial sponsors will provide access to clinical data for each protocol (CT1, CT2, FIM) involving tetraplegic participants as outlined in Annex 5 needed for post-processing and statistical analysis. Animal experimentation data in WP5 will be accessible to involved partners and available upon request to others.

Any access rights not covered by the Grant or Consortium Agreements are at the owning Party's discretion and subject to agreed terms between parties.

Please find below a summary of the results which the project is expected to generate, including purpose, storage and accessibility:

3.1 Accessibility of project data

WP	Type of action	Type of data generated	GDPR[2]?	Data collection purpose	Is data FAIR[3]?
WP2	Development of cuff with cable suitable for system integration and animal/human studies	Technical data: 1) Impedance data 2) Readouts from validation steps to assess reliability and stability of cables, connectors and the cuff interface	No	Evaluate safety and performance of electrodes for future improvements	Data available on request by partners in connection with publication output (when not in conflict with potential IP protection and secret knowhow). • As impedance data underlies the commercial interests of CorTeC and NEURINNOV (private companies), it is not open, and access can only be granted on a case-by-case basis through management permission (traceability of access permissions). • Data will be stored on a central UFR server and/or on the CorTec's data storage solution and/or NEURINNOV data storage solution with regular backups, not accessible to project and management staff. • Data interoperability is ensured by adhering to widely accepted standardized formats.
WP3	Data related to the design, development and manufacturing of the Digital Stimulation Pattern Generator	Technical data: Data are composed of a set of in vitro measurements of the ASIC technical performances	No	Evaluate safety and performance of the Digital Stimulation Pattern Generator (ASIC = core technology)	• Data produced and deemed open for sharing and re-use are deposited and made available on request by partners in connection with publication output (when not in conflict with potential IP protection/secret knowhow). • As technical data (ASIC specifications) underlies the commercial interests of NEURINNOV (a private company), it is not open, and access can only be granted on a case-by-case basis through management permission (traceability of access permissions). • Data will be stored on a NEURINNOV data storage solution with regular backups, not accessible to project and management staff.
WP4	Data related to the final design and specification of the Active Implanted Medical Device (AIMD)	Technical data: Same as above	No	Evaluate safety and performance of the final Active Implanted Medical Device (including IPG and external parts)	Same as above
WP5	Invasive animal experiment protocol	Anatomo-physiological data collected from pigs (electrophysiology signals, nervous tissue	No (except for the personal	1) To optimize peripheral nerve stimulation for scientific publications purposes and device	1) Some data (electrophysiology, movement) may be opened (reusable to other researchers); it will be stored saved in a dedicated Inria encrypted server accessible to a restricted list of identified people; The others

[2] General Data Protection Regulation (GDPR): Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016
[3] Data which meet principles of findability, accessibility, interoperability, and reusability (FAIR)

		samples and histology tests, videos and pictures)	data of the team involved)	performances enhancement; 2) To validate the performance and long-term biocompatibility of the implant	(technical data from the implant) will be stored on a secure server at NEURINNOV and will be available only on request. 2) No external accessibility: trade secret. • Data will be available for involved partners in the protocols and on demand for other parties. • Data interoperability is ensured by adhering to widely accepted standardized formats.
WP6	Human clinical trial protocol CT1	• Motion data: technical data (kinematics, EMG, IMU, etc.); • Videos and pictures, voice recordings; • Questionnaires	Yes (informed consent)	1) Assessing performances in using new sensors to control target on the screen. 2) Assessing performances of the patient's interfaces before their future use in the FIM.	• Partial protocol is open and published on public clinical trial registers. • Some pseudonymized human data (movement kinematics and dynamics data) can be shared with project partners upon request. It will be stored in a dedicated Inria encrypted server accessible to a restricted list of identified people only. Some other pseudonymized data (raw EMG and IMU, voice recordings, questionnaires and videos) will be stored on a secured server hired by NEURINNOV for assessing patient's interfaces. These data won't be shared except for scientific publication needs. Data related to TARGETTRACK software will be stored by Inria. • Clinical data are digitized, anonymized and securely stored on the server of the trial sponsor and authorized investigators, on-premises and accessible to specific persons only. Each patient is associated with a unique identifier, ensuring traceability without compromising individual identities. A correspondence table is accessible solely by one researcher through a password-protected mechanism. Only anonymized data is transmitted during project-related data transfers, ensuring the confidentiality of sensitive information. • Data interoperability is ensured by adhering to widely accepted standardized formats.
WP6	Human clinical trial protocol CT2	• Motion data: technical data (kinematics, EMG, IMU, etc.); • Clinical data (personal data from patients and medical staff); • Videos and pictures	Yes (informed consent)	Identification of parameters for the musculo-skeletal development	• Partial protocol is open and published on public clinical trial registers. • Some pseudonymized human data (movement kinematics and dynamics data) can be shared with project partners upon request. It will be stored in a dedicated Inria encrypted server accessible to a restricted list of identified people only. • Clinical data are digitized, anonymized and securely stored on the server of the trial sponsor and authorized investigators, on-premises and accessible to specific persons only. Each patient is associated with a unique identifier, ensuring traceability without compromising individual identities. A correspondence table is accessible solely by a restricted list of identified people through a password-protected mechanism. Only

					anonymized data is transmitted during project-related data transfers, ensuring the confidentiality of sensitive information. • Data interoperability is ensured by adhering to widely accepted standardized formats.
WP7	First in Man protocol	Investigation human data: • Technical data (implantation report, impedance, technical log, stimulation configuration, etc.); • Clinical data (questionnaires from patients, personal data from patients, helpers and medical staff); • Videos and pictures • Raw data from EMG IMU and VOICE interfaces	Yes (informed consent)	1) Evaluate the safety, the performance and the clinical benefit of the entire medical device following Article 62 of the MDR 2017/745; 2) Validation of novel approaches of neural selective stimulation, hand gesture estimation, modelling and grasping force estimation.	• Restricted accessibility: data needed for publications, CE marking conformity check will be shared among partners. No other clinical trial utilizes the same approach, devices and indications. • Partial protocol is open and published on public clinical trial registers. • Some anonymized human data (movement kinematics and dynamics data) can be shared with project partners upon request. It will be stored in a dedicated NEURINNOV HDS server accessible to a restricted list of identified people. • The rest of non-clinical data are stored on a protected data storage solution (NEURINNOV secured server). • Clinical data are digitized, anonymized and securely stored on the trial sponsor's storage solution, on-premises and accessible to a restricted list of identified people only. Each patient is associated with a unique identifier, ensuring traceability without compromising individual identities. A correspondence table is accessible solely by one researcher through a password-protected mechanism. Only anonymized data is transmitted during project-related data transfers, ensuring the confidentiality of sensitive information.

3.2 Data confidentiality

All AI-HAND partners involved in data generation and collection are responsible for securely recovering, storing, and transferring both personal and non-personal data. The consortium operates with different levels of data confidentiality:

- "Confidential to partner" applies when data collected by a specific partner includes personal information that cannot be protected once disclosed;
- "Confidential to consortium members" is used for data containing confidential information or with limited use and long-term value;
- "Open" (public) accessibility is for unrestricted data.

In general, long-term preservation, maintenance, backup and versioning and archival of all data in AI-HAND is handled by the data owners during the project and up to 5 years after its end. Access to legal and operational project documents is facilitated through the Alfresco/Share tool hosted by Inria, ensuring high security and flexible access for external partners. The AI-HAND site serves as a repository for all public project information.

Partners undertake to maintain confidentiality of project results, especially regarding long-term data utility and limitations due to personal data protection. They commit to secure data handling practices, including encryption and anonymization where applicable, and not to use it for any purpose other than the purposes described in the Grant and Consortium Agreements, and only with written prior consent. Clinical data involving sensitive patient information will not be publicly deposited but securely stored locally by clinical partners, and open access to all data won't be allowed due to potential identification and to avoid compromising commercialisation prospects. Partners also pledge to comply with GDPR regulations, ensuring proper data processing and security measures. When these practices are not sufficient, ad-hoc interventions may be required such as the signature of a non-disclosure agreement (NDA). AI-HAND partners are experienced in conducting clinical trials, including invasive procedures, with high security standards and regular backups. In compliance with EU regulations, partners will obtain necessary approvals and documents before commencing experimental trials. Following the completion of the project, all the responsibilities concerning data recovery and secure storage will go to the repository storing the dataset.

If EU classified information is used or generated by the project, strict security protocols apply, including special procedures for handling and disclosure with explicit approval from the granting authority. For more information on these aspects, please refer to deliverable D1.3 "Data Management Plan" and to the Consortium Agreement.

3.3 Open access and data dissemination policy

Partners are committed to disseminating their results as soon as possible in a publicly accessible format, considering any intellectual property protection, security rules, or legitimate interests. In EU-funded projects, open access means providing online access to scientific information that is free for end-users and reusable. Scientific information in research and innovation contexts include:

(i) Peer-reviewed scientific research articles;

(ii) Research data (data underlying publications, curated data, and/or raw data).

Data accessibility options:

- "Open Access" provides free access and usage rights, highly recommended by Horizon Europe funding and EU Grants guidelines;
- "Embargoed Access" delays open access until data underlying publications is released to preserve authorship. In this case, information about data will be published and details of when the data will become available will be included in the metadata;
- "Restricted Access" monitors and approves access as per specified conditions;
- "Closed Access" restricts access to private, non-confidential data.

Collected public data will be openly available once ready for dissemination. Research datasets, including patient data, will be used by project partners. These datasets are essential for validating research results and are recognized by the scientific community as primary sources for scientific research.

The consortium aims to provide open access to project data as much as possible, while respecting intellectual property protection and confidentiality requirements. Each time a French academic author is involved in a publication, AI-HAND ensures long-term open access to peer-reviewed articles, conference papers, and research data via the HAL platform, a French public open science initiative. This makes publications easy to find internationally and interconnected with services like ORCID and preprint servers. Open-source codes are also made available via HAL to ensure reproducibility, if there are no valorisation issues. Or, at a minimum, with a copyleft license choice: AGPL (or GPL).

Some of the project data will be made available in open access on platforms like Research Data Gouv. Partners will choose journals [4] or conferences that allow immediate public access on institutional repositories or have a short embargo period. They will ensure open access to peer-reviewed scientific publications by:

- Depositing a machine-readable electronic copy of the published version or final peer-reviewed manuscript in a trusted repository at the time of publication;
- Providing immediate open access via the repository under the latest Creative Commons Attribution International Public License (CC BY) or a license with equivalent rights; for monographs and other long-text formats, licenses may exclude commercial uses and derivative works (e.g., CC BY-NC, CC BY-ND);
- Providing information via the repository about any research output or tools needed to validate the conclusions of the publication.

The AI-HAND academic partners of the consortium support exploring and using open-source opportunities for some technological developments, and some software results might be released under an open-source license.

[4] Preliminary list of journals of interest: *Nature Biomedical Engineering, Science Translational Medicine, J. of Neural Engineering; IEEE TNSRE, IEEE TBME, Archives of Physical Medicine & Rehabilitation; Neurorehabilitation & Neural Repair, and J. of Neurotrauma.*

For more details, refer to Annex 5 of the Grant Agreement, to the AI-HAND Dissemination and Communication Plan (D1.4) to the Data Management Plan (D1.3), which will be updated for up to four years after the end of the project.

4| PROTECTION OF RESULTS

Managing **intellectual property rights (IPR)** is crucial to ensure that the project results are accessible to those interested in utilizing the methodologies and technologies developed. Consortium partners contribute with their resources and intellectual property solely for the project's implementation. Thorough identification and discussion of IPR issues among partners enable safe knowledge disclosure, proof of ownership of results, potential for commercial exploitation, and deterrence of unauthorized use.

Partners are obligated to adequately protect project results for an appropriate duration and territorial coverage where feasible and justified. This includes assessing **each result's potential for IP protection** before publication. Results with IP potential will undergo patent, license, or copyright applications to facilitate commercialization and ensure post-project exploitation. Results not suitable for IP protection will be openly published in peer-reviewed journals.

IPR management is governed by the **Consortium Agreement**, currently being signed by all partners, which specifies the allocation of IPR associated with project results and data. It delineates partner rights to use and exploit these results, along with rules for publication and dissemination. The Consortium Agreement establishes a shared policy on intellectual property to protect both individual and collective interests of the partners.

Each partner defines their specific **background** contribution to the project, which remains their own but is shared with others for project implementation purposes. **Foreground** ownership will belong to partners primarily responsible for its development. Regarding publications arising from the project, partners or authors will do their best to make their work freely accessible to the public, as required by open access policies, while safeguarding their own commercial and academic interests.

4.1 Types of IPR protection

Licensing entails the holder of intellectual property (licensor) granting permission to another partner (licensee) under specified conditions outlined in a license agreement. To facilitate reuse, each dataset deposited by AI-HAND will be accompanied by a specific license, such as those provided by Creative Commons (CC) licenses. This allows for broad reuse while ensuring compliance with project obligations. Some datasets might be close-access, following the principle “open as possible, closed as necessary”.

Exclusive licenses may be granted only if all relevant partners waive their access rights or if approved by the granting authority, taking into account any specific domains of exclusivity. Access rights in AI-HAND do not include **sublicensing** unless otherwise agreed upon in writing by the granting partner.

Patents protect inventions from unauthorized use for a limited period, granting exclusive exploitation rights within a defined technical scope, duration, and geographic area. This prevents exploitation even if independently developed by others. While previous elements in AI-HAND were patented, only a few new patents are expected from the project. Any additional patents, if any, are likely to emerge from work in Work Package 6.

Design, drawing and model protection: NEURINNOV will be filed "design, drawing and model" protection (EUIPO) for a research electrode design used in animal experiments, excluding the manufacturing process (ownership of CorTec), agreed with CorTec.

Copyright safeguards the expression of ideas but not mere facts or data. Software, including components in the final AIMD, is protected under copyright. The Consortium Agreement outlines access rights to software components necessary for exploiting results, covering object code, APIs, and source code.

These measures ensure that intellectual property within the AI-HAND project is managed effectively to foster collaboration while protecting innovation and commercial potential.

4.2 AI-HAND possible avenues for IPR protection

Type of result	Example in AI-HAND	Patent	License	Design & drawing (model)	Copyright	Trademark	Confidential information
Invention	Final AIMD	x					x
Software	Software for computer-vision based automatic grasp selection	x	x		x	x	x
Scientific article	Open access, peer reviewed papers				x		
Design of a product	Design of research electrode		x	x			x

Name of a product/service	Name of final AIMD		x		x	x	
Know-how	Detailed surgical procedure		x				
Website	AI-HAND official website					x	

5| EXPLOITATION OF RESULTS

The technological innovations in this project represent a substantial investment with **transformative potential**. They include advanced technologies leading to a highly personalized AIMD, a software-free implant approach built on novel concepts, and the Digital Stimulation Pattern Generator (DSPG). These advancements are pivotal in achieving the project's ambitious goals, particularly in developing a ground-breaking solution to restore essential hand functions for individuals with hand paralysis, for whom there is no solution to date.

By focusing on creating an efficient and intuitive system capable of restoring key functions for day-to-day lives, such as grasping various object types and sizes, the project addresses **critical unmet needs** for individuals with complete quadriplegia. The envisaged solution involves a **permanently implanted and CE-marked AIMD**, poised not only to improve patients' quality of life and social integration but also to reduce the need for extensive healthcare support and enhance overall health outcomes.

Moreover, these innovations are strategically positioned to lead Europe in advanced neurorehabilitation technologies with fully implanted solutions. Beyond their immediate impact, they promise significant long-term **benefits for the European economy and society**. The project aims to establish a renewed European healthcare and medical device industry that can compete globally, contributing to Europe's strategic autonomy in healthcare.

Furthermore, the project prioritizes **business sustainability** by planning for a long product lifecycle and preparing for commercialization. Project partners are dedicated to bringing these innovations to market, utilizing IPR opportunities to maximize their impact across wider clinical applications. For up to four years after the project's completion, partners will actively seek to exploit their results directly or indirectly through transfer or licensing agreements. They will self-fund additional development areas not fully detailed in the AI-HAND proposal. The exploitation of these innovations for broader clinical use will hinge on the licensing potential of the intellectual property, supported by CE marking of the AIMD technology. Negotiations are underway among partners to establish bilateral agreements ensuring long-term business commitments.

In summary, these technological innovations not only promise to revolutionize neurorehabilitation but also hold immense potential to deliver substantial socioeconomic benefits, ensuring that public investments yield tangible advancements for society as a whole.

5.1 Key Exploitable Results (KER)

During the project, partners will assess key assets to determine whether they should be openly accessible or restricted. This evaluation will guide the monitoring of exploitation activities, facilitated through the creation of a **Result Ownership List** (ROL), securely stored on Alfresco/Share, which will be finalized and included in the last periodic report. The strategy aims to maximize the scientific outcomes of the project by identifying exploitable results and ensuring their intellectual property protection. This approach also enhances their transferability to stakeholders interested in commercialization. Access rights to results will be granted under fair and reasonable conditions.

5.2 Potential ownership, exploitation and protection of Key Exploitable Results (KER)

Questions with * need to be filled in only for KER. Questions with ** need to be filled in only for KER + if 'Result type' is: PROD, SERV, PROC, BUS, DSG, or METH.
For some of the information we still need to decide between the option. We indicated TBD = To Be Decided or NA = Not Applicable.

Work Package	**Result name**	**Result type**	**Key exploitable results (KER)** *(do results have a high potential ?)*	**Description of high potential*** *(max. 200 characters)*	**Who owns the result?**	**Will the owners exploit the result?**	**Who will use the results?** Audience or target group *(multiple choice)* *	**Steps undertaken towards exploitation**** *(multiple choice)*	**Market maturity**** *(state of the market targeted by this result)*	**Any constraint?**	**In which form will the result be made available to other consortium members and/or third parties?**	**Does the exploitation of the results require access to background of one or several consortium members?**	**Does the exploitation of the results require access to third party IPR?**	**Is the result already protected?**	**For software: is the source code planned to be open or close?**
WP2	Manufacturing of the research electrodes (final version will be included in the final AIMD)	PROD	High technologic, business or economic potential	Cuff Electrodes are more and more widely used in implantables for treating disorders of the periheral nervous system	Manufacturing Processes: 100%	yes	Consortium Members	Prototyping in production environment Pilot, demonstration or testing Intellectual property management Complying with regulatory framework	Emerging: growing demand, scarce supply	none	Secret/non-disclosure agreement: Share of development documentation	CorTec background IP used (patents on electrode manufacturing and contact design)	no	There is CorTec filed process IP and also design IP	N/A
WP3	Digital Stimulation Pattern Generator (ASIC = core technology)	TBD	TBD	TBD	100% NEURINNOV	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD
WP4	Final design and specification of the Active Implanted Medical Device	TBD	TBD	TBD	100% NEURINNOV	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD

	(including IPG and external parts)														
WP5	Design of the research electrodes for animal experiments (which will not be included in the final AIMD)	DSG	High scientific potential	Potential improvement of stimulation selectivity compared to neural electrodes currently on the market	100% NEURINNOV	Yes	*Consortium members Inria will publish the results Neurinnov might be interested in commercializing a product using this design	Pilot, demonstration or testing Pilot design and experimental tests	Not yet existing and not clear if market can be created	Patent or design registration to a patent office	No disclosure agreement	Yes - design proposed by Neurinnov and manufactured by Cortec	TBD	No	TBD
WP5	Evoked EMG processing routines	METH	High scientific potential	Automatic processing of electrophysiological responses	50% Inria 50% NEURINNOV	TBD	Inria NEUROINNOV	NA	NA	NA	TBD	Yes, Inria and NEURINNOV	No	No	CLOSE
WP6	Hand simulator	SCI	High scientific potential	Realistic Simulations	100% Inria	TBD	Inria	NA	NA	NA	Software will be filed for licensing	Yes, Inria	TBD	No	CLOSE
WP6	Hand Force Estimation solution	SCI	High scientific potential	Feedback information for patients	100% Inria	TBD	Inria	NA	NA	NA	TBD	No	No	No	CLOSE
WP6	Clinical interface for online assessment of hand gestures	Software	NA	TBD	100% Inria	TBD	Inria	NA	NA	NA	TBD	No	No	No	CLOSE
WP6	TargetTrack software for force modulation	Software	NA	TBD	100% Inria	TBD	Inria	NA	NA	NA	TBD	No	No	No	CLOSE
WP7	Neurisoft: Medical device software for the implant configuration during the implantation	TBD	TBD	TBD	100% NEURINNOV	TBD	TBD	TBD	TBD	TBD	Software will be filed for licensing	TBD	TBD	No	No access is given to Source code.

WP7	Neurisence: Medical device software for patient training after the implantation	TBD	TBD	TBD	100% NEURINNOV	TBD	TBD	TBD	TBD	TBD	Software will be filed for licensing	TBD	TBD	No	No access is given to Source code.
WP7	Script Neurinnov: management and transformation of raw data	TBD	TBD	TBD	100% NEURINNOV	TBD	TBD	TBD	TBD	TBD	Software will be filed for licensing	TBD	TBD	No	No access is given to Source code.

5.3 Dissemination and exploitation actions

During the project, AI-HAND partners identified relevant and potential users of project results to facilitate their adoption and future use. They engaged to raise awareness from the project's outset and throughout its duration, so that the results and benefits may reach the following **target stakeholders**:

1. Biomedical engineering and research community: the primary audience for dissemination (e.g., IEEE EMBS, IFESS, REHABWEEK, INS);
2. Patient organizations: the consortium will maintain two-way communication with these organizations, keeping them informed of project progress and inviting them to the final AI-HAND workshop;
3. Associations of medical doctors: Professional associations of orthopaedic and neurosurgeons (ex. SOFMER in France) will join the final workshop to discuss their expectations and concerns regarding AIMD;
4. European and national policy-makers: the consortium plans to engage with influential institutions involved in healthcare, industry, and innovation policy, such as Maison Irène et Frédéric Joliot-Curie in Brussels, and establish connections with European and national policymakers. Medica professional conference

External **communication and dissemination** activities are strategically executed to effectively engage the scientific community, stakeholders, and the general public. These efforts are guided by a precise communication strategy and utilize dedicated channels while coordinating contributions from the partners' communication services. This dissemination does not override obligations to protect results, maintain confidentiality and security, or comply with GDPR, as detailed in the Grant Agreement.

The consortium will leverage **synergies with similar projects** and participate in large EIC-led conferences, such as the EIC Summit, to engage with other research and economic interest groups. This engagement will be part of the project's strategy to maximize impact.

An independent scientific board, including at least one medical doctor and one researcher chosen for their expertise and collaboration with project partners, will oversee the FIM clinical trial. This board will also function as the **External Expert Advisory Board (EEAB)**, appointed by the General Assembly to assist and facilitate decision-making. This Board might include industry representatives and will actively promote the exploitation of project results. The Coordinator will ensure that non-disclosure agreements are executed between all parties and each EEAB member to protect confidential information.

At the end of the project, the final **workshop** will gather European Key Opinion Leaders in the medical sector will, patients, researchers and policy makers to share the projects outputs and scientific progress about neuroprosthesis for people with high impairments, and foster future collaborations building on the results of AI-HAND.

Before project completion, partners will define future commercial agreements to ensure the project's sustainability and socio-economic impact. They will maintain contact with potential industry partners, explore spin-off opportunities, and use EIC services and platforms to exchange information on AI-HAND results.

The development of the final AIMD will yield crucial scientific data that will significantly **support national and EU policy-making** by:

1. Deepening the understanding of the research community's needs, thereby refining strategic research planning, funding, and support;
2. Improving the lives of paralyzed patients by providing innovative solutions that enhance their quality of life, autonomy, and socio-economic integration.

5.4 Commercialization

In the short term, the project focuses on developing a neuroprosthesis for hand movement recovery in patients with complete quadriplegia. The **long-term goal** is to offer therapeutic solutions with the same kind of motor impairments but with larger indications, for micturition, stimulation, and eventually contribute to Brain-Computer Interface (BCI) development or in addition to BCI to allow an individual experiencing functional deficiencies to regain control over certain organs or functions.

The work performed on the final AIMD will be the basis for future **commercialization** in the European Union. NEURINNOV envisions to commercialize the project with CorTec as electrode's provider, leading to a clear path towards CE marking and future commercialization, firstly in Europe. Large medical device companies and start-ups may be later interested and benefit from the project's technology through licensing or external growth for which NEURINNOV and CorTec will be key players. Due to confidentiality, this public deliverable does not convey the full business vision for AI-HAND exploitation, which can be disclosed to the European Commission upon request. Detailed information about the AIMD embedded software and hardware cannot be disclosed for confidentiality and safety reasons; however, essential scientific features are disclosed.

Project partners negotiate **commercial agreements**, including licensing, for further exploitation during the project's execution as at least liabilities and compliance to the MDR 2017/745 European regulation is needed for the FIM clinical trial. Access rights to the results for internal research and educational purposes will be granted on a royalty-free basis, subject to non-disclosure of industrial or intellectual secrets. Developments from academic partners included in a commercial product will require a license agreement between the developing and receiving partners, finalised when the commercialisation phase begins.

As NEURINNOV, and as electrode's provider, CorTec, aim at commercializing the AI-HAND developed solution, the path to the market is clearly set and the success of the valorisation much safer. In the case of a successful AI-HAND project, in particular the FIM clinical trial, NEURINNOV envisions to go through a pivotal study clearing the path for **CE marking**.

To optimize project valorisation, consortium members will actively engage with their respective **Technology Transfer Offices**, who assist in the exploitation strategy, bridge the gap between research innovation and marketable products, manage IPR, and work with economic stakeholders to commercialize new ideas.

6| OUTCOMES' GOVERNANCE AND PLANNING FRAMEWORK

6.1 Governance structure

The organisational structure of the consortium comprises the following bodies, who are responsible for the effective management, protection and valorisation of project's results at different levels:

- The General Assembly, the ultimate decision-making body of the AI-HAND consortium, will be consulted for any contractual decision, as well as the patenting, licensing, and publishing processes;
- WP leaders meet every 2 months to report to the consortium on the progress and work performed. These meetings ensure smooth collaboration and consistent information sharing within the consortium. These meetings will also cover events and publications related to AI-HAND and provide updates to partners involved in other work packages;
- The Coordination Team (including the Project Coordinator, WP Leaders' main contacts and the Project Manager), will oversee the project's execution, including day-to-day assessment of results and potential minor adjustments to future work;
- The Project Coordinator is the legal entity responsible for the project's data management from both scientific and technical perspectives, will handle patent, license, and copyright filings. Additionally, the Coordinator acts as the intermediary between partners and the Granting Authority, performing tasks as described in the Grant Agreement and Consortium Agreement;
- Each partner must adhere to the policies set out in the Data Management Plan, registering datasets and metadata collected during their assigned tasks, and backing up data for sharing through open access repositories. Quality control of these data is the responsibility of the relevant Work Package leader, supported by the Project Coordinator.

Project partners are committed to **collaboratively reporting and evaluating new results** generated during the project in the ROL, in collaboration with their Technology Transfer Offices. They will determine whether these results should be openly accessible or restricted and will assess the need for exploitation and intellectual property protection.

The Consortium Agreement, signed by each partner, serves as the legal framework for managing results and IPR, and to amicably resolving potential disputes. It also outlines the internal **approval process for disseminating results**. Partners must provide at least 30 days' notice before any planned publication, allowing time for objections. This provision applies during the project and for one year after its conclusion. Partners cannot include another beneficiary's results or background

in any dissemination activity without prior written approval, unless the information is already published.

The governance of knowledge and IPR within AI-HAND is supported by several **working tools** designed to help partners collect insights and achieve organisational objectives by making the best use of knowledge generated by the project:

- IPR Registry: this internal tool on Alfresco/Share keeps all partners updated with IPR-related project developments;
- European IPR Helpdesk: partners can access free first-line support on IPR matters;
- External IPR Advisory Firm: an external firm may be contracted for ad-hoc legal arrangements needed for accessing, re-using, and/or commercializing project results.

6.2 Expected roadmap

In alignment with the Grant Agreement, the initial months of the AI-HAND project have highlighted several partner needs:

- Clarify asset ownership and avoid hindrances to their exploitation;
- Ensuring robust IPR protection for assets;
- Managing IPR policies to make results fully operational after the project ends.

To translate such priorities into actions for the months to come, prominent exploitation and IPR management steps - defined in accordance with procedures and roles already illustrated before are:

- Inventory of project assets: establishing the ROL and cataloguing there all assets developed during the project; it is also important to take into account the inventory of the background included in the Consortium Agreement and evaluate the dependency between this background and the project results;
- Exploitation strategy consolidation: reaching a consensus on the exploitation strategy at the consortium level;
- Identification of ownership rights: determining ownership on project assets through the IP Registry;
- Examination of potential IPR protection and open-access measures;
- Drafting of IPR agreements and governance models in line with the exploitation strategy;
- Execution of exploitation actions: implementing exploitation actions according to the present exploitation strategy and the key milestones of the project.

These steps ensure that project assets are effectively protected, managed, and exploited, both during and after the grant period.

7| CONCLUDING REMARKS AND NEXT STEPS

AI-HAND, an ambitious EU-funded project, is dedicated to advancing the field of electrical stimulation (ES) of the peripheral nervous system (PNS) with disruptive methods and technologies

that promise ground-breaking therapeutic outcomes. By employing disruptive methods and technologies poised to revolutionize therapeutic approaches, the project aims to address the critical unmet needs of individuals with complete quadriplegia, by restoring essential hand movements through innovative and complex interleaved stimulation techniques.

The project recognizes the importance of exploitation activities in ensuring the long-term sustainability and widespread impact of its results beyond the consortium. Central to this effort is rigorous knowledge and intellectual property rights (IPR) management, considered fundamental for maximizing the project's societal and economic benefits.

The present deliverable, released in the initial phase of project, outlines the principles, practices, and planned measures for systematic IPR management and exploitation of project results. It details internal procedures aligned with the Grant Agreement and Consortium Agreement, highlighting initial asset types pivotal for upcoming exploitation efforts.

Moving forward, AI-HAND will continue to refine these innovations, navigate regulatory pathways, and foster collaborations to accelerate the adoption of its pioneering technologies. The project remains committed to data protection standards, conducting rigorous clinical and preclinical trials.