CLARA

Center for Artificial Intelligence and Quantum Computing in System Brain Research

Deliverable 6.4

Title: Exploitation strategy

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Confidentiality

Does this report contain confidential information?	Yes ☐ No ☑
Is the report restricted to a specific group?	Yes ☐ No ☑ *If yes, please precise the list of authorised recipients*:

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Executive Summary

CLARA is an interdisciplinary center of excellence driving next-generation AI, machine learning, and quantum-centric supercomputing to advance neurodegenerative research, with a particular focus on Alzheimer's disease. By harnessing large-scale biological and clinical data, CLARA accelerates both technological innovations and real-world solutions for the benefit of society. Through its domain-specific hybrid computing and data infrastructure—backed by emerging EuroHPC Joint Undertaking resources—CLARA plays a pivotal role in strengthening the European computing and data ecosystem for system brain research. CLARA will operate as an autonomous division of the International Neurodegenerative Disorders Research Center (INDRC) in Prague, Czech Republic.

CLARA's exploitation strategy aims to translate cutting-edge research in AI, machine learning, and quantum computing into clinical, commercial, and societal benefits for neurodegenerative disease treatment. By strategically managing knowledge, intellectual property, fostering collaboration between partner`s Technology Transfer Offices and the CLARA IPR & Innovation Officer, and leveraging mechanisms like a dynamic business plan and Grant Lab, the project establishes a clear path from discovery, through (pre)seed activities to market-ready solutions.

The CLARA project is implemented by six key institutions working closely together:

1 International Neurodegenerative Disorders Research Center (INDRC) in Prague, Czechia,
2 Ceske Vysoke Uceni Technicke v Praze (CTU) in Prague, Czechia,
3 Fakultni Nemocnice u sv. Anny v Brne (ICRC) in Brno, Czechia,
4 Institut du Cerveau et de la Moelle Epiniere (PBI) in Paris, France,
5 Bayerische Akademie der Wissenschaften (BAdW-LRZ) in Munich, Germany, and
6 VSB Technical University of Ostrava (VSB-TuO) in Ostrava, Czechia.

The Exploitation Strategy defines how these institutions can work together to generate knowledge, protect intellectual property, creating tangible value for society, taxpayers, patients, researchers, and industry.

1 Introduction

The exploitation strategy for the CLARA project is designed to provide a comprehensive overview of the anticipated results, ownership structures, and pathways for their successful commercialization and implementation. CLARA aims to significantly advance

our understanding and treatment of neurodegenerative diseases by leveraging cutting-edge technologies, including artificial intelligence (AI), machine learning (ML), and quantum supercomputing. The project's key exploitable results revolve around four principal pillars: Excellence, Sustainability, Innovation, and Reputation. This strategy not only supports immediate and future exploitation efforts but also fosters collaboration, innovation, and long-term sustainability, positioning CLARA as a leader in neurodegenerative research.

Main ideas:

- Collaboration
  - **How increase our capabilities?**
- IP protection
  - **How protect our IP rights?**
- Market analyses and deployment
  - **Who is our target group, how to build a product/service?**

2 Exploitation strategy

At this early stage, the primary goal of this initial version is to provide a clear overview of the project's expected results, their respective ownership, and potential exploitation routes. This foundation will support exploitation efforts in the coming years by identifying each result's potential and the possibility of bringing these results to the market.

The CLARA project aims to revolutionize our understanding and treatment of neurodegenerative diseases by harnessing advanced **artificial intelligence** (**AI), machine learning (ML), and quantum supercomputing** to process massive biological and clinical datasets. By focusing on proteins such as **ABeta, APOE, and Tau**, knowledge mapping and simulation, all organized alongside the use case as the proof-of concept of the CLARA approach (Evaluating Calcium Brain Aging and APOE Cascade hypotheses), the project seeks to provide crucial insights for developing more effective diagnostics and therapies and even more importantly, the strategy and tools to maintain the optimal performance of the brain system. Bridging research gaps across Europe and target groups (co-creation activities within the CLARA Collaboratorium) will strengthen the continent's position in omics, quantum computing, and AI, driving innovation and reducing the global economic burden of dementia. Ultimately, the project fosters a more competitive and cohesive European research ecosystem, accelerating breakthroughs in precision medicine, improving patient outcomes, and cultivating a sustainable environment for future scientific discovery.

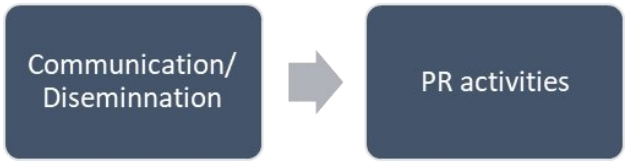
The exploitation strategy centers on CLARA's principal Key Exploitable Results (KERs), encompassing three main pillars: **Excellence, Sustainability, Innovation**.

1. **Excellence**
    - Publishing of articles in leading academic journals
    - Production of scholarly monographs
    - Presentation at high-profile conferences
    - Development of educational and training programs
    - Implementation of proof-of-concept (PoC) use case
2. **Sustainability**
    - Establishment of a Grant Lab Strategy
    - Introduction of a Donor Program
    - Creation of an Industrial Chair Program to secure long-term funding
    - Establishment of the Commercialization & Innovation Office
    - Establishment of pre-seed and seed activities in collaboration with private sector, investors and venture capital
    - Philanthropic activities and reputation management
        - Donor program
        - Positioning CLARA as a Center of Excellence (CoE) with an integrated research agenda focused on neurodegenerative diseases (ND), AI, and high performance computing and quantum computing (HPCQC)
        - Establishing Czechia and Prague as a Central and Eastern European hub for research on ND and emerging technologies
3. **Innovation**
    - Discovery of novel high-affinity inhibitors targeting APOE protein
    - Development of software tools and AI models, including:
        - A knowledge management map
        - Multimodal neurological patient data software
        - Software for predicting protein interactions
        - Harmonized datasets

During the project, we expect to deliver multiple types of results. Based on the type of result, we can classify them to the three main categories that will be used for dissemination, communication, and exploitation activities.

Publication results:

- Peer-reviewed scientific article – Jimp, Jsc, Jost
- Paper in conference proceedings
- Others:
    - Books and chapters

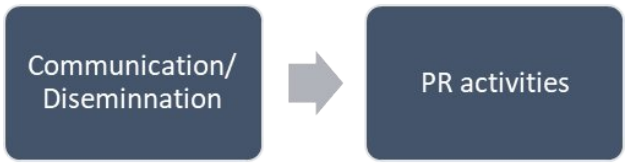


Applicable technological results:

- Patent
- Utility model
- Industrial design
- Software, system and platform components
- Prototype
- Functional sample

Visibility & Processes:

- Organization of a conference
- Organization of a workshop
- Organization of an exhibition
- Results incorporated into legislation and standards
- Methodologies
- Treatment procedures
- Database
- Datasets, data models and digital twins
- Educational and training programs or courses
- Recommendations for policies



3 Exploitation activities

Through exploitation activities, CLARA aims to maximize the impact of its research, fostering innovation and contributing to advancements in healthcare and computing for the benefit of society.

Key Exploitation activities					
Intellectual Property (IP) Management	**Commercialization & Market Uptake**	**Technology Transfer**	**Policy Impact**	**Dissemination & Stakeholder Engagement**	**Further Research & Development**
Protection of Innovations IP Ownership and Licensing Software, system and platform components Databases	Development of Business Models Industry Partnerships Preparation for Investment and Spin-offs (pre-seed and seed activities, venture capital involvement)	Dissemination to Industry and Startups Collaborations with Technology Centers Real-world Demonstrations	Influencing Policy Engagement with Policymakers Provision of Policy Recommendations	Publication of Research Organizing Outreach Events Collaborative Initiatives Social media and science popularization	Integration into Future Research Securing Additional Funding Strengthening Research Collaborations

Exploitation activities are closely intertwined with market analysis and the development of the business model and business plan to ensure that each outcome of the project aligns with real-world demand and is positioned for long-term financial sustainability. By continuously scanning the competitive landscape, tracking emerging industry trends, and engaging with stakeholders such as clinicians, researchers, industry partners, and policymakers, these activities enable the project to adapt its exploitation pathways and refine potential revenue strategies.

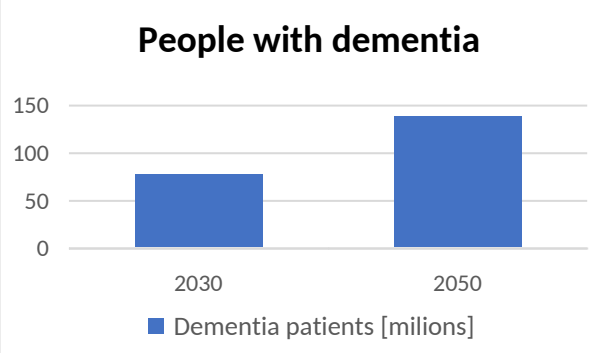
In parallel, the business model clarifies value propositions, revenue streams, cost structures, and possible collaborations. In contrast, the business plan details the concrete steps, timelines, and resource allocations required to bring innovations to market effectively. Taken together, these elements create a cohesive framework that not only maximizes the impact of research and technological advancements but also fosters an environment where discoveries can be efficiently translated into viable products, services, and collaborations that benefit patients, healthcare systems, and society at large.

The CLARA project is going to yield a wide array of results poised to significantly impact several key areas:

- **Commercialization**
- **Industry**
- **Policy influence**
- **Standards development**
- **Excellent research and development**
- **Educational and training programs**

4 Market analysis

Neurology is expected to become one of the top areas of pharmaceutical spending. The neurodegenerative disease market is experiencing significant growth, driven by the increasing prevalence of conditions such as Alzheimer's, Parkinson's, and multiple sclerosis, coupled with advancements in treatment options. By **2030**, the number of people with dementia is projected to reach **78 million**, and by **2050**, it could rise to **139 million**. Parkinson's disease affects over six million people worldwide, experts anticipate that this figure will double by 2040[1,2]. Alzheimer's, Parkinson's, Huntington's, and Multiple Sclerosis – represent a growing global health challenge. Despite scientific advances, they remain largely incurable with limited therapeutic options. The combination of aging populations and potential new therapies is driving strong growth prospects across neurodegenerative disease markets. Alzheimer's disease is poised for especially rapid expansion.[3,4]



[1] https://www.alzint.org/about/dementia-facts-figures/dementia-statistics/#:~:text=Numbers%20of%20people%20with%20dementia&text=This%20number%20will%20almost%20double,this%20will%20rise%20to%2071%25.

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC9767134/#:~:text=Abstract,to%20be%20doubled%20by%202040.

[3] https://finance.yahoo.com/news/global-neurodegenerative-disease-market-set-143000660.html

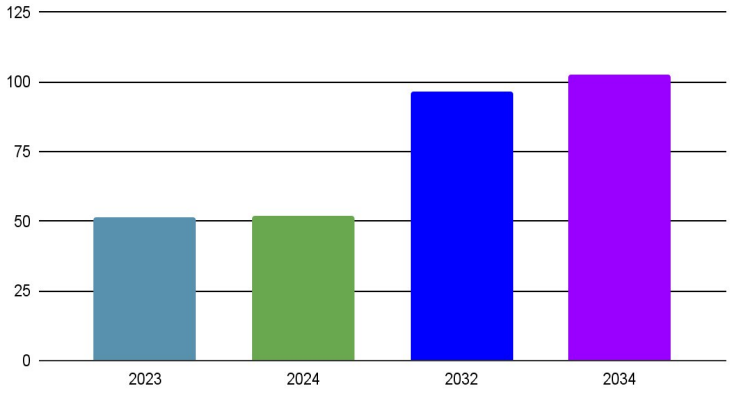
[4] https://finance.yahoo.com/news/neurodegenerative-disease-market-size-reach-121000620.html

Below is a concise overview of the projected Compound Annual Growth Rates (CAGRs) for the neurodegenerative disease market from 2024 to 2034, organized by country:

Neurodegenerative Disease Market CAGR (2024–2034)[5]

- **United States:** 6.90%
- **United Kingdom:** 8.60%
- **Canada:** 7.50%
- **China:** 7.00%
- **India:** 9.40%

Global Neurodegenerative Disease Market Size (Past/Current/Expecatation); USD bilions



This data highlights the varying growth expectations across different regions, with India anticipated to see the highest growth rate (9.40%), followed by the United Kingdom (8.60%), Canada (7.50%), China (7.00%), and the United States (6.90%). These projections are influenced by multiple factors, including increased awareness of neurodegenerative conditions, advancements in diagnostic and therapeutic technologies, and evolving healthcare infrastructure within each country. The main factor in these numbers will be changes in population demographics.

The global increase in the older population [6]

- By 2030, there will be **1.4 billion** people aged 60 years or older, up from **1 billion** in 2020.
- By 2050, the global population of older people is projected to reach **2.1 billion**.

Proportion of older adults

- Between 2015 and 2050, the proportion of the world's population over 60 years of age will nearly double, from **12%** to **22%**.
- By 2030, **1 in 6** people worldwide will be aged 60 or older.

[5] https://finance.yahoo.com/news/global-neurodegenerative-disease-market-set-143000660.html

Oldest age group (80+)

- The number of people aged 80 years or older is expected to triple between 2019 and 2050, rising from **143 million** to **426 million**.

Regional shifts

- The largest increases in the number of older people are occurring in developing countries; around **80%** of older people will be living in low- and middle-income countries by 2050.

These figures emphasize the rapid and continuing shift in global demographics, with older populations growing especially quickly in regions that have historically had younger populations.

Key Market Segments

- Alzheimer's disease
- Parkinson's disease
- Huntington's disease
- Multiple sclerosis

A recent trend is the involvement of technology companies and artificial intelligence (AI) in funding and partnerships. AI is seen as a catalyst for neuroscience drug discovery and diagnostics. In 2023, there were over $12 billion worth of life-science deals involving AI/ML, including a notable multi-billion collaboration between Roche and Shape Therapeutics to use AI in developing gene therapies for neurodegenerative diseases.[7]

Venture capital (VC) funding in neurology has risen markedly. Specialized funds such as the Dementia Discovery Fund (backed by firms like Gates Ventures, J&J, Biogen) have committed hundreds of millions specifically to dementia startups. Traditional life science VCs are also back in the space – evidenced by large financing rounds like Asceneuron's $100 million Series C in 2024 to develop tau inhibitors for Alzheimer's, led by prominent investors (Novo Holdings, EQT, Orbimed, etc.).[8]

In summary, investment trends from 2024–2034 indicate a robust and growing funding ecosystem for neurodegenerative R&D. Private sector spending is rising, as evidenced by

[7] https://www.ishares.com/us/insights/finding-investment-opportunities-neuroscience-ai#:~:text=ARMING%20NEUROSCIENCE%20COMPANIES%20WITH%20AI

[8] https://asceneuron.com/asceneuron-secures-100-million-series-c-financing/#:~:text=Therapeutics%20in%20Neurodegenerative%20Diseases

large VC financings and big pharma deal premiums. Public and non-profit funding continues to grow, often targeting enabling tools (genomics, longitudinal patient data, etc.) to support drug development.

The neurodegenerative market is ripe with opportunity, but also full of barriers: **scientific, strict regulatory/payer gauntlets, competition from industry**, **challenges of delivering complex therapies**.

Regulatory:

- USA - FDA
- Europe - EMA
- China - NMPA
- India - CDSCO/DCGI

Even after regulatory approval, market access can be a major hurdle in the neurodegenerative space. New therapies – especially biologics or gene therapies – often come with very high costs, and payers (insurers and governments) scrutinize their value given typically modest clinical outcomes. One prominent example is the launch of Aducanumab (Aduhelm) for Alzheimer's: despite FDA approval, the U.S. Medicare program severely limited coverage to patients in clinical trials due to questions about efficacy[9]. In emerging markets and lower-income regions, affordability is the key barrier. In China, authorities typically negotiate significant price cuts with pharma companies before adding novel drugs to the national insurance formulary.

Major pharmaceutical companies have long been leaders: Biogen and Eisai, Eli Lilly, Roche/Genentech, Novartis, Johnson & Johnson, AbbVie and AstraZeneca. In this highly competitive environment can be difficult for new companies to grow market share with their products. Securing a strategic partnership with a major pharmaceutical company for closer collaboration and funding of research and development activities would be highly beneficial. This type of cooperation is common in the biotech sector, as it enhances innovation, accelerates product development, and significantly increases the likelihood of successful market penetration.

[9] https://www.clinicaltrialsarena.com/analyst-comment/unmet-need-alzheimers/#:~:text=antibody%20,is%20granted%20for%20the%20drug

5 Business model and business plan

The business model and business plan will be developed (Deliverable D6.3, M12) in close alignment with the project's exploitation strategy, using insights derived from anticipated results, identified ownership, and market needs (CLARA IPR radar and audit activities, Deliverable D6.5, M32). As a foundational step for developing CLARA's business model, the Business Model Canvas was created. This visual framework will systematically capture the essential elements and key relationships critical to the project's success. It will highlight the primary value propositions related to CLARA's advancements in neurodegenerative disease research and innovative AI-driven solutions, delineate customer segments such as clinicians, research institutions, industry partners, and policymakers, and outline essential resources, partnerships, and revenue streams. The Business Model Canvas will serve as a strategic visual aid, facilitating clear communication and providing fundamental information required for subsequent phases of the project and ensuring effective and sustainable business management aligned with CLARA's overarching objectives.

Drawing on this strategy, the business model will outline the key value propositions, revenue streams, cost structures, and partnerships needed to sustain long-term financial viability—particularly for the envisioned Center of Excellence. The business model for CLARA is not intended as a formal deliverable but rather as internal documentation crucial for guiding project activities. It will systematically outline the necessary strategies, relationships, and operational details required throughout the project's lifecycle.

In contrast, our business plan will be a comprehensive document detailing the concrete strategies and actionable steps required to effectively realize the objectives set forth in the exploitation strategy. It includes an in-depth market analysis customized to the project's anticipated outcomes, clearly defines the value propositions and revenue streams, outlines targeted marketing and sales strategies, and presents precise financial projections alongside recommendations for funding and resource allocation. Concurrently, the business plan will translate these elements into actionable steps, including timelines, resource allocations, and risk mitigation measures, ensuring smooth implementation and scalability. By integrating stakeholder feedback—from clinicians, researchers, industry partners, and policymakers—the plan will remain adaptive and relevant, reflecting the project's commitment to bridging research gaps, driving innovation, and delivering tangible societal impact.

In the first year of the project, a Business Plan will be created, which allows us to set crucial plans for exploitable results in case of the commercialization. This plan will be modified and updated during the life cycle of project based on the needs of the specific results.

- Deliverable D6.2 – **Business Plan** – Due Date (month) 12
- Deliverable D6.3 – **Business Plan – update** – Due Date (month) 48

Business Model Canvas initial draft*

CLARA – Exploitation strategy

** will be finalized as part of the Business Plan.*

Key Partners

Internal:

- VSB - Technical University of Ostrava
- Ceske Vysoke Uceni Technicke V Praze
- Fakultni Nemocnice U Sv Anny V Brne
- Institut Du Cerveau Et De La Moelle Epiniere
- Bayerische Akademie der Wissenschaften
- International Neurodegenerative
- Disorders Research Center

External:

- Biotechnology companies, Industrial partners, Research organization
- Venture capital

PPP:

- Business acceleration engine (joint venture of INDRC/CLARA, partners and industrial sector)

Key Activities

- R&D
- Knowledge mapping and simulation
- AI and ML
- Quantum-centric supercomputing
- Technology transfer

Key Resources

- Human
- Knowledge
- Intellectual (know-how, patents)
- Datasets
- AI and ML
- Financial (strong and long term funding)
- Hardware

Value Propositions

- Artificial intelligence (AI), Machine learning (ML) algorithms, and hybrid computing
- Innovative diagnostic and therapeutic solutions
- Harmonized dataset
- Identification of new molecules and inhibitors
- Knowledge map

Customer Relationships

- B2B
- Open source
- Contracted research
- Licencing

Channels

- Dealflow.eu
- Horizonresultsbooster.eu
- Individual propagation to potentional investors
- Web/Online platforms

Customer Segments

- Patients
- Pharmaceutical and Biotechnology Industries
- Industrial partners
- Clinicians and Healthcare Providers
- Research Community
  - Researchers
  - Research Organisations
- European Computing Ecosystem
- Government

Cost Structure

Taxes, Hardware, R&D, Legal (patents, IPR protection), Employees, Salaries, Utilities

Revenue Streams

During and after project: Licences, Patents, Start-ups, Grants, Spin-offs, Industrial cooperation, Clinical studies, Datasets, AI solutions, Software, Donation, VC, PE, Business angles, Education & Training Programs and Events.
Currently: Clara funding approximately 43 mil. EUR.

6 Intellectual Property Rights / Intellectual property management

Effective management of Intellectual Property Rights (IPR) is integral to the project's exploitation strategy and overall sustainability. A dedicated IPR & Innovation Officer, embedded within the newly established Technology Transfer Office (TTO), will oversee IPR audits at strategic intervals (M32) to monitor the creation, ownership, and status of all generated IP. In instances of joint IPR, all relevant partners will establish clear rules – covering ownership, access to Background/Foreground IP, protection measures, and confidentiality – prior to project initiation, as outlined in the project consortium agreement (PCA). The IPR & Innovation Officer, in close collaboration with the Technology Transfer departments at partner institutions, will oversee and manage the identification and protection of intellectual property rights.

Technology Transfer (TT) offices at participating institutions will operate independently (however in compliance with Grant Agreement and PCA), with each institution determining how and to what extent they will collaborate with the IPR & Innovation Officer. Nonetheless, institutions are expected to provide all necessary information, background and creating/protecting value of the research to fulfil the objectives of the CLARA project and to prepare any documentation requested by the European Commission. This document outlines general guidelines for effective collaboration; however, the final approach remains at each institution's discretion.

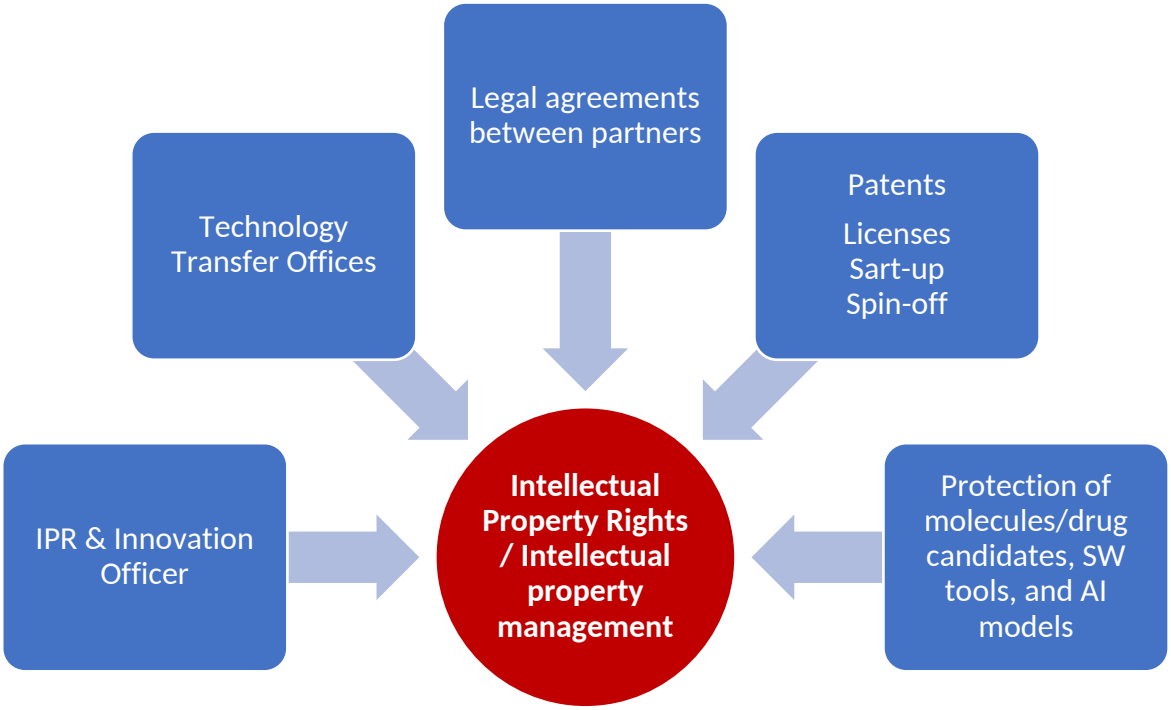
CLARA IPR & Innovation Officer (empowered by the CLARA Director) has the full authority to manage the process of technology transfer and commercialization only in two cases:

- CLARA partner(s) directly ask(s) for the service of the IPR & Innovation Officer
- Case concerns joint intellectual property rights developed at CLARA by two or more parties, but the parties have not reached the consensus on the technology transfer and commercialisation aspects.

Once project results are formally protected, where appropriate, publishing in scientific journals can proceed, ensuring that valuable innovations are safeguarded while also disseminating findings to the broader research community. Further reflecting the project's commitment to scientific advancement and societal benefit, partners will grant **free licenses for research and educational purposes**, facilitating wide adoption of innovations without compromising commercial potential. Additionally, the IPR & Innovation Officer will engage regularly with stakeholders to track evolving market needs and product/service offerings,

guided by standards such as **CEN/TS 16555**. Through this proactive approach, the project ensures that IPR is managed transparently, promotes collaborative research efforts, and maximizes the impact of its intellectual assets.

Intellectual Property Rights (IPR) protection and commercial considerations, including the appropriate allocation of returns based on each party's contribution, will be clearly defined through dedicated legal agreements between partners where appropriate. These provisions will also apply to spin-offs and start-ups.



The main types of results for IPR protection would be the **protection of molecules/drug candidates, SW tools (including system and platform components)**[10], and **AI models.**

7 Innovation management

CLARA will designate an IPR & Innovation Officer (leading the TTO of INDRC) to work with stakeholders, monitoring evolving requirements and relevant products/services on the market. Establish a robust business model that ensures CLARA remains financially sustainable over the long term. In parallel, continuously assess evolving market demands and

10 The IPR management of software and platform/system components has the choice of an appropriate license as a core aspect, and - as other IPR management - has to be in line with institutional policies, which can require e.g. open licensing.

technological developments throughout the project to guide strategic decision-making and maintain relevance.

The TTO plays a pivotal role in bridging the gap between research and market application by managing intellectual property (IP) and facilitating the commercialization of innovations. This involves identifying valuable IP, securing appropriate protections such as patents or copyrights, and developing strategies to bring these innovations to market.

Effective innovation management necessitates continuous engagement with intellectual property rights (IPR) throughout the entire lifecycle of a product or service. This begins at the **idea generation** phase, where it's crucial to identify and document potential IP assets, ensuring that novel concepts are protected from the outset. During the **development phase**, proactive IP management involves securing appropriate protections—such as patents, trademarks, or trade secrets—to safeguard the innovation as it evolves. To maximize both societal impact and commercial potential, it's crucial to identify research outcomes with strong patentability and to strategically select relevant geographical regions for patent protection.

- **Prioritizing High-Impact, Patentable Innovations**
  - **Neurodegenerative Disease Treatments**
    - Innovations that improve outcomes for patients with neurodegenerative diseases, such as Alzheimer's, hold significant societal value and commercial potential. Despite inherent challenges and higher risks, the demand for effective therapies in this field is substantial.
  - **AI and Machine Learning Developments**
    - While protecting software, AI, and machine learning innovations through patents can be complex, these technologies often present opportunities for startup ventures or the creation of commercially valuable products. Notably, the European Patent Office (EPO) considers AI inventions patentable if they possess a "technical character" and contribute to a technical field, such as image processing or speech recognition. [11]
- **Robust Patent Strategy**

[11] https://www.reuters.com/legal/legalindustry/patenting-generative-ai-technologies-opportunities-challenges-2024-11-11/

- **Selecting Relevant Geographical Areas**
  - Selection of jurisdictions for patent protection based on factors such as market size, manufacturing hubs, and regions with strong intellectual property enforcement. For instance, securing patents in major markets like the United States, European Union, and Japan can provide substantial commercial advantages.
- **Assessing Market Needs**
  - Specific needs and demands within target markets to ensure the innovation addresses relevant challenges.
- **Strong Patents**
  - Securing patents that offer broad and enforceable protection, ensuring they cover key aspects of the innovation.
- **Regulatory Incentives**
  - **USA**
    - Leverage frameworks like the Orphan Drug Act of 1983, which offers benefits such as market exclusivity and tax credits for treatments targeting rare diseases.

- **Other IP Strategies**
  - **Trade Secrets**
    - Algorithms and data
  - **Copyright**
    - Code and trained models

Finally, in the **implementation and commercialization** stage, ongoing IP oversight ensures that the product or service is not only protected in the market but also leveraged effectively to maximize its value. This comprehensive approach ensures that IP considerations are integrated at every stage, thereby enhancing the innovation's success and longevity.

How to set IP protection?

- Responsible person:
  - Technology Transfer (TT) office
  - dedicated or nominated person at the institution who is responsible for TT or IP handling in case of not existence of TT office at the institution
  - IPR & Innovation Officer

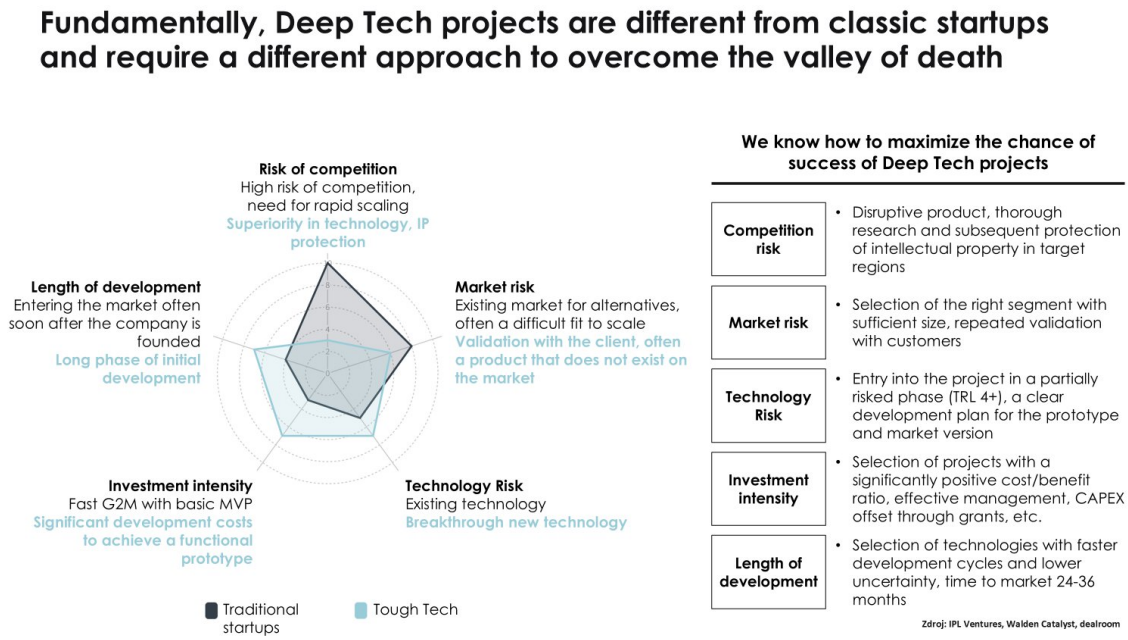
- At the earliest stage of the Project possible (with update possibilities as the IPRs will be evolving during the project implementation), all parties shall identify the types of Intellectual Property (IP) that may arise, including but not limited to inventions, software, designs, data, and know-how. Each party shall maintain comprehensive documentation of any relevant developments, experiments, and contributions to establish proper authorship or inventorship. This documentation will serve as the foundation for future legal or contractual processes pertaining to IP rights.
    - **Protection strategies for possible results**
        - Patents
        - Trade Secrets
        - Copyright
        - Trademarks
        - Open Licensing
        - Licensing
        - Identifying potential intellectual property (IP) at the earliest possible stage can allow us to prepare possible strategies.This initial framework will be continually adapted throughout the project lifecycle based on emerging results and findings.
- Where an IP protection case requires elaborate handling (e.g. patent application), the parties shall designate an IP lead for IP protection case, whose main responsibility will be communication with patent attorney. It can be the Technology Transfer Office (TTO), the IPR & Innovation Officer or another responsible person. IP lead will coordinate all IP-related activities for specific result. In addition, a clear communication protocol shall be implemented to ensure transparency and timely exchanges of information among the parties regarding IP matters. This protocol will facilitate alignment on ownership, protection measures, and the overall management of any significant resulting IP.
    - Licensing and other intellectual property (IP) protections will be managed based on the number of participants and the specific requirements of each institution. If IP management is not necessary for the project's purposes, an IP lead does not need to be designated.
- Protection of intellectual property (IP) arising from the project will be coordinated through clear communication and collaboration among the research team, the

institution's Technology Transfer (TT) office or dedicated/nominated person at the institution who is responsible for TT or IP in case of not existence of TT office at the institution, and the IPR & Innovation Officer. In cases where multiple partners have contributed, their respective roles and contributions will be assessed to determine appropriate ownership shares.

- Once ownership shares are agreed upon, a formal contract will be drawn up among all participating institutions to detail each party's percentage and responsibilities. With this contract in place, the TT office—together with the IPR & Innovation Officer or another responsible person—will initiate the necessary legal steps for IP protection, which may include filing patent applications, registering trademarks, or other relevant actions, ensuring that the results are fully safeguarded.
    - The purposing scheme will be employed specifically for types of results that require institutional investment for legal protection, such as patents, or when a particular result is identified as having significant commercial potential and the ability to generate cash flow.

IP leadership, cooperation, and coordination will be determined on a case-by-case basis to meet each institution's and project's specific needs. To facilitate effective transfer of IPR to real-life results, individual institutions will have an opportunity on per-project basis to participate in the newly established CLARA incubator programme, VentureLab[12]. The Venture Lab Program is designed to provide a comprehensive, structured pathway for the commercialization of intellectual property (IPR) emerging from participating research institutions, should they decide to participate in the programme. Recognizing that deep tech spinouts—particularly those rooted in cutting-edge scientific research—differ significantly from conventional startups in terms of risk profile, development timelines, and capital requirements, VentureLab fills a critical gap in the innovation ecosystem. The Venture Lab Program will be led by the CLARA IPR&Innovation Officer.

[12] The VentureLab Program shall be implemented by the newly established business vehicle (working title COMENIA Ventures). This vehicle shall be established by the Coordinator (solely or in collaboration with other partners/research organization) together with the business sector as the private for profit company. This company shall act as the commercialization service provider for CLARA partners and other relevant research partners, thus representing acceleration&incubation engine.



Deep Tech/Tough Tech spin-outs vs Traditional startups

Our core mission is to nurture and accelerate the growth of highly competitive spinouts from partner universities, equipping them with the strategic, operational, and financial resources necessary to succeed in global markets. However, the incubator will also be structured to offer flexible support for a broad range of commercialization needs across individual institutions and Technology Transfer Offices (TTOs). This includes tailored advisory, access to specialized funding, industry partnerships, and expert mentorship, ensuring that research-driven ventures can effectively bridge the gap from lab to market.

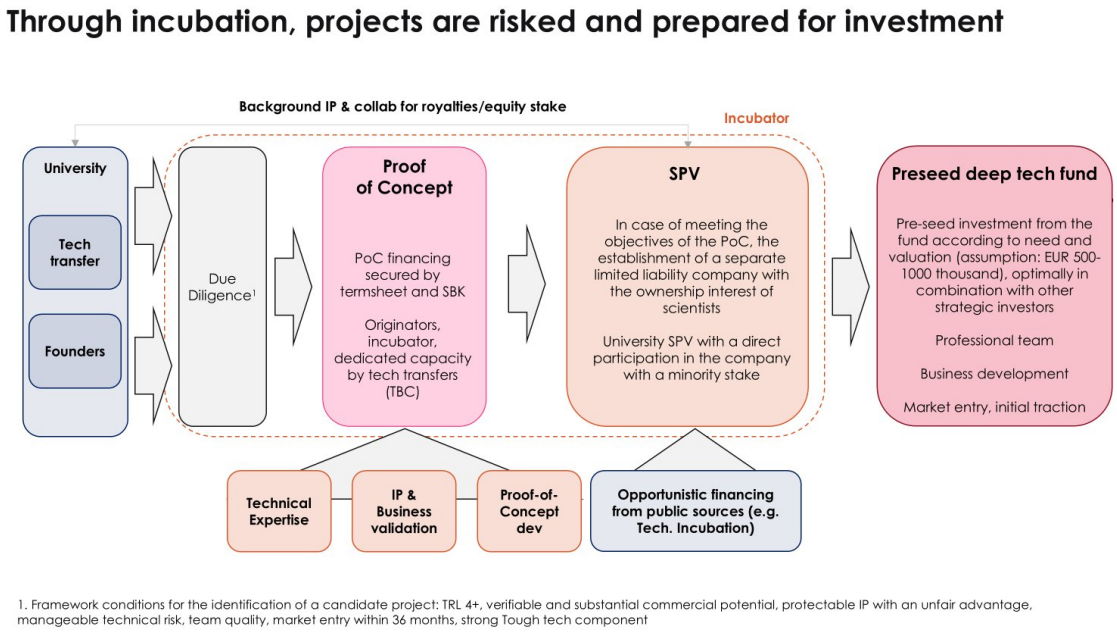
By fostering a deep tech-focused incubation environment, VentureLab Program aims to create a sustainable pipeline of transformative innovations, strengthening the overall commercialization capacity of the ecosystem.

The Incubator will provide a structured, high-impact support system for deep tech commercialization, ensuring that promising technologies and research teams successfully transition from academia to market. Its core activities will span the entire commercialization lifecycle, starting with consulting on applied research focus to identify potential commercial applications. The incubator will offer in-depth market insights, covering both target and adjacent disciplines, to help spinout companies to position themselves effectively. Additionally, expert guidance on intellectual property (IPR) strategy will be provided to ensure robust protection and strategic hardening of IP assets.

A critical function of the incubator will be the commercial validation of technologies highlighted by Technology Transfer Offices (TTOs). This will involve comprehensive due diligence on high-potential innovations to assess their market viability, scalability, and investment readiness. To streamline commercialization efforts, the incubator will also offer project management services, overseeing key milestones from incubation and proof-of-concept (PoC) phases to full-fledged commercial operations. Furthermore, dedicated support will be available for structuring licensing agreements, ring-fencing spinout companies, and establishing robust venture frameworks.

To ensure that startups are well-capitalized for early-stage growth, the incubator will actively assist in securing pre-seed and seed funding. Recognizing the need for a balanced approach to deep tech commercialization, the incubator will operate as a joint ventures between research institutions and private sector expert management. This structure will combine the research depth of academia with the business acumen of experienced operators, aligning incentives for long-term commercial success. Performance metrics will be clearly defined at the incubator level, with **Service Level Agreements (SLAs)** set up for participating TTOs. **A Ways of Working (WoW) document** will be provided to clarify engagement rules and operational frameworks for all stakeholders.

The primary focus of the incubator will be on developing high-potential technologies and teams into commercially viable, stand-alone spin-outs. It will typically support projects at Technology Readiness Levels (TRL) 3 or 4, ensuring that selected teams possess strong motivation, well-protected IP, and a clear path to significant market opportunities. Each project's investment requirements, risk profile, and time-to-market expectations will be assessed individually, ensuring an optimal balance between risk and reward. Ultimately, the incubator aims to build a sustainable pipeline of scalable deep tech ventures capable of driving meaningful industry impact.



Proposed VentureLab incubator ecosystem

To further strengthen the commercialization pipeline, the incubator will be closely integrated with an **independent deep tech venture capital (VC) fund**[13]. This fund will focus on **providing pre-seed and seed financing** to the most promising spinouts emerging from the incubator, ensuring that they have the necessary financial backing to progress beyond early-stage development. By aligning investment strategy with incubation support, the fund will help accelerate the path to market while reducing the funding gap that often hampers deep tech ventures. This approach will not only increase the chances of commercial success but also position the incubator as a key driver of a self-sustaining deep tech ecosystem.

A critical priority for the incubator will be to **carefully balance the interests of all stakeholders,** particularly ensuring that **institutions of origin are fairly compensated** for their intellectual contributions while creating a **highly investable and globally competitive spinout portfolio**. Deep tech ventures often require significant external funding, and the incubator will work to establish **commercially viable equity and licensing structures** that do not deter future investors. This means crafting agreements that align the incentives of

[13] Possibly SICAV or alternative investment fund in CZ or LUX, with expected following parameters: EUR € 30M fund size with a 5 + 5 year horizon; Initial fund to establish the model and develop a track record with a larger follow-up fund in a quick succession; Pre-seed/ Seed investment stage with average investment of ~ € 1M per project; De-risked projects through in-house incubation coupled with public, non-dilutive funding where appropriate; expected ~10 projects invested per year.

research institutions, founders, and investors in a way that maximizes long-term value creation. By implementing **best-in-class governance, equity allocation frameworks, and IP licensing models**, the incubator will help avoid common pitfalls that can hinder the scalability and attractiveness of spinout companies.

At its core, **the high-level objectives of the incubator are fourfold**:

1. **Develop and launch a portfolio of highly competitive spinouts,** ensuring that they have the technological, operational, and commercial strength to succeed.

2. **Ensure sustainability**, by providing not just initial funding and support but also a long-term strategy for scaling and securing follow-on investment.

3. **Provide hands-on commercial support**, including interim management where necessary, to ensure that early-stage teams have access to experienced leadership capable of navigating critical growth phases. This will be particularly vital for deep tech ventures, where technical founders often need strong business guidance to transition into successful entrepreneurs.

4. **Significantly contribute to the sustainability of all participating institutions**, reinforcing their ability to generate, protect, and commercialize groundbreaking innovations in a way that benefits the broader ecosystem.

By embedding these principles into its structure, the incubator will play a transformative role in bridging the gap between research and commercialization, ultimately establishing a robust foundation for deep tech innovation.

8 Instruments of Exploitation

Effective exploitation of project results relies on a variety of complementary instruments, each tailored to maximize the scientific, commercial, and societal impact. Key exploitation instruments include:

1. **Patents and Licensing**
    - **Protection of Innovations**
        - This includes securing patents, trademarks, and copyrights, as well as establishing clear guidelines for ownership and usage rights among project partners.

- **Licensing Agreements**
  - Collaborating organizations and external entities can obtain licenses, generating revenue while promoting broader application of the newly developed technologies.
  - FRAND terms applied.

2. **Technology Transfer and Spin-Offs, Startups**
   - **Technology Transfer Office (TTO)**
     - Coordinates the transfer of project outcomes to industry and research stakeholders. TTOs play a pivotal role in identifying market opportunities, negotiating partnerships, and supporting the commercialization process.
   - **Spin-Off Companies**
     - Encourages the establishment of start-ups to commercialize new discoveries, driving entrepreneurship and job creation.
3. **Joint Ventures and Public-Private Partnerships**
   - **Collaborative Business Models**
     - Pool expertise and resources from academia, industry, and public institutions to streamline the path to market.
   - **Shared Risk and Investment**
     - Leverages combined resources to fund large-scale initiatives, reducing barriers and ensuring sustainability.
4. **Research Contracts and Consultancy**
   - **Tailored Services**
     - Partners can offer specialized consulting or contract research.
5. **Open-Access Publications and Knowledge Sharing**
   - **Academic Dissemination**
     - Publishing results in high-impact, open-access journals.
   - **Conferences, Workshops, and Training**
     - Fosters networking, skill enhancement, and collaboration across disciplines, amplifying the overall impact.
   - **Other type of results**
     - Academic thesis
     - Books
     - Chapters

6. **Educational and Research Tools**
    - Free Licenses for Research and Education
7. **IT Platforms**
    - Open-Source Component Repositories
    - FAIR, Shared or Open Data Platforms
8. **Standards and Policy Contributions**
    - **Regulatory Engagement, Influencing Public Policy**
        - By providing evidence-based recommendations, projects can impact public health, environmental regulations, and other critical areas.

To ensure the successful exploitation of our project's results, we are integrating the European Commission's **Innovation Radar methodology** as a central component of our exploitation strategy. This approach provides a **systematic framework** for identifying, assessing, and advancing our innovations toward the market, allowing us to align technical development with genuine market needs and opportunities.

Innovation Radar methodology			
Innovation Potential Indicator	**Innovator Capacity Indicator**	**Maturity Levels of Innovations**	**Maximizing Market Impact**
Innovation Readiness Innovation Management Market Potential	Innovator's Ability Innovator's Environment	Market Ready Tech Ready Business Ready Exploring	Map Current Innovation Maturity Implement Targeted Actions Accelerate Market Uptake Align with Stakeholder Needs

9 Key impact

Under Horizon Europe, the *impact* is understood as the far-reaching, enduring consequences—encompassing societal (including environmental), economic, and scientific spheres—that emerge from investments in research and innovation (R&I). Adopting an impact-centric philosophy, Horizon Europe outlines three principal Key Impact Pathways (KIPs), each divided into three thematic strands:

1. **Scientific Impact**
    - Producing top-tier, novel knowledge
    - Enhancing research and innovation capacities among professionals
    - Encouraging the widespread exchange of knowledge and promotion of open-source principles
2. **Societal Impact**
    - Tackling European policy objectives and global challenges through R&I
    - Generating tangible results and public value via R&I missions
    - Increasing the acceptance and integration of R&I outcomes within communities
    - Creating higher-quality employment opportunities
3. **Economical impact**
    - Industry collaboration
    - Job opportunities for highly skilled workforce
    - Commercial opportunities
        i. Spin-off
    - Regional economic growth
        i. Strengthens Europe's competitive position in genomics and AI
    - Maximizing and attracting further investments in R&I
    - Development of sustainable private financing of participating institutions through effective valorization of IPR
4. **Technological Impact**
    - Driving growth rooted in innovation
    - Cutting-edge artificial intelligence (AI), machine learning (ML), and quantum supercomputing
    - Understanding and treating neurodegenerative diseases
        i. Novel inhibitors
        ii. Predictive AI models
        iii. Advanced software tools
        iv. Precision diagnostics and therapeutic interventions

Spheres	Description
Scientific impact	Groundbreaking developments in **artificial intelligence (AI), machine learning (ML), and quantum-centric supercomputing** pave the way for more nuanced analysis of

	extensive biological and clinical datasets. By deploying **ML foundation models** to decipher the mechanisms behind neurodegenerative diseases (NDs)—particularly involving **proteins like ABeta, APOE, and Tau**—researchers can better capture how these molecules assemble and interact. Special attention is given to **APOE's three isoforms**, given their recognized genetic influence on Alzheimer's disease (AD). Leveraging **deep learning techniques** accelerates the process of binding lipids and small molecules to APOE and refines our knowledge of potential intervention points. Meanwhile, **large-scale generative AI models**, trained via **hybrid supercomputing on multimodal datasets** from over 40,000 participants with detailed neuroimaging (and genetics data from more than 400,000), enable rigorous testing of hypotheses—such as the **Calcium Brain Aging** and **APOE Cascade** models—thus forming a comprehensive picture of brain health and neurodegeneration.
Societal Impact	By expanding our understanding of **neurological disorders** (e.g., Alzheimer's, Huntington's, and Parkinson's), this initiative unlocks **innovative diagnostic and therapeutic solutions**. Better clarity on disease mechanisms and potential intervention points can bolster **precision medicine**, ensuring patients receive the **most effective treatments** at optimal times. This not only enhances care but also significantly reduces the emotional and economic burden on families, healthcare systems, and societies at large.
Economical and Technological impact	Building a vibrant **European computing and data ecosystem** is central to this vision. By prioritizing collaboration across Central and Eastern Europe (CEE) and Western Europe, the project aims to shrink existing research disparities and promote equitable capacity-building. The rising prevalence and associated costs of dementia—**over 50 million global cases**

	and US$1 trillion in annual expenses, both projected to roughly double by 2030—highlight the economic urgency of breakthroughs in NDs. Additionally, bolstering Europe's leadership in **genomics, quantum computing, and AI** helps close innovation gaps with major players like the United States and China. The result is a fertile environment for developing **cutting-edge products and services** relevant to the pharmaceutical and biotech sectors while fostering a **competitive research landscape** that supports national-level R&I reforms and fortifying the broader European Research Area.

From an exploitation strategy standpoint, these pathways provide a structured blueprint for turning project outputs into real-world benefits. Exploitation involves identifying and refining market or stakeholder needs, protecting intellectual property, fostering collaborations, and guiding innovations toward effective adoption. By aligning with each of the three impact areas, projects can more purposefully direct research findings, technologies, and methodologies – ensuring not only compliance with Horizon Europe objectives but also delivering concrete societal, economic, and scientific gains.

10 Beneficiaries (end-users)

Based on the key impact areas we can identify the main beneficiaries (main end-users) of this project and thanks to that it is possible to cover the whole process of exploitation and dissemination for results. This ensures that scientific discoveries transition seamlessly into tangible solutions, fostering clinical advancements, commercial innovations, and meaningful societal impact. In turn, each stakeholder group is equipped with the necessary resources, knowledge, and support to maximize the project's benefits and drive long-term adoption across Europe and beyond.

A diverse set of stakeholders stands to benefit from this project's advancements:

- **Patients and Caregivers:**
  - Enhanced diagnostics and targeted therapies for neurodegenerative diseases will lead to better health outcomes and reduced care-giving burdens.
  - ***Exploitation & Dissemination Approach*:**

- Close collaboration with patient advocacy groups and healthcare institutions to ensure findings are translated swiftly into accessible treatment protocols and support resources.

- **Clinicians and Healthcare Providers:**
  - Improved clinical decision-making, thanks to precision medicine tools and robust data insights, will streamline patient management.
  - ***Exploitation & Dissemination Approach*:**
    - Publish clinical guidelines, present findings at medical conferences, and incorporate results into training and educational materials.
- **Pharmaceutical and Biotechnology Industries:**
  - Access to cutting-edge AI models and large-scale datasets provides novel opportunities for drug discovery and therapeutic innovation.
  - ***Exploitation & Dissemination Approach*:**
    - Develop patent strategies, foster public-private partnerships, and promote technology transfer to spur commercial applications.
- **Research Community:**
  - Collaborative networks, new computational methods, new platforms for computing, and open data resources boost the pace of scientific progress and cross-disciplinary knowledge exchange.
  - ***Exploitation & Dissemination Approach*:**
    - Ensure open-access publications, encourage data sharing, and host workshops or hackathons to spark new lines of inquiry and interdisciplinary synergy.
- **European Computing Ecosystem:**
  - Strengthening both hardware infrastructures (e.g., quantum-focused supercomputing) and software, system and platform innovations fosters a more competitive and cohesive research environment across Europe.
  - ***Exploitation & Dissemination Approach*:**
    - Promote collaboration among EU research centers, industry, and policymakers; use and co-develop appropriate standards and protocols for data exchange; and offer training programs to build a skilled research workforce.

- **Society at Large:**
  - By addressing pressing healthcare challenges and reducing associated costs, the project contributes to healthier populations and bolsters economic growth on a broad scale.
  - ***Exploitation & Dissemination Approach*:**
    - Engage the public through outreach events, policy briefs, and accessible communication channels, ensuring societal benefits are transparent and widely understood.

11 Monitoring/audits/cooperation

The **IPR Audits Report** (Deliverable D6.5) will document the audits conducted by the IPR & Innovation Officer throughout the project. This report will provide a systematic review of intellectual property rights (IPR) owned, used, or acquired by the project stakeholders. The primary objectives of these audits are to:

- Assess and manage risks associated with IPR.
- Identify and remedy potential issues in intellectual property ownership.
- Implement best practices in IP asset management to ensure compliance and strategic utilization.
- Provide a detailed analysis of title and ownership of the IPR generated during the project.

This deliverable ensures that all intellectual property aspects are well-documented, risks are mitigated, and project innovations remain protected under proper ownership structures.

Deliverable No	**Deliverable Name**	**Work Package No**	**Type**	**Dissemination Level**	**Due Date (month)**
D6.5	IPR audits	WP6	R — Document, report	SEN - Sensitive	32

The **monitoring of IPR and ownership** of the IPR generated during the project will be managed by the **IPR & Innovation Officer**, with the **full cooperation of all stakeholders**. This approach ensures a transparent, well-regulated process, maintaining compliance with

intellectual property standards and safeguarding project innovations. For this purpose will be set regular meetings with relevant stakeholders during the whole existence of CLARA project. These regular meetings also increase **cooperation** between institutions.

12 Sustainability

Key elements of CLARA's sustainability	
Strategic Research and Innovation Agenda (SRIA)	CLARA's scientific goals and research priorities are encapsulated in a regularly updated SRIA, reflecting ongoing advancements, market developments, and the evolving needs. Newly established Research Programs (RPs) led by experts guide the research agenda, ensuring that CLARA remains agile, competitive, and responsive to emerging challenges.
Grant Lab for Fundraising and Growth • Deliverable D3.6 – Grant Lab Strategy • Deliverable D3.7 – Grant Lab Strategy - update	A central element in CLARA's sustainability plan is the Grant Lab, which functions as both a strategic platform and a physical office supporting the preparation of national, EU, and international grant proposals. Bringing together experienced project managers—who often have deep knowledge in social sciences, financial, and business fields—the Grant Lab increases CLARA's competitiveness, diversifies its funding sources, and fosters collaboration with early-stage researchers (e.g., ERC, MSCA) and broader European initiatives (e.g., COST Actions).
Business and Financial Strategy • Deliverable D6.2 – Business Plan • Deliverable D6.3 – Business Plan - update	CLARA's Business Plan (periodically updated and reflecting real-world revenues and cash flows) details multiple revenue streams to secure the project's financial health: **a.** Exploitation Revenues and Contractual Research: Licensing, intellectual property rights (IPR), and contractual projects with industrial partners. **b.** Grant Funding: Targeting national, European, and international resources with special attention to high-impact and collaborative grants.

	c. Fee-Based Services: E.g. access to the respective CLARA Testbed nodes if allowed by applicable rules, expert evaluations, consulting, and technology maturing services. **d**. Donor Program: Managed by the Technology Transfer Office (TTO), attracting philanthropic and corporate donations. **e**. Education & Training: Revenues from training workshops, scientific events, networking activities, and industry-oriented programs. **f.** Data/Testbed-Related Revenues: Income from offering customized solutions utilizing specialized data sets and advanced testbed infrastructure where possible and in compliance with applicable rules.
Long-Term Outlook and Risk Mitigation	By diversifying funding sources, developing robust industry collaborations, and maintaining active grant-seeking efforts, CLARA creates a resilient financial environment. The combined structure of grants, contractual research, fee-based services, donor programs, and training initiatives helps balance potential shortfalls.
Other initiatives that helps with achieving long-term goals	**a.** Tenure Track Policy for Scientific Excellence **b.** Assesses market trends and societal needs **c.** Clear KPIs, responsibilities, and an evaluation process **d.** CLARA Collaboratorium as a complex co-working and collaborative dynamic hub enabling co-creation activities, popularization of advancements of CLARA research

Conclusion

Neurodegenerative diseases pose a substantial and growing challenge to global healthcare systems. Although significant research efforts have yielded valuable insights into the mechanisms underlying these disorders, effective treatments remain limited, and cures continue to be elusive. Addressing this urgent healthcare issue requires comprehensive multidisciplinary research that integrates breakthroughs in genetics, molecular biology, artificial intelligence, and personalized medicine.

Through targeted stakeholder engagement – including patients, clinicians, industry partners, and policymakers – CLARA bridges the gap between fundamental research and real-world impact. This holistic approach, underpinned by sustainable funding models, rigorous IPR management, and aligned scientific objectives, positions CLARA as a leading European hub for innovation and excellence in the fight against neurodegenerative diseases.