

# Health-AI System Breakthrough Project

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**Planned duration** : 48 months

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## Summary

### 1. Problem analysis and proposed solution

The Health-AI project addresses the limited accessibility and availability of health data within the Dutch health sector, which impedes the development and validation of AI applications in health. This sector faces complex issues such as administrative inefficiencies, workforce retention concerns, health disparities, and suboptimal electronic data exchange. The "Integraal Zorgakkoord" (IZA) of 2022 has highlighted these challenges, projecting a need for 25% of the workforce to be employed in the health sector by 2040 and a threefold increase in health costs by 2060 if left unaddressed.

Artificial Intelligence (AI) holds the potential to mitigate these challenges by optimizing resource utilization, encouraging patient involvement, facilitating timely interventions, and streamlining administrative tasks. However, the effectiveness of AI in health relies on efficient access to patient data, which poses privacy concerns.

The Health-AI project proposes a transformative solution through federated AI development and validation. This approach establishes a secure and privacy-preserving ecosystem that allows various stakeholders, including health organizations, researchers, and companies, to collaborate in harnessing AI's power while safeguarding sensitive patient data. The project encompasses data provision, federated data infrastructure, AI algorithm development, privacy preservation, compelling use cases, and an open-source ethos.

Health-AI aims to revolutionize data accessibility, promising cost-effective, efficient, and equitable health delivery. It aspires to enhance health of individuals while bolstering the economic well-being of the Netherlands.

In the proof-of-concept phase, we successfully demonstrated a functional federated data infrastructure. This infrastructure allowed us to train a select set of AI algorithms using actual patient data from hospitals, all while maintaining privacy and avoiding the need for data sharing.

But further development is needed. AiNed's financial contribution is crucial to bridge the knowledge-translation gap, facilitating practical implementation and validation of federated AI development and addressing system failure, market stagnation, societal harm, and economic losses. This investment will unlock the potential of federated AI learning from sensitive data, benefiting both commercial entities and society, fostering innovation, economic prospects, and improved health outcomes. And not just for health, federated AI development and validation from sensitive data is of utmost outspoken interest to other sectors including the logistics, intelligence, crime, financial and energy sector.

### 2. Plan development and intended results

The Health-AI project is structured into four distinct work packages, each allocated a specific budget percentage:

Work Package 1 - Coordination (11%) focuses on ensuring effective project management, overseeing project coordination and objective adherence, document management and communication, dissemination, ethical, legal and societal aspects (ELSA), data and software management, security & privacy, intellectual property and exploitation.

Work Package 2 - Data (11%) aims to make health data Findable, Accessible, Interoperable, and Reusable (FAIR) within a federated setting across health organizations. This is essential for enhancing data privacy, security, and compliance while optimizing data utility for AI development.

Work Package 3 - Infrastructure (12%) provides the necessary technical foundation for secure federated AI model training. It enables the secure exchange of AI algorithms and results among project partners, supporting AI development and validation.

Work Package 4 - AI (66%) represents the core of the project, dedicated to achieving high Technology Readiness Levels (TRL) in open-source federated AI solutions. Within this work package, advanced AI innovations are developed, validated, and fine-tuned using real-world use cases and data.

The project anticipates benefits for various stakeholders, including citizens/patients, health organizations, health-related businesses, medical technology firms, health AI developers, governments, health insurance and pharmaceutical companies. It envisions AI supporting streamlined operations, improved prevention, diagnostic and treatment precision, and cost-effective interventions to address pressing health needs in the Netherlands.

Moreover, the project builds on federated learning approaches that ensure secure and privacy-preserving utilization of sensitive data. This approach maintains data integrity and supports advancements across industries reliant on sensitive data for AI development. As such its scope extends beyond health to encompass broader societal and economic value.

An important aspect of Health-AI is its empowerment of data holders, enabling active participation and benefits from AI advancements without compromising data security and privacy. Concurrently, the project is committed to developing open-source federated AI software with the potential to benefit diverse industries.

In summary, the Health-AI project adopts a comprehensive and pragmatic approach. It positions the Netherlands as a leader in responsible AI development, fostering sustainable growth, economic prosperity, and societal well-being. This narrative is characterized by innovation, collaboration, and responsible leadership within the AI domain.

### 3. Consortium

The Health-AI consortium comprises 16 organizations, including academic institutions, industry players, and health sector entities. Partner roles within the consortium are categorized into Coordinator (WP1), Data provider (WP2), Infrastructure provider (WP3), and AI user/developer (WP4). Compared to the proof-of-concept phase, the Health-AI consortium has expanded with eight additional partners.

All partners have committed themselves through the consortium agreement or letters of intent (LoIs) to access to the consortium, and are recipients of grants. The consortium embraces an open and inclusive approach, welcoming new partners with diverse perspectives and backgrounds. Prospective partners, including VGZ (an insurance company) and Janssen (a pharmaceutical giant), will participate in the External Advisory Board.

Health-AI actively incorporates foreign expertise and international connections, leveraging global knowledge and fostering collaboration beyond national boundaries. Partners like IQVIA and Philips, operating on a global scale, contribute extensive networks and health AI expertise. Knowledge-oriented partners have established international collaborations, extending the project's impact globally.

The project actively seeks collaboration and knowledge-sharing opportunities, engaging with various stakeholders, including NLAIC/AiNed initiatives (AI Hubs, ELSA Labs, Working group Health and upcoming ones such as Innovative Labs, Learning Communities, EU Collaboration, and Breaking

Barriers), Health-RI nodes, and European initiatives. This approach positions Health-AI as a catalyst for transformative advancements in health AI research and innovation.

The governance structure of Health-AI is based on the Horizon Europe DESCA model agreement. The General Assembly, composed of one representative from each partner, serves as the decision-making body. A project management team ensures adherence to deliverables and timelines, compliance, manages finances, and facilitates internal communication.

This governance framework establishes clear procedures for decision-making, conflict resolution, and risk management, providing a solid foundation for effective project management and collaboration. It allows for adaptability to accommodate the dynamic nature of the project.

#### 4. Financial substantiation

For this four-year project, the summarized budget is given in the below table. More details can be found in the full proposal.

Category	Partners	Activity	Funding rate	Total budget	In-kind contribution	Requested contribution
Private Partners – Small (<50)	Medical Data Works Brightlands Health-RI BranchKey Roseman Labs Linksight	Experimental Development Collaboration	60%	3.2M€	1.4M€	2.0M€
Private Partners – Medium (<250)	eScience	Experimental Development Collaboration	50%	0.8M€	0.8M€	0.8M€
Private Partners – Large (>250)	Philips Isala Maastro IQVIA	Experimental Development Collaboration	40%	3.0M€	1.8M€	1.2M€
Knowledge Institutions	Maastricht University Radboudumc UMCG TNO NKI-AVL	N/A	100%	1.0M€	0.0M€	1.0M€
TOTAL				9.0M€	4.0M€	5.0M€

There is no direct financial income expected during the project. The financial setback that might be expected is that meeting the deliverable takes more human resources and thus costs than budgeted. This will be absorbed by each individual party by increasing the in-kind contribution.

## 1 Suggested solution

### 1.1 The Challenge

The Health-AI project is a strategic response to a market and system failure within the Dutch health sector, a challenge of paramount importance. This challenge revolves around the limited accessibility and availability of health data, a crucial issue impeding the advancement and validation of AI applications in health.

The Dutch health sector, representing approximately 11% of the Gross Domestic Product (GDP) and currently employing 16% of the national workforce, confronts a complex array of issues. These encompass administrative inefficiencies, workforce retention concerns, disparities in health outcomes, and suboptimal electronic data exchange. Notably, the "Integraal Zorgakkoord" (IZA) of 2022 underscores these challenges and forewarns that without intervention, an alarming 25% of the workforce may need to engage in the health sector by 2040, a scenario that neither the labor market nor health affordability can accommodate. Moreover, the IZA cautions that without corrective measures, health costs could surge threefold by 2060.

Artificial Intelligence (AI), while not a panacea, holds the potential to mitigate these issues by aligning with core IZA principles: It can deliver value-driven care centered on the patient, optimize resource utilization, encourage patient involvement in care plans, facilitate timely interventions, shift the emphasis toward preventive health, and streamline administrative tasks for health professionals.

Nonetheless, the efficacy of AI in health hinges upon efficient access to and utilization of health data. A significant impediment arises from the sensitive nature of health data and reluctance to share it for broader research and development. Innovative solutions that prioritize patient privacy while enabling collaborative health data usage are urgently required to fully harness AI's potential.

The Health-AI project reimagines this market and system failure as an opportunity for transformation. It addresses key aspects such as cost reduction, heightened efficiency, and increased labor productivity through the deployment of AI-driven solutions. According to a 2023 study by McKinsey, widespread AI adoption for efficiency enhancement could result in health spending savings of 5 to 10 percent, amounting to 5 to 10 billion euros in the Netherlands with a large part of these savings reached through workforce reduction. Moreover, AI's contribution extends beyond efficiency gains to include more effective health, featuring earlier and improved diagnoses, personalized medicine, and quicker identification of promising treatments. The World Economic Forum's 2022 report on AI in health emphasizes that, as health's fourth industrial revolution accelerates, AI will play a crucial role in enhancing health efficiency and effectiveness.

Furthermore, the sensitivity of data is not exclusive to the health sector; it holds relevance for other industries such as finance, logistics, defense, and more. The secure and responsible handling of sensitive data thus has far-reaching implications beyond health, extending to broader data privacy and security concerns.

During our successful proof-of-concept phase, we demonstrated a deep understanding of this problem statement and showcased promising strategies to address it. However, these strategies require further development to reach a higher Technology Readiness Level (TRL) and widespread implementation.

In summary, the Health-AI project aspires to rectify the market and system failure prevalent in the Dutch health sector by revolutionizing data accessibility. This transformation, driven by AI innovations and privacy-preserving algorithms, promises cost-effective, efficient, and equitable health delivery. The endeavor not only enhances patient care but also augments the economic well-being of the Netherlands.

## 1.2 The System Breakthrough

The System Breakthrough Project Health-AI, represents a strategic initiative aimed at transforming the landscape of health by addressing a central challenge in the field of health AI—the accessibility and usability of sensitive patient data. In concrete terms, the project focuses on developing and implementing innovative solutions that enable the federated development and validation of AI applications. This project's core breakthrough is the creation of a secure, collaborative, and privacy-preserving ecosystem that empowers various stakeholders, including health organizations, academic researchers, and companies, to collectively harness the power of AI while safeguarding sensitive health information.

### Functional Description

At its core, the Health-AI undertakes a systematic approach to revolutionize how AI is developed and validated in health. This approach comprises several key components:

1. **Data FAIRification**: The project begins by creating a common data model that encompasses various types of health data, such as clinical, imaging, genomics, laboratory, treatment, and outcome data. It then defines a FAIR (Findable, Accessible, Interoperable, Reusable) implementation profile and knowledge graph to ensure data consistency and interoperability across health organizations.
2. **Federated Data Infrastructure**: Health-AI deploys and adapts federated data infrastructures in collaboration with multiple partners. These infrastructures facilitate secure and privacy-preserving connectivity of FAIR data points within health organizations. This forms the backbone for collaborative AI development and validation.
3. **AI Algorithm Development**: A critical aspect of the project involves the development, adaptation, and optimization of AI algorithms specifically tailored for federated data settings. These algorithms encompass a wide array of machine learning techniques, from traditional methods like logistic regression to advanced deep learning models like convolutional neural networks and transformers.
4. **Privacy Preservation**: The project places a strong emphasis on privacy preservation, actively evaluating different approaches to safeguard sensitive patient data during AI development and validation.
5. **Compelling Use Cases**: Health partners within the consortium collaborate to define compelling use cases that serve as showcases for the capabilities of the Health-AI solutions.
6. **Openness and Transparency**: Health-AI follows an open-source and open-access ethos, ensuring that AI innovations are accessible to a broad spectrum of stakeholders. This approach fosters an open and transparent market model for the development of AI applications, not only in health but also in other sectors.

### Technical Description

From a technical perspective, the project involves the establishment of data infrastructures that adhere to FAIR principles. These infrastructures connect health organizations securely, allowing the federated development of AI models across distributed data sources. To achieve this, various software tools for data preprocessing, analysis, and algorithm development are developed and integrated into the federated environment.

The AI algorithm development phase encompasses the implementation of AI models, covering the entire spectrum from conventional statistical techniques to cutting-edge deep learning algorithms. These models are fine-tuned to operate within a federated data ecosystem, enabling them to learn from distributed data while preserving data privacy and security.

Privacy preservation mechanisms are continually monitored and enhanced to ensure that patient data remains protected throughout the AI development and validation process. This includes encryption, anonymization, and other privacy-enhancing technologies.

The functional and technical elements mentioned above have been successfully implemented on a small scale, involving a subset of the Health-AI consortium partners during the proof-of-concept (PoC) phase. This phase provided concrete evidence of our capabilities, demonstrated through live use cases utilizing authentic patient data from multiple health organizations in a fully federated environment. These use cases encompassed various applications, including a cohort discovery dashboard, a logistic regression model for lung cancer patient survival prediction, and a clustering algorithm to find patients with similar outcomes.

Simultaneously, during the PoC phase, the main applicant, in collaboration with a select group of consortium partners, embarked on a global endeavor focused on federated deep learning, specifically utilizing a 3D U-Net model. This effort has already yielded the successful development and validation of an AI application designed to delineate lung tumors in three dimensions from CT scan data.

As a result, the PoC phase has instilled a high level of confidence in our ability to comprehend the problem at hand and effectively address it. We are poised to build upon the achievements of the PoC phase as we advance further into the Health-AI project.

The end product of the Health-AI System Breakthrough project is a transformative ecosystem where AI applications in health can be developed and validated collaboratively, efficiently, and securely. The combination of deliverables includes the following:

- *Common Data Model*: A standardized data model that encompasses diverse health data types.
- *FAIR Implementation Profile and Knowledge Graph*: A framework for ensuring data FAIRification and interoperability.
- *Federated Data Infrastructures*: Secure, privacy-preserving infrastructure for connecting health organizations.
- *AI Algorithms*: Developed and adapted AI algorithms optimized for federated data settings at high TRL.
- *Privacy Preservation Strategies*: Protocols and technologies to protect sensitive data during AI development.
- *AI applications*: Real-world health applications showcasing the capabilities of the Health-AI solutions.
- *Open-Source Tools*: Software tools and resources made accessible to the broader AI community.
- *Ethical, Legal, and Societal Aspect (ELSA) Guidelines*: A white paper outlining policies for responsible AI application development and fairness.

Ultimately, what changes at the end of the Health-AI project is the very nature of AI development and validation in health. It shifts from a fragmented, data-siloed process to a collaborative, privacy-preserving, and open ecosystem. This transformation empowers stakeholders to leverage the full potential of AI while respecting patient privacy, thereby revolutionizing the way health and AI intersect. The project's outcomes contribute not only to the advancement of health but also serve as a foundational resource for future AI initiatives, shaping the long-term trajectory of AI in various sectors, including health, finance, logistics, and more.

### 1.3 Motivation for contribution AiNed resources

AiNed's financial contribution is urgently needed to address the knowledge-translation gap in developing AI applications from sensitive patient data, mitigating system failure, market stagnation, societal harm, and economic losses.

In the current landscape, a glaring system failure is evident, where the theoretical foundations of federated AI development are well-established, yet practical implementation and validation remain underdeveloped. This critical gap jeopardizes the secure and reliable handling of sensitive data, hindering progress in health, research, and other sectors.

Market failure compounds this issue, stifling the potential of federated AI applications from sensitive data. Entry barriers deter market players from investing, leading to a lack of competition, innovation, and growth within the AI sector.

Societal damage is a stark consequence, as patients, researchers, and health providers are denied access to the transformative benefits of advanced AI solutions. This delay in AI technology adoption prolongs patient suffering and diminishes the overall quality and efficiency of health services.

Economic damage further exacerbates the problem, with economic stagnation affecting AI-focused companies that cannot develop and validate their solutions and increased health costs due to the absence of AI-driven solutions optimizing health processes, reducing errors, and enhancing care.

By funding this project, AiNed will foster innovation, leading to mature, adaptable, and well-documented solutions for federated AI learning. This support will also facilitate the creation of user-friendly demonstrators, reducing the learning curve and encouraging widespread adoption.

This investment will unlock the vast potential of federated AI learning from sensitive data, benefiting commercial entities and society at large. It is an opportunity to drive innovation, create economic prospects, and enhance health outcomes for the Netherlands.

## 2 Plan development

### 2.1 Describe the action plan

The Health-AI project, spanning four years with a budget of €9 million, is designed to ensure its feasibility and effectiveness in addressing the central challenge in the field of health AI—access to sensitive patient data. With 16 consortium partners spanning academia, industry, and health, the project is poised to make substantial contributions to the intersection of health, data, and AI.

The Health-AI project is well-founded and supported by a comprehensive plan. The consortium's composition, task allocation, and deliverables are all carefully structured to ensure that the project's system breakthrough objectives are both achievable and innovative. The approach is designed to ultimately expedite the development of high-TRL (Technology Readiness Level) solutions for federated AI development and validation and it is on this task where most time and budget is spent (66%). By focusing on well-established AI algorithms and tools and leveraging existing technology for federated data infrastructure and data FAIRification, the project can proceed efficiently.

Health-AI is committed to openness and transparency. The project operates on the premise that AI innovations should be accessible to a broad spectrum of stakeholders. By embracing an open-source and open-access ethos, Health-AI aims to create an open and transparent market model for its central application area —artificial intelligence in health. This approach ensures that companies, regardless of size, and academic researchers can utilize Dutch health sector data in a privacy-preserving manner to develop AI applications. Moreover, this open approach is not confined to the health sector, as the project's infrastructure and federated solutions can be adapted to other domains, such as finance and logistics – sectors in which our partners already operate. In essence, Health-AI's strategy fosters a more inclusive and equitable market model for the development of AI applications.

Health-AI is firmly embedded within the broader AI landscape in the Netherlands. The Health-AI project has its roots in the Netherlands AI Coalition (NLAIC) and continues to draw upon many of its NLAIC/AiNed initiatives and projects. Notably, this project is spearheaded by the NLAIC Brightlands AI hub. In addressing ethical, legal, and societal aspects (ELSA), we collaborate closely with the NLAIC/AiNed ELSA Lab Northern-Netherlands, facilitated through our partner UMCG. This lab, supported by AiNed, specializes in ELSA matters related to health. A vital component of Health-AI's outreach strategy involves engagement with the NLAIC working group on Health and participation in established Interhub meetings focusing on health-related AI. Given that all NLAIC AI Hubs share a common mission regarding health, this collaborative approach ensures the widest possible dissemination of Health-AI's outcomes.

Throughout the project, we actively seek interaction with existing and forthcoming NLAIC/AiNed initiatives, including innovation labs and "MIT" projects such as led by Deeploy (AI for mental health). Furthermore, we are committed to knowledge sharing and capacity building. To this end, we plan to collaborate on disseminating information and developing training programs for federated AI development. This effort will involve partnering with established NLAIC/AiNed learning communities initiated by applied universities and the newly formed "AI ready" learning community, with a dedicated focus on health-related applications. By engaging with these networks and communities, Health-AI aims to foster a collaborative and knowledge-sharing ecosystem that extends beyond the boundaries of the project, ultimately contributing to the broader landscape of AI in health.

Looking beyond the grant period, Health-AI envisions several structural changes. The project aims to bring about a fundamental shift in the landscape of health AI. By fostering an open and transparent market model, Health-AI lays the groundwork for sustainable, collaborative, and ethical AI development. This structural transformation will empower companies, researchers, and institutions to harness sensitive data responsibly while promoting innovation, fairness, and knowledge sharing within

the industry. The project's deliverables and outcomes will serve as a foundational resource for future AI initiatives, shaping the long-term trajectory of AI in health and beyond.

Health-AI's work plan is structured into two distinct phases. The initial phase includes foundational activities such as contract agreements, data preparation, infrastructure setup, and legal and technical groundwork. These activities are concentrated in the first 18 months, setting the stage for the subsequent phase which focuses on developing high-TRL solutions for federated AI development and validation. Led by a neutral foundation (eScience), Health-AI's main software development activities are designed in this latter phase to facilitate collaborative agile development leading to solutions which can easily be disseminated, valorized, maintained and further improved after the project.

Managing such a substantial consortium, comprising both commercial and non-commercial entities across health, technology, and knowledge sectors, embarking on a four-year journey demands impeccable coordination and management. The primary responsibility for coordinating these efforts falls upon the Brightlands AI hub in which partners MDW, Maastro, and Brightlands are co-located and participate. This physical proximity ensures streamlined communication and efficient day-to-day management. Overseeing the project is our experienced main applicant, well-versed in managing large-scale initiatives at the intersection of health, data, and AI. He will lead a proficient project management team, composed of work package leaders and supporting staff from various partners. This approach has already demonstrated its success during the proof-of-concept phase.

Beyond project coordination, Health-AI partners are tasked with addressing three key challenges, each delineated as a dedicated work package. WP2 is devoted to the critical objective of rendering health data Findable, Accessible, Interoperable, and Reusable (FAIR). Leveraging the expertise of Health-RI, the Dutch health initiative committed to constructing an integrated health data infrastructure for research and innovation, this foundation collaborates with five health organizations to ensure the FAIRness of sensitive patient data. Their support will be bolstered by a knowledge institute with a substantial track record in FAIR data management (UM) and a leading company specialized in assisting hospitals with data accessibility for research purposes (IQVIA).

WP3 focuses on deploying and enhancing the federated data infrastructure. Six proven infrastructure solutions, implemented by partners active in the Netherlands (Philips, MDW, TNO, BranchKey, Roseman Labs, LinkSight), are part of the Health-AI consortium. Under the guidance of Philips, a major technology company dedicated to health, these partners will ensure secure and privacy-preserving connectivity of FAIR data points within health organizations. This framework will enable a real-world test and implementation bed for federated AI development and validation. While these partners are competitors in the real world, the consortium's formation ensures that AI developments from Health-AI will be compatible with a variety of infrastructures, thereby promoting an open and transparent market model.

The heart of the project resides in WP4, where federated AI solutions will be developed collaboratively and in an open-source manner, guided by eScience. Knowledge institutions, health organizations, and companies will collaborate to create high-TRL tools for learning from federated data. And the health organization and companies IQVIA and Philips will develop AI use cases that show the Health-AI solutions lead to novel and groundbreaking health AI applications. The foundational principle of open source will underscore our efforts whenever feasible, promoting a proven open and transparent market model. This approach enhances the project's sustainability and instigates a structural shift and system breakthrough in the health AI landscape.

The project's Gantt chart, illustrating the task interdependencies within the work packages and the project's timeline and phasing, can be found in Appendix A.

In summary, Health-AI presents a comprehensive, well-planned project that not only addresses critical challenges in health AI but also contributes to the broader AI landscape in the Netherlands. Its commitment to openness, collaboration, and structural transformation positions it as a pivotal initiative in shaping the future of AI in health and other domains.

## 2.2 Work packages

WP	1 - Coordination			WP Leader			MDW	
Partner	MDW	UM	Philips	RUMC	UMCG	TNO	NKI-AVL	Isala
PM	24	3	6		4			
Partner	Maastro	Brightlands	Health-RI	eScience	BranchKey	RML	IQVIA	Linksight
PM	12	36	9	3				
<b><u>Objective:</u></b> To establish essential project management, collaboration mechanisms, and documentation, ensuring effective communication, compliance with legislation, ethical considerations, and standards for the Health-AI project.								
<b><u>Description:</u></b> In the initial phase of WP1, we will establish essential project management, reporting and collaboration mechanisms. This includes creating a project collaboration and documentation environment using Office 365, which will be continuously maintained throughout the project. We will also form the External Advisory Board (EAB) as one of the first actions (T1.1, MDW, Brightlands, Maastro, M01-M48). We will form the project management team (PMT), consisting of the main applicant, work package leaders and support staff from Maastro and Brightlands, conducting weekly PMT meetings and monthly consortium meetings to ensure effective communication and coordination. Additionally, we will organize a project kick-off meeting, inviting partners, EAB members, AiNed, and external stakeholders, marking the first of five annual meetings (Task 1.2, Brightlands, MDW, M01-M48). Early in the project, we will finalize crucial contractual agreements based on our experience from the proof-of-concept phase. These agreements cover consortium accessions, infrastructure usage, licensing, and joint data controller agreements. We will also stay updated on legislative developments, engaging in regular discussions within the consortium (T1.3, Health-RI, M01-M48). Our dissemination efforts will begin immediately, starting with press releases, website creation, and establishing a social media presence. As the project progresses, dissemination will shift towards sharing project results and knowledge with various stakeholders (T1.4, Brightlands, M01-M48). Moving forward, WP1 will focus on internal consortium tasks including a data management plan to ensure compliance with relevant legislation (T1.5, UM, M07-M18). Simultaneously, a software management plan will facilitate collaborative development of high-quality, well-documented, and high-TRL software within an open-source community. A sustainability plan for this community will be made (T1.6, eScience, M07-M24). Ethical, legal, and societal considerations will be documented in a white paper together with the NLAIC/AiNed ELSA-NN and the Health-RI ELSI community, guiding our policies to ensure responsible AI application development and promote fairness, competitiveness, and knowledge sharing within the industry (T1.7, UMCG, Health-RI, M07-M24). We will establish information security and privacy standards policies for the consortium's infrastructure (T1.8, Philips, M13-M24). In later stages, we will shift our focus to post-project activities, including developing an intellectual property management strategy (T1.9, Philips, M25-M48) and planning exploitation strategies (T1.10, Brightlands, M25-M48).								
<b><u>Deliverables (month, type)</u></b>								
D1.1: Reports (M06, M12, M18, M24, M30, M36, M42, M48, Document)								
D1.2: Annual meetings (M01, M12, M24, M36, M48, Document)								
D1.3: Consortium, infrastructure and data agreements (M12, Document)								
D1.4: Dissemination strategy (M12, Document)								
D1.5: Data management plan (M18, Document)								

- D1.6: Open source community (M18, Demo)
- D1.7: ELSA white paper (M18, Document)
- D1.8: Information security and privacy standards policy (M18, Document)
- D1.9: IP strategy (M36, Document)
- D1.10: Exploitation strategy (M36, Document)

WP	2 - Data				WP Leader		Health-RI	
Partner	MDW	UM	Philips	RUMC	UMCG	TNO	NKI-AVL	Isala
PM		12		12	12		12	12
Partner	Maastro	Brightlands	Health-RI	eScience	BranchKey	RML	IQVIA	Linksight
PM	12		24				12	

Objective: To establish a unified data model, create a FAIR implementation profile and knowledge graph, and configure tools for making data FAIR, ensuring efficient data handling and interoperability across health organizations.

Description: We will initiate WP2 by establishing a common data model, encompassing clinical, imaging, genomics/biological, laboratory, treatment, process, and outcome data, to facilitate collaboration across health organizations, ensuring a robust testing environment and enabling valuable health insights for the Health-AI solution developed in WP4, with each health organization seeking the necessary ethical approvals for their respective data (T2.1, NKI-AVL, UMCG, RUMC, Isala, Maastro, M01-M12).

Simultaneously, we will construct a FAIR implementation profile (FIP) and knowledge graph in collaboration with WP3, defining the specifics of FAIR data within our context, including syntactic and semantic interoperability aspects for the infrastructures of WP3. This detailed framework will guide the interoperability standards and formats for our data (T2.2, UM, Health-RI, M01-M18). Subsequently, we will employ the insights gained from the previous tasks to set up tools for rendering the data compliant with FAIR principles. This entails configuring Extract, Transform, Load (ETL) tools, data warehouses/marts, and mapping data elements to the target knowledge graph. Ultimately, we will establish these data as FAIR data points within each health organization to facilitate data access through the federated infrastructure of WP3. This process will include pseudonymization and enrichment steps as needed. This task will continue during the remainder of the project as per our experience both source and target data models change often given the use case. (T2.3, Health-RI, UM, NKI-AVL, UMCG, RUMC, Isala, Maastro, IQVIA, M01-M48).

#### Deliverables (month, type)

- D2.1: Common data model for Health-AI (M12, Document)
- D2.2: FAIR implementation profile and knowledge graph paper (M18, Document)
- D2.3: FAIR data points adhering to D2.1 and D2.2 at each health organization (M24, Demo)

WP	3 – Infrastructure				WP Leader		Philips	
Partner	MDW	UM	Philips	RUMC	UMCG	TNO	NKI-AVL	Isala
PM	15		15			15		
Partner	Maastro	Brightlands	Health-RI	eScience	BranchKey	RML	IQVIA	Linksight
PM			18		15	15		

Objective: To establish, deploy, and adapt federated data infrastructures to support the Health-AI project's AI development and validation process while ensuring compliance with information security and privacy standards.

Description: WP3 will initiate the establishment of necessary agreements between partners providing federated data infrastructures and collaborate with data providers to acquire IT resources through these health organizations' IT departments, followed by infrastructure deployment and testing using non-sensitive data, with ongoing support for data providers throughout the project (T3.1, Philips, MDW, TNO, BranchKey, RML, Linksight, M01-M48). In a second task, WP3 will

engage with end-users from WP4 to align infrastructure with AI development and validation needs, and collaborate with WP1 to ensure compliance with information security and privacy standards (T3.2, Health-RI, MDW, TNO, Philips, BranchKey, RML, Linksight, M13-M36).

*Deliverables (month, type)*

D3.1: All federated data infrastructures deployed (M18, Demo)

D3.2: Adherence to user and security/privacy requirements (M36, Document)

WP	4 – AI			WP Leader			UM	
Partner	MDW	UM	Philips	RUMC	UMCG	TNO	NKI-AVL	Isala
PM	23	13	84	7	3	4	7	36
Partner	Maastro	Brightlands	Health-RI	eScience	BranchKey	RML	IQVIA	Linksight
PM	75		30	154	33	33	48	33

*Objective:* To develop, adapt, and implement AI algorithms for federated AI development and validation in the context of health applications, encompassing literature reviews, software development, algorithm implementation and defining compelling use cases.

*Description:* WP4 initiates with a comprehensive literature review focused on federated AI development and validation, specifically within the realm of health applications, emphasizing narrow AI encompassing statistical, machine, and deep learning. This review will review horizontal and vertical partitioned data scenarios, recognizing the distinct mathematical and methodological requirements for each. A list of prevalent health AI algorithms will be made, establishing a foundation for subsequent tasks (T4.1, UM, M01-M12).

Concurrently, the consortium undertakes the migration of existing lower Technology Readiness Level (TRL) software to higher TRLs, addressing routine but essential AI project components that now demand a federated approach. These tasks encompass cohort discovery, dashboard development, data preprocessing including missing data imputation, outlier detection, categorization, and binning. It further encompasses statistical assessments to uncover biases across cohorts, as well as augmentation and internal validation techniques such as bootstrapping, oversampling, leave-one-out validation, cross-validation, and split-sample methodologies.

Federated external validation, AI performance and calibration reporting, and visualization are integral components of this phase. These applications are meticulously designed and tested for compatibility with the diverse infrastructures within WP3 (T4.2, eScience, MDW, TNO, BranchKey, RML, Linksight, IQVIA, Isala, Philips, Maastro, M01-M24).

Building upon the findings of T4.1, the consortium proceeds to implement select AI algorithms tailored for high TRL development, optimizing them for federated data settings. The specific algorithms to be employed will be determined, with the current knowledge encompassing LASSO, Logistic regression, SVM, Cox models, Random Forests, Bayesian networks, Gradient Boosting Machine, Deep learning (including CNNs, RNNs, GANs, and transformers), as well as clustering techniques such as k-means. Rigorous testing ensues across diverse WP3 infrastructures, utilizing the varied data types from WP2, and exploring various partitioning scenarios (T4.3, UM, UMCG, RUMC, NKI-AVL, TNO, eScience, MDW, BranchKey, RML, Linksight, IQVIA, Philips, M13-M48). In parallel, we will research privacy preservation of different approaches as the balance between privacy and usability of data is not the same in various permutations of AI algorithms, type and amount of data and data partitioning (horizontal/vertical) (T4.4, Philips, M13-M36).

Finally, health and industry partners within the consortium collaborate to define compelling use cases that serve as showcases for the Health-AI solution's capabilities (T4.5, Isala, IQVIA, Maastro, RUMC, NKI-AVL, Philips, M25-M48). Although the exact use cases will be decided later, examples of AI applications we expect to develop, in a federated manner, are ones that:

- Support self-medication of diuretics in chronic health failure patients (Bayesian Networks)
- Summarize electronic hospital records (Generative Transformers)
- Advise lifestyle interventions for cardiovascular risk reduction (Cause-specific hazard)
- Predict in Crohn's disease benefit from early biological therapy (LASSO, SVM, RF, XgBoost)

- Segment in 3D a lung tumor on a CT scan (CNN)
- Find “patients-like-me”, their treatments and outcomes (Clustering)
- Stain a pathology whole slide image virtually (GAN)
- Predict outcomes in rare anal cancer (Cox proportional hazards)

Deliverables (month, type)

- D4.1: Review paper on the current state of federated AI learning (M12, Document)  
 D4.2: Federated software tools for common tasks in AI development and validation (M24, Demo)  
 D4.3: Implemented AI algorithms in federated data settings (M36, Demo)  
 D4.4: Report on privacy preservation in federated AI development and validation (M36, Document)  
 D4.5: Report on AI applications developed using the Health-AI solutions (M48, Document)

## 2.3 Reporting

Our project's reporting approach aligns closely with the reporting guidelines established by NWO “Perspectief” as that is well known to us. We will submit regular progress reports that encompass:

- Detailed accounts of project activities undertaken.
- Substantiated indicators reflecting our progress.
- An inclusive list of project participants, along with their specific contributions.
- Breakdowns of participants' contributions, both total and individual, including in-kind contributions.
- Allocation of funding across various activities.
- Descriptions of how knowledge and results are disseminated and shared with external stakeholders.

We propose a reporting cycle every 6 month but will adhere to the any reporting policy AiNed dictates. The progress report will be prepared by the project management team with input and review by all partners.

In addition to the above, we will hold a hybrid annual meeting (one kick-off, three intermediate and one final meeting) in which internal and external stakeholders will be invited. These will include all partners, AiNed, the external advisory board and any other stakeholders with an interest in our project. A report of the Annual Meeting will be added to the regular progress report that follows the annual meeting. At the project's conclusion, we provide a final report adhering to AiNed requirements including all financial / audit requirements and will hold a final meeting in which the main outcome of the project is presented to all.

Reporting is led by partner **MDW** with support from **Brightlands** and **Maastro** as a task in WP1.

## 2.4 ELSA

Health-AI has the handling of sensitive personal data at its core and is committed to addressing ethical, legal, and societal aspects while fostering fairness, competitiveness, and knowledge-sharing. Through partner UMCG, Health-AI will work closely together with the ELSA AI lab Northern Netherlands (ELSA-NN) which focuses on health and is funded by NLAIC/AiNed. Partner Health-RI will also be very actively involved in addressing this topic through their ELSI community. Specifically, Health-AI will commit to the following principles:

Societal Aspects

- Active engagement with diverse stakeholders, including patients and the public, ensure societal perspectives shape the project.
- Regular consultations facilitate open dialogue with societal partners, reducing the risk of isolated decision-making.
- Ethical guidelines uphold individual rights, privacy, and societal benefits.
- Promotion of a fair and competitive industry environment, preventing monopolies and fostering knowledge sharing

### Ethical Aspects

- Rigorous ethical reviews uphold principles throughout the project, especially regarding sensitive patient data.
- Robust data privacy measures protect sensitive data.
- Guidance on consent to all partners ensures transparency and ethical standards.

### Legal Aspects

- Strict compliance with relevant legal and regulatory frameworks especially GDPR, AI act, EHDS and MDR
- Clear data ownership and rights agreements
- Legal considerations on liability and accountability incorporate safeguards for all parties

The above aspects are part of WP1 as a task of partners **UMCG** and **Health-RI** and will ensure AI applications are developed responsibly while promoting fairness, competitiveness, and knowledge-sharing.

## 2.5 (EU) Legislation

The Health-AI project prioritizes strict compliance with existing and upcoming legislation, including the European Union's AI Act, Medical Device Regulation (MDR), the European Health Data Space, the General Data Protection Regulation (GDPR), and associated Dutch laws. Here's how the project addresses each of these regulatory aspects:

### General Data Protection Regulation (GDPR)

Health-AI prioritizes GDPR compliance in all data processing and AI model development. Robust data protection measures, including federated learning, de-identification and encryption, will safeguard sensitive data. Transparent consent mechanisms and privacy impact assessments will be integral to GDPR compliance.

### EU AI Act

Health-AI commits to adapting swiftly to the forthcoming EU AI Act, assessing its requirements, and ensuring compliance. The project will rigorously test, validate, and monitor AI applications to meet the Act's safety and performance standards.

### Medical Device Regulation (MDR)

Health-AI recognizes that most health AI applications will fall under MDR. It will support the post-project success of these applications to conform to MDR's safety and performance requirements, by implementing rigorous documentation and quality management processes.

### European Health Data Space

Health-AI focuses on secure, interoperable data management and sharing to comply with the European Health Data Space. Collaboration with stakeholders will promote data standardization and portability while respecting privacy and data protection regulations.

### Associated Dutch Laws

Health-AI acknowledges the relevance of Dutch laws in health and data governance. The project aligns with national regulations that complement EU laws, ensuring seamless integration into the Dutch legal framework.

The above aspects are part of WP1 and will ensure Health-AI considers all relevant legislation. This task will be led by partner **Health-RI**.

## 2.6 Dissemination

In the Health-AI project we are committed to effective knowledge sharing, communication, and outreach, particularly relevant to companies developing health AI applications.

### Knowledge Sharing

- Cross-Collaboration: We prioritize close collaboration both among project members and with outside parties from diverse backgrounds. The consortium is also very open to the accession of new members. This collaborative mindset accelerates the exchange of expertise and insights crucial for developing health AI models using federated sensitive data.
- Knowledge Hub: Our website will host a knowledge repository that is easily accessible, housing research papers, datasets, and essential documentation relevant to federated health AI development. This central hub streamlines access to project-related knowledge critical for innovators and companies in this field.

### Publishing

- Specialized Journals: Publishing in specialized journals is considered the primary way to reach AI researchers and foster new collaborations with both academia and industry.
- AI-Specific Conferences: Participation in AI-specific conferences allows us to showcase our findings, gather invaluable feedback, and demonstrate how our work might benefit others.

### Communication

- Website: Our online platform provides stakeholders, including health AI companies, with real-time updates on our AI development objectives, progress, and outcomes, ensuring they can access relevant information tailored to their needs.
- Social: Leveraging social media and online health AI communities, we actively share key milestones and engage with a broader audience, including companies, interested in AI development from federated sensitive health data.
- Engagement with the NLAIC: We will make sure our work features prominently in meetings, conferences and communications of the NLAIC to demonstrate a successful implementation of the NLAIC/AiNed approach.

### Outreach

- Stakeholder Involvement: We engage in ongoing dialogues with relevant stakeholders, including health AI practitioners and industry leaders, to understand their specific needs and concerns. This ensures that our AI development approach aligns with real-world requirements in the health AI sector.
- Webinars and Workshops: Organizing webinars and workshops dedicated to AI development from federated sensitive health data allows us to facilitate knowledge exchange and foster discussions around its implementation and impact, actively involving health AI companies.

The above aspects are part of WP1 and will ensure our knowledge sharing, publishing, communication, and outreach efforts are tailored to enhance the understanding and adoption of this specific approach to AI development. This task will be led by partner **Brightlands** which will work closely with the working group Health of the NLAIC, the other NLAIC Hubs and the existing and upcoming learning communities.

## 2.7 Data

In the Health-AI approach, sensitive data is sourced through a federated approach, emphasizing data ownership and strict adherence to data privacy regulations, such as GDPR and EHDS. Data remains under the control of the original data holders, primarily health organizations.

To facilitate this, contractual agreements are established for each federated AI development use case. These agreements define data acquisition specifics, data processing procedures, the intended AI application, and responsible parties for data, AI applications, and infrastructure. These agreements also outline roles and liabilities in cases of data breaches or security incidents. Existing infrastructure and consortium agreements, developed and signed during the proof-of-concept phase, address these aspects comprehensively and these agreements will be made available as open access for use by others.

The project's outcomes are designed to enable continued use within the value chain. Federated data infrastructure solutions are readily available from various vendors, including some Health-AI partners. The federated AI development and validation applications will be open-source, allowing accessibility and adaptation to evolving needs.

However, third-party access to health data is subject to individual contractual arrangements, as health regulations necessitate clear purposes for data usage. As such, the solution's extensibility to third parties, market entrants, or other organizations in the value chain is contingent upon establishing specific contractual agreements tailored to each use case. Health organizations cannot provide health data without knowing the precise intended use, aligning with legal requirements.

The above considerations will be written down in a data management plan at the start of the project and continuously updated, which is a task of partner **UM** in WP1.

## 2.8 Open (Source)

The Health-AI project is committed to open and transparent practices in its results and collaboration.

As a principle, all foreground source code generated by the project will be made openly accessible under the permissive Apache license. This allows for broad usage, collaboration, and further development within the AI and health communities. The code will be hosted on GitHub, facilitating easy access and contributions.

Dissemination artifacts, including project findings and documentation, will be openly available under a CC BY license. This ensures that outcomes are accessible to a wide audience, fostering transparency and knowledge sharing. While we aim for openness, health data used in the project cannot be made open due to legal constraints.

Although open source and open access are our principles, we recognize that there may be situations where open source or open access is not or no longer appropriate. This can be due to reasons of legislative, commercial or other reasons. Therefore, before results are made public, a review will take place within the consortium allowing each partner to object to making the results public. If a motivated objection is received, the consortium will discuss and use its governing body (General Assembly) to reach a decision.

Within the consortium, partners may contribute background knowledge, some of which may be proprietary. To safeguard the project's openness, consortium agreements are structured to ensure that proprietary background knowledge does not hinder the project's results or subsequent use. This alignment follows the EU-DESCA model agreement, fostering collaboration without compromising openness.

The task of managing open source aspects within the project, including code sharing and licensing, falls under the responsibility of partner **eScience** in WP1.

## 2.9 Documentation

In the Health-AI project, our approach to project documentation is structured and efficient, serving two distinct purposes.

The first category encompasses project communications, agreements, decisions, reports, presentations, and publications. To streamline this aspect, we utilize the Office 365 suite, hosted by our partner Maastro, building on the successful practices established during the proof-of-concept phase. This ensures clear and organized documentation of project-related activities and milestones.

The second category focuses on documenting the core project outcomes, primarily in the form of software. Our consortium follows an agile software development approach, emphasizing collaboration, user feedback, and incremental deployment. To manage and document this software effectively, we rely on GitHub (and associated products) and the experience and policies of our partner eScience. They have developed a comprehensive "national practical guide to software management plans," which will guide our software management and documentation efforts.

The responsibility for establishing and maintaining these documentation policies and environments lies with a collaborative effort between partner **Maastro, MDW** and **eScience** in WP1.

## 2.10 Data quality

Ensuring data quality, precise algorithms, and robust data analysis are central pillars of the Health-AI project.

The heart of our project lies in the development of high-TRL, high-quality AI algorithms and data analysis applications. These critical components must be mathematical and methodological correct, user-friendly, efficient, comprehensively documented, and utilize local compute resources optimally. We will vigorously test our algorithms so that they meet these criteria.

Furthermore, we recognize that algorithms should also be findable, accessible, interoperable and reusable. In Health-AI we thus feel that FAIR is not just about data but also about services. Our algorithms will therefore be described, cataloged, and accessible in a FAIR manner that promotes seamless integration and utilization.

While data quality is a shared responsibility between AI developers and health organizations, we embrace a dynamic perspective. Rather than defining data quality in absolute terms, we emphasize the notion of fitness for purpose. In essence, data quality is contingent on the specific AI development or validation use case at hand. Health-AI partners have a proven approach for this that involves identifying, curating and then FAIRification of data that aligns with the intended purpose.

We would like to stress that we do not do FAIR data for FAIR's sake. Rather, when data resides across health organizations we need these data to be FAIR for federated AI development and validation efforts to be possible. In other words, our FAIRification process will not transform data into open data, but it ensures that within a federated infrastructure, machines can seamlessly locate, access, and interpret sensitive health data.

The FAIRification of data and services will be jointly led by partners **UM** and **Health-RI** in WP2 and WP4.

## 2.11 Security, privacy

The Health-AI project is designed with privacy at its core. Through a federated infrastructure, we eliminate the need for personal data sharing. This approach inherently aligns with GDPR data protection principles, including Purpose limitation, Data minimization, Lawfulness, fairness, and

transparency, and Integrity and confidentiality.

We furthermore rely on established infrastructure solutions provided by our partners. These solutions are built with security in mind, adhering to industry standards and best practices. They incorporate essential features such as robust encryption, multi-factor authentication, and fine-grained authorization controls. Moreover, many of our partner organizations hold ISO27001 certifications or are in the process of obtaining these, signifying their commitment to rigorous information security policies.

Additionally, our data providers, health organizations, are bound by Dutch law to meet the stringent NEN 7510 information security standard, further reinforcing the security of the data within our project.

Establishing information security and privacy standards and the adherence to these within the consortium, is a task of partner **Philips** in WP1.

## 2.12 Intellectual Property

In the Health-AI consortium agreement, we adopt an intellectual property (IP) approach aligned with the EU DESCA model agreement, emphasizing openness in the foreground and flexibility in the background. The agreement main points with respect to IP are:

### Foreground

Results generated within the project, including code and findings, are treated with openness and are designated as open source. This ensures that project outcomes are accessible, encouraging collaboration and further development.

### Sideground

Many Health-AI partners are actively developing and improving their products and services that include (federated) health data infrastructures and health AI applications. These improvement and innovations may occur during but outside the project. Such sideground results remain with the generating party and are considered outside the project scope.

### Background

Background knowledge contributed by partners may vary, with the option for it to be proprietary or open as determined by each partner. This flexibility respects the preferences of individual partners while fostering collaboration.

### Ownership and Access Rights

As stated above, Health-AI follows open source and open access principles, but (see section “Open Source”) there may arise a situation where this is not possible or desirable. In that case, ownership of results remains with the generating party. In cases where contributions cannot be separated, joint ownership is established, allowing each joint owner to use, license, and grant licenses to third parties. Fair and reasonable compensation is provided in the case of third-party involvement, and protection measures are agreed upon in advance. Access rights are granted based on necessity for implementation or exploitation, ensuring fairness and adherence to IP terms. These rights are crucial for utilizing project outcomes effectively.

The IP management is a task in WP1 of partner **Philips**.

## 2.13 Patents

The Health-AI project itself does not plan to pursue patents. However, as it aims to simplify AI development on sensitive data, it potentially leads to new insights and patent opportunities outside the project scope (Sideground).

## 2.14 Sustainability

To ensure the sustainability of Health-AI's primary outcome, which is the creation of advanced, well-documented solutions for federated AI development and validation, we are adopting a proven strategy: fostering an open source community. This approach has consistently demonstrated long-term viability in collaborative software development, particularly within the fields of computer science and AI.

A noteworthy example of the successful collaboration between academia and industry in sustaining open source projects is the Apache Software Foundation. Apache hosts a wide array of projects, including Hadoop for big data analytics and Apache Spark for machine learning. These projects have garnered active participation from both academic institutions and leading tech companies, resulting in ongoing development, improvements, and widespread adoption.

Another compelling illustration is TensorFlow, an open source machine learning framework developed by Google. TensorFlow has evolved into a thriving ecosystem with contributions from academic researchers, startups, and tech giants like Intel and NVIDIA. This collaborative effort has not only sustained TensorFlow's relevance but also accelerated its growth and innovation.

In a similar vein, Health-AI aims to cultivate a dynamic open source community that bridges the gap between academia and industry. This community will continue to refine and expand the app store, ensuring its sustainability long after the subsidized phase of the project concludes. Through active participation, contributions, and ongoing development, we anticipate that Health-AI's solutions will remain at the forefront of federated AI development and validation.

In the project a sustainability plan will be written as a task of WP1 led by partner **eScience**.

## 2.15 Exploitation

Within the Health-AI project, we anticipate multiple promising avenues for future exploitation and valorization.

First, a significant opportunity awaits in the domain of health organizations. Health-AI's innovative federated data infrastructure promises to empower these entities, enabling them to effectively utilize their sensitive health data while maintaining ethical and legal integrity. Recent development such as the European Health Data Space, show that the inherent costs associated with providing health data is recognized, and our approach offers a sustainable means for data provision including cost recovery. Health organizations can act as responsible data stewards while facilitating data usage for research and innovation, including potential collaborations with commercial entities.

Our project furthermore has the potential to substantially enrich the market landscape for infrastructure providers. Health-AI represents a paradigm shift in the accessibility and usability of these infrastructures. This transformation is expected to attract a broader user base and expand market opportunities for infrastructure providers, providing them with a compelling value proposition.

Developers of Health AI applications are also poised to benefit significantly from our project's outcomes. Our high-TRL, streamlined federated AI development and validation software will enable them to create innovative solutions more efficiently, thus accelerating the pace of AI-driven advancements in health.

Beyond health, Health-AI holds cross-sector opportunities. Many of our project partners have established a strong presence in sectors beyond health. Our project's outcomes, particularly its ability to work with sensitive data, unlock new frontiers for innovation and commercialization across various domains, including personal, business, and government data applications.

Notably, Health-AI embraces an open-source approach for its primary results, promoting an open and transparent market model. This commitment ensures accessibility and encourages collaboration within the broader AI development community.

Partner **Brightlands** will take the lead in crafting an exploitation strategy tailored to the unique needs of various stakeholders as a task in WP1.

### 3 Consortium and Cooperation

#### 3.1 Composition

The Health-AI consortium is a powerful coalition of 16 organizations, each contributing unique expertise and capabilities to the project. This consortium, comprised of partners from academia, industry, and the health sector, forms the cornerstone of the project's mission to revolutionize the field of health AI and federated data. Partner roles within Health-AI are categorized into four primary roles: Coordinator (WP1), Data provider (WP2), Infrastructure provider (WP3), and AI user/developer (WP4). Below is an overview of each partner's expertise, size (classified as small company <50, medium <250, or large >250 employees), and their specific roles in the Health-AI project:

- 1. Medical Data Works B.V. (MDW):** MDW is a small company specializing in open-source, federated health data solutions. Their primary role is as the Coordinator of the project, and they also serve as Infrastructure providers and AI developers.
- 2. Maastricht University (UM):** UM is a large knowledge institute with a commitment to education and research in health care and artificial intelligence. They play a primary role as AI developers and a secondary role as Coordinators.
- 3. Philips Electronics Nederland B.V. (Philips):** Philips is a large global health technology company with a significant presence in the commercial sector. They primarily serve as Infrastructure providers and play secondary roles as AI users/developers and Coordinators.
- 4. Stichting Radboud universitair medisch centrum (RUMC):** RUMC is a large knowledge institute and academic medical center involved in patient care and research. They are Data Providers primarily and AI users/developers secondarily.
- 5. University Medical Center Groningen (UMCG):** UMCG is a large knowledge institute, academic medical center, and one of the Netherlands' largest hospitals. They primarily act as Data Providers and secondarily as AI users/developers and Coordinators.
- 6. Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek – TNO (TNO):** TNO is a large knowledge institute dedicated to applied scientific research. They primarily serve as Infrastructure providers and secondarily as AI developers.
- 7. Stichting Het Nederlands Kanker Instituut – Antoni van Leeuwenhoek Ziekenhuis (NKI-AVL):** NKI-AVL is a large knowledge institute comprising a renowned research institute and a large cancer clinic. Their primary role is as Data Providers, with a secondary role as AI users/developers.
- 8. Stichting Isala Klinieken (Isala):** Isala is a large hospital foundation providing health services. They primarily serve as Data Providers and secondarily as AI users.

These eight partners were instrumental in the successful PoC phase of Health-AI. The consortium has expanded with eight additional partners for the next phase:

- 9. Maastro Clinic (Maastro):** Maastro is a large foundation and top-clinical institute dedicated to cancer treatment and research. Their primary role is as Data Providers, with secondary roles as AI users and Coordinators.
- 10. Campus Heerlen Management & Development B.V. (Brightlands):** Brightlands is small company specializing in managing innovation communities and lead the Brightlands AI hub with a focus on data, AI and health. They primarily serve as Coordinators.

**11. Stichting Health-RI (Health-RI):** Health-RI is a small foundation working to build an integrated health data infrastructure for research and innovation. They primarily act as Data Providers and secondarily as Coordinators.

**12. Stichting Netherlands eScience Center (eScience):** eScience is a medium-sized foundation dedicated to enhancing the use of computing and digital technologies in academic research. They primarily serve as AI developers and secondarily as Coordinators.

**13. BranchKey B.V.(BranchKey):** BranchKey is a small company providing federated machine learning solutions. They primarily act as Infrastructure providers and secondarily as AI developers.

**14. Roseman Labs B.V. (RML):** RML is a small company specializing in privacy technology based on secure multi-party computation. They primarily serve as Infrastructure providers and secondarily as AI developers.

**15. IQVIA Solutions B.V. (IQVIA):** IQVIA is an affiliate of a large global company operating at the intersection of health information technology and clinical research. They primarily serve as AI users/developers and secondarily as Data Providers.

**16. Linksight B.V. (Linksight):** Linksight is a small company offering privacy-friendly analysis and easy and secure data collaborations between multiple parties. They primarily serve as Infrastructure providers and secondarily as AI developers.

The above 16 partners have committed themselves either through signing the consortium agreement (all partners from the PoC phase) or signing a letter intent (LoI) to do so (new partners) and will be grant recipients. Both the consortium agreement and the LoIs can be found in the Appendix B. Besides the PoC many current and previous collaborations exist between the partners. All have at some point worked together with at least one other partner in the consortium.

This consortium forms a robust and multidisciplinary partnership perfectly suited to achieving the Health-AI project's breakthroughs and action plan. Each partner's distinct expertise and resources significantly enhance the consortium's collective ability to advance AI applications in health and establish an open and transparent market model for this critical domain.

Besides these consortium partners, additional stakeholders have expressed their willingness and interest to interact with this consortium, but could not become members due to time or budget constraints. These stakeholders include all university medical centers of the Netherlands, health insurance company VGZ and pharmaceutical company Janssen. These organizations and patient advocacy groups will be invited to the annual meeting and will be asked to delegate members to the external advisory board.

In terms of further development and scaling up of project results, different partners have various strategies. Infrastructure providers can expand their AI algorithm offerings, while data providers can work more efficiently with AI developers. Large companies will leverage Health-AI to meet customer needs more effectively, and organizations with societal missions will scale up services to the innovation community at the intersection of data, health, and AI. This collaborative effort ensures that Health-AI's impact will extend beyond the project's conclusion, positively influencing the health landscape.

### 3.1.1 Open structure

Health-AI is committed to openness and inclusivity, embodying a diverse consortium of partners, ranging from small to large, commercial to non-commercial entities. The consortium agreement has already incorporated provisions for new partners to accede. This approach has been effectively implemented, with the consortium welcoming eight new partners and thus doubling the size of the consortium following the proof-of-concept phase, even in cases where they may be direct competitors. This open-door policy underscores the consortium's willingness to embrace fresh perspectives and foster collaboration.

Notably, Health-AI has attracted partners with diverse approaches and backgrounds, making it an inclusive and expansive initiative. For instance, the consortium now counts the eScience Center, a foundation driven by a societal mission and a commitment to open-source principles, among its members. Conversely, it has also seen the inclusion of IQVIA, a data-driven commercial entity, highlighting the consortium's capacity to accommodate a wide spectrum of contributors.

Furthermore, the consortium's openness extends beyond its traditional boundaries. Prospective partners like VGZ, an insurance company, and Janssen, a pharmaceutical giant, have expressed a keen interest in joining Health-AI, affirming their commitment by participating in the external advisory board. This willingness to engage with diverse sectors showcases the consortium's flexibility in welcoming valuable input and perspectives from other domains. Our dissemination strategy will build on this openness and will ensure newcomers will be able to find and engage with us.

Health-AI partners are actively engaged in cross-sector collaborations that promote cross-pollination of ideas and foster promising connections. For instance, partners UM and MDW have established collaborations with the Fiscal Information and Investigation Service (FIOD), banks, and the police in the fight against subversive crime, demonstrating the consortium's adaptability in engaging with partners from non-health sectors. Additionally, partner BranchKey operates across various sectors, including maritime, energy, finance, and security, showcasing how Health-AI encourages crossover interactions with domains beyond health.

In summary, Health-AI is a clear example of an open and inclusive consortium that actively welcomes newcomers, embraces diverse perspectives, and actively collaborates across sectors.

### 3.1.2 International connections

The Health-AI project actively incorporates foreign expertise and international connections, demonstrating a commitment to leveraging global knowledge and fostering collaboration beyond national boundaries.

Large commercial partners such as IQVIA and Philips are prominent participants in the consortium. These global companies operate on an international scale, and their involvement ensures that the project benefits from their extensive global networks and expertise in health and AI. This international perspective contributes to the project's mission to advance AI in health on a global level.

Knowledge-oriented partners (UMCG, UM, RUMC, TNO, NKI- AVL) within the consortium have established numerous international collaborations. These collaborations extend the reach of the project's impact beyond Dutch borders. By engaging with international research and academic communities, the consortium gains access to a wealth of global knowledge and expertise, fostering innovation and excellence.

Brightlands is primarily working in the Euregional context of the Netherlands, Belgium, and Germany, exemplifies the project's regional-to-global approach. The collaboration within this cross-border region facilitates cross-pollination of ideas and expertise, enriching the project with a diverse set of insights.

Even small companies like MDW have extensive international networks spanning Asia, Australia, North America, South America, and Europe. These global connections demonstrate that the project's impact extends far beyond the Netherlands, thanks to the diverse backgrounds and reach of its partners.

In summary, the Health-AI project embraces foreign expertise and international collaborations, acknowledging the value of global connections and knowledge sharing. By doing so, the consortium

enhances its capabilities, fosters innovation, and positions itself to contribute significantly to the advancement of AI in health on a worldwide level while preventing any undue leakage effects of investments.

### 3.1.3 Collaboration, knowledge sharing

Opportunities for collaboration, knowledge sharing, and synergies with existing links and programs are integral to the Health-AI project. The consortium actively seeks to leverage and exploit various avenues for collaboration and knowledge exchange with knowledge institutions, civil society organizations, consumer organizations, regional development agencies (ROMs), and knowledge networks. Key opportunities and strategies include:

*Brightlands AI Hub:* The Brightlands AI Hub - co-funded by the Province of Limburg - plays a crucial role in fostering collaboration, exploitation, and dissemination. As one of the AI Hubs within the Netherlands AI Coalition (NLAIC), it is strategically positioned to share the knowledge and outcomes of Health-AI with the other seven hubs, all of which share a focus on health-related AI applications. This cross-hub collaboration offers substantial potential for synergies and knowledge transfer.

*Health-RI Limburg:* The main applicant is the head of node for Health-RI Limburg and holds a pivotal position in disseminating Health-AI's results to other Health-RI nodes. Health-RI's engagement spans analytical perspectives, ethical, legal, and social aspects (ELSA), as well as participation in the FAIR data community. This multifaceted involvement opens up additional opportunities for collaboration within the Health-RI ecosystem.

*Collaborative Initiatives:* Health-AI has a direct link to ELSA North Netherlands through partner UMCG, reinforcing the collaborative approach to ethical, legal, and social considerations. Furthermore, the consortium actively participates in the NLAIC working group on Health, ensuring alignment with other AI initiatives within the Netherlands.

*Monitoring European Collaborations:* Health-AI partners are engaged in ongoing European-funded projects and collaborations. The project remains vigilant in monitoring opportunities for further collaboration and funding calls at the European level, allowing for potential synergy and expansion of the project's impact.

*AiNed Program Components:* Health-AI strategically aligns with other components of the AiNed program, such as ELSA Labs (ELSA-NN), AI-Hubs and the NLAIC working group Health. It will continue to do so with any relevant upcoming initiative such as Innovative Labs, Learning Communities, EU Collaboration, and Breaking Barriers. These interconnections will enable the project to draw upon existing initiatives, share knowledge, and capitalize on synergies across the broader NLAIC/AiNed ecosystem.

In summary, Health-AI actively seeks collaboration and knowledge-sharing opportunities, recognizing the importance of leveraging existing links and programs to maximize its impact. The project's engagement with various stakeholders, including AI Hubs, Health-RI nodes, and European collaborations, ensures a well-rounded and interconnected approach to advancing health-related AI research and innovation. By fostering collaboration at regional, national, and international levels, Health-AI positions itself as a catalyst for transformative advancements in health AI.

## 3.2 Governance

The governance and organization of the Health-AI project are modeled in accordance with the Horizon Europe project model and the DESCA model agreement, both familiar to most partners. The key elements of the governance structure are as follows:

*General Assembly:* The General Assembly serves as the central decision-making body of Health-AI. Comprising one representative from each partner involved in the project, it empowers each member to actively participate in discussions and decisions related to consortium activities. MDW, the

coordinator, also acts as a partner member and facilitates General Assembly meetings. Decisions made within the General Assembly hold binding authority for all partners.

**Operational Procedures:** The General Assembly follows established operational procedures to ensure transparency and efficiency. Annual meetings are scheduled, with MDW responsible for convening both ordinary and extraordinary sessions. All members receive adequate notice and agendas before meetings, allowing for the inclusion of additional agenda items through unanimous agreement during sessions.

**Decision-Making:** Decisions within the General Assembly are typically reached through a two-thirds majority vote. Each member present or represented holds one vote. Veto rights are granted to partners if a decision significantly impacts their interests, provided there is a written justification. Resolution efforts are undertaken for vetoed decisions to achieve a consensus.

**Minutes:** MDW maintains comprehensive records of each meeting, producing draft minutes shared with all members within ten calendar days. Acceptance of these minutes occurs unless a member raises an objection within 15 calendar days. Accepted minutes serve as the official record of decisions made.

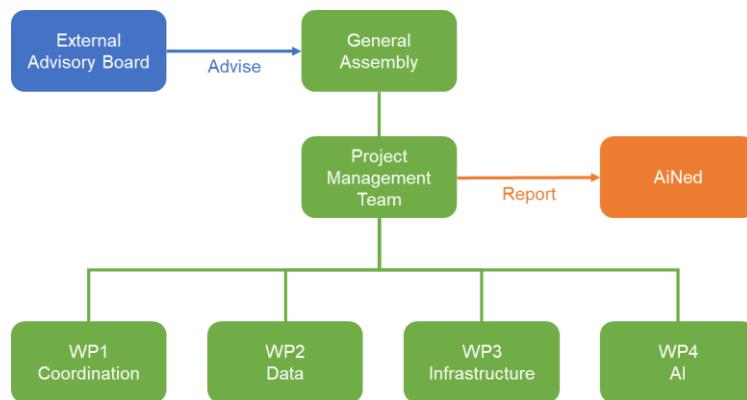
**Scope of Decisions:** The General Assembly exercises decision-making authority across various aspects, including content, finances, intellectual property rights, partner entry and withdrawal, breach identification, defaulting partner remedies, partner terminations, and changes to the coordinator.

**MDW's Role:** MDW, in addition to being a partner member, acts as the Coordinator and serves as the intermediary between consortium partners and AiNed, the funding body. MDW's responsibilities encompass monitoring compliance, contact information management, collecting and submitting reports and deliverables to AiNed, chairing General Assembly meetings, financial contribution management, and communication facilitation.

**Change of Coordinator:** In the event of MDW failing in its coordination tasks, the General Assembly retains the authority to propose changing the coordinator to AiNed.

The outlined governance structure, as detailed in the Consortium Agreement, establishes well-defined procedures for decision-making, communication, conflict resolution, and risk management within the Health-AI consortium. It ensures that all partners collaborate effectively toward the project's objectives, with MDW playing a central role in coordinating these activities.

The General Assembly convenes yearly at the annual consortium meeting, while a project management team, including MDW, Maastro, and Brightlands and all WP leaders, will meet weekly and manage operational project coordination, providing managerial support for various work packages.



This proposed governance structure provides a solid foundation for effective project management and collaboration, ensuring that roles and responsibilities are clearly defined and that decision-making processes are both decisive and transparent. It allows for adaptability and evaluation, as necessary, to accommodate the dynamic nature of large, multi-year programs.

## 4 Financial underpinnings

### 4.1 Motivation

The project activities in Health-AI constitute a coherent whole, with a direct and logical link between the various activities and their associated costs, for several compelling reasons:

**Comprehensive Approach:** Health-AI addresses the development and validation of federated AI solutions for health comprehensively. It encompasses coordination, incl. ELSA, security/privacy, dissemination and exploitation (WP1), real patient data for multiple health organization (WP2), multiple federated infrastructures (WP3) and federated AI model development, validation and real-world use cases (WP4), ensuring a holistic approach to health AI.

We would like to point out we have considered earlier criticism that the funding should be directed more to AI development and use cases (WP4) than to data (WP2) and infrastructure (WP3). This had now been integrated into the budget (see chart)

**Interdependence:** The project components are interdependent. Without a data and privacy-preserving infrastructure, federated AI model development and real-world health applications would be severely limited. Conversely, without AI model development and real-world applications, the federated data infrastructure's value would diminish.

**Proof-of-Concept (PoC):** The success of the PoC phase demonstrated the feasibility and value of the proposed activities and that the partners can work together well. The subsequent phase builds upon this foundation to achieve broader impacts.

**Diverse Expertise:** The consortium comprises partners with diverse expertise, ranging from data providers to AI developers and infrastructure providers. Each partner contributes a unique aspect, making their collective effort essential for success.

**Health Impact:** Ultimately, the project aims to improve health outcomes through AI-driven solutions. Realizing this goal requires a unified approach involving all project components.

As for other financiers, while the primary funding source is the subsidy mentioned, the Health-AI project leverages significant in-kind contributions from the participating consortium partners meeting the requirements.

Regarding the phase after the subsidy period, the vision is to ensure the sustainability and scalability of the project's outcomes. This includes:

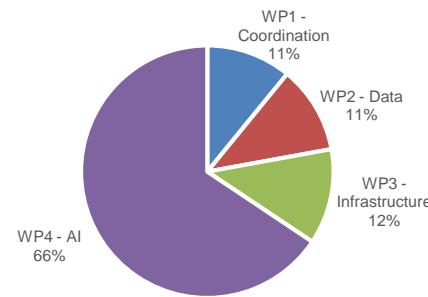
**Continued Collaboration:** Partners have prior to this project and will after the project maintain collaborations established during the project, ensuring ongoing support and development of AI solutions in health.

**Market Readiness:** Efforts will be directed towards refining and commercializing Health AI applications developed as sideground during the project, making them available for broader use within the health sector.

**Scaling Impact:** Partners will explore opportunities to expand the project's impact nationally and internationally, potentially involving additional stakeholders, institutions, and regions.

**Sustainability:** Strategies will be developed (WP1) to ensure the sustained operation of data infrastructure and AI models beyond the project's duration, potentially involving commercialization or integration with health systems in the Netherlands or abroad.

In summary, the Health-AI project's components are intricately linked, forming a cohesive whole essential for success. The project leverages both subsidy and partner investments, with a focus on



sustainability and scalability beyond the subsidy period, ensuring the continued advancement of AI in health.

## 4.2 Budget

Our costing framework operates under the assumption that the average salary scale for personnel possessing the necessary expertise corresponds to scale 11.2, in accordance with the Dutch universities' collective labor agreement. This aligns with the criteria outlined by the national science foundation NWO for individuals with academic qualifications. Employing the direct labor cost + 50% rule as a basis, we have budgeted an average annual labor cost of €10,158.22 per person-month (PM). It is important to emphasize that the number of person-months is provided as a reference, with the monetary amount being the primary determinant utilized in the subsequent budgeting process.

WP	Task	Partner	PM	Amount
1 Coordination	1.1 Management	MDW	12	€ 121,899
		Brightlands	12	€ 121,899
		Maastro	12	€ 121,899
	1.2 Communication	Brightlands	12	€ 121,899
		MDW	12	€ 121,899
	1.3 Agreements	Health-RI	6	€ 60,949
	1.4 Dissemination	Brightlands	6	€ 60,949
	1.5 Data management	UM	3	€ 30,475
	1.6 Software management	eScience	3	€ 30,475
	1.7 ELSA	UMCG	4	€ 40,633
		Health-RI	3	€ 30,475
	1.8 Information security	Philips	3	€ 30,475
	1.9 Intellectual property	Philips	3	€ 30,475
	1.10 Exploitation	Brightlands	6	€ 60,949
Subtotal			97	€ 985,348
2 Data	2.1 Common data model	NKI-AVL	6	€ 60,949
		UMCG	6	€ 60,949
		Isala	6	€ 60,949
		RUMC	6	€ 60,949
		Maastro	6	€ 60,949
	2.2 FAIR implementation profile	Health-RI	24	€ 243,797
		UM	3	€ 30,475
	2.3 Data FAIRification	NKI-AVL	6	€ 60,949
		UMCG	6	€ 60,949
		Isala	6	€ 60,949
		RUMC	6	€ 60,949
		Maastro	6	€ 60,949
		IQVIA	12	€ 121,899
Subtotal			99	€ 1,005,664
3 Infrastructure	3.1 Infrastructure provision	Philips	9	€ 91,424
		MDW	9	€ 91,424
		TNO	9	€ 91,424
		BranchKey	9	€ 91,424
		RML	9	€ 91,424
		Linksight	9	€ 91,424
	3.2 Infrastructure end-user engagement and security	Health-RI	18	€ 182,848
		MDW	6	€ 60,949
		TNO	6	€ 60,949
		Philips	6	€ 60,949

		BranchKey	6	€ 60,949
		RML	6	€ 60,949
		Linksight	6	€ 60,949
Subtotal			108	€ 1,097,088
4 AI	4.1 Literature review	UM	6	€ 60,949
	4.2 Federated common data science tasks	eScience	24	€ 243,797
		MDW	11	€ 111,740
		BranchKey	12	€ 121,899
		RML	12	€ 121,899
		Linksight	12	€ 121,899
		IQVIA	12	€ 121,899
		Isala	12	€ 121,899
		Philips	12	€ 121,899
		Maastro	27	€ 274,272
4.3 Federated AI algorithms	UM	7	€ 71,108	
	UMCG	3	€ 30,475	
	TNO	4	€ 40,633	
	eScience	130	€ 1,320,569	
	MDW	12	€ 121,899	
	BranchKey	21	€ 213,323	
	RML	21	€ 213,323	
	Linksight	21	€ 213,323	
	IQVIA	12	€ 121,899	
4.4 Privacy preservation in federated AI	Philips	48	€ 487,595	
	4.5 AI use cases	Health-RI	30	€ 304,747
		Isala	24	€ 243,797
		IQVIA	24	€ 243,797
		Maastro	48	€ 487,595
		RUMC	7	€ 71,108
		Philips	24	€ 243,797
Subtotal		NKI-AVL	7	€ 71,108
			583	€ 5,922,244
<b>Total</b>			<b>887</b>	<b>€ 9,010,344</b>

### 4.3 Financing

The funding allocation for each partner is determined by the organization's classification, denoted as S (Small), M (Medium), L (Large), or K (Knowledge Institute). Private partners conduct exclusively "experimental development" work, supplemented by the collaboration component. It is important to reiterate that the provided number of person-months serves as a reference, with the monetary amount being the primary factor in determining funding distribution and determining the required co-funding.

Partner	Type	Co-funding		Funding rate	Subsidy
		PM	Amount		
MDW	S	25	€ 251,924	60%	€ 377,886
UM	K	0	€ -	100%	€ 193,006
Philips	L	63	€ 639,968	40%	€ 426,645
RUMC	K	0	€ -	100%	€ 193,006
UMCG	K	0	€ -	100%	€ 193,006
TNO	K	0	€ -	100%	€ 193,006
NKI-AVL	K	0	€ -	100%	€ 193,006
Isala	L	29	€ 292,557	40%	€ 195,038
Maastro	L	59	€ 603,398	40%	€ 402,266
Brightlands	S	14	€ 146,278	60%	€ 219,418
Health-RI	S	32	€ 329,126	60%	€ 493,690

eScience	M	79	€ 797,420	50%	€ 797,420
BranchKey	S	19	€ 195,038	60%	€ 292,557
RML	S	19	€ 195,038	60%	€ 292,557
IQVIA	L	36	€ 365,696	40%	€ 243,797
Linksight	S	19	€ 195,038	60%	€ 292,557
<b>Total</b>			<b>€ 4,011,482</b>		<b>€ 4,998,861</b>

#### 4.4 Reporting and accountability

The Health-AI project maintains a robust system for internal and external financial reporting, ensuring transparency, accountability, and compliance with established regulations. The consortium comprises partners with extensive experience in financial reporting across diverse subsidy situations.

Additionally, Maastro, a partner with a wealth of expertise in leading multi-stakeholder projects, will take responsibility for this.

The reporting cycle is structured to occur every six months, providing regular updates on financial activities. A well-established Excel-based reporting template (see figure), based on successful project management practices from previous endeavors, serves as the foundation for financial reporting.

Each partner, encompassing both funded and in-kind costs, is responsible for submitting a comprehensive financial report every six months to the project lead, MDW. These reports form the basis for the subsequent end-of-project audit report, ensuring financial integrity and adherence to regulatory standards.

Partners are well-versed in the regulations outlined on the official website (<https://www.rvo.nl/onderwerpen/subsidiespelregels/ezk>), including the requirement for an audit report following the project's conclusion. This knowledge ensures that reporting aligns with stipulated guidelines and expectations.

In addition to financial reporting, partners are required to provide a concise written progress report detailing advancements in tasks and deliverables outlined in the project plan. This dual reporting structure ensures that not only financial aspects but also project progress are closely monitored and evaluated.

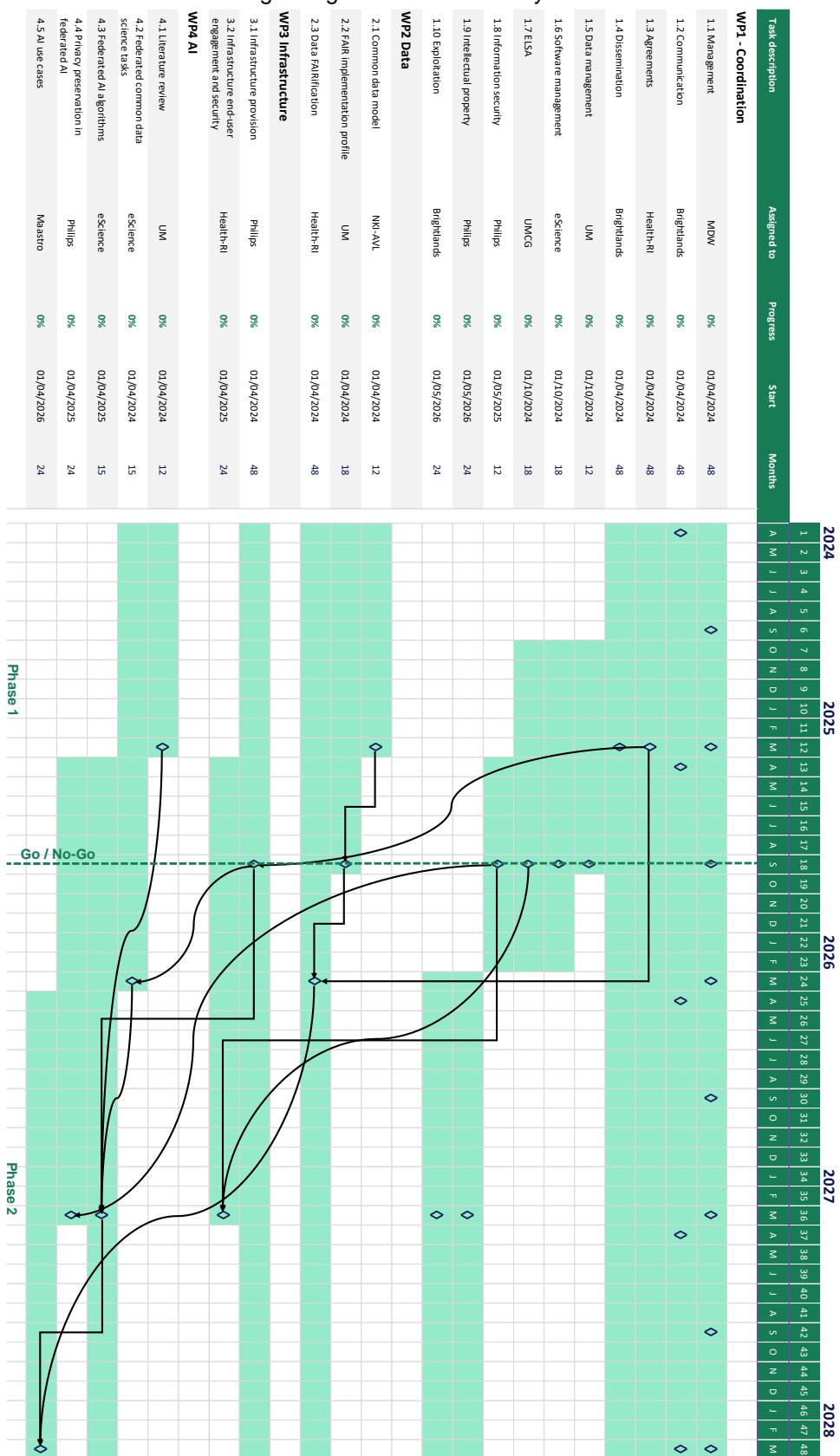
Furthermore, MDW, as the lead party, implements a pre-financing payment system that disburses each partner's share every six months, contingent upon the submission of both the financial report and the progress report of the last period. This practice reinforces the importance of delivering high-quality reports consistently and fosters accountability within the consortium.

By integrating rigorous financial reporting mechanisms, Health-AI maintains a transparent and accountable approach to project management. This framework ensures that financial and project progress information is readily available, contributing to the successful execution of the initiative while adhering to regulatory standards.

A		B	C	D	E	F
1	Health-AI: Use of Resources Report	Periodic Reporting Period	1		From Jan 2024 to Mar 31 2024	
2						
3						
4						
5	Beneficiary Short Name					
6	Beneficiary number					
7	PM rate					
8						
9						
10	WP1					
11	T1.1	Funded				
12	T1.2	In-kind				
13	T1.3	Funded				
14	T1.4	In-kind				
15	T1.5	Funded				
16	T1.6	In-kind				
17	T1.7	Funded				
18	T1.8	In-kind				
19	T1.9	Funded				
20	T1.10	In-kind				
21	T1.11	Funded				
22	T1.12	In-kind				
23	T1.13	Funded				
24	T1.14	In-kind				
25	T1.15	Funded				
26	T1.16	In-kind				
27	T1.17	Funded				
28	T1.18	In-kind				
29	T1.19	Funded				
30	T1.20	In-kind				
31	<b>TOTAL Personnel Costs</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-</b>	
32		Type	Expenses		Cost	
33	T1.1	Funded				
34	T1.2	In-kind				
35	T1.3	Funded				
36	T1.4	In-kind				
37	T1.5	Funded				
38	T1.6	In-kind				
39	T1.7	Funded				
40	T1.8	In-kind				
41	T1.9	Funded				
42	T1.10	In-kind				
43	T1.11	Funded				
44	T1.12	In-kind				
45	T1.13	Funded				
46	T1.14	In-kind				
47	T1.15	Funded				
48	T1.16	In-kind				
49	T1.17	Funded				
50	T1.18	In-kind				
51	T1.19	Funded				
52	<b>Total Other goods, works and services</b>				<b>-</b>	
53	<b>Subtotal WP1</b>				<b>-</b>	
54						

## A. Appendix - Gantt Chart

The Gantt chart below consists of all tasks and the lead partner for that task. The diamonds indicate deliverables/milestones in those tasks. The lines indicate the interdependency between the deliverables. The dotted line is the go-no go decision boundary at M18.



## B. Appendix - Consortium Agreement and Letters of Intent

## **CONSORTIUM AGREEMENT**

This Consortium agreement is entered into on March 1<sup>st</sup> 2023, hereinafter referred to as the Effective Date

### **BETWEEN:**

**Medical Data Works B.V.**, having its principal office at Dr Tanslaan 12, 6229ET, Maastricht, The Netherlands, hereinafter referred to as "Coordinator" or "MDW".

AND

**Philips Electronics Nederland B.V.** having its principal office at High Tech Campus 52, 5656 AG, Eindhoven, the Netherlands, hereinafter referred to as "PEN".

AND

**Maastricht University**, more specifically the Faculty of Health, Medicine and Life Sciences/ School for Oncology and Reproduction (GROW), with its principal office at Universiteitssingel 40, 6229 ER Maastricht hereinafter referred to as "UM"

AND

**Stichting Radboud universitair medisch centrum** having its offices at Geert Grootplein 10 P.O Box 9101, 6500HB in Nijmegen, the Netherlands registered with the company register of the chamber of Commerce and Industries for Centraal Gelderland, Arnhem the Netherlands as number 80262783 represented by, J.Sjoerts, MSc, Director Valorisation/Technology Transfer acting as its legal representative hereinafter referred to as "RUMC".

AND

**University Medical Center Groningen**, established by virtue of the Higher Education and Research Act (Wet hoger onderwijs en wetenschappelijk onderzoek), having its principal office at Hanzeplein 1, 9713 GZ Groningen, the Netherlands, represented by a member of the Board of Directors, on behalf of its Department of Radiation Oncology, hereinafter referred to as "UMCG"

AND

**Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek – TNO**, having its principal office at Anna van Burenplein 1, 2595 DA Den Haag, the Netherlands , hereinafter referred to as "TNO"

AND

**Stichting Het Nederlands Kanker Instituut – Antoni van Leeuwenhoek Ziekenhuis** with its principal office at Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands hereinafter referred to as "NKI-AVL".

AND

**Stichting Isala Klinieken** with its principal office at Dokter van Heesweg 2, 8025 AB Zwolle, The Netherlands, hereinafter referred to as "Isala"

hereinafter, jointly or individually, referred to as "Parties" or "Party"

**PoC-fase Ketenproject: Stichting AiNed**

hereinafter referred to as "Project"

**WHEREAS:**

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project and a request for a project funding at the Stichting AiNed.

The Stichting AiNed has decided to award funding to this Project.

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the Project Agreement (see Annex 4), in a separate agreement (hereinafter "Consortium Agreement").

The Stichting AiNed program description, the Project Plan and the Budget Plan are an integral part of the Consortium Agreement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

## **1 Definitions**

### **1.1 Definitions**

Words beginning with a capital letter shall have the meaning defined either herein or in the Project Agreement including its Annexes.

#### **"Affiliate" or "Affiliates"**

Affiliate or Affiliates means, in relation to either Party, any legal entity which is directly or indirectly (i) owned or controlled by that Party; (ii) owning or controlling that Party; or (iii) owned or controlled by the legal entity owning or controlling that Party, but any such legal entity shall only be considered an Affiliate for as long as such ownership or control exists.

For the purpose of this definition, a legal entity is "controlled" if more than 50% (fifty per cent) of its voting stock is owned by the controlling legal entity or if such controlling legal entity has the ability to direct the business activities of the legal entity or to appoint the majority of the directors of the legal entity concerned.

#### **"Consortium Plan"**

Consortium Plan means the combination of the Project Plan, the related Budget Plan and the Stichting AiNed program description, as first defined in the Project Agreement.

#### **"Controlled Licence Terms"**

Controlled Licence Terms means terms in any licence that require that the use, copying, modification and/or distribution of Software or another computational work (hereinafter referred to as "Work") and/or of any computational work that is a modified version of or is a derivative computational work of such Work (in each case, "Derivative Work") be subject, in whole or in part, to one or more of the following:

- a) (where the Work or Derivative Work is Software) that the Source Code or other formats preferred for modification be made available as of right to any third party on request, whether royalty-free or not;

- b) that permission to create modified versions or derivative works of the Work or Derivative Work be granted to any third party;
- c) that a royalty-free licence relating to the Work or Derivative Work be granted to any third party.

For the avoidance of doubt, any Software licence that merely permits (but does not require any of) the things mentioned in (a) to (c)) is not a Controlled Licence (and so is an Uncontrolled Licence).

**“Controller”**

Controller means the legal entity or natural person which alone or jointly with others determines the purposes and means of processing of Personal Data.

**“Coordinator”**

The coordinator is the Party which is the central contact point for the Stichting and represents the consortium towards the Stichting. The Coordinator has to be part of the Consortium Plan and needs to be one of the Parties receiving contributions from the Stichting.

**“Stichting”**

means the body awarding the contribution for the Project: Stichting AiNed.

**“Defaulting Party”**

Defaulting Party means a Party, which the General Assembly has identified to be in breach of this Consortium Agreement and/or the Project Agreement as specified in Section 4.2 of this Consortium Agreement.

**“Force Majeure”**

Force Majeure means any one or more events beyond the control of the relevant Party, which occur(s) after the date of signing of this Consortium Agreement, were not reasonably foreseeable at the time of signing of this Consortium Agreement, and the effects of which are not capable of being overcome without unreasonable expense and/or unreasonable loss of time and/or resources to the Party concerned. Events of Force Majeure shall include, without limitation, war, civil unrest, natural disasters, exceptional weather conditions, breakdown or general unavailability of transport facilities, accidents, fire, explosions, pandemics and general shortages of energy.

**“General Assembly”**

The General Assembly is the governing body within the project governance structure serving as the ultimate decision board for the Project.

**“Indirect Utilisation”**

Indirect Utilisation means that Access Rights for Exploitation granted pursuant to this Consortium Agreement and the Project Agreement shall include the right for a Party and its Affiliates to whom such Access Rights are granted, to have a third party make, only for the account of and for the use, sale or other disposal by such Party's and its Affiliates' products and/or services, provided that the substantial portion of the specifications of such products and/or services has been designed by or for such Party and such Affiliates.

**“Needed”**

means:

*For the implementation of the Project:*

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

*For Exploitation of own Results:*

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

**“Personal Data”**

Personal Data means any information relating to an identified (or identifiable) individual.

**“Project Agreement”**

Project Agreement means the contract signed between the Coordinator and the Stichting AiNed as given in Annex 4.

**“Software”**

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.

## **2 Purpose**

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning inter alia liability, ownership of Results, Access Rights and dispute resolution.

## **3 Entry into force, duration and termination**

### **3.1 Entry into force**

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorised representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

A legal entity becomes a new Party to the Consortium Agreement upon signature of the accession document (Attachment 2) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

### **3.2 Duration and termination**

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the Project Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement.

If

- the Project Agreement is not signed by the Stichting or a Party, or
- the Project Agreement is terminated, or
- a Party's participation in the Project Agreement is terminated,

this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement.

### **3.3 Survival of rights and obligations**

The provisions relating to ownership of Results, Access Rights, Dissemination and confidentiality, for the time period mentioned therein, as well as for liability, applicable law, settlement of disputes and all other provisions which by nature should survive the termination of this Consortium Agreement shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Project incurred prior to the date of termination, unless otherwise agreed between the General Assembly and the leaving Party. This includes the obligation to provide all necessary input, deliverables and documents for the period of its participation.

The Parties agree that if a Party requests to terminate its participation in this Consortium Agreement, this request will be considered as a request for termination in the Project Agreement. The provisions of the Project Agreement and of this Consortium Agreement regarding termination shall apply as hereafter complemented.

If a Party wishes to terminate its participation in the Project Agreement and this Consortium Agreement, it shall send a request in writing to the Coordinator. Such request shall fully set out the reasons for which such withdrawal is deemed necessary. The Coordinator submits the request to the respective General Assembly, who may require that the withdrawing Party, in the interest of the Project, fulfills certain conditions.

In case of one Party's withdrawal, the other Parties shall use reasonable endeavors to reach a timely agreement on how to reallocate the requesting Party's tasks under the Consortium Plan, and their related budget and Stichting's contribution, so that the overall objectives of the Project can still be met after the Party's withdrawal. Following the decisions above, the Coordinator shall promptly notify the Stichting, for its approval and any needed Project Agreement amendment procedure.

## **4 Responsibilities of Parties**

### **4.1 General principles**

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Project Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by applicable law.

Each Party undertakes to notify promptly the Stichting and the other Parties, in accordance with the governance structure of the Project, of any significant information, fact, problem or delay likely to affect the Project.

Each Party shall promptly provide all information reasonably required by the Coordinator to carry out its tasks.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties and promptly correct any error therein of which it is notified. Each Party shall not knowingly make available to other Parties any information or materials where such provision violates third party rights.

The Parties agree that a Material Transfer Agreement shall govern all transfers of materials in the frame of the Project. Parties may use their own template for such an agreement.

#### **4.2 Breach**

In the event that the General Assembly identifies a breach by a Party of its obligations under this Consortium Agreement or the Project Agreement (e.g. improper implementation of the Project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the General Assembly, will give formal notice to such Party requiring that such breach will be remedied within 30 calendar days from the date of receipt of the written notice by the Party.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the General Assembly may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof which may include termination of its participation.

#### **4.3 Involvement of third parties**

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities or other Participants) in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement and of the Project Agreement. Such Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Project Agreement.

#### **4.4 Compliance**

Specifically, each Party shall ensure that its work on the Project complies fully with all applicable local, government and international laws, regulations and guidelines that are effective during the period of the Project Agreement, including those governing health and safety and data protection. In this regard, each Party shall maintain the confidentiality, in accordance with this Consortium Agreement, of all samples and data relating to the use of human subjects, which is created or used in the course of the Project.

Each Party shall secure all necessary approvals from the relevant research ethics committees before undertaking any part of the Project requiring ethics committee approval and shall, if required, obtain proper consent and acknowledgement forms from any human subjects or their legal guardians who they will involve in the Project. Where any part of the Project takes place in a hospital, the Party involved shall first obtain all necessary approvals and agreements from that hospital, when required.

## **5 Liability towards each other**

### **5.1 No warranties**

In respect of any information or materials (incl. Results and Background), other than Personal Data, supplied by one Party to another (or its Affiliates) under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties, unless otherwise stated in this Consortium Agreement.

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Party granting Access Rights shall be liable vis-à-vis any of the other Parties in case of infringement of proprietary rights of a third party resulting from any other Party (or its Affiliates) exercising its Access Rights.

### **5.2 Limitations of contractual liability**

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts.

A Party's aggregate liability towards the other Parties collectively shall be limited to once the Party's share of the total costs of the Project as identified in the Project Agreement.

A Party's liability shall not be limited under either of the two foregoing paragraphs to the extent such damage was caused by a wilful act or gross negligence or to the extent that such limitation is not permitted by law.

In case of a breach of a Party's obligations under Section 10 of this Consortium Agreement a party's total liability shall be limited to twice the Party's share of the total cost of Project.

### **5.3 Damage caused to third parties**

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

### **5.4 Force Majeure**

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the General Assembly of any Force Majeure without undue delay, describing the Force Majeure event, its anticipated duration and use reasonable efforts to resume performance as soon as possible. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notice, the transfer of tasks - if any - shall be decided by the General Assembly.

### **5.5 Import and Export control**

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement due to a restriction resulting from import or

export laws and regulations and/or any delay of the granting or extension of the import or export license or any other governmental authorisation, provided that the Party has used its reasonable efforts to fulfil its tasks and to apply for any necessary license or authorisation properly and in time.

Each Party will notify the General Assembly of any such restriction without undue delay. If the consequences of such restriction for the Project are not overcome within 6 weeks after such notice, the transfer of tasks - if any - shall be decided by the General Assembly.

## **6 Governance structure**

### **6.1 General structure**

The organisational structure of the consortium shall comprise the following Consortium Bodies:

The **General Assembly** is the decision-making body of the consortium.

The **Coordinator** is the legal entity and one of the Party members, acting as the intermediary between the Parties and the Stichting. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Project Agreement and this Consortium Agreement.

### **6.2 Members**

The General Assembly shall consist of one representative of each Party (hereinafter referred to as "Member").

Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in Section 6.3.7 of this Consortium Agreement.

The Coordinator shall chair all meetings of the General Assembly, unless decided otherwise by the General Assembly.

The Parties agree to abide by all decisions of the General Assembly.

This does not prevent the Parties from exercising their veto rights, according to Section 6.3.5, or from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in Section 11.8 of this Consortium Agreement.

### **6.3 Operational procedures for the General Assembly:**

#### **6.3.1 Representation in meetings**

Any Member:..

- should be present or represented at any meeting;
- may appoint a substitute or a proxy to attend and vote at any meeting;
- and shall participate in a cooperative manner in the meetings.

### **6.3.2 Preparation and organisation of meetings**

#### **6.3.2.1 Convening meetings**

The chairperson shall convene ordinary meetings of the General Assembly at least once every six months and shall also convene extraordinary meetings at any time upon written request of any Member.

#### **6.3.2.2 Notice of a meeting**

The chairperson shall give written notice of a meeting to each Member as soon as possible and no later than 14 calendar days preceding an ordinary meeting and 7 calendar days preceding an extraordinary meeting.

#### **6.3.2.3 Sending the agenda:**

The chairperson shall prepare and send each Member an agenda no later than 14 calendar days preceding the meeting, or 7 calendar days before an extraordinary meeting.

#### **6.3.2.4 Adding agenda items:**

Any agenda item requiring a decision by the Members must be identified as such on the agenda.

Any Member may add an item to the original agenda by written notice to all of the other Members no later than 7 calendar days preceding the meeting and 2 days preceding an extraordinary meeting.

#### **6.3.2.5**

During a meeting of the General Assembly the Members present or represented can unanimously agree to add a new item to the original agenda.

#### **6.3.2.6**

Meetings of the General Assembly may also be held by tele- or videoconference or other telecommunication means.

#### **6.3.2.7**

Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 6.3.6.2.

### **6.3.3 Decisions without a meeting**

Any decision may also be taken without a meeting if

- a) the Coordinator circulates to all Members of the General Assembly a written (even via email) suggested decision with a deadline for responses of at least 10 calendar days after receipt by a Party and
- b) the decision is in writing (even via email) agreed by 51 % of all Parties.

The Coordinator shall inform all the Members of the outcome of the vote.

A veto according to Section 6.3.5 may be submitted up to 15 calendar days after receipt of this information.

The decision will be binding after the Coordinator sends a notification to all Members. The Coordinator will keep records of the votes and make them available to the Parties on request.

#### **6.3.4 Voting rules and quorum**

##### **6.3.4.1**

The General Assembly shall not deliberate and decide validly in meetings unless two-thirds (2/3) of its Members are present or represented (quorum).

If the quorum is not reached, the chairperson of the General Assembly shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members is present or represented.

##### **6.3.4.2**

Each Member present or represented in the meeting shall have one vote.

##### **6.3.4.3**

A Party, which the General Assembly has declared according to Section 4.2 to be a Defaulting Party, may not vote nor shall its presence account for the necessary quorum. The Coordinator may not vote on decisions regarding a proposal to the Stichting for a change of the Coordinator.

##### **6.3.4.4**

Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

#### **6.3.5 Veto rights**

##### **6.3.5.1**

A Party which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of the General Assembly may exercise a veto with respect to the corresponding decision or relevant part of the decision. The exercise of the veto shall be supported by a written justification by the Party exercising such veto. The justification will be made available to all Parties.

##### **6.3.5.2**

When the decision is foreseen on the original agenda, a Party may only veto such a decision during the meeting.

##### **6.3.5.3**

When a decision has been taken on a new item added to the agenda before or during the meeting, a Party may veto such decision during the meeting or within 15 calendar days after receipt of the draft minutes of the meeting.

#### 6.3.5.4

When a decision has been taken without a meeting a Party may veto such decision within 15 calendar days after receipt of the written notice by the chairperson of the outcome of the vote.

#### 6.3.5.5

In case of exercise of veto, the Parties shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all Parties.

#### 6.3.5.6

A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.

#### 6.3.5.7

A Party requesting to leave the consortium may not veto decisions relating thereto.

### **6.3.6 Minutes of meetings**

#### 6.3.6.1

The chairperson shall produce minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send draft minutes to all Members within 10 calendar days of the meeting.

#### 6.3.6.2

The minutes shall be considered as accepted if, within 15 calendar days from receipt, no Party has sent an objection to the chairperson with respect to the accuracy of the draft minutes by written notice.

#### 6.3.6.3

The chairperson shall send the accepted minutes to all the Members, and to the Coordinator, who shall retain copies of them.

### **6.3.7 Decisions of the General Assembly**

The General Assembly shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein.

The following decisions shall be taken by the General Assembly:

Content, finances and intellectual property rights

- Proposals for changes to the Project Agreement to be agreed by the Stichting
- Changes to the Consortium Plan to be agreed by the Stichting
- Modifications or withdrawal of Background in Attachment 1 (Background Included)
- Additions to Attachment 3 (List of Third Parties for simplified transfer according to Section 8.3.2)

Evolution of the consortium

- Entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party, to be agreed by the Stichting
- Withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal, to be agreed by the Stichting
- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Project Agreement
- Declaration of a Party to be a Defaulting Party
- Remedies to be performed by a Defaulting Party
- Termination of a Defaulting Party's participation in the consortium and measures relating thereto, on which the Stichting needs to be informed
- Proposal to the Stichting for a change of the Coordinator
- Proposal to the Stichting for suspension of all or part of the Project
- Proposal to the Stichting for termination of the Project- and the Consortium Agreement

In the case of abolished tasks as a result of a decision of the General Assembly, Members shall rearrange the tasks of the Parties concerned. Such rearrangement shall take into consideration any prior legitimate commitments which cannot be cancelled.

## **6.4 Coordinator**

### **6.4.1**

The Coordinator shall be the intermediary between the Parties and the Stichting and shall perform all tasks assigned to it as described in the Project Agreement and in this Consortium Agreement.

### **6.4.2**

In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations under this Consortium Agreement and the Project Agreement
- keeping the address list of Members and other contact persons updated and available
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certification) and specific requested documents to the Stichting
- preparing the meetings, proposing decisions and preparing the agenda of General Assembly meetings, chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings
- transmitting promptly documents and information connected with the Project to any other Party concerned
- administering the financial contribution of the Stichting and fulfilling the financial tasks described in Section 7.2
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

If one or more of the Parties is late in submission of any Project deliverable, the Coordinator may nevertheless submit the other Parties' Project deliverables and all other documents required by the Project Agreement to the Stichting in time.

#### **6.4.3**

If the Coordinator fails in its coordination tasks, the General Assembly may propose to the Stichting to change the Coordinator.

#### **6.4.4**

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Project Agreement or this Consortium Agreement.

#### **6.4.5**

The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Project Agreement.

## **7 Financial provisions**

### **7.1 General Principles**

#### **7.1.1 Distribution of Financial Contribution**

The financial contribution of the Granting Authority to the Project shall be distributed by the Coordinator according to:

- the Consortium Plan
- the approval of reports by the Granting Authority, and
- the provisions of payment in Section 7.2.

A Party shall be funded only for its tasks carried out in accordance with the Consortium Plan.

#### **7.1.2 Justifying Costs**

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs (and those of its Affiliated Entities, if any) with respect to the Project towards the Granting Authority. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs towards the Granting Authority.

#### **7.1.3 Funding Principles**

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded in accordance with its units/actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

#### **7.1.4 Excess payments**

A Party has received excess payment

- a) if the payment received from the Coordinator exceeds the amount declared or
- b) if a Party has received payments but, within the last year of the Project, its real Project costs fall significantly behind the costs it would be entitled to according to the Consortium Plan.

In case a Party has received excess payment, the Party has to inform the Coordinator and return the relevant amount to the Coordinator without undue delay. In case no refund takes place within 30 days upon request for return of excess payment from the Coordinator, the Party is in substantial breach of the Consortium Agreement.

Amounts which are not refunded by a breaching Party and which are not due to the Granting Authority, shall be apportioned by the Coordinator to the remaining Parties pro rata according to their share of total costs of the Project as identified in the Consortium Budget, until recovery from the breaching Party is possible.

#### **7.1.5 Revenue**

In case a Party earns any revenue that is deductible from the total funding as set out in the Consortium Plan, the deduction is only directed toward the Party earning such revenue. The other Parties' financial share of the budget shall not be affected by one Party's revenue. In case the relevant revenue is more than the allocated share of the Party as set out in the Consortium Plan, the Party shall reimburse the funding reduction suffered by other Parties.

#### **7.1.6 Financial Consequences of the termination of the participation of a Party**

A Party leaving the consortium shall refund to the Coordinator any payments it has received except the amount of contribution accepted by the Granting Authority or another contributor.

In addition, a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform the leaving Party's task and necessary additional efforts to fulfil them as a consequence of the Party leaving the consortium. The General Assembly should agree on a procedure regarding additional costs which are not covered by the Defaulting Party or the Mutual Insurance Mechanism.

### **7.2 Payments**

#### **7.2.1 Payments to Parties are the exclusive task of the Coordinator.**

In particular, the Coordinator shall:

notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references

perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts

undertake to keep the Granting Authority's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

With reference to Article 22 of the Grant Agreement, no Party shall before the end of the Project receive more than its allocated share of the maximum grant amount less the amounts retained by the Granting Authority for the Mutual Insurance Mechanism and for the final payment.

### **7.2.2**

The transfer of the initial pre-financing, the additional pre-financings (if any) and interim payments to Parties will be handled in accordance with Article 22.1. and Article 7 of the Grant Agreement following this payment schedule:

Funding of costs included in the Consortium Plan will be paid by the Coordinator to the Parties after receipt of payments from the Granting Authority without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Granting Authority will be paid to the Party concerned.

The Coordinator is entitled to withhold any payments due to a Party identified by the General Assembly to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Beneficiary which has not yet signed this Consortium Agreement.

The Coordinator is entitled to recover any payments already paid to a Defaulting Party except the costs already claimed by the Defaulting Party and accepted by the Granting Authority. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Granting Authority.

## **8 Results**

### **8.1 Ownership of Results**

Results are owned by the Party that generates them.

### **8.2 Joint ownership**

Two or more Parties own results jointly if:

1. they have jointly generated them and

2. it is not possible to:

- Establish the respective contribution of each Party, or
- separate them for the purpose of applying for, obtaining or maintaining their protection.

In case of joint ownership:

- 1) each of the joint owners shall be entitled to use the joint Results for commercial and/or non-commercial purposes as it sees fit, and to grant non-exclusive licenses, without obtaining any consent from, paying compensation to, or otherwise accounting to any other joint owner, unless otherwise agreed between the joint owners.
- 2) each of the joint owners shall be entitled to grant non-exclusive licenses to third parties (without any right to sub-license), if the other joint owners are given:

- (a) advance written notice, except in the case of broad-scope licenses and/or in the case of one or more transactions in the framework of mergers and/or acquisitions; and
- (b) fair and reasonable compensation on any Net-Monetary Income. For the purposes of this Agreement, "Net Monetary Income" means direct licencing income resulting from a licencing agreement between the Party involved and the third party, minus all costs incurred for generating this licence income.

The joint owners shall agree on all protection measures and the division of related cost in advance.

### **8.3 Transfer of Results**

#### **8.3.1**

Each Party may transfer ownership of their results, including its share in jointly owned Results, provided this does not affect compliance with their obligations under the Consortium Agreement. Notwithstanding the aforementioned, each Party may transfer ownership of its own Results and share(s) in jointly owned Results jointly with other Parties to any of its Affiliates without notification to any other Party.

#### **8.3.2**

Each Party may identify specific third parties it intends to transfer the ownership of its Results to in Attachment (3) of this Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to such a transfer to listed third parties.

#### **8.3.3**

The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties under the Consortium Agreement and the Project Agreement will not be affected by such transfer. Any addition to Attachment (3) after signature of this Consortium Agreement requires a decision of the General Assembly.

#### **8.3.4**

The Parties recognise that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give at least 45 calendar days prior notice for the transfer as foreseen in the Project Agreement.

#### **8.3.5**

The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

### **8.4 Dissemination**

#### **8.4.1**

For the avoidance of doubt, the confidentiality obligations set out in Section 10 apply to all dissemination activities described in this Section 8.4 as far as Confidential Information is involved.

#### **8.4.2 Dissemination of own (including jointly owned) Results**

##### **8.4.2.1**

During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the Project Agreement, subject to the following provisions.

Prior notice of any planned publication, including the draft of the publication, shall be given to the other Parties at least 45 calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Project Agreement by written notice to the Coordinator and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

##### **8.4.2.2**

An objection is justified if

- a) the protection of the objecting Party's Results or Background would be adversely affected, or
- b) the objecting Party's legitimate interests in relation to its Results or Background would be significantly harmed, or
- c) the proposed publication includes Confidential Information of the objecting Party.

The objection has to include a precise request for necessary modifications.

##### **8.4.2.3**

If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

##### **8.4.2.4**

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted, provided that the objections of the objecting Party have been addressed.

#### **8.4.3 Dissemination of another Party's unpublished Results or Background**

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published. The mere absence of an objection according to Section 8.4.2 of this Consortium Agreement is not considered as an approval.

#### **8.4.4 Cooperation obligations**

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

In accordance with scientific customs, the Party's contributions will be expressly reflected in all written or oral public disclosures concerning Results by acknowledgment or co-authorship, as appropriate. An appropriate reference to the Stichting support must be included in all such disclosures and publications in accordance with the Project Agreement.

#### **8.4.5 Use of names, logos or trademarks**

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval. In all cases with all oral, digital and physical dissemination results, the logo of Stichting needs to be used according to the format provided by the Stichting.

### **9 Access Rights**

#### **9.1 Background included**

##### **9.1.1**

In Attachment 1, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access Rights to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment 1 shall not be the object of Access Right obligations regarding Background.

Each Party agrees not to use, in the implementation of the Project, any Background that is not identified in Attachment 1 (the "Unlisted Background"). However, if a Party uses its own Unlisted Background in the implementation of the Project in a manner that such Unlisted Background becomes Needed by any other Party for the implementation of the Project or exploitation of any Results, then such Unlisted Background shall be deemed identified in Attachment 1 and shall not be excluded from obligations to grant Access Rights in accordance with the Project Agreement and this Consortium Agreement.

##### **9.1.2**

Any Party may add additional Background to Attachment 1 during the Project provided they give written notice to the other Parties. However, approval of the General Assembly is needed should a Party wish to modify or withdraw its Background in Attachment 1. For avoidance of doubt, under no circumstances should the withdrawal of any Background impair the implementation of the Project.

## **9.2 General Principles**

### **9.2.1**

Each Party shall implement its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts, Background and/or Results within the Project do not knowingly infringe third party property rights.

### **9.2.2**

Any Access Rights granted exclude any rights to sublicense unless expressly stated otherwise.

### **9.2.3**

Access Rights shall be free of any administrative transfer costs.

### **9.2.4**

Access Rights are granted on a non-exclusive, non-transferable and worldwide basis, if not otherwise agreed in writing by the Parties concerned.

### **9.2.5**

Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

### **9.2.6**

All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

### **9.2.7**

The requesting Party must show that the Access Rights are Needed.

### **9.2.8**

In addition to the obligations pursuant to the Project Agreement, each Party shall, to the fullest extent it can lawfully do so, ensure that it can grant Access Rights and fulfil the obligations under the Project Agreement and this Consortium Agreement, notwithstanding any rights of its employees or Subcontractors in Results so created.

#### **9.2.9 Have made rights**

Any and all Access Rights for Exploitation granted pursuant to this Consortium Agreement include the right of Indirect Utilisation as such term is defined in Section 1 of this Consortium Agreement.

## **9.3 Access Rights for implementation**

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Attachment 1.

## **9.4 Access Rights for Exploitation**

### **9.4.1 Access Rights to Results**

Access Rights to Results if Needed for Exploitation of a Party's own Results shall be granted on fair and reasonable conditions, but only to the extent that written notification about the existence of those Results is sent to the other Parties, including sufficient details to enable the Parties to trace such Results (e.g. application number, title, priority date, applicants and filing office). Said written notification shall be provided within a reasonable period, but in no event shall such written notification be provided at a date later than six (6) months after the end of the Project. If no notification is submitted within the agreed period, access rights to Results during exploitation shall be against fair and reasonable compensation taking into account the non-notification.

Access Rights to Background if Needed for Exploitation of a Party's own Results, shall be granted on fair and reasonable conditions and upon written agreement between the concerned Parties.

Access rights to Results for internal research and for teaching activities shall be granted on a royalty-free basis.

### **9.4.2**

A request for Access Rights may be made up to 2 years after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

## **9.5 Access Rights for Affiliates**

Affiliates have the same Access Rights as though those Affiliates were the Party they are affiliated to.

Access Rights to Affiliates shall be granted on the same conditions of the Party they are affiliated to.

Affiliates which obtain Access Rights in return fulfil all confidentiality obligations accepted by the Parties under the Project Agreement or this Consortium Agreement as if such entities were Parties.

Access Rights granted to any Affiliate are subject to the continuation of the Access Rights of the Party to which it is affiliated, and shall automatically terminate upon termination of the Access Rights granted to such Party.

### **9.5.2 Cessation of Affiliates**

#### **9.5.2.1 Rights granted to Affiliates**

Upon any legal entity ceasing to be an Affiliate of a Party, any Access Rights granted to such legal entity shall lapse. Notwithstanding the preceding sentence, and upon written request by the legal entity, such legal entity shall be granted a non-exclusive license on Results and/or Background on terms and conditions similar to those granted to the Party the legal entity was affiliated to, provided that:

(i) the legal entity has been granted Access Rights to Results and Background pursuant to the Project Agreement and this Consortium Agreement prior to such legal entity's cessation of being an Affiliate to a Party; and

(ii) such Results and Background are incorporated into the products, processes or services of such legal entity, as such legal entity may prove in writing; and

(iv) that no legitimate interest of such Parties opposes the grant of such licences.

A request for the grant of a license pursuant to this Article 9.5.2.1 may be made in writing up to six (6) months after the cessation of such legal entity being an Affiliate of a Party.

#### 9.5.1.2 Rights granted by Affiliates

Upon any legal entity ceasing to be an Affiliate of a Party, the licenses or user rights previously granted by such legal entity to any Party and/or its Affiliates under or in respect of Background or Results shall continue in full force and effect.

### 9.6 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by the Project Agreement or this Consortium Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties.

### 9.7 Access Rights for Parties entering or leaving the consortium

#### 9.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the conditions applying for Access Rights to Background.

#### 9.7.2 Parties leaving the consortium

##### 9.7.2.1 Access Rights granted to a leaving Party

###### 9.7.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the General Assembly to terminate its participation in the consortium.

###### 9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation.

It may request Access Rights within the period specified in Section 9.4.2., except that such period of time shall start counting from the date of the termination of such non-defaulting Party's participation

##### 9.7.2.2 Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Project Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

### 9.8 Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software.

Parties' Access Rights to Software do not include any right to receive source code or object code ported to a certain hardware platform or any right to receive respective Software documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

The intended introduction of intellectual property (including, but not limited to Software) under Controlled Licence Terms in the Project requires the unanimous approval of the General Assembly to implement such introduction into the Consortium Plan.

## **10 Non-disclosure of information**

### **10.1**

All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

### **10.2**

The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Project Agreement, during the Project and for a period of 5 years after the end of the Project:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided the Recipient complies with the confidentiality obligations herein contained with respect to such copy.

### **10.3**

The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

### **10.4**

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;

- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Project Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder.

## **10.5**

The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care

## **10.6**

Each Recipient shall promptly inform the relevant Disclosing Party by written notice of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

## **10.7**

If any Recipient becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

## **11 Privacy and data protection**

In the performance under this Consortium Agreement, Parties shall comply with their respective obligations under applicable data protection laws including the General data Protection Regulation (GDPR) . Parties apply appropriate privacy safeguarding measures (e.g. pseudonymization) limiting the disclosure of Personal Data.

Where, during or in connection with the Consortium Agreement, Personal Data may be or are intended to be processed, the Parties involved shall enter into an appropriate privacy and data protection agreement prior to any such processing.

When acting as Controller over the same set of Personal Data, each Party shall:

- (i) be solely responsible for collecting and further processing the abovementioned set of Personal Data in accordance with applicable data protection laws, in particular for

- justifying any transmission of such Personal Data to the other Party (including providing required notices and obtaining required consents) and its decisions concerning the processing of the Personal Data; and
- (ii) not do anything which may cause the other Party to violate any applicable data protection law.

Where Parties transfer Personal Data – subject to EU Regulation 679/2016 (GDPR) – to each other and Parties are acting as Controller over the same set of Personal Data, Parties shall process the Personal Data only within countries member of the European Economic Area, unless:

- (iii) Parties have entered into the appropriate EU Standard Contractual Clauses;
- (iv) Parties have implemented binding corporate rules that have received European approval and that cover all Personal Data that Parties will receive in their capacity of Controller;
- (v) the countries where Parties will process such Personal Data have received a binding adequacy decision by the European Commission; or
- (vi) another validly executed transfer mechanism applies to the transfer of Personal Data to such countries that have not received a binding adequacy decision by the European Commission.

## 12 Miscellaneous

### 12.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and:

- Attachment 1 (Background included)
- Attachment 2 (Accession document)
- Attachment 3 (List of third parties for simplified transfer according to Section 8.3.2)

In case the terms of this Consortium Agreement are in conflict with the terms of the Project Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

### 12.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

### 12.3 Formal and written notices

Any notice to be given under this Consortium Agreement shall be addressed to the recipients as listed in the most current address list kept by the Coordinator.

Any change of persons or contact details shall be immediately communicated to the Coordinator by written notice. The address list shall be accessible to all Parties.

Formal notices:

If it is required in this Consortium Agreement (Sections 4.2, 9.7.2.1.1, and 12.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery with acknowledgement of receipt.

Written notice:

Where written notice is required by this Consortium Agreement, this is fulfilled also by other means of communication such as e-mail.

#### **12.4 Assignment and amendments**

Except as set out in Section 8.3, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.

Amendments and modifications to the text of this Consortium Agreement not explicitly listed in 6.3.7 require a separate written agreement to be signed between all Parties.

#### **12.5 Mandatory national law**

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

#### **12.6 Language**

This Consortium Agreement is drawn up in English.

#### **12.7 Applicable law**

This Consortium Agreement shall be construed in accordance with and governed by the laws of The Netherlands.

#### **12.8 Settlement of disputes**

All disputes arising out of or in connection with this Consortium Agreement (other than disputes relating to the infringement and/or validity of intellectual property rights which shall be the jurisdiction of the competent court), which cannot be solved amicably, shall be finally settled by Dutch courts.

The foregoing shall be without prejudice to the right of any Part to seek injunctive relief or other equitable compensation before any court in any place where any unauthorized use of its intellectual property rights or Confidential Information occurs or threatens to occur.

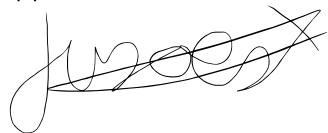
## **13 Signatures**

### **AS WITNESS:**

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written. The signature of a Party via a scanned or digitized image of a handwritten signature (e.g. scan in PDF format) or an electronic signature (e.g. via AdobeSign), shall have the same force and effect as an original handwritten signature for the purposes of validity, enforceability and admissibility. Each Party receives a fully signed copy of this Consortium Agreement. Delivery of the fully signed copy via e-mail or via an electronic signature system shall have the same force and legal effect as delivery of an original hard copy of the Consortium Agreement.

**Medical Data Works B.V.**

Signature(s)

A handwritten signature in black ink, appearing to read "Johan van Soest".

Name(s) **Johan van Soest**

Title(s) **CEO Medical Data Works**

Date **15-9-2023**

**Philips Electronics Nederland B.V.**

Signature(s)



*Electronically signed by: Paul Put  
Reason: Approved on behalf of  
Betsabeh Madani  
Date: Sep 11, 2023 17:08  
GMT+2*

Name(s)      Paul Put

Title(s)      Head of Research EU Professional Care

Date            **Sep 11, 2023**

**Maastricht University**

Signature(s)

A handwritten signature in black ink, appearing to read "M. van Engeland".

Name(s) Prof. dr. M. van Engeland

Title(s) Scientific director GROW-Research Institute for Oncology and Reproduction

Date 27-09-2023

**Stichting Radboud universitair medisch centrum**

Signature(s)

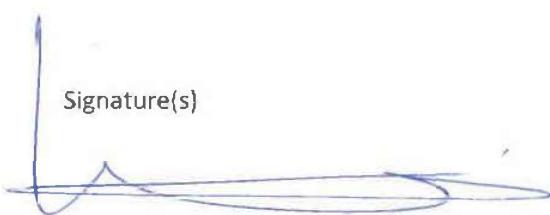


J. Sjoerts MSc

Director Valorisation/Technology Transfer

Date 30-08-2023

Signature(s)

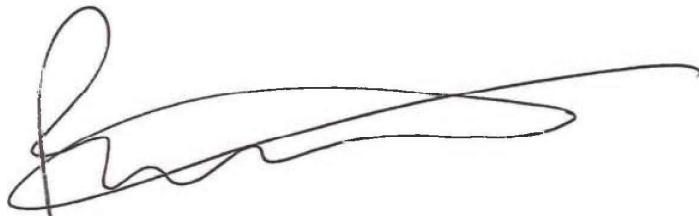


Prof. Dr. M. Verheij

Head department Radiotherapy

Date 20/08/2023

Signature(s)



Dr. R. Monshouwer

Principal Investigator

Date 25-8-2023

As Witness:

The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorized representatives in separate signature pages.

Partner: University Medical Center Groningen

Signature:

 ValidSigned door Prof. Dr. W.J. Niessen  
op 28-09-2023

Name: Prof. Dr. W.J. Niessen

Title: Member Board of Directors

Date: 28-09-2023

Read and acknowledge:

Signature:

 ValidSigned door dr. ir. P.M.A. van Ooijen  
op 26-09-2023

Name: dr. ir. P.M.A. van Ooijen

Title: coordinator Machine Learning Lab Data Science Center

Date: 26-09-2023

**Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek – TNO**

Signature(s)

ValidSigned by Marc Zegveld  
on 2023-07-20 14:44:48

Name(s) M.A. (Marc) Zegveld

Title(s) Managing Director ICT, Strategy & Policy (ISP)

Date 20-7-2023

**Stichting Het Nederlands Kanker Instituut – Antoni van Leeuwenhoek Ziekenhuis**

Signature:

DocuSigned by:  
  
Henri van Luenen  
9326534DE89D408...

Name:

Henri van Luenen

Title:

Director of Operations

Date 18 September 2023

Signature:

DocuSigned by:  
  
3F50982046464DF...

For Acknowledgment

Name:

Tomas Janssen

Title:

Klinisch fysicus RT

Date 15 September 2023

**Stichting Isala Klinieken**

Signature(s)



Name(s) Dr. H. H. Kuper

Title(s) Boardmember

Date 23-01-23

## **Attachment 1: Background included**

'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is:

- held by the parties before they acceded to the Agreement and
- needed to implement the action or exploit the results.

If background is subject to rights of a third party, the beneficiary concerned must ensure that it is able to comply with its obligations under the Agreement. Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the Project. This is the purpose of this attachment.

As to **Medical Data Works B.V.**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

<b>Describe Background</b>	<b>Specific restrictions and/or conditions for implementation.</b>	<b>Specific restrictions and/or conditions for Exploitation.</b>
Federated Learning Infrastructure	None	None

This represents the status at the time of signature of this Consortium Agreement.

As to **Philips Electronics Nederland B.V.**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

<b>Describe Background</b>	<b>Specific restrictions and/or conditions for implementation.</b>	<b>Specific restrictions and/or conditions for Exploitation.</b>

This represents the status at the time of signature of this Consortium Agreement.

As to **Maastricht University**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

<b>Describe Background</b>	<b>Specific restrictions and/or conditions for implementation.</b>	<b>Specific restrictions and/or conditions for Exploitation.</b>

This represents the status at the time of signature of this Consortium Agreement.

As to **Stichting Radboud universitair medisch centrum**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

<b>Describe Background</b>	<b>Specific restrictions and/or conditions for implementation.</b>	<b>Specific restrictions and/or conditions for Exploitation.</b>

This represents the status at the time of signature of this Consortium Agreement.

As to **University Medical Center Groningen**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

<b>Describe Background</b>	<b>Specific restrictions and/or conditions for implementation.</b>	<b>Specific restrictions and/or conditions for Exploitation.</b>

This represents the status at the time of signature of this Consortium Agreement.

As to **Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek – TNO**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

<b>Describe Background</b>	<b>Specific restrictions and/or conditions for implementation.</b>	<b>Specific restrictions and/or conditions for Exploitation.</b>
Blueprint for large scale interoperability, defined in previous projects, combining data sharing technologies, distributed ledgers and semantics.	The described Background will be made accessible to project partners for the purpose of implementation of the Project.	Exploitation involving any of the stated Background will be subject to contract, in all cases prior consent must be obtained from TNO.
TNO reference implementation of the IDS architecture owned assets (e.g. identity provider, secure gateway(s), broker, clearing house)	The described Background will be made accessible to project partners for the purpose of implementation of the Project.	Exploitation involving any of the stated Background will be subject to contract, in all cases prior consent must be obtained from TNO.

This represents the status at the time of signature of this Consortium Agreement.

As to **Stichting Het Nederlands Kanker Instituut – Antoni van Leeuwenhoek Ziekenhuis**, it is agreed between the Parties that, to the best of their knowledge:

No transfer of data, know-how or information is needed by another Party for implementation of the Project or Exploitation of that other Party's Results, as data from NKI-AVL will not be transferred to the other Parties, all data will only be made available for the PoC fase of this Project via federated learning algorithms. For the avoidance of doubt, the data shall not be made available for future following up projects. Article 9.1.1. regarding the Unlisted Background is not applicable for NKI-AVL. NKI-AVL Unlisted Background shall not be used for commercial purposes.

This represents the status at the time of signature of this Consortium Agreement.

As to **Stichting Isala Klinieken**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

<b>Describe Background</b>	<b>Specific restrictions and/or conditions for implementation.</b>	<b>Specific restrictions and/or conditions for Exploitation.</b>
Patient data	<ul style="list-style-type: none"> <li>- No subject-level patient data shall be transferred, only anonymous aggregated/statistical data shall be transferred according to the principle of federated learning.</li> <li>- Prior approval shall be sought for each specific purpose of patient data processing if this purpose is materially different from prior approved purposes. Materially different includes different patient cohorts, different data elements on the same cohort and different questions to those data elements.</li> </ul>	<ul style="list-style-type: none"> <li>- Any result from patient data shall be considered a joint result with joint ownership and/or revenue sharing</li> </ul>

This represents the status at the time of signature of this Consortium Agreement.

## **Attachment 2: Accession document**

ACCESSION

**of a new Party to**

**[Acronym of the Project] Consortium Agreement, version [..., YYYY-MM-DD]**

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE Project Agreement]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

[OFFICIAL NAME OF THE COORDINATOR AS IDENTIFIED IN THE Project Agreement]

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].

This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)

Name(s)

Title(s)

[Date and Place]

[INSERT NAME OF THE COORDINATOR]

Signature(s)

Name(s)

Title(s)

**Attachment 3: List of third parties for simplified transfer according to Section 8.3.2.**

None

## Attachment 4: Project Agreement



Stichting AiNed  
Bezuidenhoutseweg 12  
Postbus 93002  
2509 AA Den Haag  
[www.ained.nl](http://www.ained.nl)

**Aan:**

Dhr. Johan van Soest  
CEO Medical Data Works  
[Johan.vensoest@medicaldataworks.nl](mailto:Johan.vensoest@medicaldataworks.nl)

<b>Datum</b>	<b>Bijlage(n):</b>	<b>Ons kenmerk</b>
17 maart 2023	- Vereisten PoC en Selectieprocedure	AiNed-005-2023

**Onderwerp** Contract Proof of Concept fase AiNed Ketenproject

U hebt op 3 november 2022 een Proof of Concept (PoC) voorstel ingediend voor werkzaamheden onder de projecttitel Health-AI, welke op 8 december 2022 door het bestuur van Stichting AiNed is goedgekeurd. Hierbij verleen ik u de opdracht tot de uitvoering van de werkzaamheden.

**Omschrijving van de opdracht**

De opdracht betreft de uitvoering van werkzaamheden zoals omschreven in uw PoC voorstel aangevuld met de feedback die vanuit AiNed op 9 december 2022 per email aan u is gegeven. Het eindresultaat bestaat uit twee delen:

1. Een werkende demo of prototype via een presentatie
2. Een uitgewerkt voorstel voor het Ketenproject met een omvang van minimaal €10 mln., waarvoor door de winnaar maximaal € 5mln. subsidie bij RVO kan worden aangevraagd.

Het eindresultaat dient in ieder geval in digitale vorm te worden aangeleverd.

Het eindresultaat van deze opdracht doet in competitieverband - met de twee andere PoC consortia - mee aan het selectie- en beoordelingsproces voor het mogen indienen van de Ketenproject aanvraag bij RVO.

**Termijn van de opdracht**

De opdracht moet zijn voltooid op 29 september 2023.

**Vergoeding**

Vergoeding vindt plaats op basis van de vaste bedrag cf. uw PoC voorstel ter waarde van €150.00,- inclusief btw en alle andere kosten bij een besteding van minimaal €300.000,-

### **Contactpersoon**

Uw contactpersoon vanuit Stichting AiNed voor de uitvoering van deze opdracht is Sander Ruiter ([sander.ruiter@ained.nl](mailto:sander.ruiter@ained.nl)).

### **AiNed Voorwaarden**

1. Op deze opdracht zijn de eerder aan u ter beschikking gestelde documenten van toepassing:
  - Format Verkort Ketenproject en beschrijving Proof of Concept
  - Vereisten PoC en Selectieprocedure
  - Informatiebrochure AiNed Ketenproject
- Voorts geldt het document Vereisten PoC en Selectieprocedure als annex bij deze opdrachtverlening.
2. De penvoerder van het consortium Health-AI kan een - middels een ieder van de betrokken partners ondertekent - document overhandigen waaruit blijkt dat penvoerder hen vertegenwoordigt.
3. De penvoerder weet dat het eindresultaat van de PoC kans maakt op het uitvoeren van het Ketenproject en erkent dat zij hier in competitieverband aan deelneemt. Penvoerder kan binnen 5 werkdagen na het ontvangen besluit bezwaar aantekenen bij het bestuur en bij geen gehoor of een niet bevredigde reactie binnen 5 werkdagen na deze indiening haar bezwaar aantekenen bij de voorzitter van de Raad van Toezicht.
4. De penvoerder levert de gevraagde informatie aan zoals vermeld in artikel 9 van de paragraaf getiteld 'Voorwaarden voor het ketenproject' uit het document Format Verkort Ketenproject en beschrijving Proof of Concept.
5. De penvoerder dient mee te werken aan evaluaties die tijdens of na afloop van het PoC fase zullen plaatsvinden tot vijf jaar na afsluiting inclusief het leveren van informatie t.b.v. AiNed Monitoring & Effectmeting.
6. De penvoerder werkt mee aan het kenbaar en beschikbaar maken van PoC resultaten via a) de NL AIC community en b) via de PR en communicatie uitingen gecoördineerd vanuit Stichting AiNed gedurende en na afloop van de PoC fase.
7. Alle ingebrachte of tijdens de PoC fase ontwikkelde intellectueel eigendom inclusief andere zaken tussen de partners wordt aan het consortium zelf overgelaten<sup>1</sup>.

### **Integriteitsverklaring**

Penvoerder verklaart dat hij ter verkrijging van de opdracht personeel van opdrachtgever geen voordeel heeft aangeboden of doen aanbieden, gegeven of doen geven. Hij zal dat ook

---

<sup>1</sup>Partijen sluiten onderling een samenwerkingsovereenkomst voor zaken als Intellectueel Eigendom voor de PoC fase. Het is daarbij van belang dat de IP-afspraken aansluiten bij de Algemene Groepsvrijstellingsverordening of AGVV in de context van statsteunkaders. Voor een uitwerking daarvan in de vorm van een checklist verwijzen we naar <https://europadecentral.nl/wp-content/uploads/2015/10/Checklist-Steun-vooronderzoek-ontwikkeling-en-innovatie.pdf>. In het algemeen kan worden gesteld dat resultaten van fundamenteel onderzoek publiek verspreid dienen te worden, en dat voor industriel onderzoek en experimentele ontwikkeling meer eisen aan verspreiden van projectresultaten wordt gesteld naar mate het steunpercentage (subsidiepercentage) hoger is. Onder verspreiding van resultaten wordt bijvoorbeeld gerekend: conferenties, publicaties, open access-repositories, of gratis of open source software.

niet alsnog doen teneinde personen in dienst van opdrachtgever te bewegen enige handeling te verrichten of na te laten.

#### **Nadere juridische bepalingen**

- a) Bij opdrachtverlening moeten de penvoerder en financiering ontvangende consortiumpartners zijn ingeschreven in het Nederlandse beroepsregister of in het handelsregister volgens de Nederlandse voorschriften van de lidstaat (EU) waar hij is gevestigd.
- b) Penvoerder verkeert niet in staat van faillissement of van liquidatie, de werkzaamheden zijn niet gestaakt, verkeert niet in surseance van betaling of akkoord, of verkeert niet in een andere vergelijkbare toestand ingevolge een soortgelijke procedure die voorkomt in de op hem van toepassing zijnde wet- of regelgeving.
- c) Voor penvoerder is niet faillissement of liquidatie aangevraagd, of is geen procedure van surseance van betaling of akkoord, dan wel een andere soortgelijke procedure die voorkomt in de op hem van toepassing zijnde wet- of regelgeving, aanhangig gemaakt.
- d) Penvoerder is in staat de opdracht met zijn bestaande financiële middelen uit te voeren. Bij penvoerder zijn geen claims of noodzakelijke investeringen bekend gedurende de periode van de uitvoering van de overeenkomst die de organisatie in een zodanige positie kunnen brengen dat de financieel-economische draagkracht of de continuïteit van de organisatie in gevaar wordt gebracht.
- e) Penvoerder is niet bij een rechterlijke uitspraak die kracht van gewijsde heeft volgens de op hem van toepassing zijnde wet- of regelgeving, veroordeeld geweest voor een delict dat de beroepsmoraliteit (van de onderneming) in het gedrang brengt.
- f) Penvoerder heeft voldaan aan zijn verplichtingen ten aanzien van de betaling van de sociale verzekeringsbijdragen overeenkomstig de wettelijke bepalingen van het land waar hij gevestigd is of in het land van de aanbestedende dienst.
- g) Penvoerder is niet schuldig aan aantoonbaar ernstig professioneel wangedrag, zoals fraude en corruptie.
- h) Penvoerder heeft aan zijn verplichtingen voldaan ten aanzien van de betaling van zijn belastingen overeenkomstig de wettelijke bepalingen van het land waar hij is gevestigd of van het land van de aanbestedende dienst.
- i) Afwijkingen van deze opdracht zijn slechts bindend voor zover zij uitdrukkelijk tussen partijen schriftelijk zijn overeengekomen.
- j) Door ondertekening van deze opdracht vervallen alle eventueel eerder door partijen gemaakte mondelinge en schriftelijke afspraken omtrent de hierbij overeengekomen werkzaamheden.

#### **Facturatie en betaling**

De betaling van het totaalbedrag vindt na ontvangst van de factuur hiertoe als volgt plaats:

- een voorschot van € 100.000,- inclusief btw na ondertekening van akkoord op deze opdrachtbrief;
- en het restant van maximaal € 50.000,- inclusief btw na ontvangst en acceptatie van de demo/ prototype, uitgewerkt voorstel voor het Ketenproject en de financiële eindrapportage voorzien van een handtekening door de penvoerder. Alle

deelbetalingen zijn pas definitief na ontvangst en acceptatie van bovengenoemd eindresultaat.

Penvoerder zendt de facturen aan [facturen@ained.nl](mailto:facturen@ained.nl) en onder vermelding van het boven deze opdracht vermelde referentienummer, de naam van de penvoerder, het consortium en de naam van de contactpersoon van Stichting AiNed. Indien de factuur niet volgens deze wijze wordt aangeboden, kan dit ertoe leiden dat de factuur niet in behandeling wordt genomen of dat de betalingstermijn wordt verlengd.

#### Ondertekening

Ik verzoek u de bijgevoegde kopie van deze opdrachtbrief rechtsgeldig voor akkoord ondertekend aan mij terug te zenden. Indien ik deze ondertekende kopie niet binnen 14 dagen heb ontvangen, behoud ik mij het recht voor om terug te komen op deze opdrachtverlening

Namens Stichting AiNed,

d.d. 17 maart 2023

Namens PoC Consortium Health-AI

d.d. 4 mei 2023



Prof. dr. W. Jonker  
Bestuursvoorzitter



Dhr. J. van Soest  
Penvoerder



Stichting AI Ned  
De Malietoren  
Bezuidenhoutseweg 12  
2594 AV Den Haag

Maastricht, September 20, 2023

Subject: Letter of Intent

Dear sir/madam,

With this letter I declare on behalf of Maastro Clinic, our interest and support of the project entitled "Health-AI". As Maastro Clinic, we will join the development of the project proposal and we are very much interested in actively participating in the project.

Maastro Clinic is an academic institution delivering top specialist cancer care. AI development and implementation are an important part of our strategy. The Health-AI project aims to make AI development easier without the need to share patient-level data and that is of great interest to us. As Maastro we will contribute data, clinical expertise & use cases for federated learning. Furthermore, our Clinical Data Science division will contribute to the engineering and testing of federated AI algorithms.

For this project, our interest is in extending our expertise in the area of federated AI learning in cooperation with partners Medical Data Works, Health-RI, Isala, UMCG, NKI-AVL and Radboudumc, amongst others.

If the project is approved and granted then as a consortium partner Maastro Clinic will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.

Yours sincerely,

Prof. Dr. M.J.G. Jacobs  
CEO

— DocuSigned by:

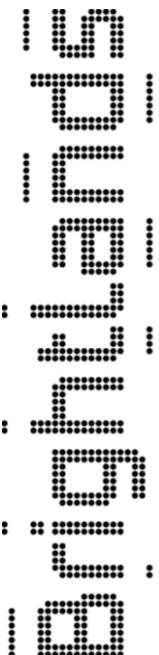
*Maria Jacobs*

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21 September 2023 | 05:28 PDT



## Brightlands Smart Services Campus



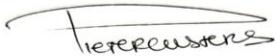
Knowledge crossing borders

To: Stichting AI Ned  
From: Brightlands Smart Services Campus  
Subject: Letter of Intent

With this letter I declare on behalf of Brightlands Smart Services Campus, our interest and support of the project entitled "Health-AI". As Brightlands Smart Services Campus, we will join the development of the project proposal and we are very much interested in actively participating in the project.

For this project, our interest is in extending our expertise in the area of project management in cooperation with partners MDW, UM, Maastro, amongst others.

If the project is approved and granted then as a consortium partner Brightlands Smart Services Campus will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.



P. Custers

September 25, 2023  
P. Custers, acting CEO

**adres**  
Smedestraat 2  
6411 CR Heerlen  
Nederland

[www.brightlands.com](http://www.brightlands.com)

Campus Heerlen Management &  
Development BV Kamer van  
Koophandel nummer(NL) 63843838

Stichting AI-Ned

Utrecht, 22 September 2023

**Subject: Letter of Intent**

Our ref: HR/LF/2023.045

Dear Madam/Sir,

With this letter I declare on behalf of Stichting Health-RI, our interest and support of the project entitled "Health-AI". As Stichting Health-RI, we will join the development of the project proposal and we are very much interested in actively participating in the project.

Stichting Health-RI aims for better health for citizens and patients by reusing health data with an integrated health data infrastructure for research, policy and innovation. Health-RI provides expertise on FAIR data implementation, data infrastructure, ELSI aspects of data access and federated learning as well as an extensive network among health care providers and research institutions, both in the Netherlands and extending out into the EU. The University Medical Centers among the consortium partners are also part of the Health-RI network.

For this project, our interest is in extending our expertise in the area of federated data infrastructure and AI in cooperation with partners Philips, TNO and NKI, amongst others.

If the project is approved and granted then as a consortium partner Stichting Health-RI will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.

Yours faithfully,

M.J. Flikweert

CEO



Netherlands eScience Center  
Science Park 140 (Matrix I)  
1098 XG Amsterdam  
+31 20 460 4770  
[info@esciencecenter.nl](mailto:info@esciencecenter.nl)



To: Stichting AlNed  
From: the Netherland eScience Center  
Subject: Letter of Intent

With this letter I declare on behalf of the Netherlands eScience Center, our interest and support of the project entitled "Health-AI". As the Netherlands eScience Center, we will join the development of the project proposal and we are very much interested in actively participating in the project.

The Netherlands eScience Center is the national center for academic research software. We can contribute our expertise on developing software for privacy preserving federated analysis.

For this project, our interest is in extending our expertise in the area of federated learning in cooperation with partners UM and Maastro, amongst others.

If the project is approved and granted then as a consortium partner the Netherlands eScience Center will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.

26-09-2023

Joris van Eijnatten

A handwritten signature in blue ink, appearing to read 'Joris van Eijnatten', is written over the date and name.

To: Stichting AI Ned  
From: BranchKey BV

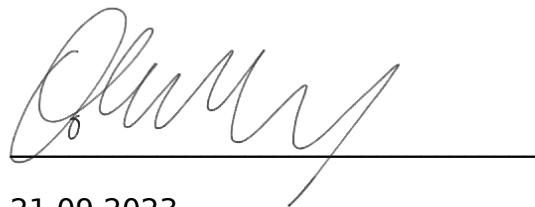
**Subject: Letter of Intent**

With this letter I declare on behalf of BranchKey BV, our interest and support of the project entitled "Health-AI". As BranchKey BV, we will join the development of the project proposal and we are very much interested in actively participating in the project.

BranchKey BV is specialized in Federated Machine Learning (FML), offering a software system for customers to plug-and-play enterprise grade deployments. In addition, the company offers supportive services in the management, development, and delivery of FML projects. Our expertise is built in Financial services, Defence & Security, and Maritime & Industrial. BranchKey BV offers this project these expertise from other countries and industries in achieving successful project execution.

For this project, our interest is in extending our expertise in the area of medical data practices in cooperation with the partners listed on the consortium agreement, amongst others.

If the project is approved and granted then as a consortium partner BranchKey BV will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.



21.09.2023

Diarmuid Kelly

September 25th, 2023

To: Stichting AINed  
From: Roseman Labs  
Subject: Letter of Intent

## Letter of Intent

With this letter I declare on behalf of Roseman Labs BV, our interest and support of the project entitled "Health-AI". As Roseman Labs BV, we will join the development of the project proposal and we are very much interested in actively participating in the project.

Roseman Labs specializes in privacy-enhancing technology and is a provider of Multi-Party Computation software. Roseman Labs works with organizations in Healthcare and the Social Domain in the Netherlands. Roseman Labs' solution (the Virtual Data Lake) enables secure collaboration between data providers, analysts and developers across a distributed infrastructure.

For this project, our interest is in sharing and extending our expertise in the area of privacy-preserving AI in cooperation with the Health-AI partners. Roseman Labs currently has a partnership with IQVIA in healthcare.

If the project is approved and granted then as a consortium partner Roseman Labs BV will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.

Utrecht, September 25th, 2023



Toon Segers



IQVIA Solutions BV  
Herikerbergweg 314  
PO Box 23595  
1100 EB AMSTERDAM ZUID-OOST  
The Netherlands  
[iqvia.com](http://iqvia.com)

To: Stichting AINed  
From: IQVIA Solutions BV  
Subject: Letter of Intent

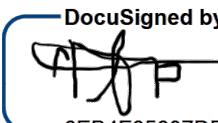
With this letter I declare on behalf of IQVIA Solutions BV, our interest and support of the project entitled "Health-AI". As IQVIA Solutions BV, we will join the development of the project proposal and we are very much interested in actively participating in the project.

IQVIA is a global leader in health data, advanced analytics, technology solutions and clinical research. IQVIA supports and collaborates with all stakeholders in healthcare. In this collaboration, IQVIA integrates health data, leading artificial intelligence (for example CTcue), connecting technology and deep knowledge of care, to deliver and implement distinctive solutions.

For this project, our interest is in sharing and extending our expertise in the area of AI in cooperation with joining partners. IQVIA has a current partnership with Roseman Labs in healthcare.

If the project is approved and granted then as a consortium partner IQVIA Solutions BV will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.

#### SIGNATURE

DocuSigned by:  
  
6EB4F65607DE42E...  
22-09-2023  
Martijn Nap, General Manager

To: Stichting AINed  
From: Linksight BV  
Subject: Letter of Intent

With this letter I declare on behalf of Linksight, our interest and support of the project entitled "Health-AI". As Linksight, we will join the development of the project proposal and we are very much interested in actively participating in the project.

Linksight enables setting up easy and secure data collaborations between multiple parties. With our service you can do privacy-friendly analysis on each other's datasets, without sharing sensitive data. Not with each other, nor with Linksight. We use advanced privacy technology (secure multiparty computation (MPC) / fully homomorphic encryption (FHE)) combined with our unique configurable collaboration rules. This gives the partners involved the opportunity to do several kinds of analysis; descriptive statistics, regression and federated learning.

Linksight is an TNO spin-off company, founded in 2021 and HealthCare is our main market. Currently we are using our Linksight service in 7 data collaborations, in total 28 partners (including almost all university medical center).

We provide knowledge in the area of:

- multiple privacy enhancing technologies, data collaboration governance and decentralized data sharing architectures (fi. Health Data Spaces) and
- legal aspects of implementing privacy enhancing technologies, with the specific exclusion that we do not provide formal legal advice, and expect that to be organized within the project or with the other project partners.

We will add to the project our experience of setting up federated data collaborations.

For this project, our interest is in extending our expertise in the area of enabling data collaboration to gain collaborative insights while the privacy of data of individuals is protected in cooperation with partners UM, RUMC, UMCG, NKI-AVL and Isala, amongst others.

If the project is approved and granted then as a consortium partner Linksight will share responsibility for prompt completion of a consortium project agreement. Upon such completion we will participate in the project as outlined in this letter of intent and the project proposal.



22-09-2023

Martine van de Gaar  
CEO of Linksight