Health-AI System Breakthrough Project

Planned start date **: 1 April 2024**

Planned duration **: 48 months**

Contributing organization **: Medical Data Works B.V. (MDW)**

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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 below.

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	59%	3.281M€	1.346M€	1.935M€
Private Partners – Medium (<250)	eScience	Experimental Development Collaboration	50%	1.595M€	0.797M€	0.797M€
Private Partners – Large (>250)	Philips Isala Maastro IQVIA	Experimental Development Collaboration	40%	3.169M€	1.902M€	1.268M€
Knowledge Institutions	Maastricht University Radboudumc UMCG TNO NKI-AVL	N/A	100%	0.965M€	0.000M€	0.965M€
TOTAL				9.010M€	4.045M€	4.965M€

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 be 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 saving 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.

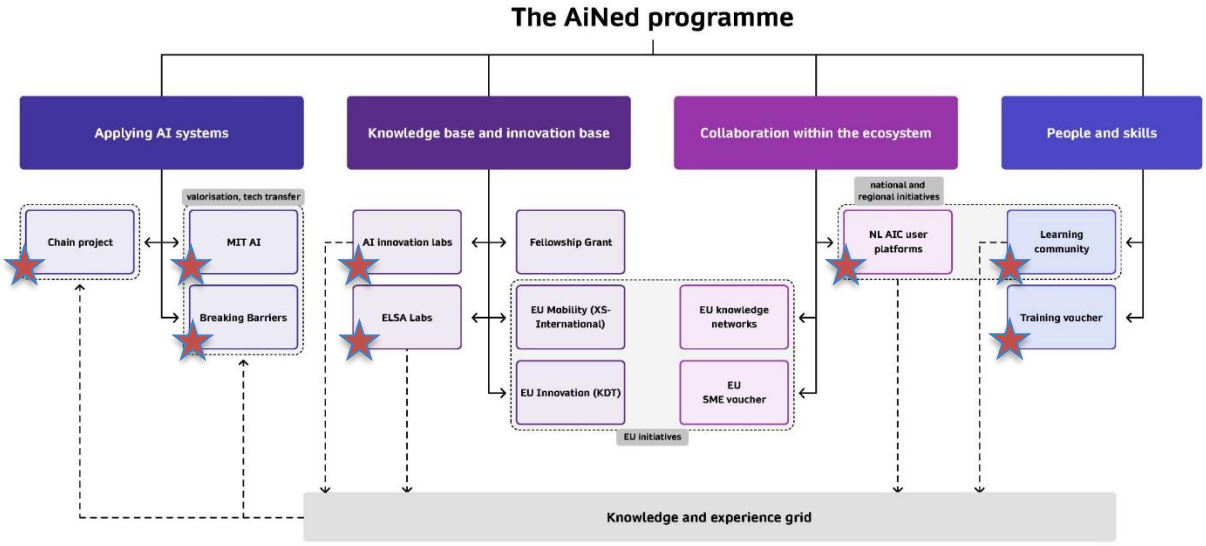
The Health-AI project is well-founded and supported by a comprehensive plan. The consortium's composition, task allocation, and deliverables are all carefully structured to ensure that the project's system breakthrough objectives are both achievable and innovative. The approach is designed to ultimately 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.

In the below diagram, we have indicated using stars in which parts of the AiNed supported programs Health-AI aims to engage. In WP1 more details are given.



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 in 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	33	3	6		4			
Partner	Maastro	Brightlands	Health-RI	eScience	BranchKey	RML	IQVIA	Linksight
PM	12	36		3				
Objective: To establish essential project management, collaboration mechanisms, and documentation, ensuring effective communication, compliance with legislation, ethical considerations, and standards for the Health-AI project.								
Description: 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, MDW, M01-M48).
Our dissemination efforts will begin immediately, starting with press releases, website creation, and establishing a social media presence. In this task, further engagement with the AiNed program is also planned. Specifically:

- Health-AI will collaborate in the AiNed Breaking Barriers program, as solving the data challenge for AI startups is an explicit goal of this program, which Health-AI is all about. Although the details of Breaking Barriers are not yet known, we expect startups in this program to benefit from the existence of Health-AI and we will engage with this program.
- The SMEs in Health-AI will submit proposals to the AiNed MIT-AI calls in collaboration with SMEs outside Health-AI.
- The companies and knowledge institutes will propose a federated AI learning AiNed Innovation Lab once the AiNed call for Innovation Labs comes available.
- The Health-AI consortium will engage (see T1.7) with the ELSA lab North Netherlands and evaluate if there is a need for a second ELSA Lab on Health-AI, which will then be proposed in one of the upcoming AiNed ELSA Lab calls. This second lab might focus more on health AI development, creating a health data market, market access for AI and regulatory aspects.
- The Health-AI consortium has already contacted Zuyd University of Applied Sciences for the possibility to setup an AiNed Learning Community for Health AI development with a focus on federated data settings. During the project this option will be explored including a reach out to other Universities of Applied Sciences to geographically broaden such a community. We expect to use the AiNed Training Voucher system to train employees from companies and knowledge institutions to use federated AI learning and benefit from the Health-AI solutions.
- Through the existing NLAIC Healthcare Working Group and the NLAIC AI Hub structure, the project results and knowledge will be shared continuously with a wide variety of 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, MDW, 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).

Deliverables (month, type)

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		3		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	33		15			15		
Partner	Maastro	Brightlands	Health-RI	eScience	BranchKey	RML	IQVIA	Linksight
PM					15	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, 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	44	13	84	7	3	4	7	36
Partner	Maastro	Brightlands	Health-RI	eScience	BranchKey	RML	IQVIA	Linksight
PM	75		9	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, Philips, 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, eScience, 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 **MDW** 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 **MDW**.

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 leads 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 singing 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

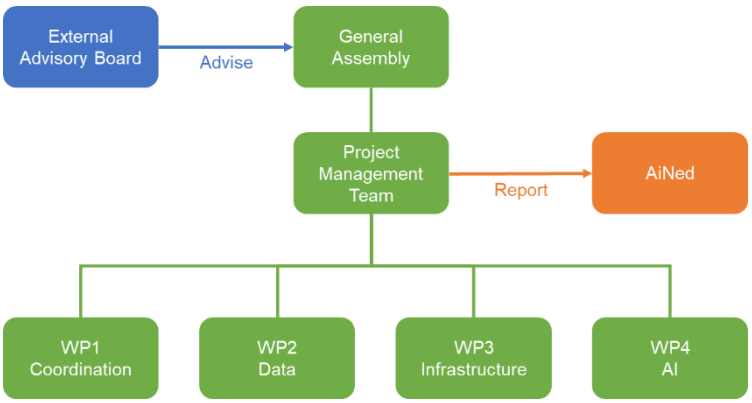
The governance and organization of the Health-AI project are modeled in accordance with the Horizon Europe project model and the DESCA model agreement, both familiar to most partners. The key elements of the governance structure are as follows:

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.

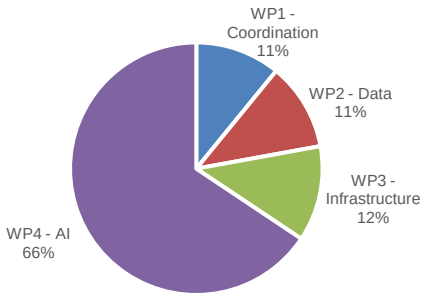


This proposed governance structure provides a solid foundation for effective project management and collaboration, ensuring that roles and responsibilities are clearly defined and that decision-making processes are both decisive and transparent. It allows for adaptability and evaluation, as necessary, 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 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	€ 121,896
		Brightlands	12	€ 121,896
		Maastro	12	€ 121,896
	1.2 Communication	Brightlands	12	€ 121,896
		MDW	12	€ 121,896
	1.3 Agreements	MDW	6	€ 60,948
	1.4 Dissemination	Brightlands	6	€ 60,948
	1.5 Data management	UM	3	€ 30,474
	1.6 Software management	eScience	3	€ 30,474
	1.7 ELSA	UMCG	4	€ 40,632
		MDW	3	€ 30,474
	1.8 Information security	Philips	3	€ 30,474
	1.9 Intellectual property	Philips	3	€ 30,474
	1.10 Exploitation	Brightlands	6	€ 60,948
Subtotal			97	€ 985,326
2 Data	2.1 Common data model	NKI-AVL	6	€ 60,948
		UMCG	6	€ 60,948
		Isala	6	€ 60,948
		RUMC	6	€ 60,948
		Maastro	6	€ 60,948
	2.2 FAIR implementation profile	Health-RI	24	€ 243,792
		UM	3	€ 30,474
	2.3 Data FAIRification	NKI-AVL	6	€ 60,948
		UMCG	6	€ 60,948
		Isala	6	€ 60,948
		RUMC	6	€ 60,948
		Maastro	6	€ 60,948
		IQVIA	12	€ 121,896
Subtotal			99	€ 1,005,642
3 Infrastructure	3.1 Infrastructure provision	Philips	9	€ 91,422
		MDW	9	€ 91,422
		TNO	9	€ 91,422
		BranchKey	9	€ 91,422
		RML	9	€ 91,422
		Linksight	9	€ 91,422
	3.2 Infrastructure end-user engagement and security	MDW	24	€ 182,844
		TNO	6	€ 60,948
		Philips	6	€ 60,948
		BranchKey	6	€ 60,948

		RML	6	€ 60,948
		Linksight	6	€ 60,948
Subtotal			108	€ 1,097,064
4 AI	4.1 Literature review	UM	6	€ 60,948
	4.2 Federated common data science tasks	eScience	24	€ 243,792
		MDW	11	€ 111,738
		BranchKey	12	€ 121,896
		RML	12	€ 121,896
		Linksight	12	€ 121,896
		IQVIA	12	€ 121,896
		Isala	12	€ 121,896
		Philips	12	€ 121,896
		Maastro	27	€ 274,266
	4.3 Federated AI algorithms	UM	7	€ 71,106
		UMCG	3	€ 30,474
		TNO	4	€ 40,632
		eScience	106	€ 1,076,748
		Philips	24	€ 243,792
		MDW	12	€ 121,896
		BranchKey	21	€ 213,318
		RML	21	€ 213,318
		Linksight	21	€ 213,318
		IQVIA	12	€ 121,896
	4.4 Privacy preservation in federated AI	Philips	24	€ 243,792
		eScience	24	€ 243,792
	4.5 AI use cases	Health-RI	9	€ 91,422
		MDW	21	€ 213,318
		Isala	24	€ 243,792
		IQVIA	24	€ 243,792
		Maastro	48	€ 487,584
		RUMC	7	€ 71,106
		Philips	24	€ 243,792
		NKI-AVL	7	€ 71,106
Subtotal			583	€ 5,922,114
Total			**887**	**€ 9,010,146**

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.

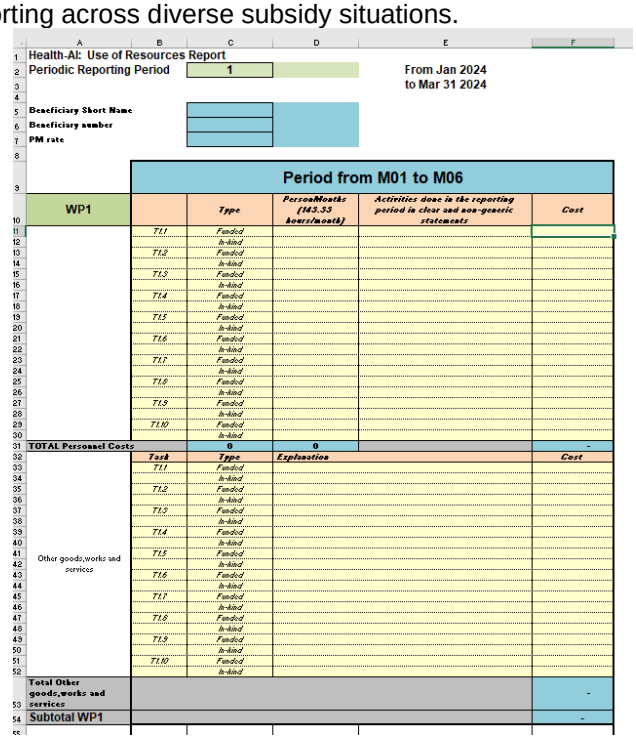
Partner	Type	Co-funding		Funding rate	Subsidy
		PM	Amount		
MDW	S	28	€ 279,345	75%*	€ 838,035
UM	K	0	€ -	100%	€ 193,002
Philips	L	63	€ 639,954	40%	€ 426,636
RUMC	K	0	€ -	100%	€ 193,002
UMCG	K	0	€ -	100%	€ 193,002
TNO	K	0	€ -	100%	€ 193,002
NKI-AVL	K	0	€ -	100%	€ 193,002
Isala	L	29	€ 292,550	40%	€ 195,034
Maastro	L	59	€ 603,385	40%	€ 402,257

Brightlands	S	14	€ 146,275	60%	€ 219,413
Health-RI	S	33	€ 335,214	0%*	€ 0
eScience	M	79	€ 797,403	50%	€ 797,403
BranchKey	S	19	€ 195,034	60%	€ 292,550
RML	S	19	€ 195,034	60%	€ 292,550
IQVIA	L	36	€ 365,688	40%	€ 243,792
Linksight	S	19	€ 195,034	60%	€ 292,550
Total			**€ 4,044,916**		**€ 4,965,230**

* Tasks were post-application shifted from Health-RI to MDW. The higher funding rate of MDW is compensated by the lower funding rate for Health-RI. Combined Health-RI and MDW have a funding rate of 58% which is in line with the normal funding rate for small companies.

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.

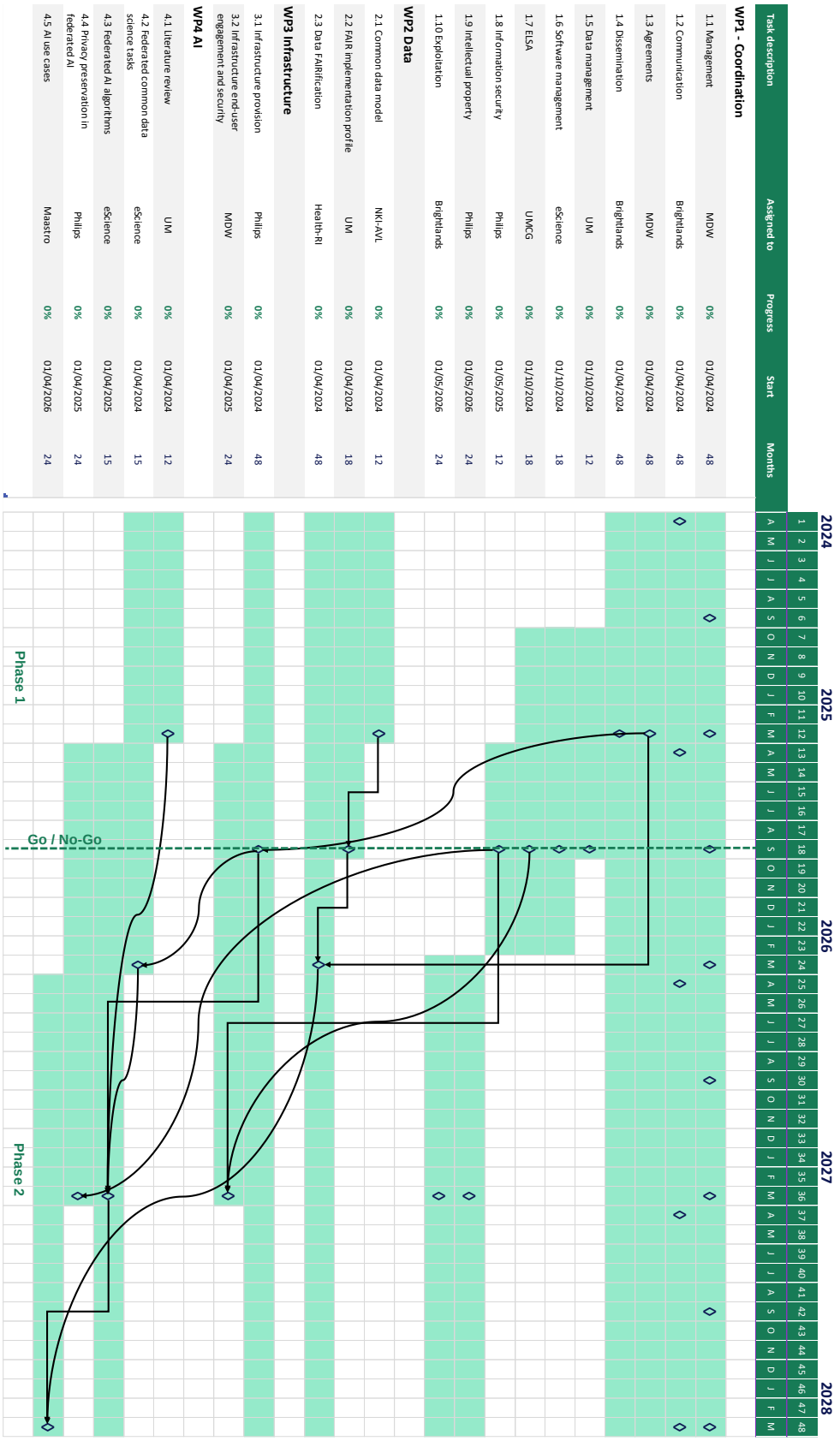
Furthermore, MDW, as the lead party, implements a pre-financing payment system that disburses each partner's share every six months, contingent upon the submission of both the financial report and the progress report of the last period. This practice reinforces the importance of delivering high-quality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