

retention

SMART HEART FAILURE MANAGEMENT

Horizon 2020 Project RETENTION

**“HEART FAILURE PATIENT MANAGEMENT AND INTERVENTIONS USING
CONTINUOUS PATIENT MONITORING OUTSIDE HOSPITALS AND
REAL WORLD DATA”**

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Abbreviations Index

Abbreviation	Full name
AI	Artificial Intelligence
BU	Business Unit
CA	Consortium Agreement
CAGR	Compound Annual Growth Rate
DoA	Description of the Action
D&C	Dissemination and Communication actions
DT	Digital Therapeutics
ER	Exploitable Results
GA	Grant Agreement
HF	Heart Failure
IP	Intellectual Property
IPR	Intellectual Property Rights
KPI	Key Performance Indicator
LVAD	Left Ventricular Assist Device
RPM	Remote Patient Monitoring
RWD	Real-World Data
TRL	Technological Readiness Level
WPs	Work Packages



1. Executive Summary

The present report aims to track progress made with dissemination, communication, impact creation, exploitation, and standardisation actions during **the first 32 months of the project** (01/05/2021–31/12/2023) to maximise RETENTION's impact so far.

This document reports actions recommended and/or guided by the project's D9.2 (Communication, Dissemination, Impact Creation, Exploitation & Standardisation plan), submitted in October 2021. All the activities undertaken in this context are addressed here, as are the challenges, risks, means of mitigation, and lessons learned from such actions.

In particular, this report examines how RETENTION has:

- Implemented communication and dissemination activities to ensure that all project results reach the appropriate audience and achieve the expected impacts,
- Monitored the impact of dissemination and adapting strategies and methodologies as deemed necessary,
- Involved all partners to execute the initial awareness and impact creation, exploitation, and standardisation strategy plan correctly and completely,
- Coordinated with external stakeholders (patients, regulatory bodies, healthcare providers, and decision makers), as well as other related projects and institutions, to ensure a high reach of communication activities,
- Prepared the ground to secure the sustainability of the project's results beyond the lifetime of the project,
- Aligned with and contributed to relevant standardisation activities.

This report not only offers a thorough summary of activities, resources, and capabilities in awareness and impact creation, exploitation, and standardisation efforts but also provides operational guidance for key partners responsible for maximising outreach and impact. The foundational approach used in drafting this report will be crucial for future assessments of the project's capacity to enhance, adapt, and leverage its outputs and achievements.



2. About this Document

The D9.3 outlines the strategies and activities employed by the project to share its findings and maximise their impact. It details the identified target audiences, communication strategies, key messages, and the range of tools and channels used for promoting the project at various levels. Additionally, the report outlines strategies for exploiting project results, including RETENTION clinical partners results sustainability approaches and the effort employed to align the project's activities with relevant standards.

This deliverable is part of Work Package 9 (Dissemination, Exploitation, Standardisation & Sustainability), led by i2Grow (i2G).

2.1 Role of deliverable

This report serves as a crucial document for the project's consortium as it provides a transparent account of the project's progress in creating impacts by disseminating knowledge, reaching audiences, networking with relevant initiatives to create synergies, strategically laying the foundations for the exploitation of the project outcomes, and ensuring the project outputs adhere to industry best practices.

Assessing the effectiveness of actions employed versus set performance indicators allows for the evaluation and measurement of the project's progress, impact, and adherence to predefined goals. This assessment helps in determining the success or areas for improvement in achieving the intended outcomes and ensures alignment with the project's objectives and key performance indicators.

2.2 Relationship to other RETENTION deliverables

The Communication, Dissemination, Impact Creation, Exploitation & Standardisation interim report acts as a nexus, synthesising information from various project components to provide a comprehensive and cohesive overview of the project's efforts in these critical areas.

2.3 Structure of the document

The document is structured into eight primary sections, along with a compilation of abbreviations utilised throughout. Its objective is to offer a comprehensive overview of the RETENTION-implemented activities, results assessment, and future strategies concerning dissemination, impact creation, exploitation, and standardisation.

Key sections comprise:

1. Executive Summary:
Briefly encapsulates key findings and document highlights.
2. About this Document:
Describes the document's structure, guiding readers through its sections.
3. Methodological Approach for Impact Creation and Maximisation:
Explores the methodology used to assess and maximise the project's impact.
4. Key Stakeholders' Expectations and D&C Actions:
Examines stakeholder expectations and outlines related actions in dissemination and communication.



5. A Close Look at the RETENTION D&C Performance (M1-M32):
Provides a detailed analysis of D&C performance from Month 1 to Month 32.
6. EXPLOITATION Actions Implemented (M1-M32):
Examines actions taken for the exploitation of project results.
7. Standardisation activities carried out (M1-M32):
Examines standardisation activities undertaken.
8. Conclusions:
Summarises key findings and insights presented in the document.



3. Methodological approach for impact creation and maximisation

To maximise the impact of the RETENTION project, a sound methodology has been designed at the beginning of the project, and actions have been and will be implemented to raise awareness about the project achievements with a view to achieving their sustainability even after the end of the funding period.

The impact creation strategy has been conceived taking into account, firstly, the main impacts that were foreseen by the EU call for proposals under which the project was presented.

In relation to the use of **multi-disciplinary, multi-source Real-world Data (RWD) to advance clinical research on complex chronic conditions (Call Impact #1)**, RETENTION demonstrates the potential for leveraging multi-source real-world data to inform heart failure policy, care treatment, and management. Through a systematic approach based on scientific literature, it was possible to generate evidence on outcomes used to assess telemonitoring interventions across three key policy areas: **improving self-care, improving clinical outcomes, and living well with heart disease.**

Indicators such as hospitalisations, emergency department visits, treatment adherence, and quality of life metrics were also scrutinised by clinicians to determine a validated set of metrics for inclusion in a policy dashboard that will inform key stakeholders. By integrating different sources of data, i.e., literature reviews, clinician perspectives, and patient data, this project synthesised the available evidence and identified a list of indicators to help assess the impacts of telemonitoring interventions for patients with heart failure.

The applied multi-disciplinary methodology underscores the potential of utilising diverse RWD sources to address evidence gaps and advance patient-centred research.

Future directions: To showcase the project's role in advancing clinical research using diverse RWD, a **meta-analysis** will be conducted in the upcoming project period. This analysis will integrate findings from the RETENTION randomised controlled clinical trial (RCT) and previous scientific evidence on telemonitoring interventions for patients at risk of or with heart failure.

The meta-analysis aims to compare the results of the RETENTION RCT with existing evidence, providing insights into any differences or similarities. The RETENTION RCT will collect multi-disciplinary, multi-source RWD from 450 patients, focusing on continuous monitoring and personalised interventions for heart failure patients. The results will be synthesised with data from past RCTs addressing home telemonitoring interventions for a similar patient population.

In the RETENTION task WP5.4, comparable RCTs were identified to support the upcoming meta-analysis. This task aimed to establish key criteria and indicators for policymaker relevant policies in cardiovascular management. A review of past RCTs, exploring telemonitoring impacts on preventing, treating, and managing heart failure, informed the selection of these criteria.

The meta-analysis has a dual purpose: firstly, to statistically determine and validate the superior patient outcomes resulting from telemonitoring interventions compared to standard care without telemonitoring; secondly, to ascertain whether the RETENTION RCT aligns with or diverges from such evidence. Key clinical outcomes from the RETENTION RCT protocol, including days lost due to unplanned cardiovascular hospitalisation, all-cause mortality, cardiovascular mortality, and all-cause and heart failure hospitalisation



rates, will be compared. This analysis will compare heart failure patients receiving home telemonitoring interventions with those receiving usual care without telemonitoring, referencing existing RCT evidence.

This meta-analysis, amalgamating findings from the RETENTION RCT and previous RCTs, aims to **ascertain the overall and subgroup effect sizes of home telemonitoring interventions on crucial patient outcomes** such as decreased mortality and hospitalisation rates compared to standard care.

Positive findings could:

- Highlight the significant capacity of remote patient monitoring and data-driven care to markedly improve outcomes for heart failure patients compared to standard care without telemonitoring.
- Aid healthcare providers and policymakers in comprehending the potential of telemonitoring interventions, fostering the eventual adoption of remote monitoring and personalised interventions for enhanced care of heart failure patients.

The RWD collected by RETENTION are managed by an **innovative platform** that allows patients' continuous monitoring and personalised interventions. In doing so, **the project seeks to advance the development of new technological tools and platforms for advanced data management (Call Impact #5).**

RETENTION actively engages with technological advancements, incorporating Internet of Things (IoT), Internet of Medical Things (IoMT), and Artificial Intelligence (AI) technologies. The project places emphasis on continuous monitoring and personalised interventions, essential components in exploring benefits and evaluating enhancements in the clinical management of patients with chronic heart failure, heart transplantation, or Left Ventricular Assist Devices (LVAD). Aligned with the trajectory of the European eHealth market, RETENTION focuses on chronic disease management, contributing to improved healthcare outcomes and cost reduction.

Leveraging IoT and IoMT technologies strategically, RETENTION underscores its dedication to evidence-based practices. The adoption of diverse data collection methodologies enhances the platform's efficacy. Recent publication, "Enhancing Healthcare through Telehealth Ecosystems: Impacts and Prospects" (Manta et al., 2023), further strengthens RETENTION's contributions, encapsulating its commitment to advancing technological tools for comprehensive data management.

Future directions: The future trajectory of RETENTION relies on continuous endeavours for regulatory alignment. Actively engaging in shaping evolving regulatory frameworks, the project guarantees the ethical, secure, and compliant cross-border exchange and processing of health data according to emerging standards. Substantial investments in research and development constitute a foundational element, positioning RETENTION at the forefront of cross-border health data exchange, particularly in the context of heart failure.

The **significant volume of real-world patient data collected by RETENTION for its clinical studies in participating pilot hospitals** underscores the project's commitment to **facilitating secure and ethical cross-border sharing of health data**. This dedication aligns with the strategic objectives of the Digital Single Market initiative in the European Union **(Call Impact #6).**

RETENTION addresses regulatory challenges in cross-border health data exchange, proactively tackling complexities. This proactive stance ensures alignment with emerging standards and regulatory considerations, reflecting the project's commitment to the Digital Single Market's goals for seamless healthcare accessibility and information exchange.



Emphasising security and privacy, RETENTION's Security Component plays a pivotal role in managing personal data securely in compliance with GDPR regulations. Global collaborations present unique opportunities, contributing to the broader discourse on cross-border health data exchange.

Future directions: The growth of cross-border health data exchange depends on regulatory considerations. **RETENTION actively engages with evolving regulatory frameworks and standards, ensuring a leading position in advancing healthcare delivery across borders.** Strategic investments in research and development are central to RETENTION's future strategies, positioning the project as a catalyst for positive change in cross-border health data exchange.

4. Key stakeholders' expectations and D&C Actions

An initial stakeholder scoping exercise has been included in D9.3 and it is serving as a guiding reference for D&C activity planning.

RETENTION involves the full range of stakeholders, i.e., patients, academia and research, public bodies, hospitals, regulators, private companies, standardisation bodies, and citizens, and therefore represents the full value chain in several countries.

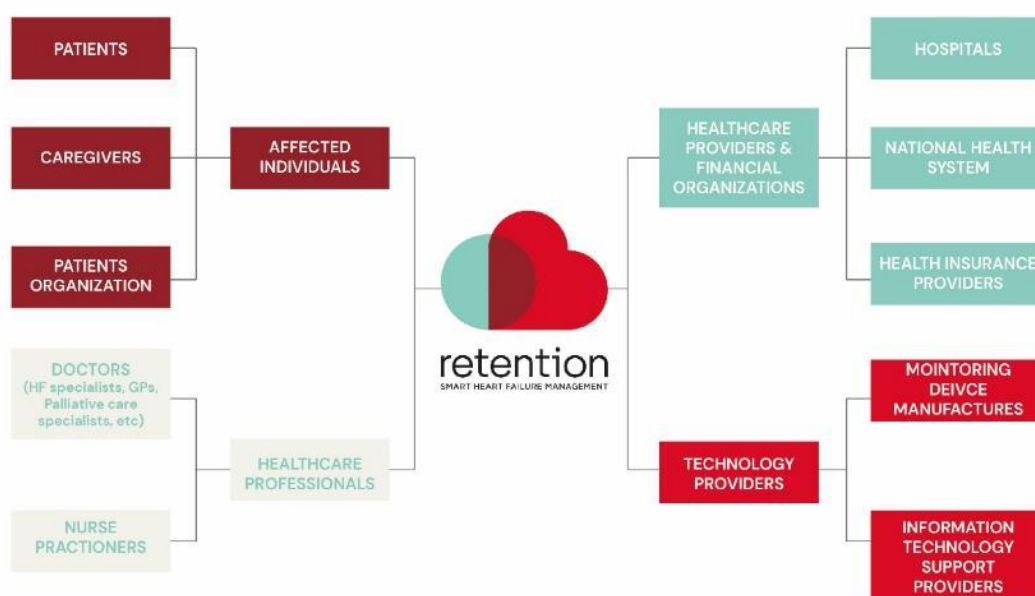


Figure 1: Stakeholder categories targeted by RETENTION D&C activities

The table below provides a list of stakeholders' categories, their relevance for RETENTION and D&C activities undertaken to engage them in the project activities.



Table 1. Relevant stakeholders, interests, expected impacts from dissemination and comms and main actions undertaken during M1-M32

Category	Relevance	DC expected impacts	Implemented actions
Patients and caregivers	Final beneficiaries of the project outcomes. The relevance of their involvement lies in the enrichment of perspectives, the alignment of solutions with real-world needs, and the empowerment of individuals who are at the heart of healthcare delivery. Their active participation ensures that the outcomes of the project resonate with the intricacies of daily life, ultimately leading to more impactful and sustainable advancements.	Communicating crucial information to patients and informal carers is not just a procedural aspect of a research project; it is a vital link in the chain of ensuring that the outcomes of the study reach those who stand to benefit the most. The success of this dissemination hinges not only on the rigour of the research but also on the effectiveness of communication channels and the thoughtful design of outreach actions. Clear, concise, and culturally sensitive communication ensures that the information resonates with patients and carers, regardless of their background or level of health literacy. Regular newsletters, webinars, and social media posts, as well as traditional communication channels, can keep the community informed and engaged throughout the duration of the project.	Regular update the RETENTION website and social media accounts with pertinent content. Release of the first and second project’s newsletters. Production of a video to showcase the benefit of the RETENTION actions for patients.
Heart failure patient organisations	The involvement of heart failure patient organisations is pivotal, in as these organisations serve as invaluable bridges between researchers, healthcare professionals, and the individuals directly affected by heart failure. Their engagement contributes to the awareness and acceptance of research initiatives within the affected community.	Patient support groups and advocacy organisations are powerful allies in the dissemination process. Collaborating with these groups ensures that information is communicated through trusted channels. This approach recognises the influence of peer-to-peer communication in healthcare and empowers patients and carers with knowledge that emanates from shared experiences. Tailoring the language and framing of research findings is crucial when reaching out to patient support	Patient organisations have played a significant role in the policy engagement workshops conducted at both EU and local (Greece) levels. Their engagement will be heightened as the clinical sites commence their pilot activities, and each site will organise local stakeholder initiative. RETENTION’s produced informational materials cater to this stakeholder category.



		groups. Emphasising the practical implications, potential benefits for patients, and real-world impact of the research ensures that the information is communicated in a way that resonates with the concerns and priorities of patients and their advocates.	
Hospitals and health professionals	Their involvement brings a practical and patient-focused perspective to research projects, ensuring that the studies are grounded in the realities of healthcare delivery. Their expertise contributes to the overall success of the research by enhancing its clinical relevance, methodological robustness, and potential for positive impact on patient outcomes.	Reaching out to healthcare professionals is a pivotal phase in ensuring that the fruits of scientific inquiry translate into tangible improvements in patient care. The success of this dissemination effort depends not only on the accuracy and relevance of the research but also on the strategic selection of channels and actions tailored to engage and inform the diverse and dynamic community of healthcare professionals. Peer-reviewed publications in medical journals, conferences, and professional gatherings can be good examples of communication channels to be used to reach out to this category, as well as using language that strikes a balance between scientific accuracy and practical applicability.	Health care service providers and professionals have been part of the audience attending a number of events in which RETENTION has been showcased (i.e., Digital Medicine, Special Symposium, Cluster.Medizin.NRW, Health Data in Cardiovascular Research, 9th Panhellenic Conference on Biomedical Technology, 19th Annual Conference Developments 2023 & Outlook 2024 in Cardiology). Clinicians were notably engaged in panel discussions dedicated to the project's liaison initiatives, as well as in the local stakeholders' engagement action held in Greece in early December 2023.
Policymakers	The involvement of key decision-makers who have the authority to provide support, allocate resources, shape regulatory frameworks, and ensure the project's integration into broader policy initiatives is crucial	Disseminating research findings to policymakers involves a strategic and purposeful approach, recognising the unique interests and priorities of these entities. The success of these dissemination actions is not only about showcasing the research outcomes but also about aligning them with the	RETENTION has undertaken specific initiatives aimed at engaging national and regional healthcare authorities, procurers, and payers. This includes policy engagement initiatives organised both at the EU and local



	<p>for overcoming challenges, ensuring scalability, and fostering sustainability. This collaboration enhances the overall impact of the RETENTION work, increasing the likelihood that its outcomes will contribute meaningfully to the betterment of society or address specific needs in the addressed sector.</p>	<p>broader objectives and concerns of the public and private sectors. Targeted reports and policy briefs, as well as dedicated meetings and workshops, represent good examples of channels and tools to interact with this category, addressing their specific queries and providing a deeper understanding of how the outcomes of the project can align with public health goals. Tailoring the language and framing of the research findings to align with the language of policymakers is crucial. It is essential to emphasise economic benefits, efficiency gains, or strategic advantages to ensure that the research is presented in a manner that resonates with the specific priorities of the public healthcare sector.</p>	<p>levels. Additionally, the RETENTION flip book (brochure) has been designed with the intention of reaching this particular audience.</p>
<p>Medical researchers and data scientists</p>	<p>Targeting medical researchers and data scientists is essential for leveraging their expertise in data analysis, research methodologies, and technology integration. Their involvement enhances the project's scientific rigour, promotes evidence-based decision-making, and contributes to the development of innovative and effective retention strategies in healthcare programs.</p>	<p>Promoting progress in scientific knowledge, informed decision-making, methodological innovation, interdisciplinary collaboration, improved patient outcomes, educational advantages, policy influence, and global collaboration exemplify the potential impacts of disseminating research findings to medical researchers and data scientists. Achieving success in dissemination to this audience demands a comprehensive strategy, including utilising channels such as scientific publications, peer-reviewed articles, participation in specialised conferences and symposiums, as well as engaging with online communities and knowledge-sharing platforms.</p>	<p>The scientific publications have already made research and innovation communities aware of the project's achievements. The project's public deliverables are accessible on the project website. All the technical, academic, industry events, and special sessions in which RETENTION has been presented have registered a large participation of the scientific community.</p>



5. A close look at the RETENTION D&C performance (M1-M32)

The i2G, RETENTION Dissemination and Communication Manager, is responsible for analysing and reporting on project communication and dissemination actions. This section reviews project performance using established Key Performance Indicators (KPIs) and targets, offering reasons for outcomes and recommendations. These suggestions aim to build on success or adjust strategies for improved results in future RETENTION activity years.

Details about the activities performed and summarised in the tables below are outlined in the next sections of this chapter.

Table 2. KPIs and outcomes for DC actions M1-M32

RETENTION OWN COMMS CHANNELS			
Communication means	KPIs	Status: December 2023	Details
Project website	≥1.000 accesses annually ≥100 downloads	https://www.retention-project.eu/	Downloads: <ul style="list-style-type: none"> • D8.2: 226 • D3.2: 199 • D3.1: 234 • D9.2: 285 Annual access: 2021: 132 2022: 1220 2023: 1121
Newsletter	≥8 newsletters	2 newsletters	Section 5.1.2
Press release	≥4 press releases	1 press release	Section 5.1.3
Scientific Communities, Social Research Networks and Social Networks	4 project accounts in Social Networks (LinkedIn, Facebook, Twitter, YouTube), ≥100 connections/followers on each	4 accounts up and running	Followers: <ul style="list-style-type: none"> • Facebook 38 • LinkedIn 137 • Twitter/X 84 • YouTube: 5
Scientific Communities, Social Research Networks and Social Networks	≥50 posts	Original posts from the RETENTION official accounts	69
Video	1 YouTube channel, ≥2 project videos	1 channel up and running; 1 project video	Section 5.1.5



Presentation Materials	≥2 flyers, ≥2 brochures (1 policymakers- 1 patients - 1 hospitals), ≥2 roll-up, ≥2 posters, ≥2.000 hard copies distribution in ≥10 events. ≥500 downloads	1 flyer, 1 roll up, 1 poster translated in all partners languages, 1 brochure in English, Greek and Spanish	Section 5.2
			Downloads: Infographic: 270 Infographic n. 2: 208 POSTER Italian: 250 POSTER ENG: 250 POSTER Spanish: 246 Poster Greek:243 Flyer: 56 Roll-Up: 106 Hard copies distributed in events: Brochure: 50 + 50 copies English and Greek

PUBLICATIONS			
Communication means	KPIs	Status December 2023	Details
Traditional media	≥1 articles/interviews to national magazines and/or newspapers per participating country	none	-
Journal publications (PEER REVIEWED)	≥6 publications	none	-
Magazine publications (NO PEER REVIEWED)	≥8	none	-
Conference publications	≥12	6	Section 5.5
Special issues in international referred technical and non-technical journals and magazines (LINKED TO SPECIAL SESSIONS AT EVENTS)	≥2 special issues, ≥10 selected papers/issue	2 special issues	Section 5.5



EVENTS			
Communication means	KPIs	Status December 2023	Details
Special Sessions in scientific events	≥2 special sessions, ≥40 attendees	2; in both instances, the participation exceeded 40 attendees	Section 5.3
International industry event	≥1 demonstration	1 (no demonstrator)	Section 5.3
EU-focused event	≥1 demonstration	1 (no demonstrator)	Section 5.3
Technical/Academic Event	≥2 demonstrations	3 (no demonstrator)	Section 5.3
Interactive face-to-face networking	≥1 participation in relevant events per year	none	Section 5.3
Collaborations with other projects	≥2 synergies established with pertinent EU project	3 (MES-CoBraD and RE-SAMPLE)	Section 5.4.1
Collaborations with policymakers	≥1 meeting with health policymakers per each clinical trial country involved in project	1 (Greece)	Section 5.4.3
	≥2 meetings with EU healthcare and/or patient associations	1	Section 5.4.3

5.1 RETENTION Digital Communications

Digital communications span a wide array of electronic methods and platforms designed for information exchange. This section specifically delves into the RETENTION digital communication channels, providing an in-depth analysis of the performance achieved during the reporting period.

5.1.1 Project's Website

The RETENTION web site visits report shows the performance and trends of the web site over a period of three years, from 2021 to 2023. Since the web site was launched in October 2021, statistics and benchmarks are significant mainly in 2022 and 2023, namely Year 2 and Year 3 of the project web site life span. The report includes the following metrics:

- New Users: The number of first-time visitors to the web site.
- Users: The number of unique visitors to the web site, including both new and returning visitors.



- Sessions/visits: The number of interactions that a user has with the web site within a given time frame, such as viewing a page, clicking a link, or filling out a form. The key performance indicator for the website was set at **≥1000 accesses** (e.g., sessions/visits) per year, and the analysis indicates project compliance with the KPI
- Page Views per session: The average number of pages that a user views during a session.
- Duration of visits (seconds): The average length of time that a user spends on the web site during a session.

The RETENTION Web site analytics shows the following results:



Figure 2: RETENTION web site analytics

According to the analysis, the web site has seen a remarkable increase in users and sessions/visits in the past three years, reaching its highest point in 2022. The analysis also reveals that the web site has enhanced its user engagement and retention, as shown by the higher number of page views per session and the longer duration of visits, which averaged almost 4 minutes in 2023. The analysis suggests that the web site has been effective in drawing and keeping its audience, and that it should keep improving its content and design to sustain and boost its performance.



It is important to pay attention to the combination of indicators such as the total number of sessions/visits, total number of downloads and stats, and the longer duration of visits, especially in the last year analysed.

The aggregate number of downloads during the assessed period (M1-M32) is 3,516, comprising approximately 1000 downloads of deliverables and technical content (10 times the designated KPI for the overall project duration as reported in the DoA) and roughly 2,500 downloads of other Media Kit materials (5 times the designated KPI for the overall project duration as reported in the DoA). The total count of visits/sessions within the same timeframe is 2,473. These figures, combined with extended visit durations, suggest a notable interest among users in RETENTION and its outcomes. This includes communication kit items (e.g., posters, brochures, etc.) and deliverables, which play pivotal roles in fostering retention and engagement.

Another aspect to highlight, as part of the communication strategy in 2023, is the use of FlipBook as a tool to make digital brochure reading more interactive and increase the web site's users' session duration. In the following figure, the contents of "top downloads" from the web site are shown:

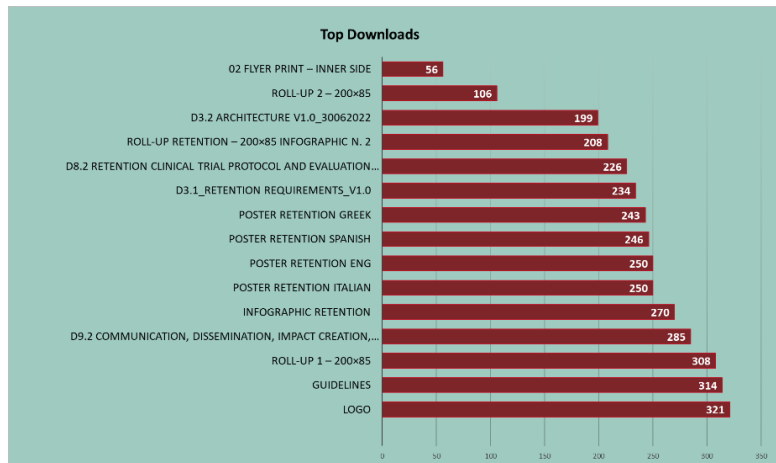


Figure 3: RETENTION web site top downloads

To complete the information about the relevance of downloads as an indicator of engagement, it can be highlighted the increased frequency of downloads along the period analysed, as shown in the figure below, and the geography of countries mostly interested in RETENTION contents, in particular Germany and Belgium in Europe, the US and Singapore in the Asian area.

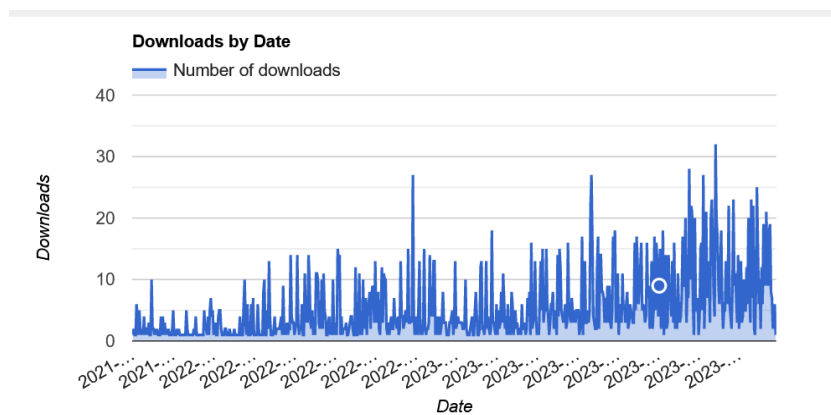


Figure 4: RETENTION web site frequency of downloads

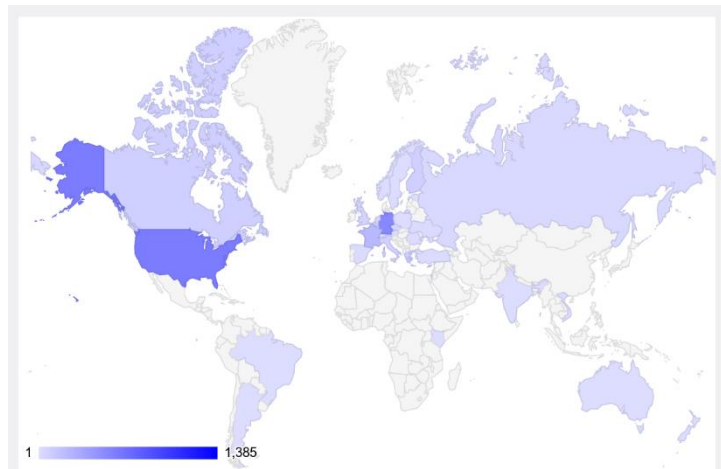


Figure 5: Countries mostly interested in RETENTION contents

Finally, an analysis of the indicators collected from the website users over the first three years enables the formulation of a strategy to be pursued in the upcoming year, such as:

- Maintaining the creation of content that is accessible and clear for the general public while preserving the quality and accuracy of the content,
- Leveraging the fourth project year to gain more insights into how website visitors are interacting with the various components of the RETENTION website and suggest ways to enhance them,
- Enhancing the content of the latest sections added to the website, as well as adding more scientific publications, potential interviews, and other relevant materials. Additional resources and links can help attract more visitors to the website and encourage them to explore it further.

5.1.2 Newsletters

Newsletters within a project serve as a versatile tool, not only conveying project achievements but also fostering continuous engagement, transparency, and a sense of community among stakeholders. This communication medium is a fundamental component of successful project management and communication strategies.

Two have been the issues produced so far by RETENTION.

The [first one](#) has been produced and distributed at the early stage of the project and has been aimed at providing stakeholders with a comprehensive overview of the project's objectives, medical benefits, and highlights about the latest activities.



Figure 6: RETENTION newsletter preview, 1st issue

The focus of the [second newsletter](#) issue revolves entirely around the commitment of the project's clinicians to implementing innovative solutions from RETENTION to enhance patients' clinical management, with a specific emphasis on improving overall health outcomes, streamlining care processes, and advancing the quality of healthcare delivery.

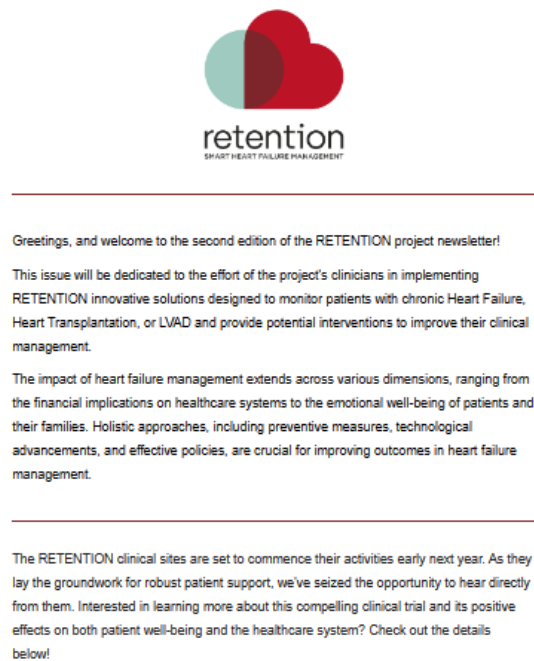


Figure 7: RETENTION newsletter preview, 2nd issue

5.1.3 Press release

Since the start of the project, [one press release](#) has been prepared and distributed to the project's partners for further dissemination to the broader public, stakeholders, and relevant media outlets.

A second press release is scheduled for early 2024 to provide evidence of the commencement of pilot activities at the clinical sites.

5.1.4 Social Media Performance

the content available on its website, and to draw attention to it through specific campaigns. The project set a KPI of having at least 100 contacts/followers on each social media channel. This goal was met on LinkedIn in the second year, but not yet on Twitter/X. The performance of Facebook and YouTube was not relevant for the period analysed, as these channels target the audience of general population patients, and the type of content provided (videos and visual information) will be more suitable for the communication strategy that will be implemented in the later stages of the project, especially during and after the pilot phase.

The data for this reporting phase were collected from M1 to M32, which corresponds to May 1st 2021 to December 31st 2023. However, as the social media platforms also use the solar year (January–December) to organise their data, we used the same yearly unit of measure to compare or aggregate data year over year. Therefore, for the purpose of this analysis, Y1 is 2021 (May–December), while Year 2 and Year 3 are 2022 and 2023 (Jan–Dec).

By looking at the platform data, the RETENTION LinkedIn page currently has 137 followers, in line with the projects funded under the same call, having the same 3-years-based project lifespan (e.g., MES-CoBraD project and the RE-SAMPLE project) while the RETENTION Twitter/X account has reached 84 followers.

For both Twitter/X and LinkedIn the **Average Engagement Rate** has been calculated by using **impressions as the denominator** to give a more realistic and dynamic engagement rate, as it reflects how many people actually saw the content and reacted. In the numerator of the formula, we have used aggregated and separated counts of engagement metrics such as Likes, applause, comments, shares, reposts, etc. counted for the 3-year period under analysis. The engagement rate for both platforms is very good, in particular on Twitter/X where it reached 12%, while LinkedIn reached 3%, which is considered good enough according to the platform parameters.

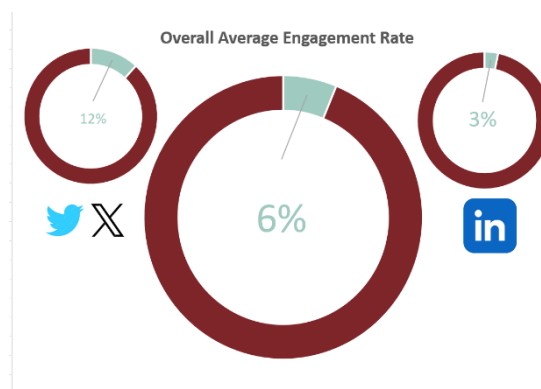


Figure 8: LinkedIn Engagement rate (overall, Twitter/X and LinkedIn)

The following metrics have been used to assess the progression and effectiveness of social media management activities, LinkedIn has been chosen thanks to the variety and granularity of data available on the platform:

- Page views are the number of times the LinkedIn page has been viewed by any LinkedIn member. Page views indicate the level of awareness and interest in the project among the LinkedIn community.
- Clicks (CTA) are the number of times the LinkedIn page visitors clicked on the call-to-action (CTA) button, which directs them to the project website.
- Unique visitors are the number of distinct LinkedIn members who viewed the LinkedIn page at least once during a given period.
- Number of new followers

The data on LinkedIn shows that **page views** have increased significantly year over year, indicating a growing popularity and visibility of the project. **Clicks (CTA)** have also increased significantly, especially in 2023 (Y3), indicating a high interest and curiosity of the LinkedIn page visitors in learning more about the project and its outcomes and the effectiveness of the project website in providing relevant and attractive content, such as digital brochures and deliverables, as well as the launch of the first video presenting the RETENTION platform features. Data shows that the **unique visitors** have also increased, indicating a broad and varied audience for the project, the expansion of the project network, and the attraction of new segments of potential stakeholders.

5.1.5 Multimedia content

To enhance comprehension and maximise the impact of project-related messages, the project initiated the development of its first audiovisual product. This decision was guided by the belief that such a mode of communication can boost engagement and accessibility when conveying difficult information.

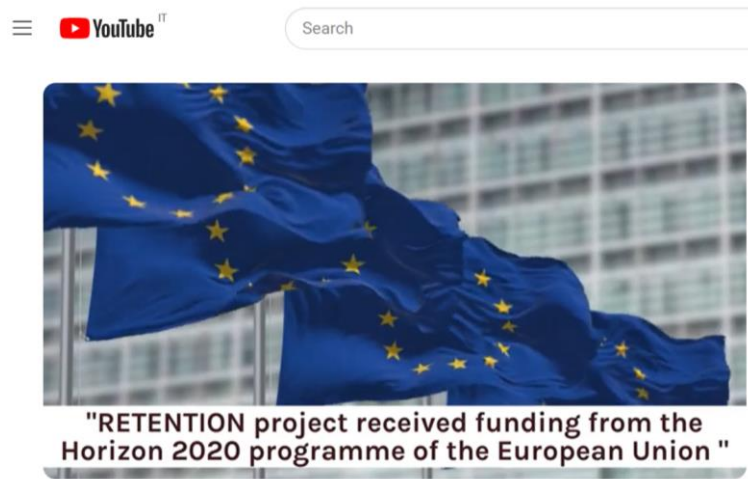


Figure 9: RETENTION Platform overview YouTube video

The video, [RETENTION Platform overview](#), actively promoted on social media and featured in conventions with key stakeholders, provides an overview of the medical issues addressed by RETENTION along with its proposed solutions.

Additional multimedia content has already been scheduled for production, considering the project's advanced stage and the fact that the project's clinical sites will soon initiate their activities. This content

will be aimed at effectively communicating the refined project outcomes, sharing insights from healthcare centre activities, and engaging a broader audience in the project's advancements.

5.2 Presentation Materials

A number of presentation materials for dissemination and communication have been produced so far by RETENTION and uploaded for public use on the project web site in the [Media Kit section](#).



Figure 10: RETENTION digital brochure in English and Greek

Graphic materials, including posters, brochures, infographics, and flyers, play a vital role in conveying project information to a wider audience, particularly when also translated into the languages of the project's partners. These materials are crafted to be visually engaging and concise, effectively communicating key messages about the project in an accessible format.

5.3 Events and gatherings showcasing RETENTION

Central to the communication, dissemination, and impact creation strategy of RETENTION is its presentation at national and international events. This involvement serves to highlight the value of the project's achievements and facilitates direct interaction with diverse audiences. The following list details the participation of partners in key conferences and events during the period under reporting, along with the stakeholders addressed by the various initiatives.

Table 3. Special Sessions gatherings showcasing RETENTION

Conference	Location	Date	Special Session	Brief description of the special session	Attending partner/s	Type of audience and n. of participants
IEEE BHI-BSN-2022	Ioannina, Greece	30/09/2022	Artificial intelligence and Real-World data for	This SS was organised by RETENTION in collaboration with	FORTH	Academics, Researchers, Business >50



			personalised support of patients with cardiovascular diseases	other EU-funded projects to exchange knowledge and ideas by making the dedicated audience familiar with the project objectives and achievements and the use of RWD for personalised support of patients with cardiovascular diseases.		
Digital Medicine, Special Symposium	Athens, Greece	04/11/2022	Digital health, Big Data and Real-World Evidence in Greece: The impact on the health ecosystem and the economy	The role of digital technology in cardiovascular diseases	OCSC	Academics, Researchers, Cardiologists, =350

Table 4. Industry Events showcasing RETENTION

Industry event	Location	Date	Description of the presentation and SPECIFY IF demonstrator	Attending partner/s	Type of audience and n. of participants	Countries addressed
The 13th International Symposium on ADVANCED TOPICS IN ELECTRICAL ENGINEERING	Bucharest, Rumania	23-25/03/2023	Presentation of a simplified approach for accurate arrhythmia detection using AutoML (no Demonstrator)	SIESRL	Researchers in various areas of theoretical and applied electrical engineering. Key leaders from private and state-owned	Worldwide



					companies, 160 participants	
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Table 5. EU-focused events showcasing RETENTION

EU-focused event	Location	Date	Description of the presentation and SPECIFY IF demonstrator	Attending partner/s	Type of audience and n. of participants	Countries addressed
Privacy & tech scenarios on reuse of health data: EU projects' roundtable	Online	19/06/2023	This seminar has been the occasion for many EU projects to discuss and exchange ideas on privacy and technical scenarios for health data reuse (no Demonstrator)	EUNL, STS	EU Commission Officers, Representatives from EU-funded projects, 30 participants	Europe

Table 6. Technical and Academic events showcasing RETENTION

Technical and Academic event	Location	Date	Description of the presentation and SPECIFY IF demonstrator	Attending partner/s	Type of audience and n. of participants	Countries addressed
Cluster.Medizin.NRW, Health Data in Cardiovascular Research	online	02/09/2021	Presentation of RETENTION Clinical study (no Demonstrator)	UKESSEN	Scientists, Doctors, 40 participants	Germany
9th Panhellenic Conference on Biomedical Technology	Thessaloniki, Greece	9-11/11/2021	Presentation of RETENTION aims and foreseen results (no Demonstrator)	ICCS	Academics, Researchers, Business, >100	Greece
19th Annual Conference Developments 2023	Athens, Greece	15-17/12/2023	Presentation of RETENTION	OCSC, NKUA	Specialist Cardiologists	Greece



& Outlook 2024 in Cardiology			platform and related functionalities (no Demonstrator)		and Cardiology Nurses, 100 participants	
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5.4 Events organised by RETENTION

This section is dedicated to providing evidence of the events organised by the project's partners to showcase the project's impact, engage stakeholders, and foster collaboration.

5.4.1 Synergies with other projects and initiatives

The RETENTION project aims at consolidating two or more stable liaisons with relevant EU projects and initiatives until the end of its funding period.

During the period under reporting, a strong relationship has been established with two EU-founded projects that originated from the same H2020 funding stream. The [MES-CoBraD](#) and [RE-SAMPLE](#) projects are relevant to RETENTION as they have similar strategic and technological approaches to prediction and diseases' management.

To strengthen the collaboration with the two initiatives, so fSIEMSar, two networking joint webinars have been organised:

Table 7. Liaisons initiatives

Title	Date	Brief description	Number of participants
Managing complex chronic conditions using real-world data	20/09/2022	In a joint project webinar, MES-CoBraD, RE-SAMPLE, and RETENTION showcased their work. These projects demonstrated innovative developments using real-world data and machine learning to address medical challenges, thereby enhancing diagnostic accuracy and the delivery of care and treatment. Originating from the same H2020 funding stream, these projects share a focus on leveraging real-world data in medical settings. The webinar offered an opportunity to assess the current state of the art in this field and explore how technical approaches are tailored to address diverse medical challenges, including brain disorders, heart disease, and pulmonary issues.	97



<p>Real-World Data in Medical Research: Harnessing their Potential and Addressing Challenges with MES-CoBraD, RE-SAMPLE, and RETENTION</p>	<p>20/11/2023</p>	<p>The webinar aimed at exploring the potential of Real-World Data (RWD) in advancing medical research and healthcare. Experts from three European research projects came together to discuss how they utilised RWD to address complex medical challenges, contributing to a digital transformation in healthcare delivery. The expert speakers shared their experiences and insights on acquiring, analysing, and applying RWD within their respective projects, while also addressing the challenges of collecting, anonymising, harmonising, and combining data.</p>	<p>41</p>
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In the near future, there are plans to organise further networking initiatives in R&D with pertinent projects. The goal is to foster a more collaborative, efficient, and impactful research environment, ultimately pushing the boundaries of knowledge and innovation.

5.4.2 Users co-design workshops

The co-design workshops organised by RETENTION aligned with the project's phases of user requirement analysis and platform design. These stages encompassed exploring user needs and profiles, evaluating the clinical application of the project's technology, and defining the solution architecture along with its related functions.

To further enrich the feedback obtained from the RETENTION clinical teams, which played a crucial role in shaping the platform design during the needs analysis phase, the project opted to revisit their insights and those of patients' representatives. Within the co-design workshops, the audience participated in a collaborative discussion covering clinical unmet needs, disease progression, clinical practices, and emerging research relevant to the follow-up management of heart failure patients. The sessions included presentations of the initial RETENTION technical solution, as well as mock-ups of the Global Insights Cloud and the Clinical Site Backend. The objective was to evaluate the RETENTION solution and propose potential refinements based on the valuable input received.

A recording of the two working sessions can be found here: 1) [RETENTION Mobile App Co design Meeting](#); 2) [RETENTION Clinical Backend Global Insight Cloud Co design meeting](#).

5.4.3 Policy engagement workshops

The involvement of the policy and decision-making level, as well as crucial and consistent communication with the main beneficiaries of the project results since the early start of the project is deemed essential to ensure alignment with stakeholders' needs, foster meaningful collaboration, and facilitate the seamless integration of project outcomes into existing systems and practices.

Two have been the initiatives within this framework organised so far by RETENTION.



One was directed at enhancing comprehension and eliciting feedback from key stakeholders at the EU level and representatives from various pilot sites involved in the project — first RETENTION **Policy Engagement Workshop**. The second was tailored for specific communication with Greek interested parties: **Stakeholders' Engagement Workshop at the ONASSIS Cardiac Centre** (GR).

1) First **Policy Engagement Workshop**, *26th January 2023*.

The panel included **Professor Christos Chizas** – President of the National eHealth Authority of Cyprus, **Dr. David Sanchez Ortiz** – Scientific Director of the Rural Medicine Foundation in Spain, **Mr. Ed Harding** – Director of the Heart Failure Policy Network, **Dr. Panos Minogiannis** – General Manager of the Onassis Cardiac Surgery Center in Greece, and **Ms. Rebecca Angerstein** – Medical Affairs at Abbott.

Following a thorough presentation of the RETENTION project, encompassing its technical platform and clinical trial design, the focus shifted to the policy aspect of the RETENTION platform. This included a detailed discussion about the policy dashboard, elucidating its expected design and its potential to aid policymakers in evaluating, adjusting, and creating new policies to address current needs.

In the panel discussion, participants enthusiastically endorsed the timely and valuable contribution of the RETENTION project to Heart Failure policy. Emphasis was placed on the platform's potential to improve healthcare providers' performance, and there were suggestions to provide insights into its effects on productivity, satisfaction, and the distribution of care responsibilities among specialists and GPs. Recommendations were made for the platform to collect data on costs and conduct stratified data analysis to identify patient groups benefiting most, assisting policymakers in addressing inequalities.

The significance of the evidence RETENTION would provide on medication adherence, hospitalisation rates, and A&E visits was acknowledged, with emphasis placed on its relevance at both hospital and policy levels.

Finally, the panellists reiterated their support for the project and their willingness to cooperate with the Consortium to facilitate RETENTION's outreach and impact.

2) The **ONASSIS Cardiac Centre Stakeholders' Engagement Workshop**, *23rd November 2023*

Through live sessions and presentations, attending physicians (40 doctors), policymakers (2), and patients (4 patients organisations) were offered thorough information about the RETENTION platform, AI analytics, and the functionalities of the home gateway. Ample time was dedicated to addressing questions from the audience, aiming to align the technological features of the RETENTION solutions with the perspectives of patients and carers.



5.5 Scientific dissemination through publications

The primary objective of the RETENTION scientific publications is to share knowledge, increase visibility, contribute to existing understanding, influence policies and practices, encourage collaboration, support educational outreach, and create a lasting impact within the scientific community and beyond. RETENTION employs various channels for this purpose, ranging from esteemed peer-reviewed journals to magazine publications and conference proceedings. The following section provides an overview of the scientific dissemination through publications accomplished thus far. With the project's results reaching an advanced level of maturity and clinical testing set to commence in early 2024, the consortium is optimistic about achieving enhanced performance within this framework in the upcoming period.

Table 8. Conference publications

Organisation (s)	Author(s)	Title	Conference name	Date	Location	Published in	Link to Paper
ICCS	V. Costarides, I. Kouris, M. Haritou, G. Matsopoulos*, D. Koutsouris, RETENTION team	A HEART FAILURE PATIENT MANAGEMENT AND INTERVENTIONS PLATFORM, USING CONTINUOUS PATIENT MONITORING OUTSIDE HOSPITALS AND REAL-WORLD DATA	9th Panhellenic Conference on Biomedical Technology - Conference Proceedings & Book of Abstract	9-11/11/2021	Athens, Greece	Conference Proceedings & Book of Abstracts	here



FORTH	M. Roumpi, Y. Goletsis, V. Pezoulas, A. Pardalis, I. Basdekis, D. Koutsouris, D.I. Fotiadis	Heart Failure Patient Management and Interventions using Real-world Data – The RETENTION case	13th FORTH Retreat 2022	15-16/07/2022	Heraklion, Crete	Conference Proceedings	here
ENUL & European University of Cyprus	Christina Nanou (Eunomia Ltd) Maria Crociani (Eunomia Ltd) Vasiliki Danilatou (Eunomia Ltd, European University of Cyprus)	New ethical challenges facing clinicians in the digital era: the paradigm of a clinical trial using AI-enabled tools for remote heart-failure patient monitoring and management	International Multithematic Conference 2022	Nov. 3rd to 5th 2022	School of Medicine, European University Cyprus	Online Library, Abstract Book	here
SIESRL	Gabriel Danciu, Irina E. Nicolae, Iulia Ilie, C. Septimiu Nechifor	Advanced Notebook: A tool for enhanced Management of Machine Learning models and procedures	ICAMCS 2023 (International Conference on Applied Mathematics & Computer Science), http://www.icamcs.co/	August 8-10, 2023	Lefkada, Greece	IEEE Explore	Not yet published here the paper preview



		in the Healthcare Domain					
EUNL, STS	Nanou Christina (Eunomia Ltd), Kampyli Maria (Eunomia Ltd), Crociani Maria (Eunomia Ltd), and Danilatou Vasiliki (Sphynx Technology Solutions)	Security shortcomings in healthcare: a preliminary investigation of Data Protection Authorities' decisions.	19th International Conference on the Design of Reliable Communication Networks (DRCN), SCENE workshop	20/04/2023	Vilanova i la Geltru, Spain	IEEE Xplore, pp. 1-6, doi: 10.1109/DRCN57075.2023.10108175.	here
ICCS (1), STS (2), SIESRL (3), AEGIS (4), FORTH (5), DM (6)	Ourania Manta (1) Nikolaos Vasileiou (1) Olympia Giannakopoulou (1) Konstantinos Bromis (1) Ioannis Kouris (1) Maria Haritou (1) Lefteris Koumakis (2) George Spanoudakis (2) Irina E. Nicolae (3)	Architectural Design for Enhancing Remote Patient Monitoring in Heart Failure: A Case Study of the RETENTION Project	HEALTHINF 2024	21–23/02/2024	Rome, Italy	SCITEPRESS Digital Library	Not yet available; Paper accepted on Dec '23



C. Septimiu Nechifor (3) Miltiadis Kokkonidis (4) Michalis Vakalelis (4) Yorgos Goletsis (5) Maria Roumpi (5) Dimitrios I Fotiadis (5) Heraklis Galanis (6) Panagiotis Dimitrakopoulos (6) George K. Matsopoulos (1) Dimitrios D. Koutsouris (1)							
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Table 9. Special issues in international referred technical and non-technical journals and magazine

Organisation (s)	Author(s)	Title	Conference	Special session	Date	Location	Published in	Link to Paper
FORTH	Maria Roumpi, Yorgos Goletsis, Vasileios Pezoulas, Athanasios Pardalis, Ioannis Basdekis, Dimitrios Koutsouris, Dimitrios I. Fotiadis	Exploiting Real-world Data for personalised Heart Failure patient interventions - The RETENTION case	IEEE BHI-BSN-2022	Artificial intelligence and Real-World data for personalised support of patients with cardiovascular diseases	27-30/09/2022	Ioannina, Greece	Special sessions	The presentation is not published.
ICCS	Ourania Manta, Nikolaos Vasileiou, Olympia Giannakopoulou, Konstantinos Bromis, Ioannis Kouris, Maria Haritou, George K. Matsopoulos, and Dimitrios D. Koutsouris	Enhancing Healthcare through Telehealth Ecosystems: Impacts and Prospects	European Federation of Medical Informatics (EFMI) Special Conference 2023	Special Topic Conference 2023 (STC2023): Telehealth Ecosystems in Practice.	25-27/10/2023	Torino, Italy	The poster will be included within the proceedings (and Pubmed-indexed)	Here



5.6 Traditional media coverage

Throughout the current year, RETENTION has not been featured in traditional media channels.

Capturing the attention of traditional media for research projects poses challenges. The intricate and specialised nature of projects like RETENTION complicates the effective communication of complex scientific or technical details to a broad audience. Journalists may face difficulties simplifying and conveying the research's significance to their readers or viewers.

Traditional media outlets operate within constraints of limited resources and tight deadlines. Journalists tend to prioritise stories that are easily digestible or align with current news trends, and research and innovation projects requiring in-depth coverage and analysis may not fit within these constraints.

As the project transitions into its piloting phase, where the human-interest angle becomes more pronounced, RETENTION is confident that the clear implications for the health and well-being of a large segment of the population affected by heart-related issues will render the project's results more likely to capture widespread interest.

In the upcoming phase, proactive engagement with the media will be promoted in order to elevate awareness and understanding of RETENTION's outcomes. This effort aims to effectively communicate the project's significance to a broader audience, fostering interest and recognition.

5.7 Partners' dissemination and communication performance

The table below presents the current individual dissemination performance of RETENTION partners, assessing it against the established Key Performance Indicators (KPIs) for the entire project duration. The analysis reveals that some partners, especially those engaged in clinical activities, are not fully involved at this stage. This is primarily attributed to the fact that the clinical intervention has not yet commenced. However, the overall performance of the project consortium has been commendable, effectively raising awareness about RETENTION activities and the expected societal benefits through the application of its methodologies.

Table 10: Partners' dissemination performance M1-M32

Partner	Dissemination type	KPI	Performance (M1-M32)
ICCS	National magazines' articles	1	-
	Peer-reviewed articles	2	-
	Scientific papers	4	2
	Conferences	6	1
	Demonstrators	1	-
	Liaisons workshops	2	2
	Meetings with EU healthcare and/or EU patient associations	1	1
OCSC	Scientific papers	2	-
	Conferences	2	2
	Liaisons workshops	2	2
	Meeting with local health policymakers	1	1



Partner	Dissemination type	KPI	Performance (M1-M32)
	Meetings with EU healthcare and/or EU patient associations	1	1
UNIBO	Scientific papers	4	-
	Conferences	6	-
	Liaisons workshops	2	-
	Meeting with local health policymakers	1	-
UKESSEN	National magazines' articles	1	-
	Scientific papers	2	-
	Conferences	2	1
	Liaisons workshops	1	-
	Meeting with local health policymakers	1	-
SERMAS	National magazines' articles	1	-
	Scientific papers	2	-
	Conferences	3	-
	Liaisons workshops	1	1
	Meeting with local health policymakers	1	-
NKUA	National magazines' articles	1	-
	Scientific papers	2	-
	Conferences	2	1
	Meeting with local health policymakers	1	1
	Meetings with EU healthcare and/or EU patient associations	1	1
FORTH	Peer-reviewed articles	1	-
	Scientific papers	2	3
	Conferences	4	1
	Demonstrators	1	-
LSE	National magazines' articles	1	-
	Scientific papers	2	-
	Conferences	2	-
	Liaisons workshops	1	1
	Meetings with EU healthcare and/or EU patient associations	1	1
STS	National magazines' articles	1	-
	Scientific papers	2	1
	Conferences	2	1
	Demonstrators	1	-
	Liaisons workshops	1	-



Partner	Dissemination type	KPI	Performance (M1-M32)
Datamed	Peer-reviewed articles	2	-
	Scientific papers	2	1
	Conferences	1	-
	Liaisons workshops	1	1
	Face-to-face networking	1	-
i2G			
i2G	National magazines' articles	1	-
	Conferences	2	-
	Face-to-face networking	1	-
	Liaisons workshops	4	2
	Meetings with EU healthcare and/or EU patient associations	1	1
AEGIS			
AEGIS	National magazines' articles	1	-
	Scientific papers	2	1
	Conferences	2	-
	Liaisons workshops	1	-
	Demonstrators	1	-
SIESRL			
SIESRL	National magazines' articles	1	-
	Peer-reviewed articles	1	-
	Scientific papers	2	2
	Conferences	2	1
	Demonstrators	1	-
EUNL			
EUNL	National magazines' articles	1	-
	Scientific papers	3	2
	Conferences	1	1
	Liaisons workshops	1	1
	Meetings with EU healthcare and/or EU patient associations	1	1

6. Exploitation actions implemented (M1-M32)

The aim of this chapter is to report the exploitation activity outcomes achieved by the RETENTION consortium at M32. The chapter includes a list of exploitable results identified so far and produced by the relevant work packages (WPs). This chapter has 3 sub-chapters, including the introduction and conclusion, with core chapters looking at: i) Methodology used in the analysis of exploitable results, a description of exploitable results (ER) currently identified and an ER driven exploitation plan from the Lead ER Owner identified, ii) description of the RETENTION Platform business model, iii) Exploitation Strategy of the Clinical partners addressing RETENTION Platform as an asset to improve healthcare delivery processes as well as RETENTION platform as a possible business unit.

In D9.2, elaborated at M5, the initial market insights and business requirements' as well as definition of RETENTION project's value proposition have been defined. From M5 to M32, Phase 3 and Phase 4 of the project exploitation phases (Figure 6) have been implemented within Task 9.2 and reported in the current deliverable D9.3.

During the implementation period, several iterations with other Tasks and WPs have been necessary to gather relevant information required to design the exploitation scenario. In details, the interaction with Task 2.4, where Innovation Management activities have been performed, allowed to elaborate the business model/scenarios for the RETENTION Platform, as well as set the bases for the intellectual property rights (IPR) rule definition to be applied to single Exploitable Results and to the RETENTION Platform. In addition, the intersection between WP9 and WP7 during the activities that led to the integration of the RETENTION platform and the achievement of MS5, has facilitated the collection of insights about the platform features to start elaborating the "competitive analysis," including the establishment of differentiation factors.

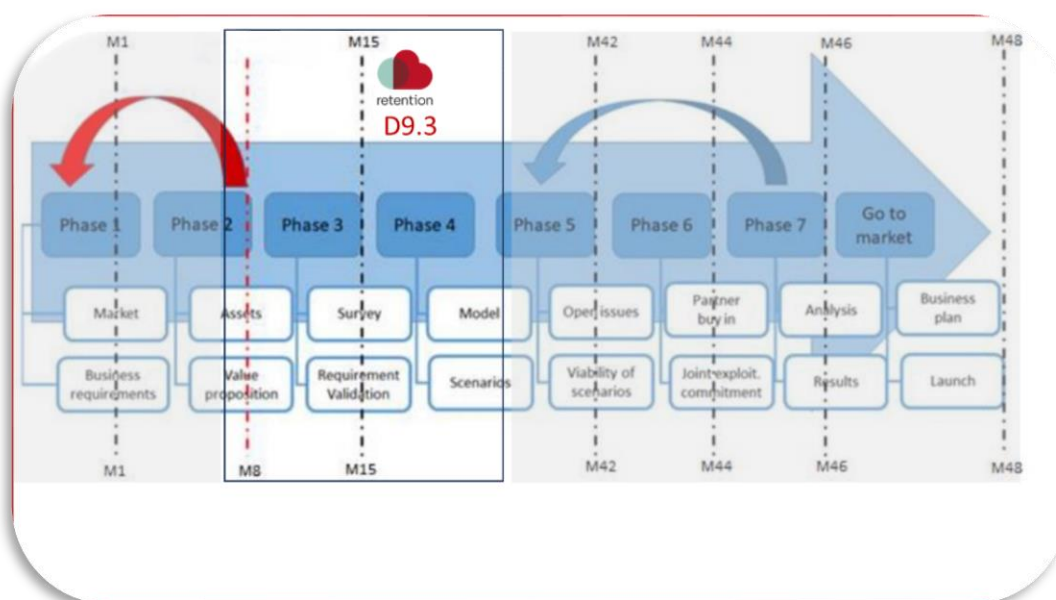


Figure 11: RETENTION Project Exploitation phases



The purpose of this Chapter is to:

- Present the methodology and map of the **Exploitable Results** identified by M32.
- Analyse each single ER by looking at the specific plan identified by the responsible partner identified as the “Lead Owner”. Lead Owner is defined as a single owner of the result or leader of a number of Joint-owners based on the definition reported in the Consortium Agreement.
As far as the Lead Owner as a single owner, it is important to highlight that the Access rights rules defined in the Consortium Agreement are always prevalent, and during the second half of the project partners will have to agree and formalise either business agreements or co-patenting agreements for each Exploitable Result.
- Describe the key exploitable results already available and applied in the project and having the potential to be used in other projects and initiatives, including the combination of ERs within the RETENTION Platform to be used as the main asset foundation for Business Models definition.
- The RETENTION Platform market perspective, indicators, and competition including the business model hypothesis were discussed and agreed upon among key business driving partners before presenting a complete plan to the consortium partners interested in joining.
- Updated Exploitation plans for clinical partners also consider the possibility of joining the RETENTION platform business model while taking into consideration the nature of the organisation as a possible user of the solution (conflict of interest) as well as the business management competencies required in the organisation in order to manage participation in a business model.

6.1 Exploitable results methodology and map

The Exploitable Results Methodology and Map were set up at M18 with the aim of achieving a coherent analysis of the exploitable results extracted from the running WPs such as WP3, WP4, WP5, WP6, and WP7. An ER data collection tool has been proposed by the WP and Task Leader (i2G), and, at the 4th Consortium Meeting, the consortium agreed on the structure. The data collection tool is available in Basecamp, the project management tool, and is open to all the partners who are invited to report the ER as soon as it is completed or whenever a final delivery date has been identified.

The ERs are categorised as follows:

Table 11: RETENTION Exploitable results categorisation

Category	Description of the guideline
Exploitable results/outcomes (name and description)	The title of the exploitable result can be identified or codified either as the name of the Task or the Deliverable or other names identifiable within the Grant Agreement (GA) and Annexes.
Ownership of result (select 8.1 or 8.2) *	8.1: My organisation claims to be the LEAD OWNER of a result (the role includes the respect of Access rights as defined in the Consortium Agreement (CA) and the management of co-patenting agreements with other partners claims along the project). 8.2: My organisation claims to be a JOINT OWNER of a result. *Definitions have been analysed, as well as references to the CA and GA articles.
If 8.2 is selected, list of Joint Owners	In the case of Joint Owners, the main partner driving the development of the ER is requested to indicate the other joint owners.



Category	Description of the guideline
#Task/s in which the exploitable result is generated	The ER may be generated for one or more tasks by the same partner or, jointly, by a group of partners.
Type of Exploitable result/ Description	<ul style="list-style-type: none"> • New knowledge: New insights, datasets, or knowledge • Methods and tools: Data models, AI models, Decision support systems, etc. • Stakeholders' engagement & new partnerships: Business partnerships, new alliances, roadmaps, etc. • Innovative solutions (new products/services/processes): prototypes leading to end-to-end solutions
Delivery Date	Expected Month of Delivery
Expected TRL (Technological Readiness Level)	TRL1-TRL9 based on the standard definition
Link to Exploitable result (if applicable)	A link to a web resource describing or hosting the ER as well as the link to open access services (e.g., Zenodo)
Target Stakeholders	Description of the beneficiaries or stakeholders to be addressed for different purposes e.g., collaboration, advice, validation, future customers, etc.

The current stage of the project does not allow us to confirm the “main ownership” or “joint ownership” claims made by some partners, as all the beneficiaries have the opportunity to request and prove a co-ownership until the project is completed. Therefore, the partners who assert their leading role or contributions in the project will have to participate in a further discussion phase to check the alignment with the Consortium Agreement articles 8.1 and 8.2.

The partners have reached a consensus that the ownership of each identified ER should be established by the project's conclusion in order to determine the IP shares and guarantee its sustainability and maintenance. The partners have also agreed to deal separately with the arrangements of IP share calculation, rights, and obligations of “single ERs” (§ 4.1.1) and the arrangements related to the potential launch and shares, royalties' calculation of the “RETENTION Platform” (§ 4.2), which is defined as a combination of both ERs developed within the project and the skills and competences needed to operate a possible Business Unit. This is because the IPR handling of the project requires different approaches for the individual ERs and the integrated platform.

EXPLOITABLE RESULTS (ERs)

- **Mandatory** for all the partners generating Foreground
- Ownership, co-ownership and Access Rights to RETENTION results (Consortium Agreement)
 - Define intellectual property (IP) share of single Exploitable results.
 - Define Exploitation plan for single Exploitable results, if applicable.

RETENTION PLATFORM (as a combination of ERs)

- Participation on a **Voluntary Basis**
- Based on the acceptance of a Business Case and Business Model



- Business Unit and Different Roles of Participants (Rights and Obligations)
- IP share and Royalties based on a method to agree (combination of ERs, direct agreement, etc.)

6.1.1 List of exploitable results

This part of the methodology focuses on presenting the identification and evaluation of Exploitable Results (ERs). The subsequent tables are structured at the Work Package (WP) level, providing updates until the 32nd month of the project.

Table 12: RETENTION Exploitable results WP4

Exploitable results/outcomes	Owners	Type of Exploitable result	Description	Expected TRL	Target Stakeholder
RETENTION Data Model	FORTH, OCSC	Methods and tools	model-driven big data analytics, personalised interventions, patterns detected (AI), etc.	TRL 7 – system prototype demonstration in an operational environment	Data analysts, healthcare providers

Table 13: RETENTION Exploitable results WP5

Exploitable results/outcomes	Owners	Type of Exploitable result	Description	Expected TRL	Target Stakeholder
Advanced Notebook: Model Specification Tool	SIESRL	Methods and tools	model-driven big data analytics, personalised interventions, patterns detected (AI), etc.	TRL 5 – technology validated in a relevant environment (industrially relevant environment in the case of key enabling technologies)	Data Scientists (Industry)
Big Data Analytics Engine and Transformations	SIESRL	Methods and tools	model-driven big data analytics, personalised interventions, patterns detected (AI), etc.	TRL 5 – technology validated in a relevant environment	Data Scientists (Industry),
Data Analytics Models for	SIESRL	Methods and tools	model-driven big data	TRL 4 – technology	Data Scientists (Industry),



Exploitable results/outcomes	Owners	Type of Exploitable result	Description	Expected TRL	Target Stakeholder
Personalised Management & Interventions			analytics, personalised interventions, patterns detected (AI), etc.	validated in the lab	Healthcare professionals
Disease Insights through Trustworthy & Verifiable AI	SIESRL	Methods and tools	model-driven big data analytics, personalised interventions, patterns detected (AI), etc.	TRL 4 – technology validated in the lab	Data Scientists (Industry), Healthcare Professionals

Table 14: RETENTION Exploitable results WP6

Exploitable results/outcomes	Owners	Type of Exploitable result	Description	Target Stakeholder
Standalone CSB Dashboard	AEGIS	Innovative solutions (new products/services/processes)	New concepts or new ways of using existing concepts and tech to solve a particular business problem. Include new technologies, updated business models, or disruptive inventions in current products and services using tools and methods.	Cardiology centres
Standalone GIC Dashboard	AEGIS	Innovative solutions (new products/services/processes)		Health policymakers, Data analysts
Standalone Home Edge Gateway	FORTH	Innovative solutions (new products/services/processes)		Healthcare organisations, Data analysts
Security Component	STS	Innovative solutions (new products/services/processes)		Healthcare organisations

6.1.2 Exploitation plan for exploitable results currently identified

Advanced Notebook: Model Specification Tool	
Outcome: Task 5.1	Description: The tool provides and exposes the functionalities to create AI/ML experiments, namely creating, training, testing, and validating models using data from both FHIR and non-FHIR databases. Researchers can interact with the data via web-based notebooks
LEAD Owner:	
SIEMENS	



Advanced Notebook: Model Specification Tool	
Type: Methods and Tools	and access the ML models metadata, artefacts and performance indicators, facilitating optimal decision-making in models' creation.
Expected TRL (end of project): TRL 5	Target user/customer/audience: Data scientists, researchers, universities, and businesses. Benefits: <ul style="list-style-type: none">• The tool allows a simple and fast deployment, fostering faster AI and ML experiments.• It offers simple management of the ML models and artefacts and automatic versioning. Supports model performance monitoring and tracking, metadata access, and performance indicator access via browser, including performance degradation monitoring.• Flexible framework that can be used in different set-ups, and in both in-lab and industrial environments. It can be easily adapted to different infrastructures and offers scalability properties. It can be either integrated into the Retention platform connected to FHIR/non-FHIR repositories or completely independent and connected to several types of databases, performing analysis upon request. This makes the solution useful in niche cases where the need for data transformation or custom modelling is not necessarily needed or can be created.• Supports privacy requirements when data cannot be shared outside premises, supporting deployment and models' storage on local PCs, private virtual machines, or multi-cloud environments, including private or hybrid clouds (private and public).• Minimal prerequisites and resources needed for usage such as a single machine or virtual machine, with resources adapted on the ML experiment.• Model Training and Model Prediction can also be separated on different sites and further support Federated Learning.• Supports different Programming Languages such as: Python, R, Julia, Scala• Supports connection to any Database type (FHIR, non-FHIR, or others). It can load data from different data sources in different formats.• Supports Big Data processing or small data sources equally well.• Supports the usage of any type of AI model, ML Apps, libraries, and even the adoption of new classes of ML algorithms.



Advanced Notebook: Model Specification Tool	
	<ul style="list-style-type: none"> Offers ML models explainability to offer a better understanding of model functioning. <p>Short term exploitation (1 year after the end of the project):</p> <p>The Advanced Notebook methodology will serve as a basis for further research, promoted in further Horizon Europe projects.</p> <p>A suitable manager will be identified for the tool, either from within the consortium or the regional networks that will host the tool and make it available beyond the project.</p> <p>The related documentation will remain public documents available as complementary information.</p> <p>The flexibility of the tool being completely independent of a specific database and infrastructure offers the possibility for later re-use in distinct set-ups and performing analysis upon request.</p> <p>Long term exploitation and preconditions:</p> <p>The innovation potential of the solution is investigated to be patented, and the tool is transferred to company's internal business units. Otherwise, it will be provided as open source, which can be extended by other users free of additional costs.</p>

Big Data Analytics Engine and Transformations	
Outcome: Task 5.1	<p>Description:</p> <p>The Big Data Analytics Engine handles data integration by efficiently distributing the data and computation necessary for ML processes and by effectively supporting the ML model training process. It also supports the pre-processing of input data before serving the resulting dataset to the ML algorithm via its Data Transformation sub-component.</p> <p>Target user/customer/audience:</p> <p>Data scientists, researchers, universities, and businesses.</p> <p>Benefits:</p> <ul style="list-style-type: none"> It offers different modalities to connect to several Big Data sources, depending on the storage environment. It can load data from different data sources in different formats, FHIR/non-FHIR. The engine (best candidate: Spark data processing framework that can quickly perform processing tasks on very large data sets) has the technical capacity to handle large quantities of data (Big Data) through various mechanisms such as paging or other algorithms found in libraries such as Spark.
LEAD Owner:	
SIEMENS	
Type: Methods and Tools	
Expected TRL (end of project):	
TRL 5	




Big Data Analytics Engine and Transformations	
	<ul style="list-style-type: none"> • Supports Big Data processing via Apache Spark and its data source connectors, and supports small data sources equally well. • It is capable of dealing not only with the volume but also with the velocity of the data collected by the various devices used for monitoring participants. • It offers automatic download and transfer, or ML models, from the global cloud to the clinical sites backends. <p>Short term exploitation (1 year after the end of the project):</p> <p>The integrated utility relies on the Advanced Notebook Tool availability, however, the engine can be packaged and shared open-source. The related data transformation mechanisms will be investigated and patented.</p> <p>Long term exploitation and preconditions:</p> <p>The standardisation capabilities of the engine will be invested to be considered as a package within existing big data libraries, and the framework will be shared as open-source within the ML community. For the data transformation sub-component, invention disclosure opportunities will be pursued.</p>

Data Analytics Models for Personalised Management & Interventions	
Outcome: Task 5.1	<p>Description:</p> <p>Advanced data analytics and ML models to predict possible future outcomes of a patient’s evolution, supporting multi-modal clinical decision-making for chronic CVD management and personalised interventions for HF, HT, and LVAD patients, and analysing the effects of these interventions on patient health, disease progression, quality of life, safety and well-being.</p> <p>Target user/customer/audience:</p> <p>Clinical experts and data scientists, HF patients and their carers, post-transplant units, businesses, professional, and patient associations, research centres, universities.</p> <p>Benefits:</p> <ul style="list-style-type: none"> • Uses model-driven big data analytics, a federation of big data repositories with medical and real-world data collected by RETENTION, including environment sensors, wearables, and medical devices. • Supports reinforcement learning aided by the clinician’s expert labelling. • Facilitates the clinical decision-making process and interventions
LEAD Owner:	
SIEMENS	
Type: Methods and Tools	
Expected TRL (end of project):	
TRL 4	



Data Analytics Models for Personalised Management & Interventions	
	<ul style="list-style-type: none"> Generates insights on disease patterns and patient health and well-being that can be leveraged for both the refinement of the associated intervention and decision-making models (thus continuously improving the effectiveness of patient management capabilities of the platform) as well as for enhancing the relevance of results from controlled clinical trials targeting CVD. <p>Short term exploitation (1 year after the end of the project):</p> <p>The data analytics models will reside on the Advanced Notebook tool, while the anonymised trained models can be shared with third-party users upon request, and the algorithms will serve as a basis for further research.</p> <p>Long term exploitation and preconditions:</p> <p>The algorithms will be shared open-source within the ML research community, e.g., on public repositories, such as OpenML for analytical models and services like SourceForge for open-source projects. To further expand the knowledge gained in Retention and to continue the development after the project ends, the implementation, along with the results of the analysis, will be disseminated in a research manuscript.</p>

Decision Support for Interventions: Models & Components	
Outcome: Task 5.2	<p>Description:</p> <p>The task involves detailing RETENTION's decision-making models, encompassing verified and non-verified interventions created by the platform. This includes tool support for model creation/editing and essential components for executing analytics and interventions within RETENTION CSB instances, ensuring efficient implementation and utilisation of intervention strategies.</p> <p>Target user/customer/audience:</p> <p>Healthcare organisations, Data analysts</p> <p>Benefits:</p> <ul style="list-style-type: none"> Improved decision-making in healthcare, Enhanced data analysis capabilities, and tailored interventions for better patient outcomes. <p>Short term exploitation (1 year after the end of the project):</p> <p>Rapid adoption by healthcare organisations for streamlined decision support and data analysis.</p> <p>Long term exploitation and preconditions:</p>
<p>LEAD Owner:</p> 	
Type: Methods and Tools	
<p>Expected TRL (end of project):</p> <p>TRL 6</p>	



Decision Support for Interventions: Models & Components

	<p>In the long term, the decision support system is envisioned to provide lasting benefits and value. The following considerations outline the strategy for sustained exploitation:</p> <p>Scenario of Exclusivity:</p> <p>If the End-User (ER) and strategic partners become integral to the business model, a scenario of exclusivity for the RETENTION Platform is anticipated. This exclusivity arrangement aims to solidify the competitive edge in the market.</p> <p>Alternative Exploitation Strategies:</p> <p>In the absence of exclusivity, alternative strategies will be explored to ensure the widespread adoption of the decision support system. This may involve adapting the system for use in other domains that do not conflict with the RETENTION Platform's business model.</p> <p>Integration with Existing Business Models:</p> <p>The decision support system will be designed to seamlessly integrate with existing business models or products offered by the organisation. This integration will facilitate a smooth transition for end-users and maximise the value proposition.</p> <p>Market Expansion:</p> <p>Efforts will be directed towards expanding the market reach of the decision support system. This includes exploring new geographical regions, engaging with additional healthcare organisations, and identifying opportunities for collaboration with data analysts.</p> <p>Continuous Improvement and Adaptation:</p> <p>To ensure sustained relevance, a commitment to continuous improvement and adaptation is essential.</p> <p>Business Model Scenarios:</p> <p>Detailed scenarios will be outlined regarding the potential business models that can be established for the ongoing exploitation of the decision support system. This includes considerations for licencing, subscription models, or partnerships that align with long-term sustainability goals.</p>
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Disease Insights through Trustworthy & Verifiable AI


Outcome: Task 5.3	Description: The module supports the data analyst with the provision of various explanations regarding the models previously trained, providing the means for model understanding and visualisation of its inner
LEAD Owner:	



Disease Insights through Trustworthy & Verifiable AI	
SIEMENS	structure and behaviour, offering also explanation (AI explainability) and trustworthiness for the black box of the machine learning models.
Type: Methods and Tools	Target user/customer/audience: Data scientists, data analysts, researchers, healthcare associations, and businesses.
Expected TRL (end of project): TRL 4	<p>Benefits:</p> <ul style="list-style-type: none"> • Provides means for ML model understanding and visualisation of its inner structure, connections, and behaviour, extracting relations between the input and the output of data, and using them to construct explanations that can aid the understanding of why the learned model has produced particular outputs (e.g., predictions, classifications) from its input data. • Offers mechanisms supporting the specification and execution of verifiable data analytics and AI, allowing for a transparent, explainable and trustworthy basis for making decisions for clinicians, encompassing the emerging ethics guidelines for trustworthy AI. • Allows for visualisation techniques enabling user-friendly interactions for handling the complexity of workflows, and their outputs, coping with the output of complex models and verifying of models and their encoded knowledge. <p>Short term exploitation (1 year after the end of the project): The availability as an integrated component relies on the further hosting of the Advanced Notebook tool, however, the non-integrated version can be packed as open-source and can serve as a basis for further research, as promoted in other Horizon Europe projects.</p> <p>Long term exploitation and preconditions: The trustworthy mechanisms could be further shared as open-source with the ML community. The assessment of the mechanisms for trustworthy AI will be investigated to be standardised, e.g., as complementing the ethics guidelines list for trustworthy AI (EU AI HLEG List, ALTAI). The assessment and mechanisms will be further described in a white paper and a research paper accordingly.</p>


Standalone Edge Mobile Application	
Outcome: Task 6.1	Description:



Standalone Edge Mobile Application	
LEAD Owner:  <small>system integration & consulting services</small>	<p>From the patients' perspective, the main avenue of monitoring and interaction with the RETENTION solution will be the RETENTION Edge Mobile Application.</p> <p>The application features a user-friendly interface that gathers and transmits usage data to CSB, informs end-users of important parameters regarding their health and well-being, and delivers basic interventions.</p>
Type: Innovative solutions (new products/services/processes)	<p>Examples of such features include the continuous and discrete monitoring of vital signs like pulse (continuous), blood oxygen saturation (discrete), blood pressure (discrete), weight (discrete), sleep (continuous) and others, reminding pill intake and facilitating communication with the monitoring clinical staff.</p> <p>The Mobile Application focuses on wearable (bioelectronic) and medical devices, as well as on maintaining the RETENTION operation while the user is not at home.</p>
Expected TRL (end of project): TRL 7	<p>Target user/customer/audience:</p> <ul style="list-style-type: none">• chronic heart failure (HF) patients,• patients with an implanted Left Ventricular Assist Device (VAD)• and heart transplant (HT) recipients. <p>Benefits:</p> <ul style="list-style-type: none">• Continuous monitoring of heart failure patients in a home environment, using the application,• Monitor the pill intake of the patient,• The application maintains a high level of abstraction and focuses on usability, as it is operated by elderly people or others without technical background. <p>Short term exploitation (1 year after the end of the project):</p> <p>Datamed is going to explore possibility to use the system with existing hospitals having heart clinics.</p> <p>Long term exploitation and preconditions:</p> <p>Datamed plans to interface and use the RETENTION system with DM's hospital information system (HIS), thus giving existing customers with heart clinics the possibility to evaluate and use the system in conjunction with the HIS.</p> <p>Also, the possibility of expanding the system to other types of conditions is on the table.</p>



Standalone Home Edge Gateway


<p>Outcome: Task 6.2</p>	<p>Description:</p>
<p>LEAD Owner:</p> 	<p>The Local Home Gateway of the Patient Edge allows the seamless integration of smart devices and services with the RETENTION platform. Based on a Raspberry Pi computer this Gateway can gather, store, and send real-time sensor data such as temperature, humidity, pollution, etc. to relevant databases.</p>
<p>Type: Innovative solutions (new products/services/processes)</p>	<p>Target user/customer/audience:</p>
<p>Expected TRL (end of project): TRL 7</p>	<p>Data analysts, healthcare professionals, and patients</p> <p>Benefits:</p> <p>No user intervention is needed, collection and transfer of measurements; it is able to collect several types of measurements from sensing devices.</p> <ul style="list-style-type: none"> • Real-time measurement of temperature values in the participant’s living place • Real-time measurement of humidity values in the participant’s living place • Real-time measurement of external temperature values in the area of interest • Real-time measurement of external humidity values in the area of interest • Real-time measurement of the pollution index in the area of interest • Automatic updates making use of an open-source platform • Several types of sensors can be integrated. <p>Short term exploitation (1 year after the end of the project) :</p> <ul style="list-style-type: none"> • Use in other projects • Use as a component of the RETENTION platform (as part of RETENTION exploitation) <p>Long term exploitation and preconditions:</p> <ul style="list-style-type: none"> • Use in other projects • Use as a component of the RETENTION platform (as part of RETENTION exploitation)

Standalone CSB Dashboard


<p>Outcome: Task 6.3</p>	<p>Description: A FHIR-compliant e-CRF system with advanced visualisation capabilities that can equally well monitor the effects of pharma-focused trials and innovative patient monitoring-focused trials, including multi-centric trials.</p>
<p>LEAD Owner:</p>	



Standalone CSB Dashboard


	<p>Target user/customer/audience: Pharmaceuticals/universities/research institutes/hospitals/CROs/project consortia conducting clinical studies and trials</p>
<p>Type: Innovative solutions (new products/services/processes)</p>	<p>Benefits: FHIR-compliance, advanced visualisations, pain-free data entry, data quality checks, intuitive UI, a SaaS model whereby hosting, data imports/exports, UI, and visualisation customisation can be performed by an expert team at client request, and interoperability with GIC Dashboard (see below).</p>
<p>Expected TRL (end of project): TRL 7</p>	<p>Short term exploitation (1 year after the end of the project) : The Standalone CSB Dashboard will be offered via a SaaS model with a tiered pricing plan, and a basic version will be offered as open-source. White-labelling opportunities with CROs will be explored. The use of the CSB Dashboard will be promoted in further Horizon Europe projects involving one or more of the RETENTION clinical partners.</p> <p>Long term exploitation and preconditions: In the long-term, the CSB Dashboard exploitation path will continue in the direction outlined above. Due to its high TRL, it will be possible to begin commercial exploitation earlier than other components of the integrated RETENTION solution. AEGIS will explore, either alone or in the context of partnerships, the possibility of providing the benefits of the CSB Dashboard to one or more Health Information System; such a development would open up new revenue streams for AEGIS but would also pave the way for subsequent integration of the entire RETENTION platform as the remaining components reach the necessary maturity that will allow joint exploitation.</p>

Standalone GIC Dashboard

<p>Outcome: Task 6.4</p>	
<p>LEAD Owner:</p> 	<p>Description: A FHIR-compliant multi-centric clinical trials/study and/or health-system-wide performance monitoring system with advanced visualisation capabilities. Whereas the CSB Dashboard visualisations offer a view focusing on a single patient and on a single clinical site, the GIC Dashboard offers an overview covering a group of centres on the basis of anonymous data.</p>
<p>Type: Innovative solutions (new products/services/processes)</p>	<p>Target user/customer/audience: Pharmaceuticals/universities/research institutes/hospitals/CROs/project consortia conducting multi-centric clinical studies and trials and health policymakers at a regional or national level</p>
<p>Expected TRL (end of project): TRL 7</p>	<p>Benefits: advanced visualisations, intuitive UI, backed a by service model whereby hosting, data imports/exports, UI, and</p>



Standalone GIC Dashboard	
	<p>visualisations customisation can be performed by an expert team at client request. Interoperability with not only the CSB Dashboard (see above) but any other FHIR-compliant systems.</p> <p>Short term exploitation (1 year after the end of the project) :</p> <p>Initially, the GIC Dashboard will only be offered as an option in the CSB Dashboard exploitation plans (see above).</p> <p>Long term exploitation and preconditions: There are clear long-term exploitation paths for the GIC Dashboard in the context of the overall RETENTION exploitation path, in the context of multi-centric clinical studies and trials conducted with the help of the CSB Dashboard e-CRF system (as an added value option). Beyond that, additional pathways will be explored. AEGIS is a member of the BDVA with a specialisation among other areas in the visualisation of large-quantities of data that highlight aspects that underline trends, regional differences, etc. and will pursue projects and partnerships that will lead to both the expansion of the scope of the GIC Dashboard functionality and its exploitation options as a tool for policymakers at a regional and national level.</p>

Security Component	
Outcome: Task 6.5	<p>Description: The security component supports a) monitoring the security of all operations, preserving privacy, and providing the data subjects and b) full control of knowing by whom and how their data are being processed in a verifiable way.</p> <p>Target user/customer/audience: STS targets both the public and private sectors, especially government facilities and healthcare.</p> <p>Benefits: Secure operations, Authentication, Authorisation, Role-based access control, privacy, and GDPR compliance</p> <p>Short term exploitation (1 year after the end of the project): Commercial exploitation and dissemination of Security Component will utilise the advertisement sponsored by the European Union in parallel with already-used channels, such as the companies' own communication channels (e.g., websites, professional social media). This has also been valuable in the B2B approach of the companies in the sectors aforementioned.</p> <p>Long term exploitation and preconditions: The software must offer a compelling value proposition, addressing the unique needs of businesses and industries while providing a clear competitive advantage. Scalability is crucial, and robust security features, compliance with industry standards, and a commitment to data privacy are non-negotiable. A flexible pricing model and transparent licencing terms will be in place in the long term, while</p>
LEAD Owner: 	
Type: Innovative solutions (new products/services/processes)	
Expected TRL (end of project): TRL 7	



Security Component	
	continuous innovation, proactive support, and a keen understanding of the evolving landscape will position the security component as a dependable and valuable asset for businesses in the long run.

6.2 Exploitation plan for RETENTION platform

The participation in the RETENTION platform exploitation activities is set as **voluntary** and depends on the agreement of each partner with the business case and business model initially proposed by i2G as task leader in Innovation Management activities (Task 2.4).

Once the business model is defined, also taking into consideration the market perspective, the partners will have to define the business unit that will manage the exploitation, as well as the roles, rights, and obligations of each participant. The IP share and royalties will have to be calculated based either on a combination of the exploitable results or a different arrangement among the partners.

The consortium partners can choose to join the exploitation activities if they agree with the business case and business model defined for the RETENTION platform.

6.2.1 Business model options

RETENTION Platform is a digital solution that aims to improve the quality of life and care for patients with heart failure and their carers. The platform leverages artificial intelligence, wearable sensors, and mobile applications to monitor, manage, and personalise the treatment of heart failure patients. The platform also provides data and insights to health care professionals, researchers, and policymakers to optimise the delivery and outcomes of care.

RETENTION Platform can adopt two different business models to reach its potential customers and stakeholders:

- **B2B Care Delivery** addressing Healthcare Systems and Cardiac Transplantation Hospitals

This model targets health care systems and cardiac transplantation hospitals as the main customers. The platform offers a comprehensive service that includes the provision of hardware (sensors and devices), software (mobile apps and dashboard), and support (training and maintenance) to health care providers. The platform may generate revenue by charging a subscription fee per patient or per hospital, depending on the contract and the level of service required.

- **B2B2B – Life sciences** addressing Pharmaceuticals and Medical Device Producers

The B2B2B model involves RETENTION providing the solution to Pharma or Medical Device Producers (e.g. ICD, LVAD etc.).

By looking at the **Pharma arm** of the model, the solution may be used to support clinical trials, which involve testing drugs for HF patients in various phases. The model implies that the RETENTION Business Unit provides RETENTION to Pharma (**B2B**) and Pharma contracts with Hospitals (**B2B2B**) to conduct the clinical trials.

The hospitals, as the final B in the model, may use RETENTION to manage patients remotely, to adjust or add patient-specific thresholds, drugs, and laboratory data from any location, as well as, collect and report on

real-world data. The hospitals can integrate RETENTION with their own systems, such as electronic health records, laboratory information systems, etc.

Considering the **Medical Device Producers**, the B2B2B scenario model implies an agreement with the medical device producer that will sponsor and support the RETENTION platform as a complementary solution for remote patient management.

RETENTION provides a Cloud platform that enables remote monitoring and management of HF patients with medical devices (e.g., LVAD, ICD, etc.). Nowadays, these devices directly communicate remote monitoring parameters, addressing clinically important data pre- and post-surgery, identifying symptoms, and preventing complications. This type of monitoring capability is market-defined as “**special monitors**”. On the other end, there’s another complementary market named “**vital signs monitoring**”, addressing parameters like ECG, non-invasive blood pressure, body temperature, respiration rate, weight, sleep, etc. RETENTION platform belongs to this segment, connected to specialised peripherals for vital sign data and sensors to collect Real-world Data dealing with contextual and environmental data.

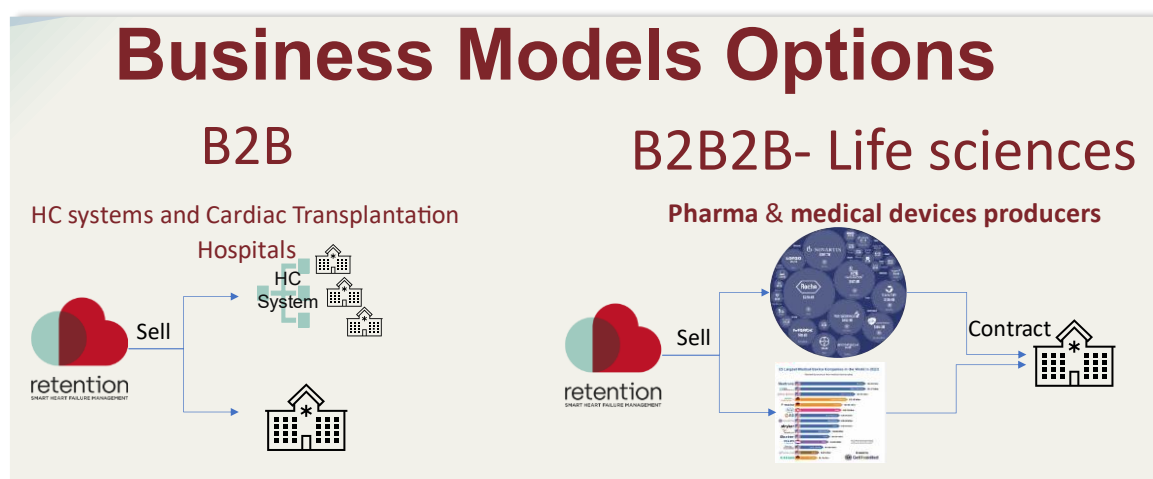


Figure 12: RETENTION Platform business models options

6.2.2 Market indicators supporting the B2B model option

The initial market analysis outline, as presented in D9.2, focused on the following aspects:

- I. The level of development and adoption of Telehealth-based models of care for HF in the EU countries
- II. The EU governments’ preferences and investments in HF care management and technology
- III. The selection of countries with a higher ratio of Hospitals per million people with cardiac transplant programmes as a potential market indicator.

The analysis identified **Germany, Italy, and Spain**, some of the countries where the RETENTION clinical trial will take place, as the ones with the highest scores in the aspects analysed.

With the aim of supporting the identified business model options with market-related indicators, a further analysis has been performed taking into account new dimensions such as:

- IV. Countries in Europe with a high prevalence of chronic heart failure (HF), heart transplantation, or LVAD



- V. Countries with an advanced level of digital infrastructure and funds to invest in digital health solutions.

In this Deliverable, additional insights have been explored to support the research on the identification of target countries. The following section presents the relevant B2B insights:

- Germany has the highest number of heart transplants in Europe, with 311 procedures performed in 2020¹. It also has the largest market for LVADs in Europe, with an estimated value of \$92.3 million in 2019². Germany has a strong digital infrastructure, ranking fourth in the EU Digital Economy and Society Index (DESI) 2020³. It also has a high level of public and private spending on health, accounting for 11.2% of its GDP in 2019⁴.
- Since January 2022, remote patient monitoring of patients with heart failure (RPM-HF) has been reimbursed by the statutory health insurance (SHI) funds in Germany. The SHI-insured population accounts for ~88% of Germany's population, i.e., ~73.3 million subjects, whereas 12% are insured by private health insurance. Remote patient monitoring of patients with heart failure is the first digital care management programme that will be implemented in the German health care system⁵.
- France has the second-highest number of heart transplants in Europe, with 285 procedures performed in 2020¹. It also has a significant market for LVADs, with an estimated value of \$37.5 million in 2019². France has a good digital infrastructure, ranking 12th in the EU DESI 2020³. It also has a high level of public and private spending on health, accounting for 11.3% of its GDP in 2019⁴.
- Italy has the third-highest number of heart transplants in Europe, with 209 procedures performed in 2020¹. The LVADs market has an estimated value of \$25.8 million in 2019². Italy has a moderate digital infrastructure, ranking 25th in the EU DESI 2020³ and has a moderate level of public and private spending on health, accounting for 8.8% of its GDP in 2019⁴.
- Spain has the fourth-highest number of heart transplants in Europe, with 201 procedures performed in 2020. It also has a developing market for LVADs, with an estimated value of \$16.6 million in 2019. Spain has a good digital infrastructure, ranking 11th in the EU DESI 2020. It also has a moderate level of public and private spending on health, accounting for 8.9% of its GDP in 2019.

¹ <https://academic.oup.com/ehjdh>

² <https://blogs.deloitte.co.uk/health/2023/11/the-future-of-health-in-europe-digital-equitable-sustainable.html>.

³ <https://www.novartis.com/stories/expanding-new-digital-healthcare-solution-across-chronic-heart-disease-management>.

⁴ <https://doi.org/10.1093/ehjdh/ztad036>

⁵ <https://doi.org/10.1093/ehjdh/ztac017>



Country	Hospitals cardiac transplantation xMillion people	# of yearly heart transplants 2020 (rank EU)	LVADs market (est. #patients 200K€ procedure)	Digital infrastructure (rank EU Digital Economy and Society Index (DESI))
	0.66	311 (1 st)	\$37.5 million in 2019 (188)	4 th
	0.26	209 (3 rd)	\$25.8 million in 2019 (129)	25 th
	0.39	201 (4 th)	\$16.6 million in 2019 (83)	11 th

Figure 13: Cardiovascular healthcare landscape in Spain, Italy and Germany

6.2.3 Market indicators supporting the B2B2B model option

Within this section, B2B2B relevant insights are presented⁶:

Pharma

An increasing number of pharma companies are collaborating with technology companies that create digital therapeutics (DT), which are software-based interventions that can complement or, in some cases, replace traditional therapies for various diseases and conditions. These partnerships aim to leverage the potential value and impact of DT on patient outcomes and healthcare costs, as well as explore new opportunities and markets for pharma products and services.

Pharma companies are investing in DT, or access to real-world data to enhance their products and services and to generate valuable data that can inform their decision-making and innovation e.g., decentralised clinical trials. DT helps generate real-world data, which is data collected outside of clinical trials, such as from electronic health records, claims, registries, sensors, apps, and wearables, that may provide insights into the effectiveness, safety, adherence, and patient experience of treatments in real-world settings.

⁶ Mckinsey “The health benefits and business potential of digital therapeutics” Jan 23



Pharma	Partnership/ acquisition	What	Strategy/Benefits
AstraZeneca	Acquired a stake in Huma.com	Platform for digital hospitals at home and decentralized clinical trials	The two companies plan to collaborate on developing software as a medical device companion apps and expediting the adoption of decentralized clinical trials
Eli Lilly	Partnered with WellDoc	A diabetes management company, to integrate WellDoc's software into its insulin products.	Provide personalized guidance, education and behavioral support to patients and healthcare providers
Otsuka Pharmaceuticals	Partnered with Click Therapeutics	conduct a remote clinical trial on Verily's Project Baseline platform	Measuring the effectiveness of a digital therapeutic intervention for adults with major depressive disorder who are on antidepressant monotherapy
Pfizer	Partnered with Kaiku Health	The platform uses predictive algorithms, digital biomarkers and real-world data to support proactive and personalized care and research	Oncology-focused platform that collects patient-reported outcomes, to monitor and manage melanoma patients

Figure 14: Pharmaceutical industry trends in digital therapeutics and RWD

Medical device producers

- Moreover, manufacturers of medical devices are channelling investments into digital therapeutics, recognising the potential value and impact of these solutions on patient outcomes and healthcare costs. Examples of medical device producers engaged in digital therapeutics include:
- Medtronic, which has partnered with Voluntis, a leading digital therapeutics company, to develop and commercialise digital solutions for diabetes management, such as insulin titration and remote monitoring,
- ResMed, which has acquired Propeller Health, a digital therapeutics company that provides connected health solutions for respiratory diseases such as asthma and chronic obstructive pulmonary disease,
- Philips, which has launched a digital therapeutics platform called HealthSuite, which offers personalised and adaptive programmes for various health conditions, such as insomnia, chronic pain, and stress.

6.3 Market overview of digital health solutions addressing heart failure

As far as market trends and opportunities from a technological offer perspective, the market for digital health solutions for chronic heart failure, heart transplantation, or LVAD in Europe is estimated to be worth USD 45.3 billion in 2022, and is projected to grow at a compound annual growth rate (CAGR) of 16.0% from 2023 to 2030⁷. Some of the drivers and barriers to growth are:

- **Drivers:** The market growth is driven by the increasing prevalence of chronic heart failure, heart transplantation, or LVAD in Europe, which creates a high demand for remote patient monitoring, telehealth, and digital health systems. The market growth is also driven by the advancement of digital technologies, such as artificial intelligence, big data, cloud computing, and wearable devices, which

⁷ <https://www.grandviewresearch.com/industry-analysis/europe-digital-health-market-report>.



enable the development of innovative and personalised solutions for chronic heart failure, heart transplantation, or LVAD management.

- **Barriers:** The market growth is hindered by the challenges and risks associated with the adoption and implementation of digital health solutions for chronic heart failure, heart transplantation, or LVAD in Europe, such as the lack of interoperability and standardisation, the data privacy and security issues, the ethical and social implications, and the regulatory and legal uncertainties. The market growth is also hindered by the resistance and scepticism of some stakeholders, such as patients, healthcare providers, and payers, who may have low awareness, trust, or acceptance of digital health solutions for chronic heart failure, heart transplantation, or LVAD.

Market trends and opportunities from patients demand perspective: Beyond technological drivers and barriers, it's important to understand what other investigation dimensions may affect the future demand and supply of RETENTION platform. Since the RETENTION platform is still in the prototyping stage, the analysis of patients' expectations and satisfaction levels^{8,9,10} with the existing solutions is a relevant indicator to create value and differentiation. Dimensions include Patients' needs, preferences, and pain points related to chronic heart failure, heart transplantation, or LVAD management, as well as, access to or use of health services or products.

- **Expectations:** The patients expect the existing solutions to provide reliable, accurate, and timely data and information on the patients' vital signs, symptoms, and adherence to treatment. They also expect the existing solutions to enable effective communication and interaction between the patients and the healthcare providers and to provide guidance and support in any critical situation. They also expect the existing solutions to be easy to use, convenient, and affordable, and to comply with the standards and regulations of data privacy and security.
- **Satisfaction:** The patients' satisfaction levels with the existing solutions vary depending on the type, quality, and performance of the solutions, as well as the outcomes and experiences of the patients. Some of the customers are satisfied with the existing solutions, as they report improved outcomes, reduced costs, increased convenience, and enhanced quality of life for patients with chronic heart failure, heart transplantation, or LVAD. They also report high levels of awareness, trust, and acceptance of the existing solutions, as well as positive feedback and evaluation from the patients and the staff. However, some of the patients are dissatisfied with the existing solutions, as they report technical issues, data errors, communication problems, and user difficulties with the existing solutions.

6.3.1 Competition

The competition analysis presented in this report relies on desk research and seeks to identify and analyse existing literature and data related to the utilisation and effects of remote patient monitoring, connected care, clinical support, clinical trials, and AI for prediction in the domain of heart failure and chronic diseases.

The sources involved in the desk research encompassed:

⁸<https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-18/e-health-in-cardiology-remote-patient-management-of-heart-failure-patients>

⁹ <https://heart.bmj.com/content/107/5/366>

¹⁰ <https://www.osplabs.com/insights/remote-patient-monitoring-and-chronic-care-management/>



- Academic articles and journals^{8 9 10} that report on the results and outcomes of remote patient monitoring, connected care, clinical support, clinical trials, and AI for prediction for heart failure and chronic diseases, such as improved patient adherence, quality of life, and survival rates.
- Industry reports and company web sites (e.g., cbinsights.com, comparable-companies.com, crunchbase.com) to get insights and trends on the market and demand of remote patient monitoring, connected care, clinical support, clinical trials, and AI for prediction for heart failure and chronic diseases, such as the size, growth, and segmentation of the market, the key players and competitors, and the opportunities and challenges.

The desk research excluded the following sources:

- Sources that focus on specific pathologies other than heart failure and chronic diseases, such as mental health and oncology, are not relevant to the scope and objectives of the research.
- Sources that deal with wearables and implantable devices and their dedicated platforms for remote patient monitoring are not the main focus of the research, which is more interested in software-based solutions for Care Delivery and Life sciences.

The regional analysis of the existing solutions is limited to companies established in the U.S., Canada, and Europe as well as main operations running in these areas.

Table 15: RETENTION competitors’ analysis

	Huma	Doccla	BioFourmis	Dignio	Medly
	huma.com	doccla.com	biofourmis.com	dignio.com	Medly.ca
Overview	A global health tech company that provides a remote patient monitoring platform that advances connected care for patients and accelerates research and therapies	A virtual hospital company that offers a tech-agnostic remote patient monitoring solution that enables clinicians to monitor patients at home and provide personalised feedback via texts and video visits	A digital therapeutics company that leverages AI and wearable sensors to optimise patient care and outcomes	A connected care company that provides a remote patient monitoring platform that allows patients to measure their own health data and share it with their healthcare providers	Medly provides self-care guidance and access to a care team right from home. Take daily readings, receive personalised support, and be in direct contact with your care team when you need it the most
Founded year	2011	2019	2015	2010	2017



Countries operations	UK, the US, Germany, Canada, and Singapore	UK	US, Singapore, Switzerland	Norway, UK, Denmark, etc	Canada
Scope	Care Delivery and Life Science	Care Delivery	Care Delivery and Life Science	Care Delivery	Care Delivery
Focus	Chronic patients	Chronic patients	Chronic patients	Chronic patients	HF and Chronic
Product Service	Huma Connected Care, Huma Companion Apps, Huma Decentralised Clinical Trials	Doccla Connected Care	Biovitals, BiovitalsHF, Biovitals Sentinel, Biovitals Oncology, Biovitals RhythmAnalytics, Biovitals Pharmacovigilance, Biovitals Predict, Biovitals Connect	Dignio Prevent	Medly apps/algos etc and Medly services
USP	Proprietary AI algorithms developed for care delivery and life sciences	The only tech-enabled virtual ward registered with the Care Quality Commission	Personalised and predictive care using AI and biosensors	Device agnostic and interoperable with a wide range of EHR systems	
Customers	NHS, Google, Bayer, AstraZeneca,	NHS trusts, community services, etc	Health systems, pharmaceutical companies, payers, etc.	Hospitals, municipalities, GPs, etc.	Patients, providers, manufacturers, etc
Market presence	Monitored patients across 10+ European countries	4,000,000+ monitored patient	100,000 patient vital signs collected every week		Ontario, British Columbia, and Alberta
Funding	Venture Capital	Venture Capital	Venture Capital	Venture Capital	Venture Capital
Stage	Series C	Seed	Series C	Series A	Series B
Total raised	130M€	3.3M\$	145M\$	5.5M\$	100M\$
Investors	General Catalyst, Speedinvest, Giant, KHP	Giant Ventures, Speedinvest, etc.	SoftBank Vision Fund 2, MassMutual Ventures, Sequoia Capital, etc	Investinor, Innovation Norway, etc.	Greycroft, Lerer Hippeau, HOF Capital.



The largest market share for RPM solutions belongs to cardiovascular disease treatment and monitoring, as they are important for the treatment and management of cardiovascular diseases. Taking into account the rising EU population that will demand these solutions in the forthcoming future, we can see that the market offer is still inadequate, especially in the EU27.

As a newcomer, the RETENTION platform will have to keep monitoring the competition and invest in differentiation with the other digital health solutions on the market. This requires a clear value proposition, a strong evidence base, and a customer-centric approach to meet the needs and expectations of end-users, such as patients, health care professionals, payers, and regulators.

The main **benchmark competitor** is the company **Huma.com**. Huma is a digital health company that offers solutions for remote patient monitoring, clinical trials, and health research. It also provides a platform for decentralised clinical trials. Huma's strengths include its global reach, its partnerships with leading pharmaceutical companies, and its innovation in digital endpoints. It's the only competitor with operations in Germany, one of the future markets of RETENTION.

RETENTION has the opportunity to build initially a market niche in countries where the pilots will run from 2024 onwards with a particular focus in Germany, Spain, and Italy, as defined in the initial section of the analysis. As far as Greece is concerned, even though the market opportunities are more limited, a market presence will be maintained, taking advantage of the market presence of RETENTION technical partners, the localisation activities performed during the project, and the exploitation interests of the two Hospitals involved in the project.

The experience gained in the Pilot studies will allow us to design and test the solution from different perspective, which is very useful to build differentiating factors such as:

- A collaborative and coordinated care delivery model among the different actors and levels of the health care system (e.g., patients, clinicians, nurses, and policymakers) served by RETENTION.
- Ethical, legal, and social implications in targeted Hospitals and territories, which implies a careful assessment and management of the risks and benefits, the protection and empowerment of the users' rights and privacy, and the alignment and compliance with the relevant standards and regulations.
- The pre-assessment of the market potential of the solution and adapting its features to specific needs.

6.4 RETENTION platform business unit

The RETENTION business unit (BU) is the term adopted by the consortium to characterise the entity authorised to advance and execute the business model of the RETENTION platform within the designated project period. At present, this definition is in its early stages, as the determination of the business model, the roles of the partners, the IPR for exploitable results, and consequently, the IPR for the RETENTION platform are subjects of ongoing discussion and development aligned with the project's maturation phases.

At this stage of the project, the consortium has achieved some results, and preliminary step toward an orientation of the business model are shaping up.

In this section, the guidelines and terminologies to be used as the basis of the decision-making process are presented, namely:



- The **Partner Type**, allowing the consortium partners to start positioning in view of the future business model implementation.
- The **Business Unit type**, aiming at presenting the possible formal or legal entity required to run the business.
- Scenarios about the definition and composition of the Business Unit **shares**.
- Scenarios about the method to apply and calculate the royalties to remunerate the owners of the IPs underlying the knowledge, patents, and solutions together compose the RETENTION Platform.

Partner type

PARTNER TYPE “ACTIVE”:

Partners **actively** involved in the business model implementation

- Rights:
 - o Get RETENTION “Business unit shares”. Share calculation may be based on the resources (financial, human, and technical) committed/invested in the implementation of the business model;
 - o Participate in the profit and loss of the Business unit based on the owned Business unit shares percentage;
 - o Participate in the Royalties distribution (based on co-ownership share rules);
 - o A seat in the Steering Committee.
- Obligations:
 - o Grant **access rights for commercial purposes** to the Exploitable results (fully or partly owned) to the RETENTION Business Management Team;
 - o Invest resources (financial, human, and technical) for the implementation of the business model based on the roadmap defined by the Product Manager in the business management team;
 - o Make all the direct and indirect efforts to promote RETENTION in the market.

PARTNER TYPE “PASSIVE”:

Partners **not actively** involved in the business model implementation but entitled to get royalties.

- Rights:
 - o Participate in the Royalties distribution based on the co-ownership shares rules;
 - o Don't participate in the Business unit profit and loss;
 - o A seat on the RETENTION business model advisory board (Optional).
- Obligations:
 - o **Grant access rights for commercial purposes** to the Exploitable results (fully or partly developed) to the RETENTION Business Management Team;
 - o Make all the directly and indirectly effort to promote RETENTION in the market.



PARTNER TYPE “PARTNERSHIP”:

Partners **not actively** involved in the business model implementation and not participating in the **Royalties distribution** but willing to establish a third-party type of partnership, including exclusivity in the use of the relevant Exploitable Result in the market addressed by the Business Unit.

- Rights:
 - o Get third-party type of fee based on conditions to be agreed case by case.
- Obligations:
 - o Follow specific contractual agreements made with the Business Unit.

The Business Unit Type

Two possible approaches to formalising and running the business unit are proposed:

- 1) The immediate setup of a **Start-up** made of partners type is defined as «Active»
- 2) The creation of a **Joint Venture** temporarily set up among partners actively involved in the business model implementation, until the business model becomes financially sustainable enough to create a Start-up (e.g., revenues, and investments)

The joint venture case requires the appointment of an **Agent** (preferably a company from RETENTION consortium) acting on behalf of and in the name of the partners actively involved in the business model implementation, and shall have the authority to negotiate, conclude and execute contracts with third parties, subject to the prior approval of the partners involved. The Agent and the partners shall establish a **steering committee** composed of representatives of each party, which shall meet periodically to monitor and supervise the progress and performance of the business model

The Business Unit Shares and Royalties

A preliminary discussion among partners included possible scenarios to be implemented for the calculation of Business Unit shares and Royalties from the RETENTION platform for future commercialisation.

Compared to the co-ownership model defined in the Consortium Agreement for the single Exploitable Results where the rule of proportionality to the intellectual contribution invested in generating the specific Result prevails, the definition of future shares in the Business Unit and Royalties require the definition of a newly commonly agreed model since additional factors shall be taken into consideration. The discussion among the consortium representatives of companies and technology providers, representing the most suitable organisation type to organise and set-up the future Business Unit, led to a selection of two possible approaches:

- An agreement among the business model participants, the Active Partners, that will take into account the plan of investment in terms of resources, human and financial, necessary to run the business unit.
- Participation based on the combination of ERs components weighted with selected coefficients such as the level of innovation, uniqueness of the component compared to market available alternatives, economic quantification of the investment made during the project, etc.

6.4.1 RETENTION Platform Business Unit – Internal orientation survey

I2G performed a project internal survey with the potential consortium business enablers, mainly companies, based on a “RETENTION business model pitch”, an internal presentation of the business models and opportunities reported in the previous paragraphs.

The survey included the following dimensions:

1. Role – Active, Passive or partnership (e.g., as a third-party provider of ER access to run the business)
2. Model (start-up, Joint venture, etc.)
3. Methods for Royalties and Business participation shares
4. Method to calculate Royalties on future revenues

The results of the survey are presented in the following picture. The majorities achieved in the different questions are encouraging and represent a good foundation to build the next step of exploitation activities, including consortium consensus, definition of resources, and agreements necessary to establish a business unit.

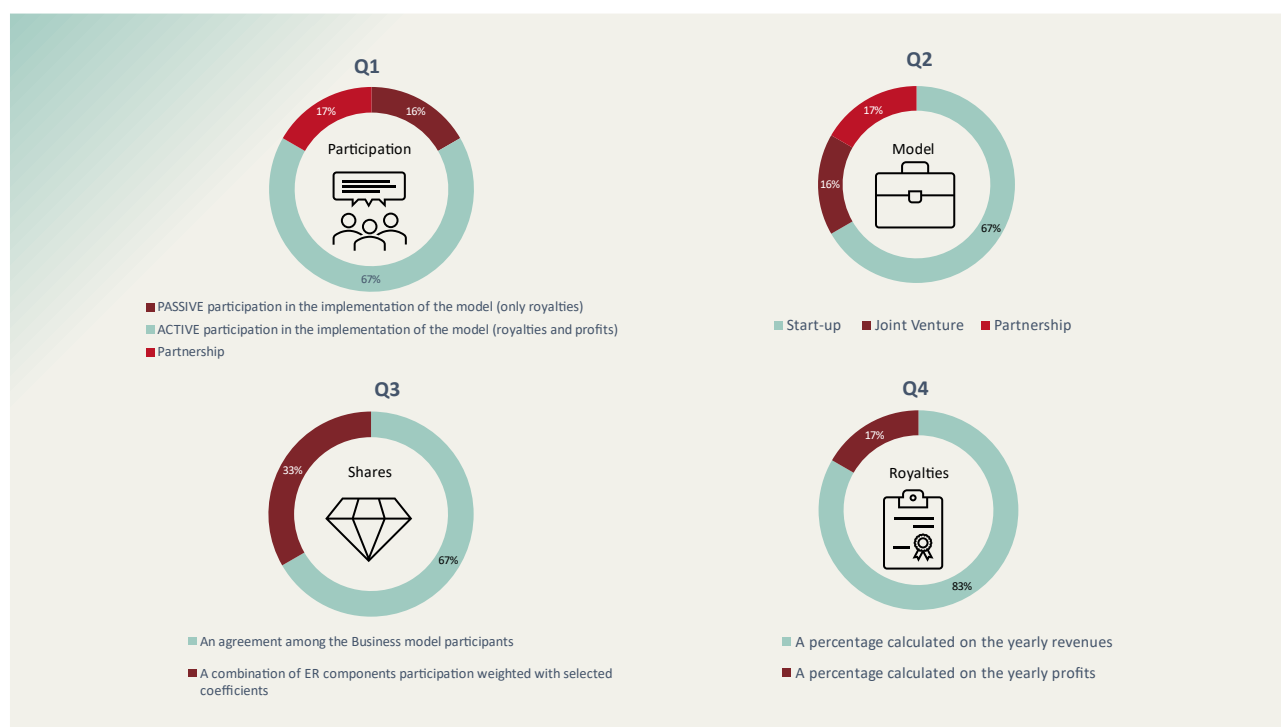


Figure 15: RETENTION Platform Business Unit – Internal orientation survey



6.5 RETENTION Clinical partners exploitation plans M32

Onassis Cardiac Surgery Centre

Relevance and applicability of the RETENTION research outcomes to the hospital's mission, vision, and values

Onassis Cardiac Surgery Centre is a highly volume specialised hospital in the field of cardiovascular diseases. It is the only hospital in Greece, which performs heart and lung transplantations.



The Heart Failure Unit at the Onassis Cardiac Surgery Centre comprises a specialised care team, including Advanced Heart Failure Specialists (cardiologists and surgeons), Heart Transplant Coordinators, and Ventricular Assist Devices Coordinators. The unit manages over 3000 patients annually.

The mission of the Heart Failure Unit is to provide comprehensive and specialised care to individuals with heart failure. This typically involves: 1) Diagnosis and Assessment 2) Multidisciplinary Care 3) Treatment and Management 4) Patient Education 5) Monitoring and Follow up 6) Research and Innovation -contributing to research efforts to advance the understanding and treatment of heart failure incorporating innovative approaches to improve patient outcomes. RETENTION platform would upgrade the standard of care and facilitate our goals in the field of advanced heart failure patients through novel monitoring strategies and methods.

Feasibility and sustainability of deploying the RETENTION platform in the hospital setting

Onassis Cardiac Surgery Centre (OCSC) and the newly established Onassis National Transplant Centre are fully digitalised hospitals-unique in their field in Greece. OCSC has the technological infrastructure to support and endorse the RETENTION platform especially if we reduce the high burden of visits and hospitalisations for heart failure patients through remote monitoring. Ongoing support updates and the scalability of the platform. OCSC has a long-term strategy that considers technological progressions, changing healthcare landscapes and evolving patients' needs. Collaboration between healthcare professionals, technology experts, and hospital administrators is crucial to overcoming challenges and ensuring the successful implementation and sustainability of a heart failure platform.

Expectations or plans for RETENTION business model evolution after the project conclusion

OCSC has experience in the participation and/or launch of start-ups through the ONASSIS FOUNDATION doctors, researchers, graduates are supported by the Onassis Foundation. We expect to regularly reassess and adapt our business model based on market feedback, changing conditions, and the evolution of the business model design now in progress.



Servicio Madrileño de Salud

Relevance and applicability of the RETENTION research outcomes to the hospital's mission, vision, and values



Servicio Madrileño de Salud (SERMAS) integrates every public hospital and other public health services of the Madrid Regional Health System. Two of these public hospitals contribute to the RETENTION Project: Hospital Universitario Ramón y Cajal (SERMAS-HURC) and Hospital Universitario Puerta de Hierro (SERMAS-HUPH). Each of them brings to the project its clinical expertise, healthcare-qualified professionals, and solid research infrastructure.

Research and Innovation are unquestionably priorities for both hospitals, which have dedicated *Foundations for biomedical research* in place to manage, improve and boost R&D activities in the hospitals. Both hospitals appear among the clinical centres of the [World's Best Specialised Hospitals 2024](#) by Newsweek and also among the [10 hospitals with the best reputation in Spain](#).

SERMAS-HURC is a 1,000-bed university hospital with over 45 years of experience. It is fully oriented to provide their patients with the best quality of health assistance based on scientific excellence, up-to-date scientific knowledge, and innovative scientific technology.

It has all the required infrastructure to perform phase I to IV clinical trials, including full laboratory and imaging equipment and an ethical committee. In 2022, it was involved in more than 110 innovation projects with 29 patent families in process. The Cardiology department of SERMAS-HURC is one of the main specialties in the hospital, with more than 45,000 annual cardiac visits. Cardiology department of SERMAS-HUPH is well known for its leadership in advanced heart failure. Its heart transplant programme is the first in Spain, with a total of 950 procedures performed. It is also the first centre in numbers of Ventricular assist devices implanted in Spain, maintains an active "Cardiogenic shock program", takes care of more than 35 shock patients per year since 2014 and performs more than 26,000 annual outpatient cardiac visits.

SERMAS-HUPH is a centre with a long history in the field of Heart Failure in Spain, a leader in the treatment of advanced Heart Failure, providing a programme of Heart Transplant since 1984 and, afterwards, actively participating in the development of other therapies, such as the implantation of left ventricular assist devices.

In addition to clinical care, SERMAS-HUPH has always been characterised by their fervent research activity, participating in multiple national and international clinical trials throughout their history.

Participation in the RETENTION project is an opportunity for our hospitals to continue their research work in one of the fields that will become increasingly important in the future: telemedicine. Since the COVID-19 pandemic, one of the strategic objectives of both centres is to transfer care from the hospital to the patient's house. Innovation and private-public collaboration are also one of the important objectives of our centres for the upcoming years.

The RETENTION project provides a very useful tool for our clinical practice and respond to those strategic objectives providing a better patient care and improving user experiences.

Feasibility and sustainability of deploying the RETENTION platform in the hospital setting

Spanish Healthcare System (SNS) is public and funded by state taxes, so the integration of the RETENTION platform into it should be supported by government policies and programs. Such adoption could involve strategic partnerships with the Ministry of Health or regional health entities. Moreover, to facilitate adoption by the national health system, cost-savings and effectiveness studies must be carried out.

In order to be efficient and effective, the implementation of the RETENTION platform could initially be tested/piloted in selected hospitals with specialised units for Heart Failure and relevant research



experience. This would allow for a more controlled approach to measuring its effectiveness and adjusting the implementation model.

Related to the capacities and infrastructures, it would be essential to provide training and support for doctors, nurses and healthcare staff to get to know the RETENTION platform and its functionalities. This training would focus on data collection, information analysis and interaction with patients through the application. All the above would require considerable initial investment to adapt hospital infrastructure, train staff and acquire licences for platform usage. However, in the long term, a reduction in hospital costs would be expected due to a lower rate of hospitalisations, unnecessary medical visits, and more efficient resource management.

Another interesting point would be that RETENTION could create partnerships with Medical Device Producers to integrate complementary technologies (such as remote follow-up of patients with cardiac defibrillators or resynchronisation therapy), which would help us to have more complete information of the patient's overall clinical status.

On the other hand, data management may be a potential barrier. Clinical data, patient private information and its storage need to be addressed in the most conservative way in order to comply with the national and regional rules. As mentioned, public national/regional health entities should be treated as strategic partners to facilitate RETENTION platform implementation.

Expectations or plans for RETENTION business model evolution after the project conclusion

In our hospital's Research Institutes, there are Innovation departments helping researchers to shift from research to market. We expect at the end of the project to contribute to at least one European patent issued from it.

Realistically, the time provided for the project is not enough to transfer to the market, so we expect a continued collaboration with the RETENTION consortium once the research project is over to implement lessons learned from the research, create the startup and try to get started in the market.

Both innovation units are part of the Spanish Platform for Innovation in Medical and Health Technologies and Industrial Dynamization (ITEMAS) founded and financed by the Subdirectorate General for Evaluation and Promotion of Research in Spain.

Each hospital (and Innovation Unit) has its own expertise and internal policies regarding technology transfer to the market.

SERMAS-HURC: The Innovation Unit (Tech Transfer Office) has more than 110 ongoing innovation projects and a portfolio of 29 active patent families. In 2022 alone, the unit signed 51 agreements to regulate private-public relations and, in particular, 10 technology transfer agreements. Moreover, this year, 4 innovations from the HURC research institute were put into clinical practice in our hospital.

In the last few years, the unit has helped to finance 4r start-ups to develop technologies originating in-house. These start-ups have raised more than 10 million euros from public and private investors. Two examples are Aptus Biotech and its spin-off Aptatargets, which recently successfully completed a Phase IIa study with a therapeutic aptamer for ischemic stroke.

This innovation unit has been certified by UNE 166002:2021 since 2017, working under a quality system for managing innovation.

SERMAS-HUPH: the Innovation Unit has been in charge of innovation management, channelling innovative ideas or proposals from the different research groups or professionals. It also participates in assessment and management so that ideas can become inventions, products or services that add value to the health system and society and advises on the protection or transfer of health results to professionals throughout



the innovation or transfer process, instilling a culture of innovation with appropriate training and promoting the entrepreneurship of talent.

During the period 2018-2020 this innovation unit has completed its maturation process by obtaining the UNE 166002 R&D&I Management Systems Certification. This certification is a seal of quality in the services provided by our innovation unit, guaranteeing that our unit covers all the essential aspects associated with innovative processes. As a differentiating aspect compared to other innovation units, our institution has been the first at the national and public level to obtain this certification encompassing the entire R&D&I Management System, thus preventing the IAU from acting in isolation and integrating the innovative culture into the rest of the common processes and services of our Research Institute. From the generation of the idea or research question to the search for and obtaining of funding, development, use of the Institute's transversal services, follow-up in obtaining results or technical solutions to a health problem, their transfer or application and their impact on improving patient care and the NHS itself.

Among the objectives of the SERMAS-HUPH innovation unit we can find:

- Identify innovation opportunities/priorities: ideas, initiatives, processes, or novel experiences carried out by our professionals.
- To instil a culture of innovation: learning must be facilitated, from the conception of the idea to the protection and exploitation of the results in terms of scientific production or the production of an invention.
- Channel in the development of innovation projects, health technologies and industrial prototypes.
- Protecting the results of research activity, promoting the dissemination and transfer of results.

Of course, SERMAS is highly interested in promoting research project results to their maximum applicability as this would lead to better health assistance for our patients. For these reasons, SERMAS would very much appreciate the opportunity to be the owner of the assets resulting from RETENTION as well as participate in the start-up process from different perspectives:

- As patent co-owners if applicable
- As advisors/consultants (for both clinical and technology transfer aspects)
- As royalties' receptors for the contribution along the whole project and the possible start-up creation, or at least a licence-free user of RETENTIO'S technology
- As members of the start-up if the research team wants to participate in the company at a personal level in certain percentage of their working time if conditions allow.



NKUA/Attikon University Hospital

Relevance and applicability of the RETENTION research outcomes to the hospital's mission, vision, and values



Attikon University Hospital is a large general hospital associated with the National and Kapodistrian University of Athens (NKUA) that provides care for a wide variety of medical conditions including cardiovascular diseases and Heart Failure. The Heart Failure Unit of Attikon University Hospital is a specialised care unit with staff including Cardiology Consultants-experts in Heart Failure and HF nurses that delivers care for a high volume of HF patients (>1000 patients yearly). The mission of HF Unit of Attikon University Hospital is to improve patients' care through traditional and novel management strategies and improve their outcomes including reduction of mortality and hospitalisations, which would assist in reduction of HF-related healthcare burden. To achieve our goals, novel patient monitoring strategies and methods to assist decision-making such as the RETENTION solution would potentially upgrade current standard of care and facilitate our goals.

Feasibility and sustainability of deploying the RETENTION platform in the hospital setting

Attikon University Hospital has implemented a digital platform where hospitalised patients' laboratory and imaging files are uploaded. The hospital aims to proceed to further digitalisation of patient files to include historical files, doctors' notes etc. through a digital solution implemented on a country-level. We expect that digital solutions that support patient monitoring such as RETENTION PLATFORM would be endorsed by our hospital, especially if they prove to improve patient outcomes and in view of the difficulties in accommodating all the needs for patient assessments currently performed only on-site, due to the high patient volumes. Further discussions will need to be undertaken with the hospital's administrators to explore ways of implementation and funding of the RETENTION PLATFORM.

Expectations or plans for RETENTION business model evolution after the project conclusion

NKUA has experience in the participation and/or launching of Start-ups through The Archimedes Center for Innovation and Entrepreneurship that began its operation in autumn 2019, as the Technology Transfer Office (TTO) and the Business Accelerator of the NKUA. Archimedes Center's services are available to the University's community. Faculty members, researchers, NKUA students and graduates, who wish to either commercialise their research product or to accelerate the business process from the idea stage to the market stage and create sustainable startups/spin-offs, are assisted in doing so by Archimedes Center. The experience of NKUA Attikon Hospital in participation or launching startups, however, is limited but through its affiliated Academic Institution (NKUA) it is expected to be assisted in this direction. Discussions are undertaken in our study team to specify our goals for the RETENTION startup and define our expectations (i.e., perpetual discounted licence of the RETENTION platform cost, participation in the royalties' distribution, or direct participation in the startup business) according to the model that will be agreed upon among the RETENTION consortium.



University Hospital of Bologna

Relevance and applicability of the RETENTION research outcomes to the hospital's mission, vision, and values



Participation in research activities aligns with the UNIBO and IRCCS University Hospital of Bologna missions of providing patient-centred care by integrating innovative technologies like remote telemonitoring and fostering proactive health management beyond traditional settings. This not only supports the hospital's commitment to quality and safety but also positions it as a leader in adopting advanced healthcare solutions, in line with its vision for technological innovation. In terms of strategic goals, the RETENTION project contributes to efficiency and effectiveness in healthcare services. Proactive monitoring of patients remotely aids in managing chronic conditions, aligning with the hospital's goal of delivering efficient and effective care. Moreover, this participation reinforces the hospital's commitment to community outreach and improved access to care, addressing broader healthcare needs. Participating in research activities elevates the hospital's reputation by showcasing its dedication to evidence-based practices and cutting-edge solutions. It positions the hospital as a centre for advancements in healthcare, enhancing its overall performance and quality while upholding ethical standards. The involvement in RETENTION research contributes to strategic goals and bolsters its performance, quality, and reputation in the healthcare landscape.

Feasibility and sustainability of deploying the RETENTION platform in the hospital setting

Feasibility is contingent on the hospital's financial resources and the current landscape of digital health solutions. Hypothetically, assuming continued interest and investment in digital health, the healthcare system might allocate funds to adopt the platform as a market-available product. Partnerships with medical device producers or pharmaceutical companies could facilitate funding through collaborative initiatives. The adequacy of resources, including staff for remote patient management, is crucial. A hypothetical assumption might be that there is a growing workforce skilled in digital health management, ensuring the platform's successful integration into hospital operations. Barriers may include initial training costs and potential resistance to change among healthcare professionals. Infrastructure readiness is another factor. In a hypothetical scenario, existing hospital systems might undergo updates to seamlessly integrate the platform. The sustainability of the platform would depend on its long-term benefits, such as improved patient outcomes and reduced healthcare costs. The hospital's commitment to innovation and its alignment with evolving healthcare trends could further support the sustained use of the platform. Overall, feasibility and sustainability hinge on strategic financial planning, workforce readiness, and the ability to navigate potential barriers while leveraging facilitators in the evolving landscape of digital health solutions.

Expectations or plans for RETENTION business model evolution after the project conclusion

The benefits from the RETENTION startup may encompass a perpetually discounted licence for the platform, ensuring cost-effective access to cutting-edge technology. Additionally, the organisation could play a pivotal role in shaping the royalty's distribution model within the consortium, fostering a fair and mutually beneficial arrangement.

By actively engaging in the startup, the organisation seeks to leverage its expertise and insights gained during the project, ensuring a seamless transition from research results to a market-qualified product. This collaborative approach not only aligns with the organisation's commitment to innovation but also positions it strategically to reap tangible rewards, fostering a symbiotic relationship between research endeavours and entrepreneurial initiatives.



Hannover Medical School

Relevance and applicability of the RETENTION research outcomes to the hospital's mission, vision, and values

The RETENTION project directly supports our mission to enhance patient care by extending the boundaries of heart failure management. The focus on continuous patient monitoring outside the clinical environment resonates with our commitment to delivering comprehensive, proactive, and patient-centred healthcare solutions. Our clinic aspires to be a leader in innovative healthcare practices and solutions. By participating in the RETENTION project, we actively contribute to realising this vision. The utilisation of real-world data and the implementation of cutting-edge monitoring technologies align with our vision of staying at the forefront of advancements in patient care.



Feasibility and sustainability of deploying the RETENTION platform in the hospital setting

There is a strong commitment to advancing the implementation of the RETENTION platform in daily clinical practice, providing heart failure patients with a cutting-edge ambulatory support solution. Securing resources will be crucial, as will utilising existing budgets for digital health solutions and exploring external funding opportunities. Over the next 5 to 10 years, efforts will be directed towards securing adequate resources through diverse funding mechanisms, including potential partnerships with medical device producers or pharmaceutical companies.

Such an effort might be accompanied by various challenges. Potential barriers, including resistance to change, data security concerns, and regulatory challenges, could be proactively addressed through mutual stakeholder engagement, robust cybersecurity protocols, and collaboration with regulatory bodies. Positive user experiences and alignment with evolving healthcare regulations are anticipated facilitators.

A thorough cost-benefit analysis will guide our decision-making process, ensuring that the investment aligns with our commitment to delivering high-quality and cost-effective healthcare services. Taking the high initial costs of implementation into consideration, we in fact foresee long-term benefits, including improved patient outcomes, reduced hospital readmissions, and enhanced operational efficiency.

Expectations or plans for RETENTION business model evolution after the project conclusion

The organisation has a lengthy history of successful collaborations and partnerships with innovative companies and startups in the biomedical industry. The intrinsic value of nurturing innovation and entrepreneurship within the healthcare ecosystem is deeply acknowledged. There is a desire to support the potential of the RETENTION Platform to evolve into a market-available product. Commitment exists to aid in overcoming implementation challenges, effectively utilising resources, and actively engaging with the startup to derive meaningful benefits in alignment with the mission of delivering exceptional healthcare services.



7. Standardisation activities carried out (M1-M32)

For RETENTION, standardisation activities form the cornerstone of establishing a robust and interoperable framework for managing healthcare information. These activities encompass the adoption and refinement of industry standards such as HL7's FHIR (Fast Healthcare Interoperability Resources), which facilitates seamless data exchange and integration across disparate e-health systems. The standardisation efforts aim to ensure consistency in data representation, terminology, and communication protocols, fostering a cohesive and interoperable ecosystem.

Additionally, adherence to recognised data standards, privacy protocols, and interoperability frameworks enhances the project's capacity to harmonise diverse healthcare data sources, promoting a unified approach to data management and analysis. By prioritising standardisation activities, RETENTION not only optimises the efficiency of healthcare information exchange but also contributes to advancements in medical research, ultimately leading to improved patient care and outcomes.

Furthermore, embracing the Privacy by Design Principles of the General Data Protection Regulation (GDPR) strengthens the project's ability to securely and privacy-consciously integrate various healthcare data sources. Adhering to recognised data standards, privacy protocols, interoperability frameworks, and GDPR principles collectively optimises the efficiency of healthcare information exchange, contributing to advancements in medical research and ultimately leading to improved patient care and outcomes.

7.1 Extension of FHIR

The standardisation activities for RETENTION have been integral to its success, particularly in extending the FHIR standard for its needs. FHIR serves as a crucial framework for exchanging healthcare information electronically and promoting interoperability among diverse healthcare systems. By extending FHIR, RETENTION has enhanced its capabilities to capture, exchange, and utilise healthcare data in a more comprehensive and standardised manner. This extension aligns with the project's objectives, ensuring seamless integration with healthcare information systems and wearable devices while fostering data sharing and collaboration among different entities in the healthcare ecosystem.

The structure of the RETENTION ontology is shaped by an examination of standards issued by HL7®, particularly focusing on the arrangement of data classes and the nomenclature of their parameters. The developed ontology incorporates the terminology associated with each specified parameter. It is imperative for medical ontologies to align with FHIR terminology specifications. Consequently, the construction of the RETENTION data model ensures compliance with extensively adopted terminology systems like SNOMED CT¹¹, ICD-10¹², LOINC¹³, and ATC¹⁴. For the extension of FHIR in RETENTION, the Forge tool was used, which is a FHIR profiling tool for building FHIR data models tailored to the specific rules that have been defined for the healthcare subdomain of interest.

More details about the adoption of FHIR and the Data transfer mechanisms of RETENTION can be found in the deliverable D4.2

¹¹ http://www.ihtsdo.org/SNOMED_CT

¹² <http://www.who.int/classifications/icd/en/>

¹³ <https://loinc.org/>

¹⁴ https://www.whocc.no/atc_ddd_index/



7.2 Adhering to Privacy by Design Principles of GDPR

The RETENTION platform is committed to embodying Privacy by Design principles of GDPR. Privacy by Design is a proactive approach that integrates privacy considerations into the design and development of systems and processes from their inception. By adopting this guideline, RETENTION aims to ensure that privacy is embedded into every facet of its architecture, providing robust safeguards for individuals' health-related information.

The principles of Privacy by Design emphasise proactive measures to prevent privacy risks rather than addressing them retroactively. In the context of RETENTION, this involved integrating privacy features into the platform's core functionalities. Consent mechanisms are meticulously designed to be transparent and user-centric, ensuring that individuals have clear and informed control over the processing of their health data. Privacy settings and controls are user-friendly, empowering individuals to manage their preferences and exercise their rights under GDPR effectively.

Furthermore, RETENTION prioritises data minimisation by collecting and processing only the necessary information for the intended purposes, minimising the exposure of personal health data. The platform implements privacy-enhancing technologies and robust security measures to safeguard against unauthorised access and data breaches.

By adhering to the Privacy by Design Principles of GDPR, RETENTION not only meets legal and regulatory requirements but also instils a culture of privacy and data protection throughout its development and operation. This approach contributes to building user trust, enhancing transparency, and fostering responsible data practices within the framework of evolving privacy regulations.

More details about privacy by design principles of GDPR within RETENTION can be found in deliverables D3.2 and D7.1.

7.3 Compliance to ISO/IEC 29100

ISO/IEC 29100 serves as a fundamental standard that delineates Privacy Principles, presenting a comprehensive framework for safeguarding personally identifiable information (PII). This global standard is crafted to assist organisations in formulating and sustaining privacy management programs, ensuring that the handling of PII aligns with ethical and legal considerations. ISO/IEC 29100 underscores essential privacy principles, including consent, purpose specification, data minimisation, and accountability. Abiding by these principles enables organisations to instil a privacy-centric approach in managing personal information, fostering transparency, user control, and responsible data governance.

In accordance with ISO/IEC 29100's Privacy Principles, the RETENTION platform places paramount emphasis on preserving the privacy of individuals' health-related information. Transparent consent forms within RETENTION empower individuals to control the usage of their personal data. Clear purpose specification is foundational, outlining the reasons for collecting and processing health data. The platform adheres to data minimisation principles, collecting only the necessary information for its intended purposes to mitigate the risks associated with unnecessary data exposure. Accountability is integral to the platform's governance structure, ensuring that all stakeholders bear responsibility for upholding privacy principles. Embracing the principles delineated in ISO/IEC 29100, the RETENTION platform strives to establish a robust and ethical foundation for the responsible management of personal health information. More information about the privacy principles can be found in deliverable D6.2.



8. Conclusions

While facing a gradual start in awareness creation, RETENTION has effectively maintained seamless communication among partners and secured a good position on the global stage of research and innovation initiatives. The intrinsic complexities in this innovative project presented challenges, prompting an insightful identification of areas for improvement within the consortium. The acquired insights are poised to play a crucial role in shaping dissemination and communication activities during the upcoming project period.

As RETENTION progresses along the promising trajectory set at its inception, it evidences visible growth across various dimensions. This upward path is anticipated to continue, especially with the imminent launch of clinical trials and the achievement of its final outputs. However, it is paramount that communication and dissemination strategies proactively capitalise on every opportunity for impact, not only to enhance the project's chances of successful uptake upon completion but also to reinforce the ongoing standardisation efforts. Recognising standardisation as the common language unifying diverse project elements for enhanced compatibility and interoperability, the project strategically incorporates this aspect into its communication and dissemination framework. This ensures a cohesive thread binding different facets together, creating an efficient and streamlined environment.

The project's commitment to openly addressing challenges and incorporating lessons for continuous improvement positions it favourably for future successes and sound results uptake. Additionally, the consortium has already demonstrated a strong commitment to developing and testing in a real-life scenario the RETENTION Platform as a lasting and reliable digital solution, and this dedication ensures a strong focus on making the project's results usable and beneficial for the long-term well-being of individuals facing challenges related to heart failure.