D6.1

Impact master plan

AUS

Funded by
the European Union

Revision v1.0

Work package	WP6
Task	T6.1
Due date	31-05-2023
Submission date	31-06-2023
Deliverable lead	AUSTRALO
Version	v1.0
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Abstract

This document outlines the project dissemination, communication exploitation strategies for the SYNTHEMA Horizon Europe project

Keywords

Impact, communication, dissemination, exploitation, community building, outreach, stakeholder management, commercialization, business models, intellectual property, standardization.

Document revision history

v0.1	25-04-2023	1st version of deliverable D6.1	Arantxa Echarte (AUS), Sara Abu (AUS)
v.02	15-05-2023	1st review	Anna Rizzo (DW)
v.03	16.05.2023	Team review	Arantxa Echarte (AUS)
v.04	16.05.2023	2nd review	Raffaella Colombatti (UPD), Maria Paola Boaro (UPD)
v.05	26.05.2023	Final review	Anna Rizzo (DW), Gustavo Hernandez (UPM)
v1.0	31.05.2023	Submission	Gustavo Hernandez (UPM)

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Document information

Nature of the deliverable		**R**
Dissemination level		
PU	Public, fully open. e.g., website	✓
CL	Classified information as referred to in Commission Decision 2001/844/EC	
SEN	Confidential to SYNTHEMA project and Commission Services	

* Deliverable types:
R: document, report (excluding periodic and final reports).
DEM: demonstrator, pilot, prototype, plan designs.
DEC: websites, patent filings, press and media actions, videos, etc.
OTHER: software, technical diagrams, etc.

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Acronyms and definitions

AI	Artificial intelligence
AML	Acute myeloid leukaemia
C&D	Communication and dissemination
C&D&E	Communication, dissemination and exploitation
DIH	Digital innovation hub
DoA	Description of action
DOI	Digital object identifier
DP	Differential privacy
DMP	Data management plan
FL	Federated learning
GDPR	General data protection regulation
HCP	Healthcare providers
HD	Haematological diseases
HPC	High performance computing
IP	Intellectual property
IPR	Intellectual property rights
KPI	Key Performance Indicators
MDS	Myelodysplastic syndrome
PPP	Public private partnerships
RD	Rare diseases
RHD	Rare haematological diseases
RIA	Research and innovation action
RTO	Research & Technology Organization
SCD	Sickle cell disease
SDG	Synthetic data generation
SME	Small and medium enterprise
SMPC	Secure multi-party computation
WP	Work package

Executive summary

This deliverable sets the framework, guidelines and means for the project **communication, dissemination and exploitation** activities. The proposed document also serves to design and build an *ad hoc* stakeholder collaboration framework, developed to identify the ecosystem of entities impacted by SYNTHEMA innovations and findings.

The **strategies** set out in this document aim to:

- Ensure the development of appropriate means of communication of the project mission, activity and results outside of its consortium, with the intention of raising awareness.
- Foster stakeholders' engagement with the consortium, in order to give consistency and continuity to the project findings and expected outcomes.
- Increase the project impact on the identified target audiences in healthcare, industry, economy and society in general.

Moreover, the communication, dissemination and exploitation plans will also serve an internal purpose: to make consortium members aware of outreach activities pursued by other partners. These plans will be subject to constant evaluation and revision throughout the duration of the project, so as to always have an updated and accurate depiction of the progress made and challenges ahead.

1 Introduction

1.1 Purpose and scope

This deliverable (**D6.1 – Impact master plan**), is presented within the framework of SYNTHEMA **WP6 – Outreach, exploitation and collaboration**, specifically addressing **T6.1 – Stakeholder collaboration framework**, **T6.2 - Dissemination and communication** and **T6.3 Innovation management, exploitation & sustainability.**

The main goal of WP6 is to fast-track and amplify knowledge transfer between SYNTHEMA and its target stakeholder base, reinforcing the value streams of the project and capitalising on the results obtained. The specific objectives related to D6.1 are to:

- Develop and operate a collaboration framework that will enable identifying and building synergies with a range of target groups and communities.
- Design and implement dissemination and communication strategies to efficiently raise awareness about the outcomes of the project, promoting the activities and results among a critical mass.
- Assess the footprint of the project through performance indicators, while developing exploitation, sustainability and business models of the key results to be delivered.

- Develop an effective framework regarding IPR management, technology transfer and fair law enforcement.
- Actively contribute to relevant standardisation bodies and committees.

D6.1 is the second of a series of WP6 deliverables. This list includes a *Project website* deliverable (**D6.4**) submitted in month three (February 2023); a *Dissemination and communication report* (**D6.2**) to be submitted in month 48 and aimed at presenting the developed D&C activity throughout the project, including results; and one deliverable regarding the developments of the *Exploitation and sustainability plan* (**D6.3**), to assess the potential paths to be followed to maximise the impact of the project activities in relation to potential new business opportunities, knowledge creation and standardisation.

D6.1 represents SYNTHEMA projection of the communication, dissemination and exploitation strategies in the initial stages of the project, hence this can be regarded as a living document, possibly subject to changes during the four-years duration of the project. This is especially relevant for the exploitation of SYNTHEMA results, for two main reasons:

- Changes in the state of the art of the technology during the duration of the project, requiring to adapt to new emerging technologies.
- Emergence of new and innovative standardisation opportunities at European and international level.

1.2 Document structure

The present document has been structured in the following way:

- **Section one** is the **introduction**, where the purpose and scope of the document are outlined.
- **Section two** is concerned with the **stakeholder collaboration framework**, where the ecosystem of organisations surrounding the project are presented.
- **Section three** explains the **communication and dissemination strategy**, where the goals, phases, timeline and tools are described.
- **Section four** details the **exploitation plan**, where the foreseen KERs are discussed in the context of the wider exploitation strategies, both by the whole consortium and individual partners.
- **Section five** explains the **monitoring of communication, dissemination and exploitation efforts** established for the project.
- **Section six** outlines the **conclusions** of this deliverable, where the final remarks about the strategies are charted.

2 Stakeholder collaboration framework

As a Horizon Europe project, SYNTHEMA is a decentralised action by nature, but one that still needs to build and navigate an ecosystem of organisations, initiatives and players with a given position of influence on the project performance and outcomes: its stakeholders. Additionally, it also calls for a responsive growth factor capable of prospecting and creating new synergies over the project lifetime, facilitating greater exposure and extending its range of action.

To that end, SYNTHEMA is implementing an **agile stakeholder engagement framework**, a methodology designed to continuously develop and strengthen communication streams with key stakeholder groups, empowering the operation of the initiative as introduced in the DoA.

Figure 1. SYNTHEMA stakeholder collaboration framework.

2.1 Phases and sprints

This framework operation follows an iterative approach based on six-month sprints along three phases (**scout**, **interact**, **learn**), to incrementally build and reinforce engagement.

2.1.1 Scout

Building upon SYNTHEMA high-level objectives and findings from previous sprints, this first phase explores, maps and classifies **target groups** (and specific individuals) in terms of their relevance to the scope and impact of the project work plan. SYNTHEMA builds upon the sound experience and active involvement of consortium members in related initiatives (e.g., Genomed4all), and also on key players that must be considered as the baseline for successful engagement.

It also takes advantage of new leads generated by second-degree partnerships and new opportunities as an outcome of the interacting phase, including emerging *public private partnerships* (PPPs) and other related Horizon Europe projects.

The key result from the scouting phase will be the project **stakeholders map**, a visual mind map to:

- Identify and list key actors (groups and/or individuals) within the context of the project.
- Classify and correlate these audiences as per their degree of impact in the project execution and success.
- Define a common terminology to be referenced throughout the project documentation.

2.1.2 Interact

This second phase comprises all interactions with the identified target groups, thus supporting the activities outlined in the dissemination, communication and exploitation plans for the project.

This is the phase where SYNTHEMA will collaborate with advocate initiatives in the intersection of ***artificial intelligence*** **(AI)**, ***high-performance computing*** **(HPC)**, ***haematological diseases*** **(HD)** and ***rare diseases*** **(RD)**. Whenever relevant, the project will formally join specific task forces and working groups, contribute to scientific publications and participate in events. Feedback extracted from previous sprints will be used to improve the efficiency and impact of these interactions.

2.1.3 Learn

In this last phase, the consortium will learn and adapt based on how these interactions play out and insights obtained from **stakeholder consultation** (i.e., quick surveys or interviews to gather valuable external feedback about the project and its operation). These best practices will in turn feed the next scouting sprint.

2.2 Key audience and target groups

Promoting SYNTHEMA and encouraging stakeholders to engage with the initiative requires first an understanding of its target audience. A deep dive in stakeholder profiles and their influence along the value chain is essential to craft successful dissemination, exploitation and communication plans.

SYNTHEMA will leverage consortium partners' networks and involvement in ongoing EU-funded projects, as well as in other EU- based initiatives, to consolidate existing cooperation and establish new synergies with R&I initiatives involved in the digital transformation of the healthcare sector.

These are the SYNTHEMA key target groups:

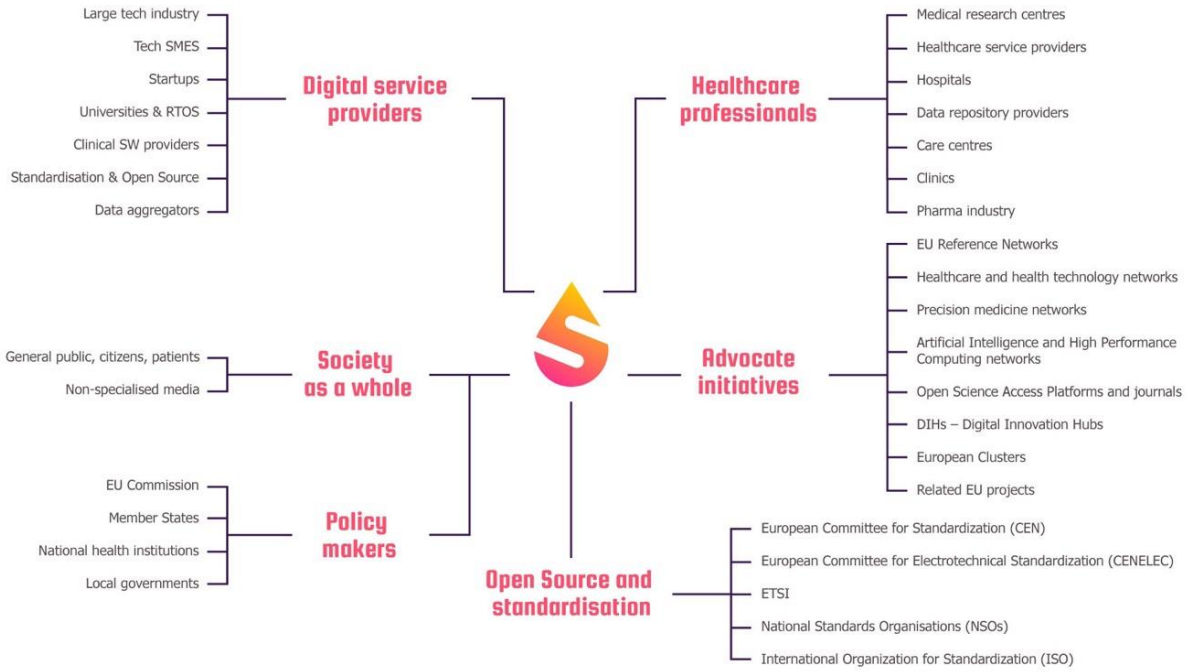

Figure 2. SYNTHEMA key target groups.

2.2.1 Healthcare professionals

SYNTHEMA will capitalise the participation of seven highly-rated clinical partners:

- **ICH** - Humanitas Mirasole Spa
- **VHIR** - Fundacio hospital Universitari Vall D'hebron
- **APHA** - Assistance Publique Hopitaux de Paris
- **UMC UTRECHT** - Universitair Medisch Centrum Utrecht
- **GLSMED LG** - Glsmed Learning Health SA
- **CHARITE** - Universitaetsmedizin Berlin
- **UNIPD** - Università degli Studi di Padova

These will serve as the starting point to engage with other organisations in the healthcare sector, namely **medical research centres**, **healthcare service providers**, **hospitals**, **data repository providers**, **clinics** and **care centres**.

This category includes healthcare professionals and organisations

- involved in the management and exploitation of hematological data and omics and health data repositories;
- interested in ethical and GDPR-compliant data research;
- interested in working across the technological and health sectors;
- interested in AI techniques for anonymization and synthetic data generation.

SYNTHEMA will curate multi-sourced data streams into meaningful insights that will enable more robust clinical research and decision making. The involvement of representatives from the health sector is extremely meaningful when it comes to obtaining requirements and feedback to support the implementation of the project, facilitating access to quality data repositories, and supporting direct patient interaction.

2.2.2 Digital service providers

SYNTHEMA will develop a ***federated learning*** **(FL)** infrastructure, equipped with ***secure multiparty computation*** **(SMPC)** and ***differential privacy*** **(DP)** strategies, connecting clinical centres bringing together standardised, interoperable multimodal datasets and computing centres from academia and SME.

Our **research** partners are:

- **UPM** – Universidad Politécnica de Madrid
- **SBA** - SBA Research Gemeinnutzige GMBH
- **UNIBO** - Alma Mater Studiorum - Universita di Bologna
- **VICOM** - Fundacion Centro De Tecnologias De Interaccion Visual y Comunicaciones Vicomtech (Digital Health And Biomedical Technologies)
- **UoS** – University of Southampton (IT Innovation Centre, Electronics & Computer Science)

Our **industrial** partners are:

- **INTRA** - Netcompany-intrasoft SA

Our **SME** partners are:

- **DW** – Datawizard
- **AUS** – AUSTRALO

Our **data governance, standardisation** and ***ethical, legal and social implications*** **(ELSI)** organisation is:

- **i-HD** - The European Institute for Innovation Through Health Data (Unit of Medical Informatics and Statistics)

These will serve as the starting point to connect with organisations involved in **information security, data aggregation and data analytics, cyber security, technological research and disruptive tech**, amongst others, as these are highly relevant to the application of AI-based technologies and service in the health data. This category will prioritise actors with a proven track record in responsible development and exploitation of digital transformation in the healthcare domain, namely **large tech**, **MedTech SMEs**, **start-ups**, **universities** and **RTOs**, **clinical software** providers, and **data aggregators**.

2.2.3 Open access and standardisation

This aspect of SYNTHEMA will be led by i-HD - The European institute for innovation through health data (Unit of medical informatics and statistics), a neutral multistakeholder institute that co-create solutions to make better use of health data to boost smarter healthcare and efficient research.

Open science and **standardisation** are priorities for SYNTHEMA. The project will develop legal and ethical frameworks to guarantee privacy by-design in the collection and processing of health-related personal data and attain an ethics-wise algorithm co-creation. Project outcomes, including pipelines, standards and data will be made openly available to stakeholders in the healthcare, academia and industry field, and contribute to existing rare disease registries.

To widen its reach, SYNTHEMA will engage with standardisation bodies at EU and international level, such as ***European Committee for Standardization*** **(CEN)**, ***European Committee for Electrotechnical Standardization*** **(CENELEC)**, **ETSI**, ***National Standards Organizations*** **(NSOs)** and ***International Organization for Standardization*** **(ISO)**, to be involved in, and possibly contribute to international debates and joint efforts for enhancement and coordination of health data standards at EU and global level.

2.2.4 Advocate initiatives

Our ambition is to establish a cross-border hub to develop and validate AI techniques for anonymisation and synthetic data generation for ethical, GDPR-compliant research in rare hematological diseases. For this reason, SYNTHEMA will actively seek to benefit from links and synergies with multiple EU health and technology networks.

2.2.4.1 European Reference Networks: ERN-EuroBloodNEt

European Reference Networks **(ERNs)** are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources.

SYNTHEMA will leverage synergies with ERN-EuroBloodNet, which is one of the 24 European reference networks established under the Directive 2011/24/EU. ERN-EuroBloodNet is a

collaborative network that brings together individuals and institutions committed to improving healthcare services in rare hematological diseases. This network of *healthcare providers* (HCPs) is comprised of 103 HCPs from 24 EU Member States, all nationally recognised centres of expertise. SYNTHEMA benefits from ERN-EuroBloodNet resources and network which provides a wealth of valuable contact points and data in the rare hematological field. Moreover, this collaboration ensures that the project research is patient-centred.

ERN-EuroBloodNet is a joint effort between the ***European Haematology Association* (EHA),** the ***European Network on Rare and Congenital Anaemias* (ENERCA),** and the European haematology patient organisations represented in both the ***EURORDIS European Patient Advocacy Groups* (ePAGS)** and the **EHA Patient Organisations Workgroup.**

Moreover, SYNTHEMA will have access and will contribute to **ENROL, the *European Rare Blood Disorders Platform*** conceived in the core of ERN-EuroBloodNet. ENROL is a patients Registry that aims at mapping RHD demographics, survival rates, diagnosis methods, genetic information, main clinical manifestations, and treatments at the EU level to obtain epidemiological figures and identify trial cohorts for research.

SYNTHEMA will also contribute to other existing data registries such as the ***European Platform on Rare Disease Registration* (EU RD Platform)** and the ***Rare Anaemia Disorders European Epidemiological Platform* (RADeep)** with data standards, pipelines and shareable data assets. These networks will be leveraged through our clinical partners, most of which are full members of this network(s).

Additionally, SYNTHEMA partners are also members of the following organisations:

- **ITHANET portal** – a resource hub for clinicians and researchers dealing with haemoglobinopathies.
- **HARMONY Alliance** – a Big Data initiative to improve outcomes for patients with blood cancers.
- **ASH** – American Society of Haematology.
- **SEHH** – the Spanish Society for haematology and hemotherapy.
- **AIEOP** – Associazione Italiana Emato-Oncologia Pediatrica
- **Big Data Value Association (BDVA)** - https://www.bdva.eu/
- **Basque Research and Technology Alliance (BRTA)** - https://www.brta.eus/
- **GraphicsVision.ai** - https://graphicsvision.ai/
- **Basque Artificial Intelligence Center** - https://www.baic.eus/en/
- **NESSI** - https://nessi.eu/
- **OASIS** - https://www.oasis-open.org/
- Collaboration Agreement with **IDSA (International Data Spaces Association)**
- (P) Member of the **IPEN community** (IPEN - Internet Privacy Engineering Network | European Data Protection Supervisor (europa.eu)
- (P) Member of Europol's Data Protection Experts Network (EDEN) - closed group
- (P) Member of the **Women4Cyber Greece** (Women4Cyber Greece)

- (P) Expert member of **EC DG HOME CERIS Experts Group** (About CERIS (europa.eu))

2.2.4.2 Healthcare and health technology networks

- **EIT Health** – a KIC (Knowledge and Innovation Community) of the European Institute of Innovation and Technology (EIT) focusing on health and aging.
- **EATRIS** – European Infrastructure for Translational Medicine.
- **EuroHealthNet** – a not-for-profit partnership of public bodies to help build healthier communities and tackle health inequalities across the EU.
- **European Public Health Association** – an umbrella organisation for public health associations and institutes in Europe.
- **European Connected Health Alliance** – the Global Health Connector for Digital Health, facilitating multi-stakeholder connections, driving sustainable change and disruption in the delivery of health and social care.
- **European Health Management Association** - a non-profit organisation to enhance the capacity and capability of health management to deliver high quality healthcare.
- **EUnetHTA** – the European Network for Health Technology Assessment.
- **MedTech Europe** – the European trade association representing the medical technology industries.
- **International Rare Diseases Research Consortium** - a global collaborative initiative launched in 2011 by the European Commission and the US National Institutes of Health to tackle rare diseases through research.
- **EU Platform on Rare Disease Registration (EU RD Platform)** - a platform that copes with the fragmentation of rare disease patients data contained in hundreds of registries across Europe.
- **European Haematology Association (EHA)** - promotes excellence in patient care, research, and education in haematology.
- **Innovative Health Initiative (IHI)** - an EU public-private partnership funding health research and innovation.

SYNTHEMA is also aware of beyond Europe initiatives like for **example PDH(WHO) – The Public Digital Health Technology team (World Health Organisation),** who engages with a variety of stakeholders in digital health to achieve normative support, market shaping and operational support.

Additionally, SYNTHEMA is part of LinkedIN expert groups such as:

- **Artificial Intelligence in Health - Utilising data science to improve global health**
- **Health Data Management | Discussion Group**
- **HealthDSA: Health Data Science & Analytics**
- **Health Data**
- **BIG DATA: Telecom, Intelligence, Analytics, Security, Science, Machine Learning, AI, IoT, Blockchain**
- **Synthetic Data**
- **Synthetic Data Enthusiasts**

- **Synthetic Data Generation and Applications**
- **Synthetic Data Generation Experts**

2.2.4.3 Personalised medicine networks

Although there is no universally accepted definition, the Horizon 2020 advisory group defines personalised medicine as 'a medical model using characterisation of individuals' phenotypes and genotypes (e.g., molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention.'

Some of the most relevant initiatives in this area are listed below:

- **EUAPM** – the European Alliance for Personalised Medicine.
- **ICPerMed** – International Consortium for Personalised Medicine.
- **ERA PerMed** – an ERA-Net Cofund to align national research strategies, promote excellence, reinforce the competitiveness of European players in precision medicine.

2.2.4.4 Artificial intelligence and high-performance computing networks

- **The European AI Alliance**: a multi-stakeholder forum engaged in a broad and open discussion of all aspects of AI development and its impact on the economy and society.
- **AI on Demand:** the first European Artificial Intelligence On-Demand Platform and Ecosystem.
- **CLAIRE:** a Confederation of Laboratories for AI Research in Europe.
- **The Big Data Value Association (BDVA):** an industry-driven international not–for-profit organisation to develop the Innovation Ecosystem that will enable the data and AI-driven digital transformation in Europe.
- **EuroHPC:** a Joint Undertaking between the EU, European countries and private partners to develop a world-class supercomputing ecosystem in Europe.
- **ETP4HPC:** an industry-led think-tank promoting European HPC research and innovation to support Europe's competitiveness.

2.2.4.5 Open access platforms and journals

Open science is a policy priority for the European Commission and the standard method of working under its research and innovation funding programmes as it improves the quality, efficiency and responsiveness of research.

Peer-reviewed publications will be published in open access journals whenever possible, or either in hybrid subscription-based journals under the open access article option, retaining authors' IPRs (gold open access); alternatively, a machine-readable electronic copy of the published version or the final accepted manuscript will be uploaded in **Zenodo** (the open-access repository developed under the **European OpenAIRE** program, within a project-dedicated collection), **Open Research Europe** or **arXiv**, at the latest at the time of publication (green open access).

Papers will be available under the latest version of the **Creative Commons Attribution 4.0 International License (CC BY 4.0)** or a licence with equivalent rights. Metadata of deposited

publications will be open under a **Creative Commons CC0 1.0 Universal Public Domain Dedication Licence (CC0 1.0)**, in line with **FAIR** principles.

SYNTHEMA will aim to contribute to:

- **European Open Science Cloud -** a pan-European project designed to create a virtual environment for sharing and accessing research data across borders and scientific disciplines.
- **ELIXIR** – an intergovernmental organisation that brings together life science resources from across Europe.

Other open access journals where members can publish their findings and research results are:

- **Sprinter: https://www.springer.com/journal/12553**
- **Journal Health Technology: https://jhealthtechnology.org/index.php/jht**
- **SJR: https://www.scimagojr.com/journalsearch.php?q=19700182124&tip=sid**
- **HT – Health Technology: https://ht.amegroups.com/**

2.2.4.6 Digital Innovation Hubs (DIHs)

In the context of digital transformation in Europe, *Digital Innovation Hubs* (DIH) are set up as one-stop shops to help companies become more competitive when creating or improving on their products and services using digital technologies. To fulfil this mission, DIHs provide innovation services, such as financing advice, training and skills development that are needed for a successful digital transformation.

Below is a non-comprehensive list of some DIHs working on the realms of eHealth, AI or cross-border collaboration:

- **DIHNET:** project to create a sustainable pan-European network of networks, with a focus on regional DIHs.
- **DIH & Digital Health Network:** a website that gathers news, evidence, case studies & success stories from the Digital Innovation Hubs, and their ecosystems, that decided to join forces to speed up digital innovation in the European healthcare landscape.
- **EUHubs4Data:** the European federation of data driven innovation Hubs for data-driven innovation and experimentation.
- **DIH-HERO:** an independent platform connecting DIHs across Europe to create a sustaining network for all those who are active in the healthcare robotics sector.
- **TechMed Innovation Hub:** a leading digital innovation hub that stimulates the development and implementation of technology for better healthcare.
- **eHealth Hub:** EU-funded cross-border initiative focused on providing business support for the digital health vertical.
- **DIH-World:** an initiative to accelerate the uptake of advanced digital technologies by European manufacturing SMEs by supporting them in building sustainable competitive advantages and reaching global markets.

2.2.4.7 European clusters

SYNTHEMA will aim to connect with relevant initiatives presented by the **30 Euroclusters,** launched in 2022, to implement the EU industrial strategy. Euroclusters are cross-sectoral,

interdisciplinary and trans-European strategic initiatives of industry clusters and other economic actors such as research organisations and companies.

2.2.4.8 Related EU projects

SYNTHEMA is expected to collaborate closely with funded projects under topic **HORIZON-HLTH-2022-IND-13-02** - *Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation*.

Beside SYNTHEMA, there are other 2 projects funded under this topic: **SECURED**, that aims to scale up secure processing, anonymization and generation of health data for EU cross border collaborative research and innovation; and **AISYm4MED**, which aims to create a synthetic and scalable data platform for medical empowered AI.

Links to other Horizon Europe projects

There are several other funded topics and projects in H2020, Marie Sklodowska-Curie Actions, ERC and Horizon Europe calls working in the intersection of haematology, clinical data, AI, privacy-preserving technologies, healthcare data, virtual patients and decision support systems and tools.

Below is a list of some of those that better suit and/or complement SYNTHEMA vision:

- **HORIZON-HLTH-2022-TOOL-11-02:** New methods for the effective use of real-world data
- **HORIZON-HLTH-2021-DISEASE-04-04:** AI for health and improved treatment
- **HORIZON-WIDERA-2021-ACCESS-03-01:** Widening participation and spreading excellence.
- **HORIZON-MSCA-2021-COFUND-01-01:** Marie Sklodowska-Curie actions (MSCA). Carreras Leaders – Carreras Postdoc Program Empowering Future Leaders to Fight Blood Cancers.
- **HORIZON-CL3-2021-CS-01-03:** AI for cybersecurity reinforcement and civil security for society.
- **HORIZON-CL3-2021-CS-01-04:** Scalable privacy-preserving technologies for cross-border federated computation in Europe involving personal data. Civil security for society
- **DT-ICT-12-2020:** Information and communication technologies. AI for the smart hospital of the future
- **DT-TDS-05-2020**: AI for health imaging.
- **DT-ICT-12-2020:** AI for the smart hospital of the future.
- **ERC-2018-STG:** European research council.
- **MSCA-IF-2014-GF:** Virtual patients.

Topic	Title	Acronym
HCO-10-2014	ERA-NET rare disease research implementing IRDiRC objectives	E-Rare-3
MSCA-IF-2014-GF	Effective clinical reasoning in virtual patients	Virtual Patients
SC1-PM-03-2017	Solving the unsolved rare diseases	Solve-RD
SC1-PM-08-2017	SLAMF7-CAR T cells prepared by sleeping beauty gene-transfer for immunotherapy of multiple myeloma – a rare hematologic disease	CARAMBA
HORIZON-HLTH-2022-IND-13-02	Scaling up secure processing, anonymization and generation of health data for EU cross border collaborative research and Innovation	SECURED
	Synthetic and scalable data platform for medical empowered AI	AISym4MED
HORIZON-HLTH-2022-TOOL-11-02	Real-world-data enabled assessment for health regulatory decision making	REALM
	Real-world evidence for decisions in diabetes	REDDIE
	More effectively using registries to support patient-centered regulatory and HTA decision making	More-EUROPA
	Implementing value-based oncology care at European cancer	ONCOVALUE
	Development, optimization and implementation of artificial intelligence methods for the real world data analyses in regulatory decision-making and health technology assessments along the product lifecycle	Real4Reg
HORIZON-WIDERA-2021-ACCESS-03-01	Twinning partnership to deliver enhanced networking for circular technological and socio-economic impact, raising research excellence and strengthening management capacity	CiRCLETECH
HORIZON-HLTH-2021-DISEASE-04-04	Optimising colorectal cancer prevention through personalised treatment with AI intelligence	OperA
	International clinical validation of radiomics artifical intelligence for breast cancer treatment planning	RadioVal
	Combining artificial intelligence and smart sensing toward better management and improved quality of LIFE in chronic obstructive pulmonary diseases	TOLIFE
	Mobile artificial intelligence solution for diabetes adaptive care	MELISSA
	AI supported picture analysis in large bowel camera capsule endoscopy	AICE

	Prediction of radiotherapy side effects using explainable AI for patient communication and treatment	PRE-ACT
	Validating AI in classifying cancer in real-time surgery	CLASSICA
	Validation of a trustworthy AI-based clinical decision support system for improving patient outcome in acute stroke treatment	VALIDATE
	Clinical validation of an AI-based approach to improve the shared decision-making process and outcomes in breast cancer	CINDERELLA
HORIZON-CL3-2021-CS-01-03	Trustworthy artificial intelligence for cybersecurity reinforcement and system resilience	AI4CYBER
	pLatform for analysis of resillient and secUre software	LAZARUS
	Cyber-kinetic attacks using artificial intelligence	KINAITICS
HORIZON-CL3-2021-CS-01-04	Federated data sharing and analysis for social utility	HARPOCRATES
	Privacy aware and privacy preserving distributed and robust machine learning for medical applications	PAROMA-MED
DT-TDS-04-2020	Genomics and personalised medicine though artificial intelligence in hematological diseases	GenoMed4ALL
DT-TDS-05-2020	Accelerating the lab to market transition of AI tools for cancer management	CHAIMELEON
	A European cancer image platform linked to biological and health data for next-generation artificial intelligence and precision medicine in oncology	EuCanImage
	A multimodal AI-based toolbox and an interoperable health imaging repository for the empowerment of imaging analysis related to the diagnosis, prediction and follow-up of cancer	INCISIVE
	An AI Platform integrating imaging data and models, supporting precision care through prostate cancer's continuum	ProCAncer-I
DT-ICT-12-2020	AI accelerator – A smart hospital care pathway engine	AICCELERATE
	Artificial intelligence-driven, decentralized production for advanced therapies in the hospital	AIDPATH
	Hospital smart development based on AI	HosmartAI
	Leveraging AI based technology to transform the future of health care	ODIN
ERC-2018-STG	Secure, private, efficient multiparty computation	SPEC

Table 1. List of related H2020, HE, and other EU-funded projects.

Moreover, SYNTHEMA will develop **training itineraries for healthcare professionals and patients (WP6, T6.4)**. The structure and content for these curricula will be curated by

consortium IT and clinical experts with the support of patient advocates, and will focus on anonymised and synthetic data, particularly their role in clinical research and care, ethical and legal implications, operational guidelines for anonymisation and SDG, data standardisation and interoperability. Each training itinerary will be articulated through a series of online/on-site sessions (webinar series) adapted to clinicians' and patients' expertise and interests. Training dedicated to clinicians will be accredited by the ***European Board for Accreditation in Hematology* (EBAH).** All the material produced will be publicly available on ERN-EuroBloodNet website and YouTube channel.

Additionally, SYNTHEMA will leverage the experience of members in the educational area. For example, SYNTHEMA will benefit from:

- ERN-EuroBloodNet progress meetings and educational webinars for healthcare professionals, patients, families and caregivers and patients' associations.
- DW think tank sessions on innovation and digital transformation.
- UNIBO seminars and summer schools at the ALMA-AI centre.
- UoS two open community events on privacy risk assessment knowledge and open-source tooling, and three workshop sessions for involvement of public in privacy risk assessment methods.
- i~HD multi-stakeholder workshops on data protection, anonymisation and robustness of SDG.

2.3 Policy makers

SYNTHEMA will aim to connect with members of government departments, legislature or any other organizations responsible for creating and enforcing policies and promoting strategies on digital transformation in the healthcare sector. This category includes the **EU Commission**, **Member States**, **national health institutions**, *national health systems* **(NHS)** and **public health bodies**, **local governments** and **regulatory agencies**, among many others.

For example**, the *European Data Protection Supervisor*´s (EDPS)** office provides an opportunity for closer cooperation and engagement with policymakers and other EU institutions present in Strasbourg, as well as with the Council of Europe. EDPS regularly publishes TechSonar reports on emerging technologies, including for example information on synthetic data and federated learning.

Additionally, in June 2022, the ***Joint Research Center* (JRC),** the European Commission´s science and knowledge service published a technical report providing evidence-based scientific support to the European policymaking process in regard to synthetic data. The complete report can be downloaded here.

2.4 Society as a whole

Novel methods and strategies for health and care are powerful ways for improving the quality of life of European society. We will encourage a common understanding on the benefits that digital healthcare brings to patients, incentivising a secure narrative around AI and its healthcare applications among **patients** and **patient associations**, **non-specialised media** and the **EU citizenship** as a whole.

2.5 Stakeholders map

The figure below depicts the first iteration of the SYNTHEMA stakeholders' map. The graph is structured in quadrants for influence and interest/availability, as per the guidelines set out by the Agile stakeholder framework:

- Y-axis shows the mutual **influence** potential between the project and a specific target group.
- X-axis depicts the mutual **interest or availability** potential between the project and a specific target group.

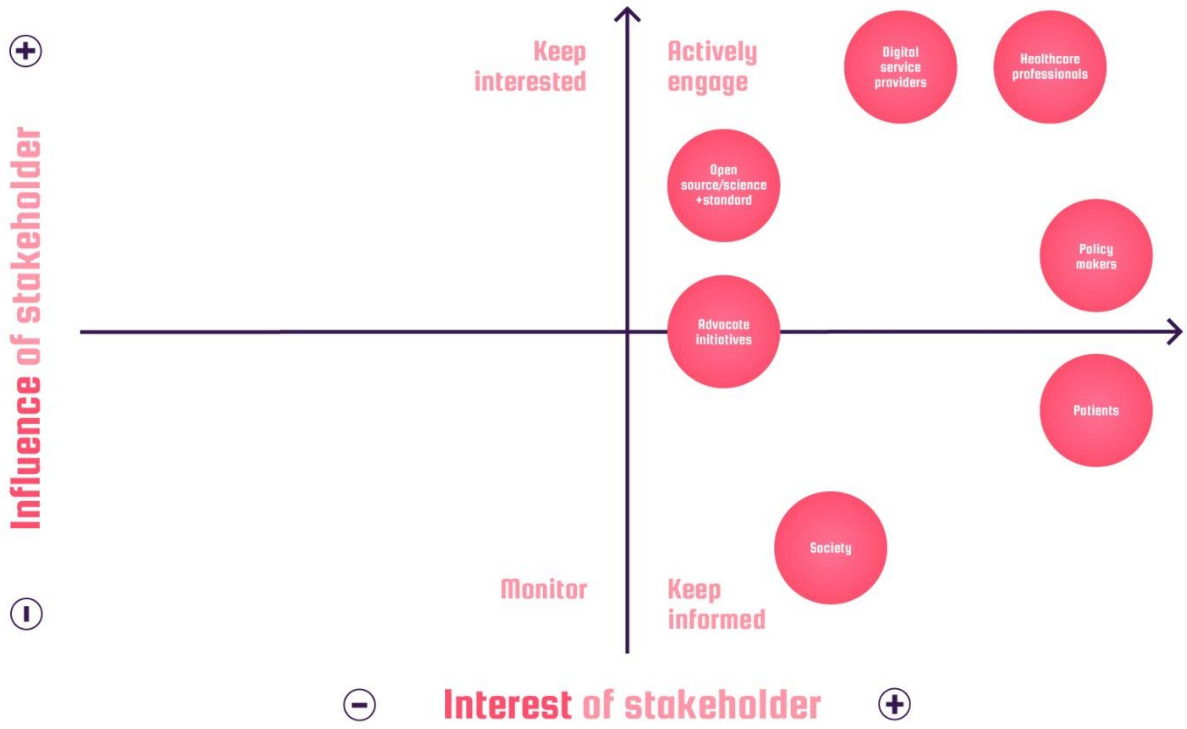

Figure 3. Stakeholder map and segmentation priorities.

The second figure below depicts the engagement position for each of the stakeholder groups. The classification is:

- **Core team:** Part of the project itself. Ongoing communication and exchange. Collaborative effort.
- **Involved:** Regularly providing input or helping to move work forward, but this project is not their sole focus.
- **Informed:** Wants to stay up to date and will provide feedback/input when necessary.

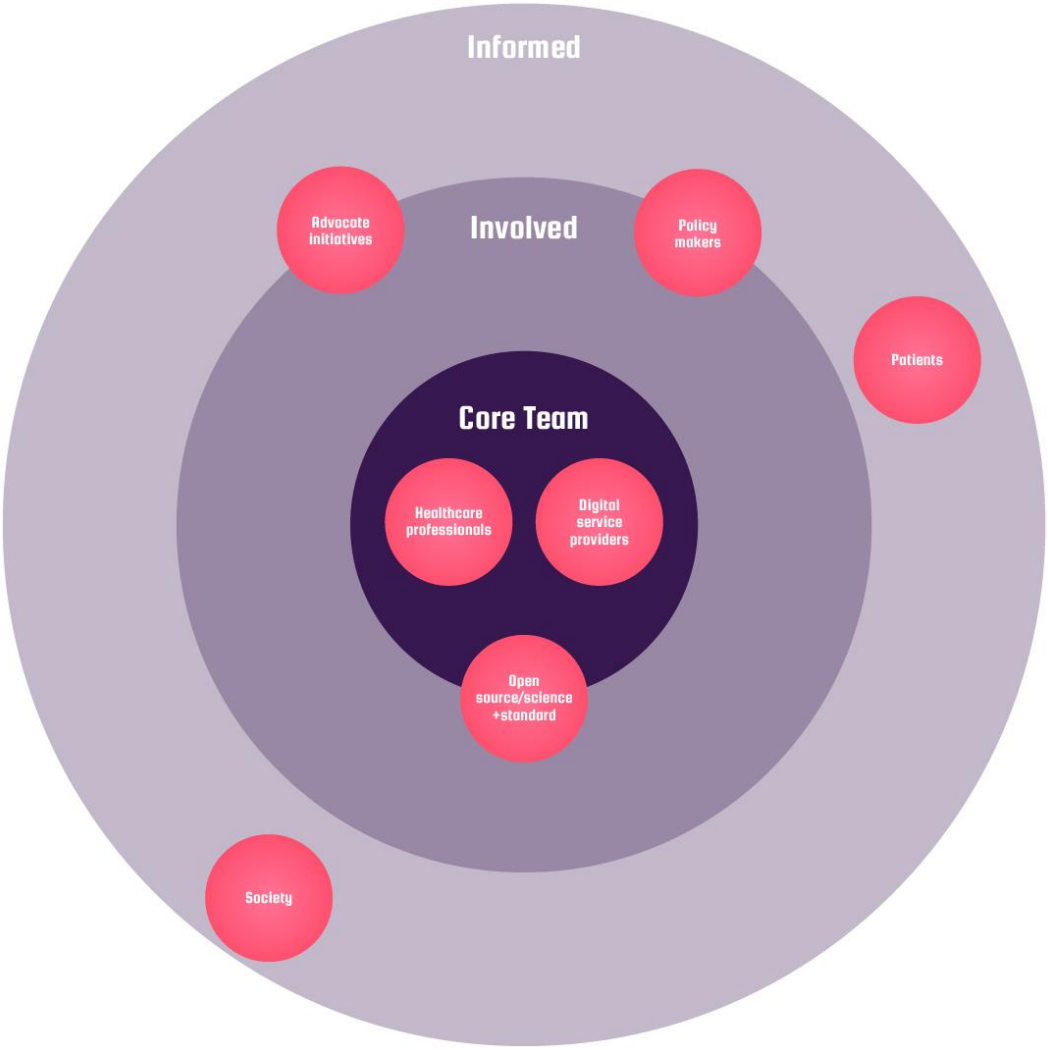

Figure 4. Stakeholder map and engagement position

3 Communication and dissemination

Effective communication and dissemination (C&D) are crucial to the success of any Horizon Europe project, and SYNTHEMA is no exception. A well-devised, engaging, and agile communication and dissemination strategy takes into account the influence of external factors

and challenges, such as the recent Covid-19 crisis, on its implementation and effectiveness. Simultaneously, it unlocks the potential to maximise the project visibility and reach.

While communication and dissemination are closely intertwined, we have opted to address them separately in this document, yet always acknowledging their interdependence. It is evident that parallels and convergences exist, and these will be thoroughly examined and leveraged throughout the project lifespan.

Figure 5. Communication and dissemination flows

3.1 Communication plan

SYNTHEMA prioritises the versatility and agility of a cohesive communication plan and adopts a streamlined approach to ensure targeted yet extensive communication with all potential target groups and stakeholders. The primary focus of this approach is to generate awareness by effectively conveying the key aspects and benefits of the project to all target audiences and end users.

Easily interpretable, comprehensible, and recognizable visual materials will be created and shared, enabling SYNTHEMA concepts and advantages to be instantly identifiable to a broader audience, while simultaneously fostering and nurturing interest in the project and its key outcomes. Bespoke content will be developed and communicated to specialised target groups, as described above, to establish and sustain an active stakeholder ecosystem. In a similar vein, pertinent information will be gleaned from project deliverables, partner interviews, pilot case studies, and industry reports, and disseminated through SYNTHEMA communication channels to bolster user engagement.

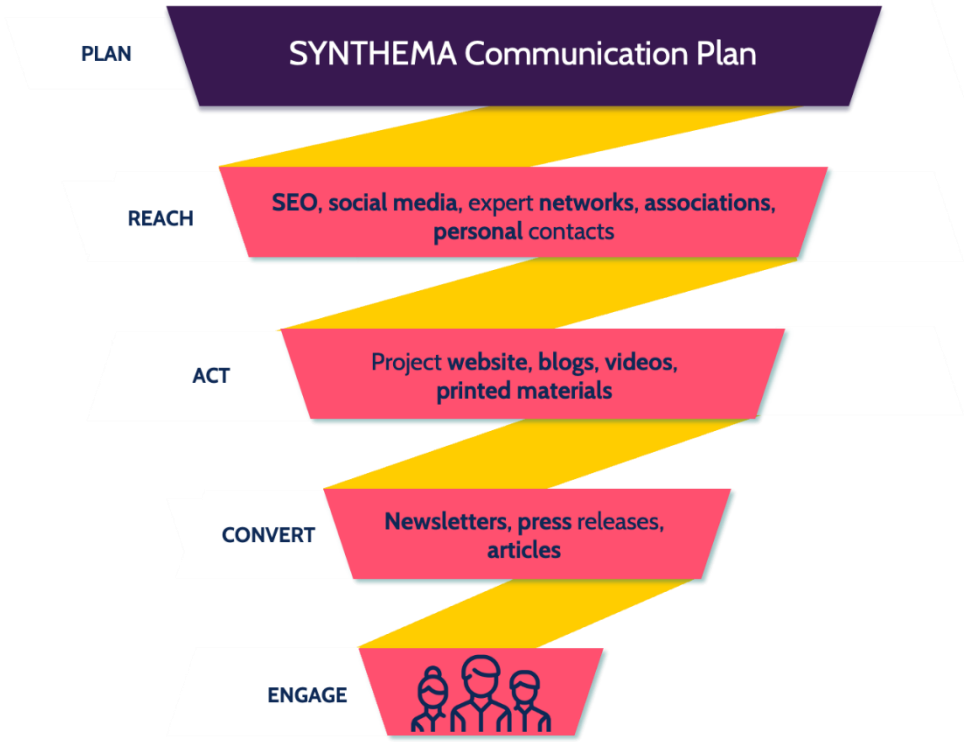

Figure 6. Communication and dissemination plan

3.1.1 Main goals

The communication plan for SYNTHEMA is designed with several key objectives in mind, which are essential for its successful implementation. While communication objectives can often be grouped together, it is important to note that some are tailored to particular target groups, and thus will be addressed with distinct tools and activities throughout the project duration.

SYNTHEMA overarching **communication objectives** include:

- **Enhancing general awareness and interest** in the project in order to establish a robust customer base and ecosystem that will facilitate effective dissemination and exploitation of the project outcomes in the future.
- **Clearly conveying technical and scientific results**, as well as their benefits, to specialised target groups and stakeholders in order to foster understanding and support for the project goals and achievements.
- **Delivering high-level messages** about the project to non-technical target groups and broader audiences, ensuring that the key insights and impacts of SYNTHEMA are accessible to all.
- **Promoting awareness** among non-specialised audiences about the unique value that SYNTHEMA brings to the table, with the aim of reaching the widest possible community and maximizing the project overall impact.

By addressing these objectives in a targeted and strategic manner, the communication plan will help ensure that SYNTHEMA mission, activity and results are effectively communicated and understood, leading to broader engagement and support for the project goals.

	Boost awareness & interest	Communicate technical & scientific results	Deliver top-level messages about the project	Raise awareness in non-specialised audience
Healthcare professionals	✓	✓		
Digital service providers	✓	✓		
Advocate initiatives	✓		✓	
Open Science and standardisation	✓	✓		
Policy makers	✓	✓	✓	
Patients	✓			✓
Society as a whole	✓			✓

Table 2. Main goals for communication

3.1.2 Phases and timeline

The implementation of communication activities for SYNTHEMA will occur in three distinct phases: **plan & revisit, early bird communication, and targeted communication**. These phases are closely intertwined with dissemination efforts as well. The primary aim of these communication activities is not only to generate excitement and interest around the project but also to actively engage a community of end-users who can interact with and offer valuable feedback to support the project's ongoing activities.

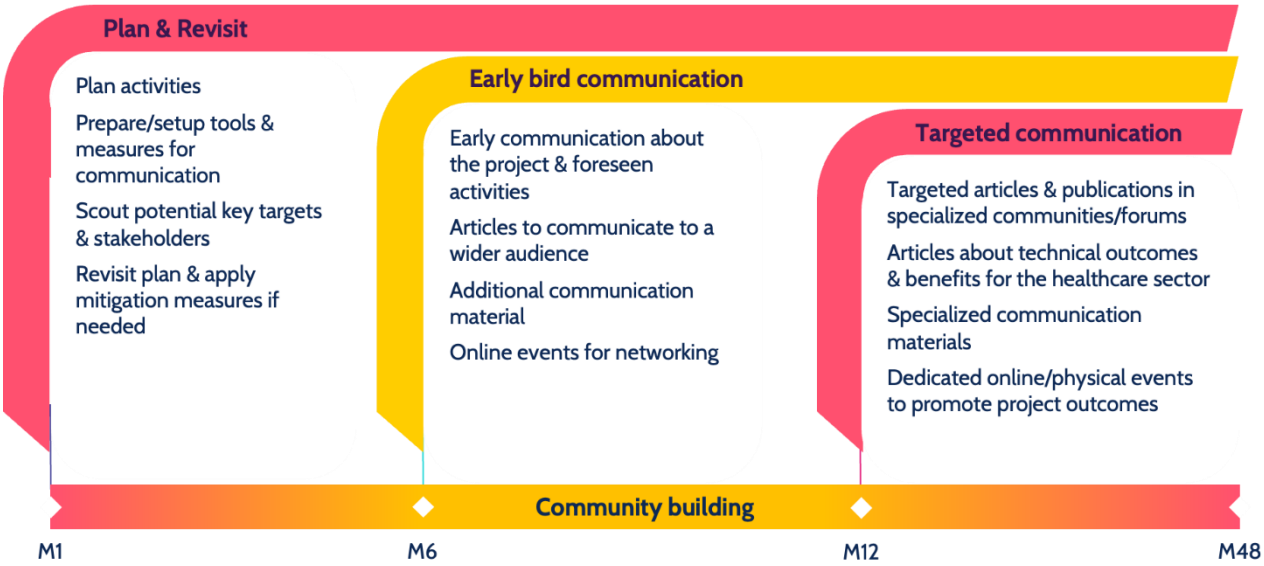

Figure 7. Phases of SYNTHEMA communication plan.

3.1.2.1 Plan & revisit

The initial communication phase will commence in the first month of the project, focusing primarily on planning all activities, establishing key communication tools and channels (such as the website and social media), and identifying potential target groups and stakeholders. It's important to note that the identification process will continue throughout the entire project. This first phase also incorporates the concept of revisiting the plan: as needed, the communication plan will be periodically reviewed and adjusted to accommodate any specific needs or circumstances that may arise. Additionally, during this phase, preliminary communication activities, such as press releases, will be carried out.

3.1.2.2 Early bird communication

The second phase, beginning in month six, will focus on implementing early bird communication activities. These efforts aim to inform both the broader public and specific communities about the project existence, as well as its upcoming activities and initiatives. Emphasis will be placed on utilizing online tools and strategies, as they tend to have a more extensive reach compared to traditional methods. During this phase, networking opportunities will be pursued through participation in webinars or other online events, along with the publication of articles about the project on platforms such as CORDIS. This phase will continue throughout the project duration, primarily concentrating on conveying the project general aspects to a wide range of stakeholders.

3.1.2.3 Targeted communication

The third communication phase will commence around month twelve, as it necessitates the project reaching a relatively mature stage with initial, tangible outcomes being released. During this phase, targeted communication activities will be carried out, such as creating and sharing articles, blog posts, or other content specifically addressing particular project outcomes and

benefits. This phase will also involve hosting and/or participating in online events (or in-person events, if feasible) to showcase SYNTHEMA innovations and producing targeted communication materials (e.g., videos) for the relevant community. This phase will run concurrently with phase two, as it concentrates on targeted communication efforts for specific audiences, rather than activities aimed at the entire community.

3.1.3 Communication tools and materials

A series of communication tools will be made available to allow the project to reach the right audiences in a friendly and coherent way. This toolkit will be tailored to specific communication needs for all phases of the SYNTHEMA Communication plan.

	Healthcare professionals	Digital service providers	Advocate initiatives	Open Science	Policy makers	Society as a whole (including patients)
Website	✓	✓	✓	✓	✓	✓
Social media	✓	✓	✓	✓	✓	✓
Newsletters	✓	✓	✓	✓	✓	✓
Press releases	✓	✓	✓	✓	✓	
Slide decks and one pagers	✓	✓	✓	✓		
General spreading	✓	✓	✓	✓	✓	✓
Expert networks	✓	✓	✓	✓	✓	
Printed materials	✓	✓	✓	✓	✓	✓
Multimedia	✓	✓	✓	✓	✓	✓

Table 3. Communication tools and target audiences

3.1.3.1 Visual identity

SYNTHEMA visual identity plays a pivotal role in establishing the project brand and message by incorporating meaningful symbolism into its design.

The logo is based on two key elements that are meant to communicate to the general audience the purpose of SYNTHEMA and the commonality between consortium partners. These two key elements are:

- a drop that transforms into an "S" through the clever use of negative space, representing the concept of synthetic data. This drop is also emblematic of haematology, showcasing the project focus on this particular field of study.
- diagonal cut lines incorporated in the design symbolize connection, reflecting the project aim to foster collaboration and communication among various stakeholders.

Overall, the SYNTHEMA visual identity not only enhances its recognition but also effectively conveys the project key themes and objectives, reinforcing its importance in the realm of haematology and synthetic data.

Figure 8. Example of SYNTHEMA visual identity

3.1.3.2 Online channels

3.1.3.2.1 Project website

SYNTHEMA public website serves as a vital tool to maximize the project visibility and acts as the primary entry point for showcasing its core ideas, approach, news, findings, and results (see D6.4 for detailed info on the website). By introducing visitors to SYNTHEMA rationale and educating them on its underlying concepts, the website effectively engages a broad audience, fostering a deeper understanding and appreciation for the project contributions in the field of hematology and synthetic data.

SYNTHEMA website www.synthema.eu

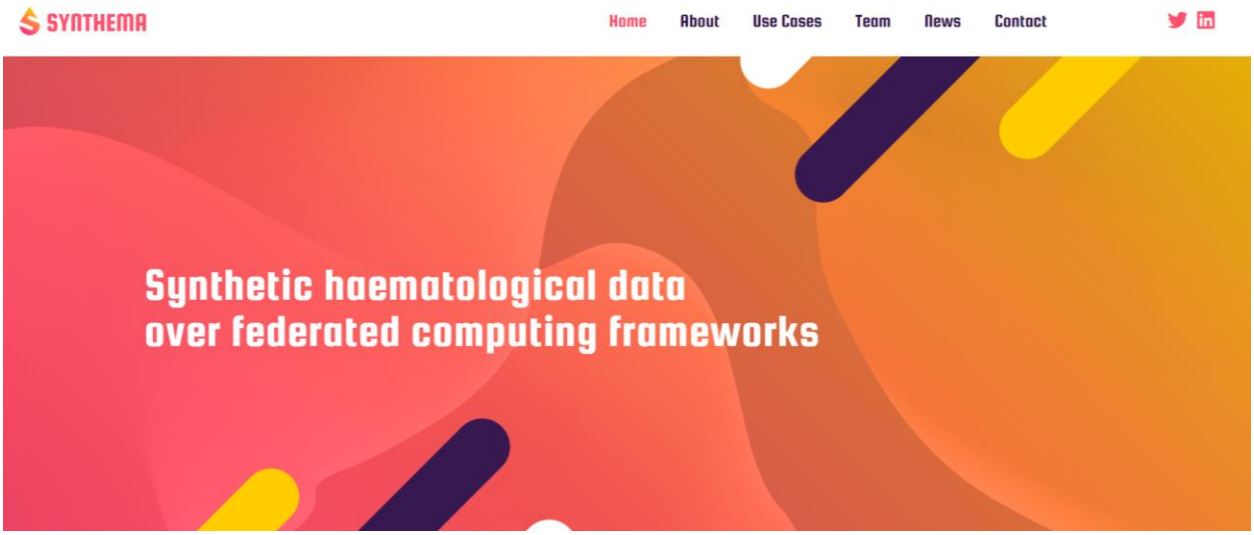

Figure 9. SYNTHEMA website – Landing page

SYNTHEMA is committed to regularly publishing original content in the form of blog posts on its website under the NEWS section, with a target of 50 blog posts throughout the project duration. These blog posts will serve as promotional material, highlighting events participated in by the project, key results, important facts, essential materials, and more. By directly linking these blog posts to our social media channels, we not only boost traction but also drive more visitors to our website, effectively increasing overall engagement and awareness of SYNTHEMA activities and achievements.

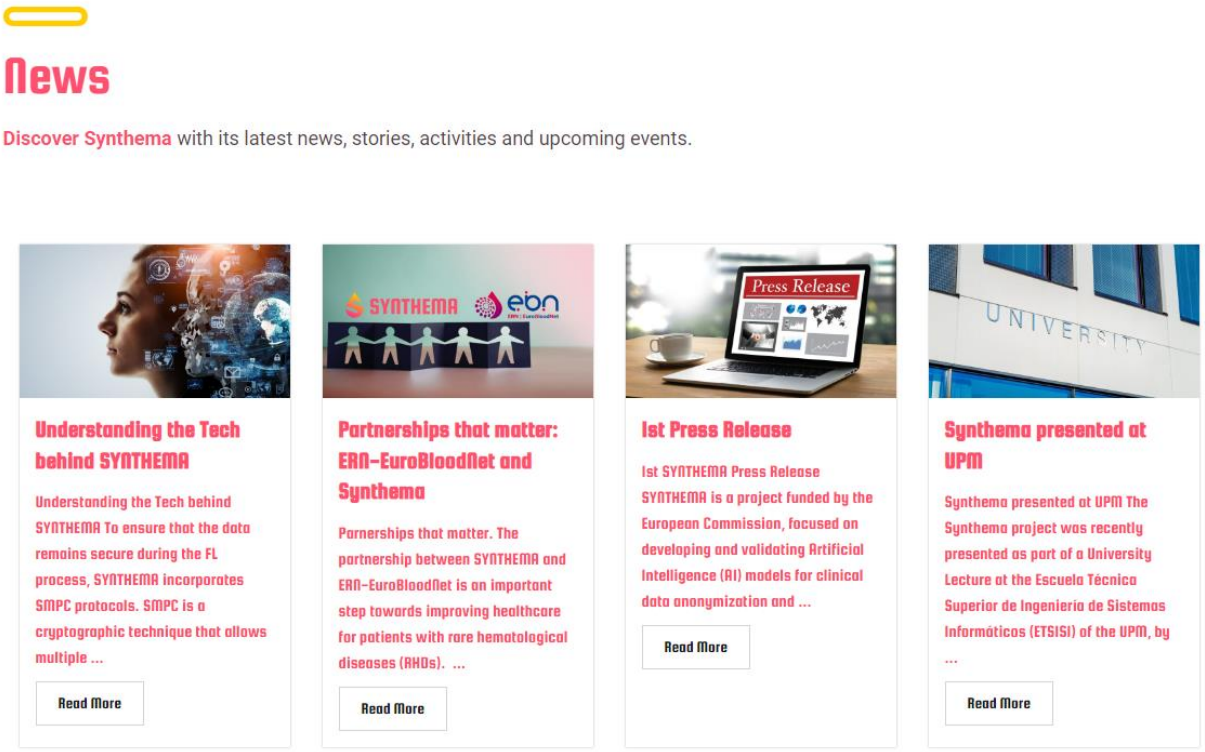

Figure 10. SYNTHEMA website – News page

3.1.3.2.2 Social media

Social media offers a swift, cost-effective medium for reaching interest groups and communities that may not typically attend events or conferences, whether in-person or online. SYNTHEMA will establish and maintain an active presence on various social media channels, with a focus on Twitter and LinkedIn, as they have proven to be highly effective in engaging with technology communities. Social media channels serve as a powerful instrument for disseminating information to the general public, enabling them to develop interest and engage with the content provided by SYNTHEMA. Indeed, general audiences constitute a vital part of our stakeholder base and are crucial in unlocking the full potential of the outcomes that SYNTHEMA seeks to achieve.

Activities on social media channels have been planned according to a social media strategy, developed to accomplish specific goals intended to garner the project awareness necessary for effective dissemination and efficient community building. These goals include increasing newsletter subscribers, website visitors, Zenodo metrics (views and downloads), and our online community of social media followers.

The overall strategy is based on key elements of social media engagement, utilizing all available variables to our advantage in reaching a broad audience and conveying our message to target stakeholders. The key elements of engagement are as follows:

- **Post regularly**: Effective posting on social media relies on consistency. The project will employ optimization and scheduling tools (e.g., Hootsuite) to post regularly and at optimal times of the day—when most traffic on Twitter and LinkedIn occurs for our target audience—thus enhancing engagement and organic views.
- **Use references and keywords in posts**: Linking our tweets to key players by actively tagging relevant accounts in the conversation and including trending hashtags—especially from our partners—to leverage their existing networks and amplify the project voice. This helps provide a wider outreach by tapping into the existing audience of these accounts.
- **Actively share content from the community**: Sharing news and information not only related to our project but also relevant to our community and the healthcare sector (e.g., scientific, academic, or legal news from channels across Europe) attracts more followers and gains more traction.
- **Differentiate posts between Twitter and LinkedIn**: Recognizing the inherent differences in tone between social media platforms (e.g., LinkedIn vs. Twitter) is essential. For instance, we might capitalize on LinkedIn professional nature and more "serious" tone, as well as the general perception that information there tends to be more reliable. This means that individuals with genuine interest in the topics that SYNTHEMA addresses will invest more time reading what we share on this platform. For this reason, information shared on LinkedIn needs to be fine-tuned, incorporating longer text, more detailed information, and highly specific hashtags. Twitter posts will be concise versions of these, conveying the same message.
- **Boost promotion of project content**: Creating and promoting a variety of project content in our social media strategy is crucial for raising awareness about SYNTHEMA across channels. Consequently, project articles will be frequently linked to via our social media channels, accompanied by various project facts, creative and appealing custom graphics, and call-to-action messages.
- **Renew and redesign social media strategy and content**: Periodically revisiting and updating the social media strategy and content every 3 or 4 months ensures that the project remains relevant and engaging to its audience. This continuous improvement process will help maintain interest and attract new followers.
- **Create traction by tagging influential partners**: Making posts that directly tag influential partners within our consortium not only fosters collaboration but also helps broaden our reach. By leveraging the established networks of our partners, we can extend our message to an even wider audience, promoting awareness and engagement with the project.

The project aims to connect with and run activities in specific communities, targeting those fostering openness and diversity (e.g., OpenStack, Red Hat, Cloudfoundry, Gitter communities, Women Who Code, Hashnode) and we for example run a Women in Science campaign in February/March 2023. As part of this campaign, we published interviews with women in the consortium and published facts about women in the Scientific sector. The project is committed to actively further advocate for female participation.

As the project progresses, we will be setting up a dedicated YouTube channel for SYNTHEMA, as a way to upload and share SYNTHEMA workshop recordings, official introductory videos, interviews and/or any other multimedia content produced throughout the project run.

SYNTHEMA Twitter Account https://twitter.com/SYNTHEMA_EU

Figure 11. SYNTHEMA – Twitter profile.

SYNTHEMA LinkedIn account https://www.linkedin.com/company/synthema/

Figure 12. SYNTHEMA– LinkedIn company page

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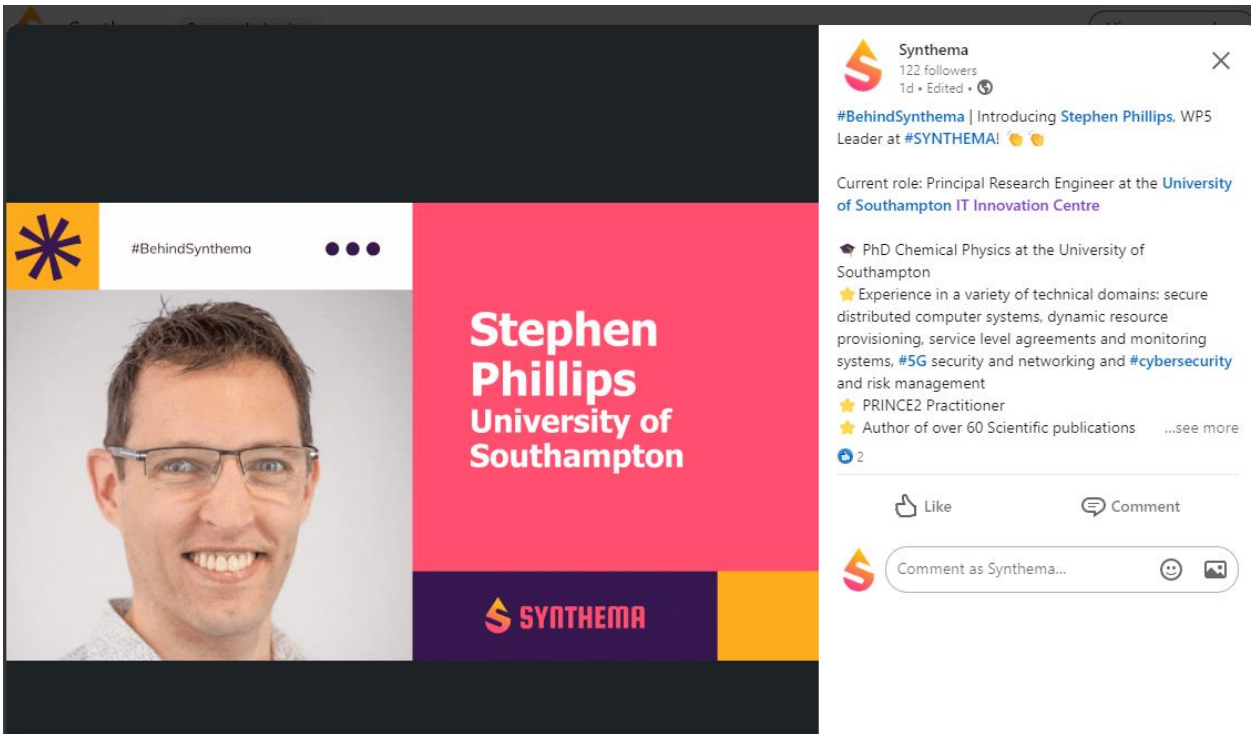


Figure 13. SYNTHEMA– Example of LinkedIN campaign

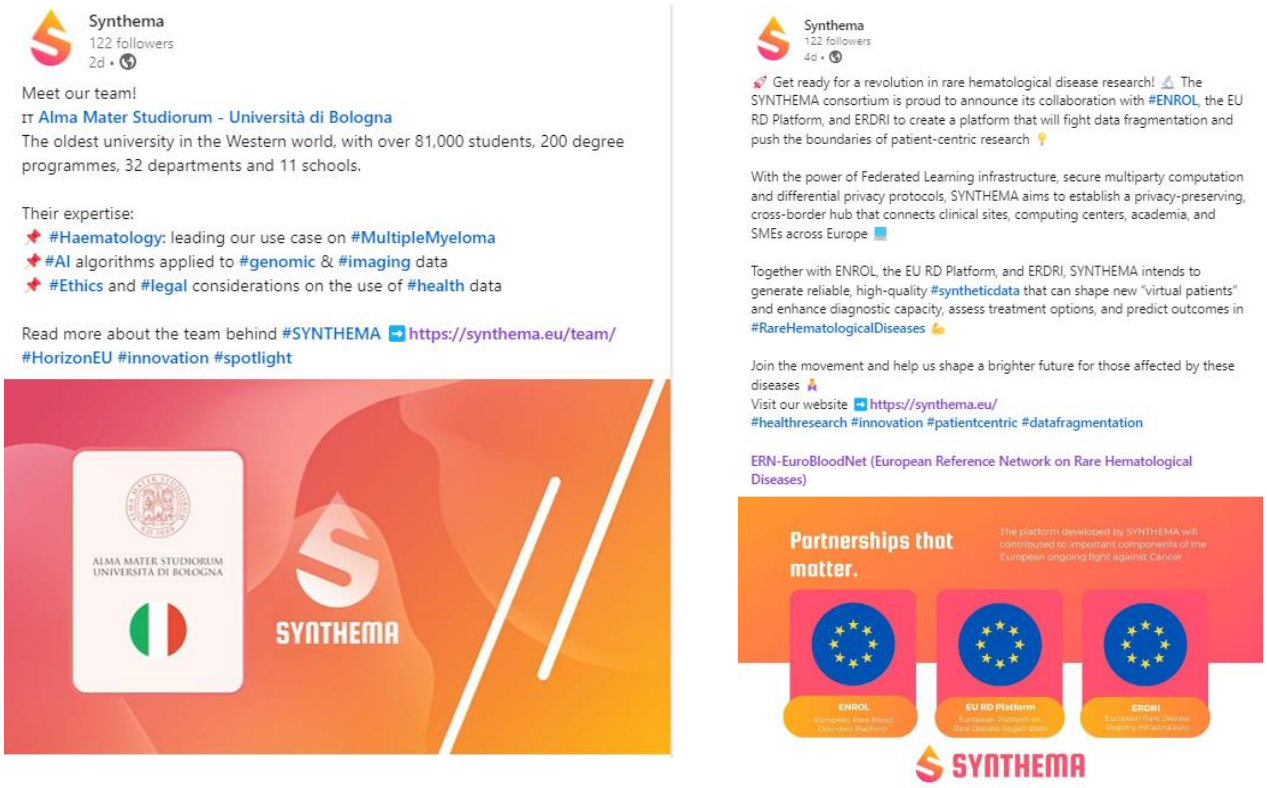


Figure 14. SYNTHEMA – Examples of LinkedIN publications

3.1.3.2.3 Newsletters

Newsletters serve as an effective engagement tool, offering insights into a project key activities and accomplishments. To maximize reach and visibility, SYNTHEMA will strategically contribute to existing newsletters and magazines with established audiences in the project primary fields of study, including AI and haematology. This approach will enable us to tap into larger networks and share our progress with interested stakeholders.

On May 24th, 2023, SYNTHEMA published its inaugural newsletter. This milestone edition features a comprehensive article providing an insightful overview of our ground-breaking project, including its purpose, methodology, and ambitious goals. Additionally, the newsletter offers valuable resources for those eager to delve deeper into our innovative technology and explore the diverse use cases we envision. Notably, it showcases highlights from our recent consortium meeting held in Lisbon, where passionate minds came together to foster collaboration and chart the course for our next steps.

The newsletter has been published on LinkedIn and Brevo. Brevo drives the website traffic, while through LinkedIN we leverage the following benefits:

- **Reaching a professional and targeted audience**: LinkedIn is a platform primarily used by professionals, making it an ideal medium to engage with stakeholders in the AI and haematology fields.
- **Expanding our network**: By using LinkedIn Newsletters, we can capitalize on our existing connections and reach their extended networks, increasing the visibility of our content.
- **Encouraging engagement**: LinkedIn enables users to like, comment, and share content, fostering interaction and discussion among our target audience.
- **Tracking performance**: With LinkedIn built-in analytics, we can monitor the performance of our newsletters and refine our strategy based on the insights gained from user engagement.

This targeted approach to newsletter dissemination ensure that we effectively communicate our progress and achievements to the most relevant audiences, fostering interest and support for the project goals and outcomes.

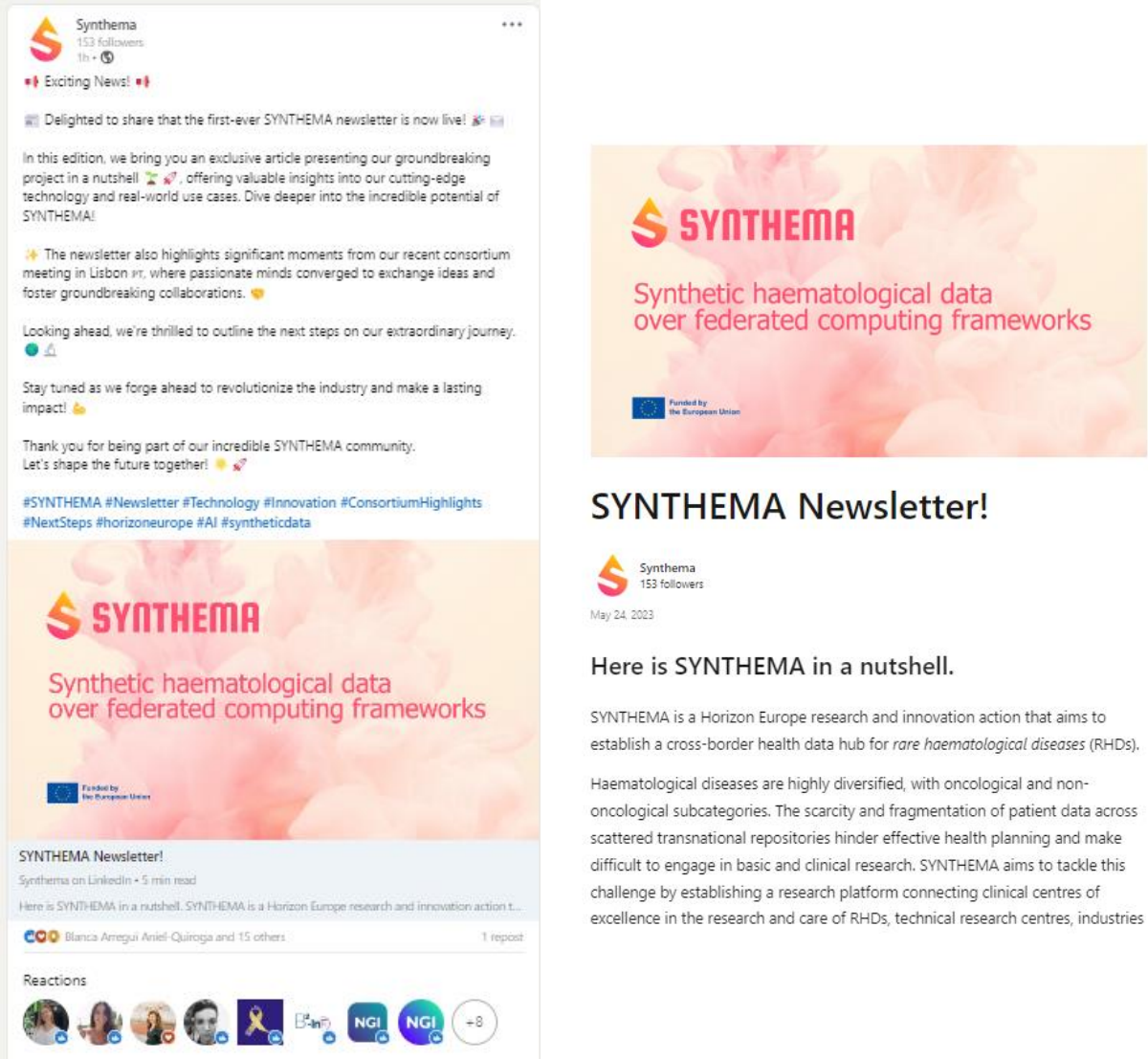


Figure 15. SYNTHEMA newsletter on LinkedIN

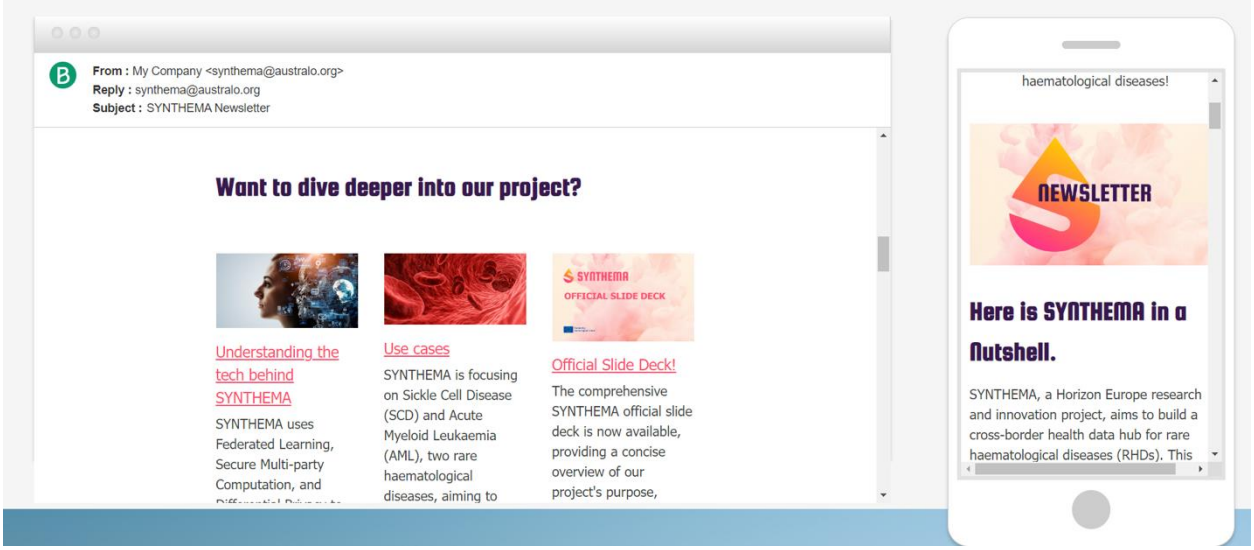


Figure 16. SYNTHEM newsletter as published on Brevo

In addition, SYNTHEMA will seek opportunities to contribute to prominent newsletters published by the European Commission or related initiatives. By collaborating with our most established partners who have extensive networks in the AI and haematological field, we can further enhance our project presence and reinforce our commitment to advancing knowledge in these domains.

For example, on **May 10th, 2023**, SYNTHEMA was showcased in the Genomed4ALL newsletter, a sister project. The feature included an informative article that provided an overview of SYNTHEMA, highlighting its technology, methodology, expected outcomes, and the partners involved.

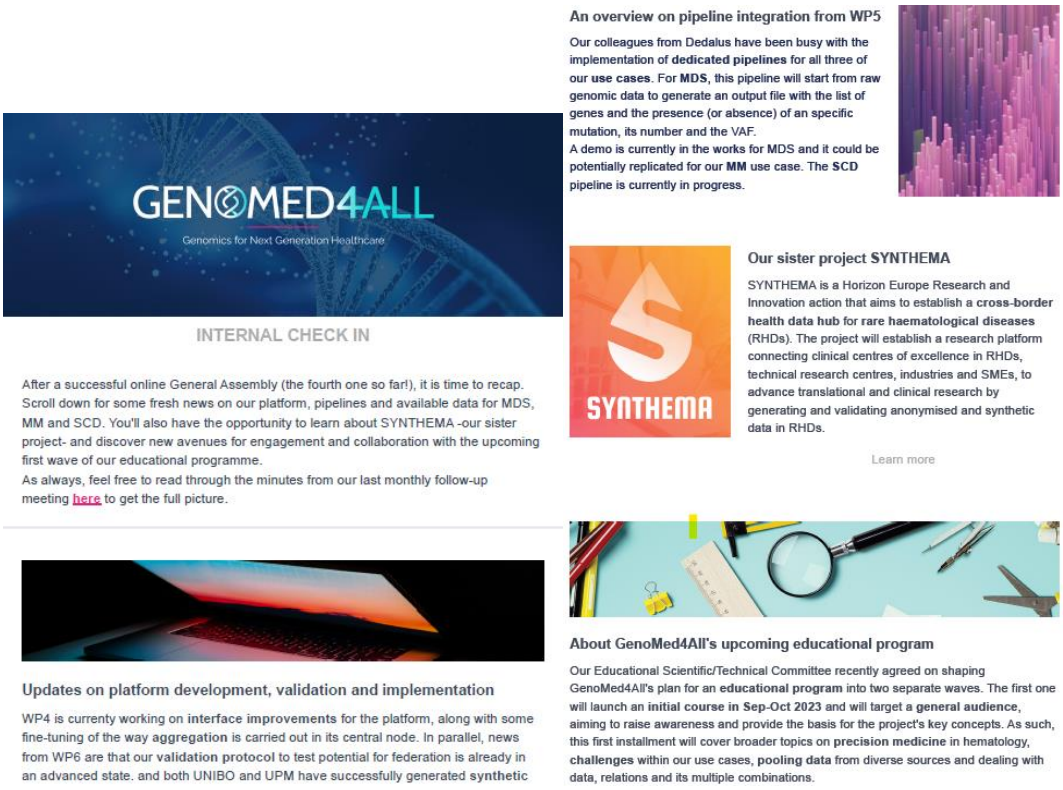
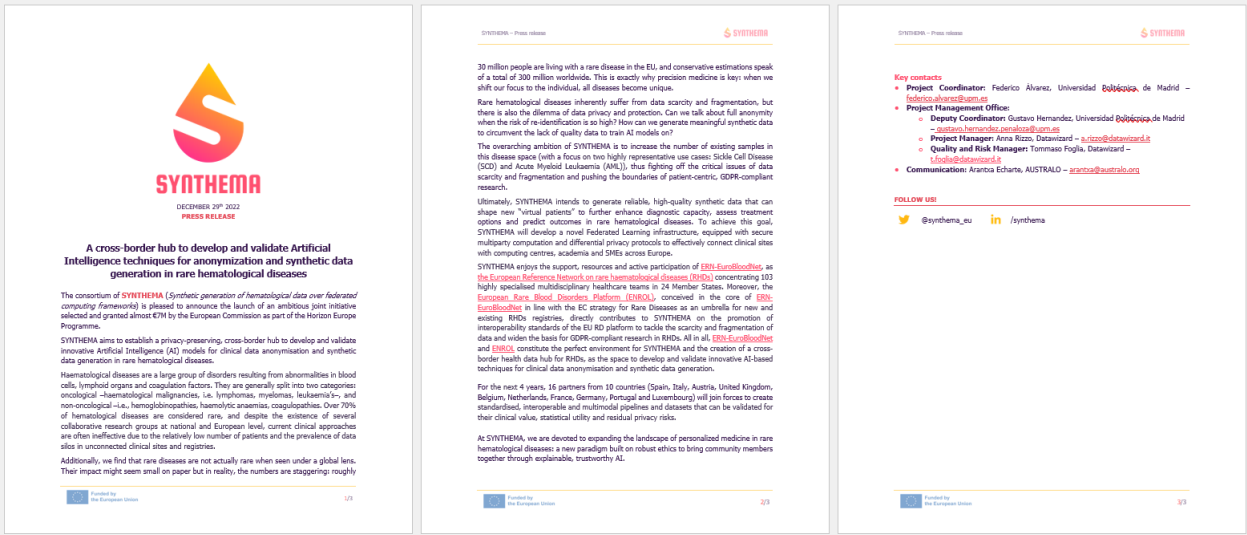


Figure 17. SYNTHEMA showcased in Genomed4ALL newsletter

3.1.3.2.4 Press releases

SYNTHEMA will create and disseminate press releases to both mainstream and specialized media outlets, as well as other relevant platforms, in order to showcase and emphasize the project significant milestones. **The project inaugural press release was published in December 2022** and can be accessed via Zenodo and the project website.

Furthermore, press releases will be shared internally among project partners, enabling them to leverage this information as a reference for communicating the project progress through their own networks, channels, and newsrooms. This coordinated approach ensures that key updates and achievements reach a wide and diverse audience, promoting increased awareness and engagement with SYNTHEMA goals and outcomes.



SYNTHEMA

DECEMBER 29th 2022

PRESS RELEASE

A cross-border hub to develop and validate Artificial Intelligence techniques for anonymization and synthetic data generation in rare hematological diseases

The consortium of SYNTHEMA (*Synthetic generation of hematological data over federated computing frameworks*) is pleased to announce the launch of an ambitious joint initiative selected and granted almost €7M by the European Commission as part of the Horizon Europe Programme.

SYNTHEMA aims to establish a privacy-preserving, cross-border hub to develop and validate innovative Artificial Intelligence (AI) models for clinical data anonymisation and synthetic data generation in rare hematological diseases.

Haematological diseases are a large group of disorders resulting from abnormalities in blood cells, lymphoid organs and coagulation factors. They are generally split into two categories: oncological –haematological malignancies, i.e. lymphomas, myelomas, leukaemia's–, and non-oncological –i.e., hemoglobinopathies, haemolytic anaemias, coagulopathies. Over 70% of hematological diseases are considered rare, and despite the existence of several collaborative research groups at national and European level, current clinical approaches are often ineffective due to the relatively low number of patients and the prevalence of data silos in unconnected clinical sites and registries.

Additionally, we find that rare diseases are not actually rare when seen under a global lens. Their impact might seem small on paper but in reality, the numbers are staggering: roughly

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SYNTHEMA

30 million people are living with a rare disease in the EU, and conservative estimations speak of a total of 300 million worldwide. This is exactly why precision medicine is key: when we shift our focus to the individual, all diseases become unique.

Rare hematological diseases inherently suffer from data scarcity and fragmentation, but there is also the dilemma of data privacy and protection. Can we talk about full anonymity when the risk of re-identification is so high? How can we generate meaningful synthetic data to circumvent the lack of quality data to train AI models on?

The overarching ambition of SYNTHEMA is to increase the number of existing samples in this disease space (with a focus on two highly representative use cases: Sickle Cell Disease (SCD) and Acute Myeloid Leukaemia (AML)), thus fighting off the critical issues of data scarcity and fragmentation and pushing the boundaries of patient-centric, GDPR-compliant research.

Ultimately, SYNTHEMA intends to generate reliable, high-quality synthetic data that can shape new "virtual patients" to further enhance diagnostic capacity, assess treatment options and predict outcomes in rare hematological diseases. To achieve this goal, SYNTHEMA will develop a novel Federated Learning infrastructure, equipped with secure multiparty computation and differential privacy protocols to effectively connect clinical sites with computing centres, academia and SMEs across Europe.

SYNTHEMA enjoys the support, resources and active participation of ERN-EuroBloodNet, as the European Reference Network on rare haematological diseases (RHDs) concentrating 103 highly specialised multidisciplinary healthcare teams in 24 Member States. Moreover, the European Rare Blood Disorders Platform (ENROL), conceived in the core of ERN-EuroBloodNet in line with the EC strategy for Rare Diseases as an umbrella for new and existing RHDs registries, directly contributes to SYNTHEMA on the promotion of interoperability standards of the EU RD platform to tackle the scarcity and fragmentation of data and widen the basis for GDPR-compliant research in RHDs. All in all, ERN-EuroBloodNet and ENROL constitute the perfect environment for SYNTHEMA and the creation of a cross-border health data hub for RHDs, as the space to develop and validate innovative AI-based techniques for clinical data anonymisation and synthetic data generation.

For the next 4 years, 16 partners from 10 countries (Spain, Italy, Austria, United Kingdom, Belgium, Netherlands, France, Germany, Portugal and Luxembourg) will join forces to create standardised, interoperable and multimodal pipelines and datasets that can be validated for their clinical value, statistical utility and residual privacy risks.

At SYNTHEMA, we are devoted to expanding the landscape of personalized medicine in rare hematological diseases: a new paradigm built on robust ethics to bring community members together through explainable, trustworthy AI.

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SYNTHEMA

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3.1.3.2.5 Promotional Slide deck

Expertly crafted slide decks or one-pagers serve as potent engagement tools, effectively conveying SYNTHEMA vision and scope to specialized audiences in a visually appealing and concise manner. The project first slide deck was published in May 2023 and can be accessed via the open access community at Zenodo and in the News section (here) on the website. The deck ensures that stakeholders can engage with the project core concepts and objectives, and also assists consortium partners in presenting SYNTHEMA effectively when invited to participate in events related to the project field.

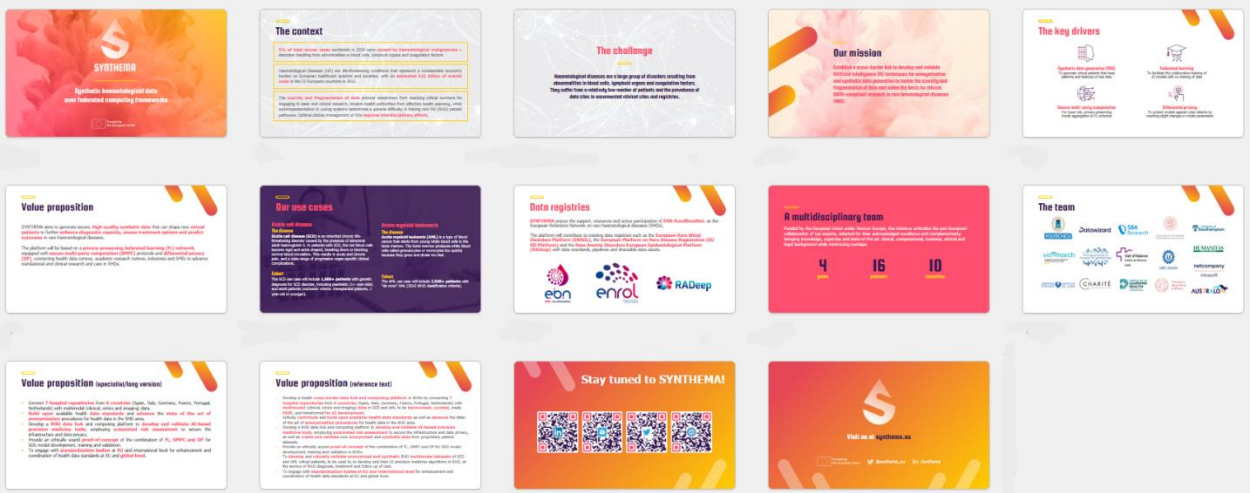

Figure 19. SYNTHEMA slide deck

3.1.3.2.6 Expert networks

SYNTHEMA seeks to establish robust synergies with leading expert networks (already identified above) in fields such as AI, HPC, eHealth, precision medicine, and haematological diseases, among others. As stated above, the project benefits from the support and active participation of distinguished organizations like ERN-EuroBloodNet, the European Reference Network in Rare Hematological Diseases, and ENROL. This collaboration strengthens the project traction and grants access to invaluable resources in terms of communication channels, webinars, databases, and networking opportunities.

Moreover, our diverse consortium, encompassing clinical, technical, and academic partners, possesses extensive networks that can considerably boost SYNTHEMA visibility and impact across multiple channels. These networks will be harnessed through platforms like social media and newsletters, ensuring the project reaches its target audiences and optimizes its overall influence.

Additionally, key actions will involve publishing online articles, blog posts, and other content pieces on various international platforms and communication outlets, such as **Cordis Wire**, **Medium**, **Horizon Magazine**, **Cordis Research*EU Magazine**, **MedTech Week Magazine**, ***Open Research Europe* (ORE)** and national/local portals. These efforts will help maximize the project visibility and reach, further contributing to its overall success.

3.1.3.2.7 Promotional materials

3.1.3.2.7.1 Printed Materials

Brochures, catalogues, posters, and other paper-based resources are valuable for promotional purposes. Most of these materials will be available in digital format, allowing for easy printing when needed, such as during events, workshops, or fairs. The first **printed materials were created in May 2023** for the **EHA2023 Hybrid Congress,** an opportunity to highlight state-of-the-art clinical practice, the latest findings in haematology research, and recent approaches on

the diagnosis and treatment of hematologic diseases. These materials are openly accessible in Zenodo - one pager and sticker.

Figure 20. SYNTHEMA one pager and sticker

Additionally, SYNTHEMA will explore innovative alternatives like branded merchandise, which has proven effective in reaching a wider audience while promoting sustainability through the use of long-lasting items.

3.1.3.2.7.2 Multimedia

Utilizing multimedia materials offers an engaging way to introduce SYNTHEMA to a broader audience through popular platforms like YouTube and Vimeo. In addition to the project introductory video, a series of video interviews will be conducted with partners throughout the project duration. These interviews will capture valuable insights and perspectives, taking

advantage of plenary meetings and other significant events to ensure a comprehensive understanding of the project progress and achievements.

For example, the material for the first of these videos was recorded at the six-month consortium meeting at Lisbon (May 2023) and a series of videos will be published shortly. See screenshot here.

Figure 21. SYNTHEMA interviews

3.1.3.3 Additional Promotional Actions

3.1.3.3.1 Communication Task Force

SYNTHEMA is committed to building partnerships with European-funded projects in related fields, beginning with Genomed4All, to form a collaborative communication cluster. The primary objective of this cluster is to cultivate synergies that enhance outreach and expand the impact of activities, ultimately reaching a broader audience.

The Communication taskforce, established as part of this collaboration, will serve as an open forum for discussions on aligning branding, communication, and dissemination strategies for the projects' research outcomes and activities. Moreover, joint initiatives, including the organization of events, workshops, blog posts, newsletters, and more, will be explored and planned during the taskforce's meetings, ensuring regular engagement and cooperation.

An initial approach has already been made to share communication efforts with sister projects **AISYm4MED** and **Genomed4All.**

3.1.3.4 Internal communication

A clear, effective internal communication strategy is key to ensure that interests are aligned within the consortium and everybody is duly informed of the latest developments.

Our internal communication strategy for example includes:

- **Verificators of public information (VPI) appointment:** We asked all consortium members to appoint a comms (VPI) representative that will attend WP6 meetings, will contribute to communication and dissemination activities and will contribute to internal and external effective and efficient communication.
- **Glossary:** we will develop a glossary of key words that will contribute to better internal communication alignment among the project members.
- **Communication plan:** We produce and present quarterly communication plans to inform consortium members about up-and-coming campaigns and C&D activity. Additionally, when relevant, we liaise directly with communication departments to further leverage C&D capabilities within the project.
- **WP6 meetings:** For the first 6 months WP6 meetings took place two weekly – with coordinating team; and monthly with all members. In the future, and while the project develops, we will establish a series of regular check-ins, either weekly or bi-weekly, designed to strengthen the project internal communication channels and make them more engaging. The objective is to utilize these check-ins to keep all members updated on the project overall progress and news.

3.2 Dissemination plan

As defined by the Horizon Europe glossary, dissemination is *"the public disclosure of the results by appropriate means (other than resulting from protecting or exploiting the results), including by scientific publications in any medium".* A dissemination plan ensures the sharing of the knowledge produced.

Dissemination is key for SYNTHEMA, as it aims not only to share results with potential users and research peers, the healthcare sector, other digital players and policy makers, but also make these results available to the wider community. To this end, SYNTHEMA has developed a flexible dissemination plan that intends to raise awareness of project results, promoting understanding and encouraging action among key target audiences. The execution of this plan will facilitate the uptake of outcomes and best practices, as well as research insights produced throughout the project lifetime, thus reinforcing the impacts described in the DoA.

3.2.1 Main goals

Dissemination goals have been previously described in the DoA. These goals are interlinked with those already set for communication activities and also with the overall project objectives: they are all geared towards creating an impact beyond the boundaries of the project. Dissemination will be directed to raising awareness of project results and aiming for action among key stakeholders, mostly through publication of results and research and business events, while

facilitating uptake of outcomes and research insights through open science practices, building the bases for a successful exploitation of results.

3.2.2 Phases and timeline

SYNTHEMA Dissemination plan will be implemented in three different phases (**identify & study**, **outreach & influence**, **embrace & accept**). The key difference with the communication plan is that these three phases do not span the whole project timeline, but instead have a start and end dates. Of course, this does not rule out the possibility to extend or adjust any of them if necessary or required.

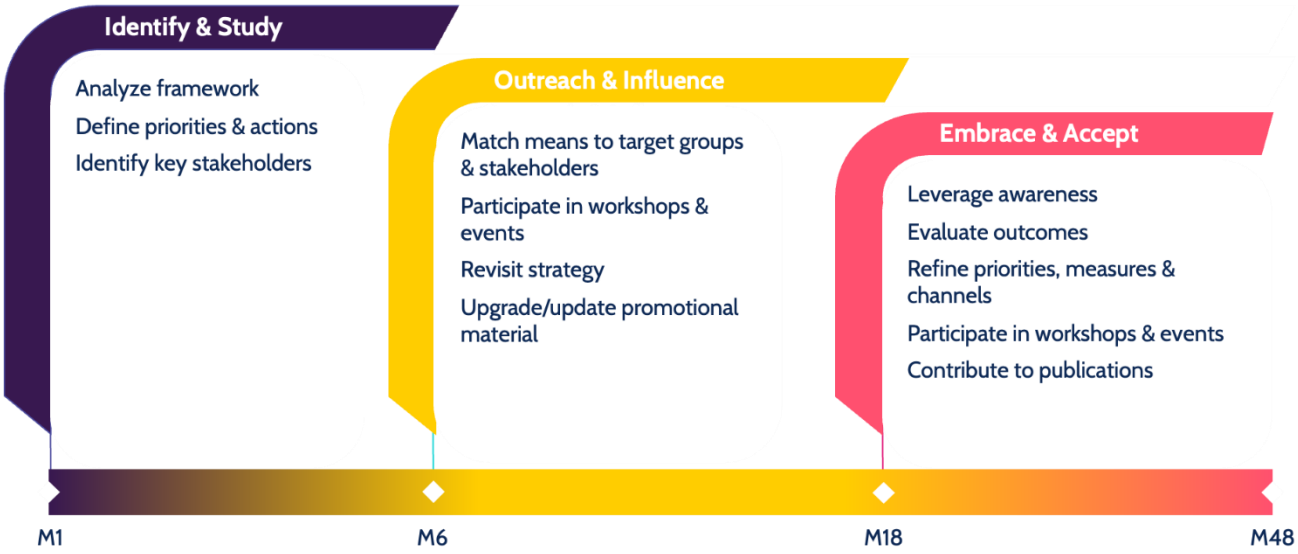

Figure 22. Phases of SYNTHEMA dissemination plan

3.2.2.1 Identify & study (present period)

During phase one, SYNTHEMA aimed to analyse the project framework as well as defined priorities and actions for the first year of the project, paying special attention to internal and external barriers that might slow down dissemination activities. For this initial phase, as seen above, a first set of material (produced in the context of SYNTHEMA Communication plan) has been prepared and delivered.

3.2.2.2 Outreach & influence

The main goal of this second phase is to increase impact and awareness generated during the first phase and showcase SYNTHEMA achievements. All channels will be adequately tailored to find the proper means to engage and collaborate with identified target groups. This will help increase the potential impact of the project results. Participation and/or hosting workshops, *ad hoc* events, tutorials/webinars (if necessary) will boost the dissemination process as a whole. For this phase, specific promotional material will be produced.

3.2.2.3 Embrace & accept

This final phase will leverage the general awareness raised by the two previous phases, with the aim of attracting more potential end users interested in SYNTHEMA results. All outcomes of the two earlier phases will be evaluated and, if necessary, priorities, measures and dissemination channels will be refined. Participation in events, workshops, conferences, together with partner contributions to publications in targeted specific media online, printed media and research journals will be key to maximize impact and boost visibility.

3.2.3 Dissemination tools and materials

As mentioned, communication and dissemination activities are inherently interlinked and therefore some tools are shared between both. Below is the list of specific dissemination tools envisioned for SYNTHEMA.

	Healthcare professionals	Digital service providers	Advocate initiatives	Open science	Policy makers	Society as a whole (including patients)
Project docs	✓	✓	✓	✓	✓	
Peer-reviewed publications	✓	✓		✓		
Technical publications	✓	✓		✓		
Open Access repository	✓	✓	✓	✓	✓	
Stakeholder consultation	✓	✓		✓		
Conferences & workshops	✓	✓	✓	✓	✓	✓
Congresses, exhibitions & demo spaces	✓	✓	✓	✓	✓	✓

Table 4. Dissemination tools and target audiences

3.2.3.1 Dissemination materials

3.2.3.1.1 Project documentation

Documentation material in the form of public deliverables will be made available through SYNTHEMA open access repository at Zenodo (see 3.2.3.2) and **CORDIS**, the European Commission's primary source of results from Horizon Europe projects. Public documentation will also be accessible through the project official website.

3.2.3.1.2 Peer-reviewed publications

SYNTHEMA intends to publish and contribute to peer-reviewed publications in top scientific journals in our main areas of research. As a *research and innovation action* (RIA), one of our primary goals is to ensure that technical and clinical achievements and experimental findings are adequately showcased and made available to a larger research community and scientific domains, in order to further collaboration and research.

Area	Journal
Clinical	New England Journal of Medicine
Clinical	Journal of Clinical Oncology
Clinical	Blood
Clinical	Blood Advances
Clinical	Hemasphere
Clinical	Leukemia
Clinical	Haematologica
Clinical	The Lancet Haematology
Clinical	American Journal of Hematology
Clinical	British Journal of Hematology
Clinical	Nature Genetics
Clinical	Bioinformatics
Technical	Nature Communications
Clinical	BMC Genomics
Clinical	Journal of the American Medical Association
Technical	IEEE Journal of Biomedical and Health Informatics
Technical	Journal of Biomedical Informatics (ScienceDirect)
Technical	Journal of Biomedical Informatics (Elsevier)
Technical /Clinical	Journal of Health and Technology (JHT)
Technical /Clinical	Health Policy and Technology (ScienceDirect)
Technical /Clinical	Health Technology and Innovation
Technical	IEEE Transactions on Information Technology in Biomedicine

Table 5. List of targeted journals

Throughout the project timeline, partners will publish and contribute with blogs posts, articles, features and more to different outlets, like for example magazines, specialized blogs, LinkedIn and the official website. These kinds of pieces can help disseminate the project main ideas and results to a wider audience, thus leveraging its impact.

3.2.3.2 Online channels

3.2.3.2.1 Open Access repository

Zenodo: https://zenodo.org/communities/synthema-heurope/

Zenodo is a part of the OpenAIRE initiative, Europe's hub for open access infrastructure research. Following the European Commission guidelines for Open Science, SYNTHEMA will provide open access to peer-reviewed publications and scientific research data generated within the project, as per our Data Management Plan. There is a dedicated Zenodo community and repository already in place for the project, where we will be uploading publications, public deliverables, data, press releases and more as the project progresses.

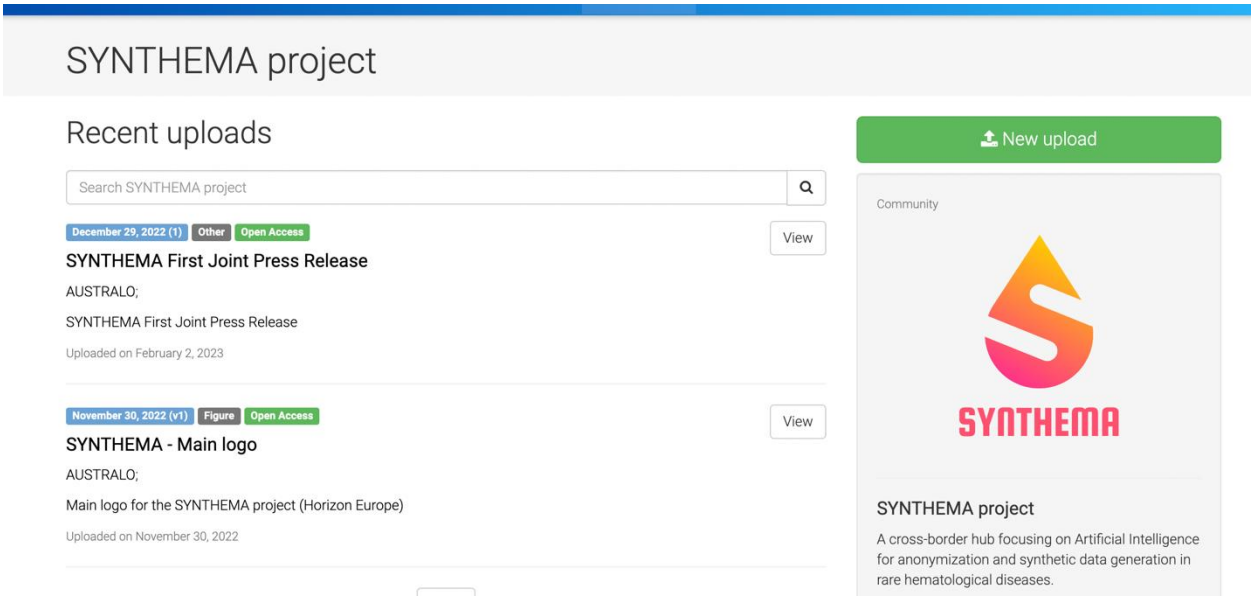

Figure 23. SYNTHEMA – open access community at Zenodo

3.2.3.2.2 Stakeholder consultation

As part of SYNTHEMA methodology for an agile stakeholder framework (see section two - Learn phase), the project will set up surveys and opinion polls among key actors to collect feedback about critical needs and potential issues (e.g., validation of priorities, execution, etc.). This will allow a broader view on the project ambition and scope and insights on how to better tailor dissemination actions to a specialised audience.

3.2.3.3 Events

Below is an indicative list of events that have been identified by the SYNTHEMA consortium as main targets. This list will be continuously updated with inputs from partners and depending on the maturity of the project at a given stage.

3.2.3.4 Conferences

The consortium will disseminate outcomes by means of presentations, talks and personal engagement. This includes participation in dedicated events, such as conferences, workshops and trade fairs as a strategic mechanism to actively interact and engage with multiple stakeholders at a time.

Area	Conference	Date	Location
Clinical	ML Conference	June 2023	Munich
Clinical	ISMB/ECCB 2023 Conference	July 2023	Lyon
Clinical	International Conference in Rare Diseases	March 2023	Athens
Clinical	DGHO Annual meeting 2023	Oct 2023	Hamburg
Clinical	ASH Annual Meeting & Exposition 2023	Dec 2023	San Diego
Clinical	ESH Conferences	Various	Various
Clinical	AIEOP annual Congress	May 2023	Valencia
Clinical	EHA Hybrid Congress	June 2023	Frankfurt
Clinical	ESHG Virtual Conference	June 2023	Glasgow
Clinical	AACR Annual Meeting	June 2023	Lugano
Technical	IEEE EMB 2023 International Conference	July 2023	Sidney
Technical	IEEE CBMS International Symposium	June 2023	L'Aquila
Technical	BIG Data and AI World	March 2023	London
Technical	Future Health Summit	May 2023	Dublin
Technical	Digital Health Care World Congress	May 2023	London
Technical	TEHDAS Towards European Health Data Space	June 2023	Helsinki
Technical	Datahack Summit	August 2023	Bangalore
Technical	VLDB 2023 International Conference	August 2023	Vancouver
Technical	Women in AI and Data Reception	Jan 2023	London

Table 6. List of targeted conferences

Other target events are: Health data forum, *European conference on rare diseases & orphan products* (ECRD), *International Conference on Rare Diseases, European Red Cell Society Meeting* (ERCS), *Annual Sickle Cell and Thalassaemia Conference* (ASCAT), *Annual Meeting of the American Society of Clinical Oncology* (ASCO), the *European Society of Medical Oncology* (ESMO), the ACM Conference on *Computer and Communications Security* (CCS) and the *Medical Informatics Europe* (MIE).

3.2.3.5 Congresses, exhibitions and demo spaces

SYNTHEMA will target specific events in the realms of AI, eHealth, precision medicine, big data, and synthetic data, in order to showcase the project most tangible outcomes (platform, AI-based services…) to a wider audience through exhibitions and demonstrations.

Event	Date	Location
AI & Big Data Expo Global	Dec 2023	London
AI & Big Data Expo Europe	Sep 2023	Amsterdam
Data Innovation Summit	April 2024	Stockholm
EATRIS events	Various	Various
Medtech Week	June 2023	Dublin
EACR Congress	June 2023	Torino
Digital Health World Congress	Tbc	Tbc
HIMSS & Health Europe	June 2023	Lisbon

Table 7. List of targeted congresses, exhibitions and demo spaces

4 Exploitation plan

4.1 Overview and strategy

4.1.1 What is meant by exploitation?

Under **Article 16** on the Exploitation of Results of the Grant Agreement, the consortium must take measures to ensure the exploitation of the results up to four years after the end of the project.

According to the Horizon Europe glossary, exploitation means "the use of results in further research and innovation activities other than those covered by the action concerned, including inter alia, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardisation activities".

The project results are defined as *"any tangible or intangible output of the action, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, which are generated in the action as well as any attached rights, including intellectual property rights".*

Therefore, the objective of exploitation is to effectively use project results through scientific, economic, political or societal exploitation routes aiming to turn R&I actions into concrete value and impact for society.

4.1.2 Exploitation goals

The SYNTHEMA objectives for the exploitation plan have been set out at the proposal stage, aiming to maximise the project impact on different layers of EU society. The project ambition is to **act as an enabler that will lead to AI solutions for anonymisation and synthetic data generation to tackle the scarcity and fragmentation of data and widen the basis for ethical, GDPR-compliant research in RHD**. In this way the project expects to pave the way for a more intense use of AI to achieve meaningful outcomes for advancing research and personalised medicine. Therefore, exploitation will focus on open science in this area to trigger innovation and entrepreneurship.

Therefore, SYNTHEMA will follow **an open science exploitation route to maximise the reuse of its results among key stakeholders from the clinical, research and business sectors, particularly to foster AI-based precision medicine in RHDs** leveraging anonymised and synthetic data. The strategy will address, on the one hand, (1) *individual key exploitable results* (KERs) generated by consortium partners, that will be managed through appropriate open science practices and on the other hand the (2) SYNTHEMA RHD data hub and FL platform, in search of a collective sustainability plan.

4.1.3 Exploitation routes

Exploitation can be achieved in a wide variety of ways, which need to be linked to one of the following means:

- **Financial exploitation**: building products, projects, or services based on project results.
- **Research & development**: by engaging in new research collaborations, projects or other initiatives at national or transnational level.
- **Education** (e.g., courses, additional lessons) at the school or university level, or in continuing education, etc.
- **Community building**: raising awareness for the addressed problems and the proposed solutions around the topics of the project.
- **Knowledge transfer**: from academia to industry, by collaboration or via employees, to realities outside the EU.
- **Contributions to open-source projects and standardisation**: providing public access to the mix-net framework and encouraging its broad adoption in commercial and public systems for interested parties.
- **Contribution to the promotion of an ethical use of AI in the healthcare field**: mainly in relation to GDPR and MDR compliance.

As part of the project exploitation strategy, individual members of the consortium are highly incentivised to pursue individual attempts to exploit project results. These efforts shall be coordinated and supported by the **Exploitation Manager**, who takes care of advising individual partners, where needed, on the best strategies to achieve effective exploitation while ensuring that no conflicts arise with regard to individual IP rights, and coordinates consortium partners in the effort of exploiting joint results, including the pursue of a collective exploitation and sustainability strategy for the project platform.

4.1.4 SYNTHEMA individual KERs

In the proposal phase, the consortium identified the following preliminary individual KERs upon which to conduct the exploitation process of the project, listed below in relation to the main implementation *work packages* (WPs).

1	Clinical data collection, harmonisation and interoperability
1.1	RHD clinical, omics and imaging datasets
1.2	*Electronic clinical report form* (eCRF)
1.3	Common data and metadata OMOP model
1.4	Data quality plan for data consistency
1.5	Data transformation plan for AI ingestion based on the GYDRA (MIDAS project)

Table 8. WP1 – Clinical data collection, harmonisation and interoperability KERs.

2	Federated learning platform development
2.1	FL infrastructure equipped with SMPC protocols and DP to ensure distributed and privacy-preserving algorithm training and global model aggregation
2.2	Data ingestion, updater and loader module
2.3	Data harmonisation and customised data integration APIs/connectors and pre-processing of information

Table 9. WP2 – SYNTHEMA FL infrastructure development KERs.

4	Anonymisation and synthetic data generation pipelines
4.1	A pipeline for the generation and validation of synthetic multimodal data for target RHD use cases, combining clinical, genomics and imaging data
4.2	Generation of two RHD specific types of synthetic data: genomics and imaging

Table 10. WP3 – Anonymisation and synthetic data generation pipelines KERs.

5	Clinical validation and statistical utility assessment
5.1	Validation pipeline for clinical data, based on time-to-event statistics (e.g., Cox Proportional-Hazard, mixed effect and multistate models).
5.2	Validation pipeline for omics data, based on statistical and manual evaluation of synthetic vs real data by clinical or technical experts
5.3	Validation pipeline for histopathological images, based on image segmentation and counting of specific cell type (e.g., lymphocytes, adipocytes etc), feature extraction, both computational (i.e., derived from GLCM matrix) and morphological (e.g., cellularity, fibrosis)

Table 11. WP4 – SYNTHEMA clinical validation and statistical utility assessment KERs.

6	Data protection and privacy assessment
6.1	A system security modelling (SSM) platform from the UoS49 to capture privacy risk knowledge and automate risk assessment
6.2	Joint Controllership Agreements (JCAs) templates for the two clinical use cases

Table 12. WP5 – Data protection and privacy assessment KERs.

7	Coordination and management - Ethical assessment framework development and implementation
7.1	Collection of ethics requirements for synthetic data generation based on ethics-by-design and value-sensitive-design frameworks, taking into account the Ethics Guidelines for Trustworthy AI and the draft AI Regulation (AI Act)
7.2	Ethics handbook including best practices and ethical standards for generated synthetic data and policy recommendations

Table 13. WP7 – Coordination and management (T7.5 - Ethical assessment framework development and implementation) KERs.

4.1.5 SYNTHEMA RHD data hub and FL platform

Other than individual KERs, the main expected result to be exploited is of course the SYNTHEMA platform itself. The **SYNTHEMA RHD data hub and FL platform sustainability plan** will pursue the creation of an **open research platform connecting (1) clinical centres for RHD research and care, (2) academic institutions and (3) industry and SMEs** engaged in AI-based precision medicine R&I on RHDs and ensure its sustainability beyond the project timeframe. This open science exploitation route will be based on three pillars:

- **A platform sustainability and onboarding roadmap**, produced by a dedicated interdisciplinary WG (WP1, WP2, WP5, WP6) describing data standards, step-by-step procedures and legal template agreements for the onboarding of external partners. This pillar is fundamental to ensure reaching a "critical mass" of onboarded centres with high-quality, harmonised data, and shareable data assets and resources for R&D in RHDs in line with GDPR and national data privacy legislations.
- **A comprehensive business plan for the platform** to ensure its sustainability after the end of the project, based on a (1) one-time connection and instalment fee and (2) a periodic subscription fee; the objective of the business plan will be to cover the set up and maintenance costs of the platform, rather than profit.
- **A solid and attractive value proposition** for each target group, based on providing access to a variety of resources (data, pipelines and data services) under a common catalogue and user interface:
    - **Clinical centres for research and care**: pipelines for anonymisation and SDG from proprietary patient datasets; shareable data assets for data augmentation; data services for harmonisation, curation, FAIRification, privacy risk assessment, statistical utility assessment, legal and regulatory compliance, ethics-wise AI co-creation.
    - **Research institutions, industries and SMEs**: anonymised and synthetic data for AI development, drug repurposing or other R&D and, in the long run, the possibility to leverage the connection with clinical research nodes for federated training or newly developed precision medicine AI.

The development of such a platform is foreseen in two main phases:

• **Phase I: onboarding of clinical partners** able to use anonymisation and SDG pipelines for creation of new shareable data assets, until reaching a critical mass of data for AI development and training.

• **Phase II: onboarding of R&I bodies from academia and SME/industry** able to leverage available data assets for AI development and training, drug repurposing and other R&D activities.

4.1.6 Exploitation phases

In synergy with platform sustainability planning, the exploitation activity is envisioned to be carried out starting on **Phase two** - Development of pipelines and resources (M13 - M36) until **Phase three** - Proof-of-concept validation, refinement and innovation transfer (M36-M48) of the project implementation. This activity envisions two different "steps" that aim to contextualise the project activities in relation to the objective of WP6 - T6.3, as described below.

Sprint #1 (M13 – M36)

Sprint #1 will develop during **Phase two** of the project implementation, while project resources and assets are being developed. This work will be devoted to some preliminary activities, including:

- **Project ecosystem building**: mapping of all the various stakeholders with a potential interest in the KERs of the project, together with the nature of their interest (e.g., commercial, research).
- **Market readiness assessment**: assessment of the state of the landing markets of project innovations, including *Market Readiness Level* (MRL), competition landscape and the identification of sustainable business models.
- **Value proposition development**: definition of a specific value proposition for the KERs with great commercial and research potential, to assess whether the different segments have an interest or not in them, as well as defining the nature of such eventual interest.

Sprint #2 (M37-M48)

Sprint #2 is intended to build upon the outcomes from Sprint #1 and exploit the relevant knowledge for the triggering of innovation and entrepreneurship, both in the open science perspective and in the commercial perspective, where relevant. These efforts will be reported into **D6.3 - Exploitation and sustainability plan (DW, M48)**, and will encompass:

- **Business plans**: definition of valid business model canvas for specifics KER of commercial value, with the goal to bring applicable project innovations to market.
- **SYNTHEMA RHD data hub and FL platform sustainability plan**: definition of the project sustainability strategy, including (1) value proposition for each target group, (2) onboarding roadmap and (3) business model to sustain the set up and maintenance costs of the platform beyond the end of the project.
- **IPR and knowledge management assessment**: assessment of the activities related to the use and exploitation of the project results and knowledge, from a knowledge-creation perspective, including both join IP and individual results.

4.1.7 Value proposition strategy

The presence of a wide variety of different actors (*industry, SMEs, clinical sites, research entities, policy makers*) both in the consortium and in the SYNTHEMA ecosystem suggest that the result value will be rather asymmetrical for each specific target group. To address this heterogeneity, SYNTHEMA will organise dedicated interactive **exploitation workshops (M13-M36)** inviting members of each specific target group, selected through the project ecosystem, to participate and impact the discussion around which is the specific value that the project has on their activities. The scope of such workshops will be twofold:

1. Engage entities strictly connected to the project scope and empower them with information about the SYNTHEMA activities, generating interest and awareness;
2. Enable the consortium – and particularly the Exploitation Manager and its team - to gather perspective from a wide variety of specific entities to increase the accuracy of the developed value proposition.

The findings gathered through such workshops fall in the scope of Sprint #1 and will be published within D6.3. They will serve as the base upon which to take any decision regarding the project sustainability plan.

4.1.8 Open science practices and FAIR data management

In line with its mission of addressing the current scarcity, fragmentation, limited accessibility and interoperability of RHD data, SYNTHEMA fits the scope and principles of **open research** and the ***Findability, Accessibility, Interoperability and Reusability*** **(FAIRness)** of data.
The ***Data Management Plan*** **(DMP, M6 and subsequent updates)** will outline project procedures and policies on open access to scientific publications, research data and other research outputs where privacy and security risk assessments allow, as well as the relevant aspects of making data FAIR, also in relation to the proposed regulation on **European data governance (*Data Governance Act*)**. The DMP will also describe what data the project will generate, whether and how it will be made accessible for verification and reuse, and how it will be curated and preserved. It will also summarise how the data collection, storage, protection, retention and destruction will be handled during the project execution.

For what concerns **research data (i.e., anonymised and synthetic data to be produced during the project)**, SYNTHEMA will consider participation in European open science initiatives with registration within data catalogues such as the **Open Research Data Pilot (ORDP),** the ***European Open Science Cloud*** **(EOSC)** ***Portal*****,** and the **Data Europe Platform**, with special regard to rare disease registries including the **ENROL Platform,** the **EU RD Platform** and the **ERDRI**. Where possible, the generated data will be published with the results of the automated privacy risk assessments and associated risk profiles.

- **Findability** for digital research materials will be ensured by the use of ***Digital Object Identifiers*** **(DOIs)**. A document's DOI will remain fixed even if the location or metadata of the document changes and can be assigned to articles, datasets, or any other shared project output. Open access to the raw datasets via the individual repositories will be ensured through SYNTHEMA community profile on specialised public access databases like

Zenodo, DataHub.io, Frictionless Data and Open-AIRE, Portal of Medical Data Models, among others. Hyperlinks to all access points will be given on the SYNTHEMA website.

- **Interoperability**: the project will use several types of **metadata** as required, including descriptive metadata to support the discovery and identification of a resource (e.g., title, abstract, author, keywords), administrative metadata to manage an information resource (e.g., provenance, processing, rights information), structural metadata to describe the relationship between parts of an information resource, especially digital resources which often consist of multiple files, technical metadata to document technical attributes of digital objects or resources, and preservation metadata to support and document the long-term digital preservation of an information resource or digital object.
- **Reusability**: all project documentation will include basic information for its correct interpretation and reuse by the consortium and other researchers (README file, README tab, Data Dictionary, as applicable). Each dataset will be accompanied by a data licence detailing permissions associated with the use of that dataset. This will include the development of Data Licencing Agreements that will define IPRs as appropriate and reuse possibilities for onward use and reuse scenarios, based upon the development of consortium wide data sharing and processing agreements that will be drafted in accordance with findings from the Data Protection Impact Assessments and ethical considerations.

With regard to **other research outputs**, algorithms and pipelines for data anonymisation and SDG will be made open source and available to the community through GitHub, GitLab or another provider for software development, source code management and distributed version control. Where possible software will be tested using Continuous Integration methods for multiple platforms and will be distributed with a permissive free and open-source licence (MIT, BSD, Mozilla, Apache), to incentivise knowledge sharing and code reuse. Other research outputs (e.g., infrastructure data model, ethics guidelines, reports and public deliverables) will be shared through Zenodo, in the context of a project-dedicated collection.

4.1.9 IPR management strategy

SYNTHEMA will also set up an effective system to protect and exploit *Intellectual Property* (IP) generated throughout the length of the project This internal mechanism is designed to grant, when and if relevant, a flexible framework possible to allow partners with a commercial interest in the project to pave the way for exploitation.

The internal entity responsible for the definition of matters surrounding IPR is the *Coordination team* (CT), which will support the Project Officer in the supervision of the Consortium-wide knowledge management activities. Moreover, the Exploitation Manager will highly encourage consortium partners to explore individual opportunities of knowledge creation, on top of the project results. These activities are regulated under the *Consortium Agreement* (CA) through the basic principle of **foreground knowledge**, which allows the project partner which solely contributes to the development of new knowledge to be able to exploit it according to its own will.

Nonetheless, in the case of a joint development of knowledge, the ownership of the innovative knowledge will be regulated under the Joint Ownership Agreements, unless the contractor concerned agrees on a different solution. The granting of Access Rights to jointly owned foreground will be royalty-free and the granting of Access Rights to own foreground will either be royalty-free based on fair and reasonable conditions, defined by the CT. Moreover, the European Community will be granted a non-exclusive royalty-free license to access to the project findings, in order to be able to generate interest around the project public knowledge materials such as reports, methodologies or case material.

The project strategy in relation to IPR Management consists of three distinct elements, envisioned to ensure the highest possible level of IP protection:

- A system that enables the **protection of IP** (e.g., patents, copyrights, brand, industrial design) that includes clarity about the ownership and use of *IP rights* (IPR),
- A **technology transfer framework**, preferably with the support of specialised knowledge transfer offices with professional staff, such as the European IPR Helpdesk.
- A **fair law enforcement system** in each partner's country that caters to dispute settlement but also that can award penalties and sanctions.

All activities related to IPR will be summarized in deliverable **D6.3**, in the context of **Phase two**.

5 Monitoring of communication, dissemination and exploitation efforts

Continuous monitoring and customization of both the Communication and the Dissemination and the Exploitation Plan are fundamental elements of SYNTHEMA success. Continuous monitoring allows the consortium to anticipate and mitigate any deviations affecting the project timeline or its resources. It also addresses potential implementation issues and helps assess whether further action is required to ensure objectives are met. On this topic, the consortium will focus on the pre-assessment of information needs, monitoring frequency and a methodology for collecting evidence.

The execution and effectiveness of these plans is dependent on close monitoring, flexible and prompt response mechanisms. Impact KPIs have already been defined for these areas, though they remain confidential and have only been disclosed to the European Commission's representatives and shared internally within the SYNTHEMA consortium. In this sense, internal Communication and Dissemination reporting tools and resources have also been made available to all partners involved, so that they may report and track their individual Communication and Dissemination efforts. These tools will also host and aid the reporting and follow-up on Exploitation-related efforts, such as: publications on standardization mechanisms, white papers on key results, demos and exhibitions for the SYNTHEMA platform and services.

5.1 C&D database

An internal database listing all shared resources available in each partners' networks: newsletters and magazines, journals, conferences and events. This database will serve as a common knowledge base for C&D efforts.

5.2 C&D&E tracker

A simple tracker to list and report all efforts linked to communication, dissemination and exploitation of the project and its results. This is a collective effort to which all partners should contribute. Whenever a partner participates in a communication or dissemination action/activity or dedicates efforts/resources to contribute and drive the project exploitation strategy, it needs to be reported to keep full traceability and collect evidence for the European Commission.

5.3 Editorial calendar

An internal calendar to plan out content for the project expected articles (short pieces linked to milestones, general progress and/or findings) and agree on the best publication dates and platforms (project website, blogs, social media, etc.). This tool will also help keep track of all external mentions, articles or press features on the project.

Figure 24. Internal communication, dissemination & exploitation tools

In order to provide a public view into SYNTHEMA exploitation related activities, the consortium will make use of the project already available online channels:

- **SYNTHEMA website**: through the project official website, we have the ambition to keep a constant communication flow about our exploitation activities to the wider EU society. The website will allow people to easily access relevant documents, public strategies and reports related to our exploitation activities.
- **SYNTHEMA social media**: the adoption of a communication strategy involving social media like LinkedIn and Twitter facilitates reaching out to the wider EU society in a direct, informal manner, while also allowing the general public to be informed about individual and consortium-wide exploitation activities.

5.4 Analysis of online channels *Key Performance Indicators* (KPIs)

Beyond recording KPIs and monitoring and publishing activity, SYNTHEMA aims to analyse KPI related data to better understand and improve the outreach of our communication effort. We record and analyse google and LinkedIn analytics to observe trends in regard to follower numbers, geolocation, occupation and industry. By consistently monitoring and analyzing this KPI related data, SYNTHEMA can make informed decisions to refine and enhance their online strategies.
We analyse the data monthly and this iterative approach ensures continuous improvement, enabling SYNTHEMA to forge stronger connections, expand its reach, and effectively communicate its message to a wider audience.

To amplify our impact and expand our reach, active involvement from all consortium partners is essential.

So far, in the first six months, SYNTHEMA has witnessed a commendable and steady rise in the number of followers on both Twitter and LinkedIn. This upward trajectory is a testament to the effective implementation of well-thought-out social media strategies and tactics aimed at nurturing a growing online presence.

To maintain this positive momentum and drive continuous growth, SYNTHEMA has employed a range of measures. These measures encompass a comprehensive approach that goes beyond merely accumulating followers. Instead, the focus lies on engaging the audience, fostering meaningful interactions, and directing their attention towards the official website.

- Through the **meticulous implementation of various social media strategies**, SYNTHEMA has successfully curated compelling content that resonates with the target audience. This content includes informative articles, engaging visuals, industry insights, and thought-provoking discussions. By consistently providing valuable and relevant information, SYNTHEMA has managed to captivate the interest of its online followers.
- In addition to **content creation**, SYNTHEMA has also utilized targeted tactics to drive traffic to their website. These tactics involve strategically placed call-to-action buttons, promotional campaigns, and optimized landing pages. By leveraging these techniques, SYNTHEMA has effectively directed the online audience towards the official website, fostering deeper engagement and facilitating the conversion of interested followers into active participants.

The steady growth in the number of followers serves as a tangible indicator of the expanding online community. Moreover, the increased interaction rates, such as likes, comments, and shares, demonstrate the level of engagement and resonance of SYNTHEMA content. The success of these efforts can be measured through various Key Performance Indicators (KPIs).

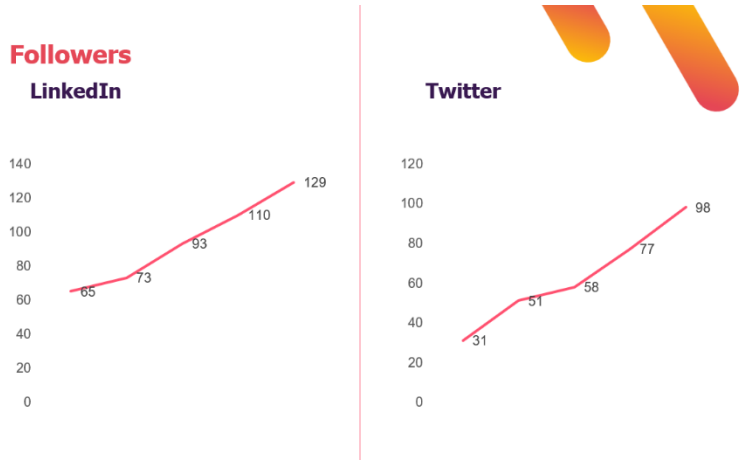

Figure 25. SYNTHEMA social media followers increase

Additionally, when examining the data on LinkedIn, which stands out as our most successful channel, we have the opportunity to delve deeper and gain valuable insights into the audience we are attracting. By analyzing the data from various perspectives, we can uncover valuable information about their geolocation, occupations, and industries of interest, offering a comprehensive understanding of our target audience.

By leveraging the diverse perspectives provided by the LinkedIn data, we can gain a comprehensive understanding of our audience's demographics, interests, and professional backgrounds. Armed with this knowledge, we can refine our content, engagement strategies, and overall approach to maximize our impact on LinkedIn. This data-driven approach allows us to build a strong and engaged community, enhance brand reputation, and establish ourselves as a go-to resource within the industry.

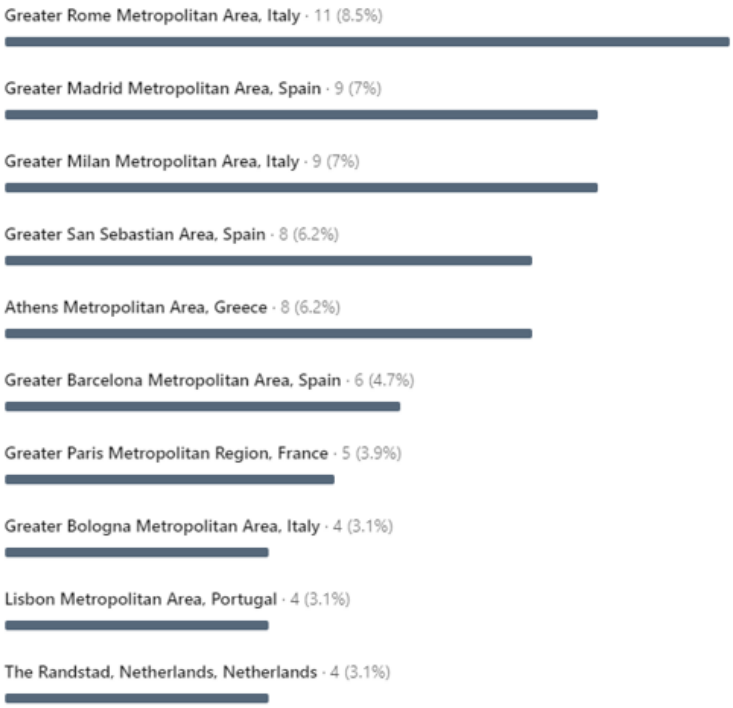

Figure 26. SYNTHEMA LinkedIN followers geolocation

Figure 27. SYNTHEMA LinkedIN outreach sectors

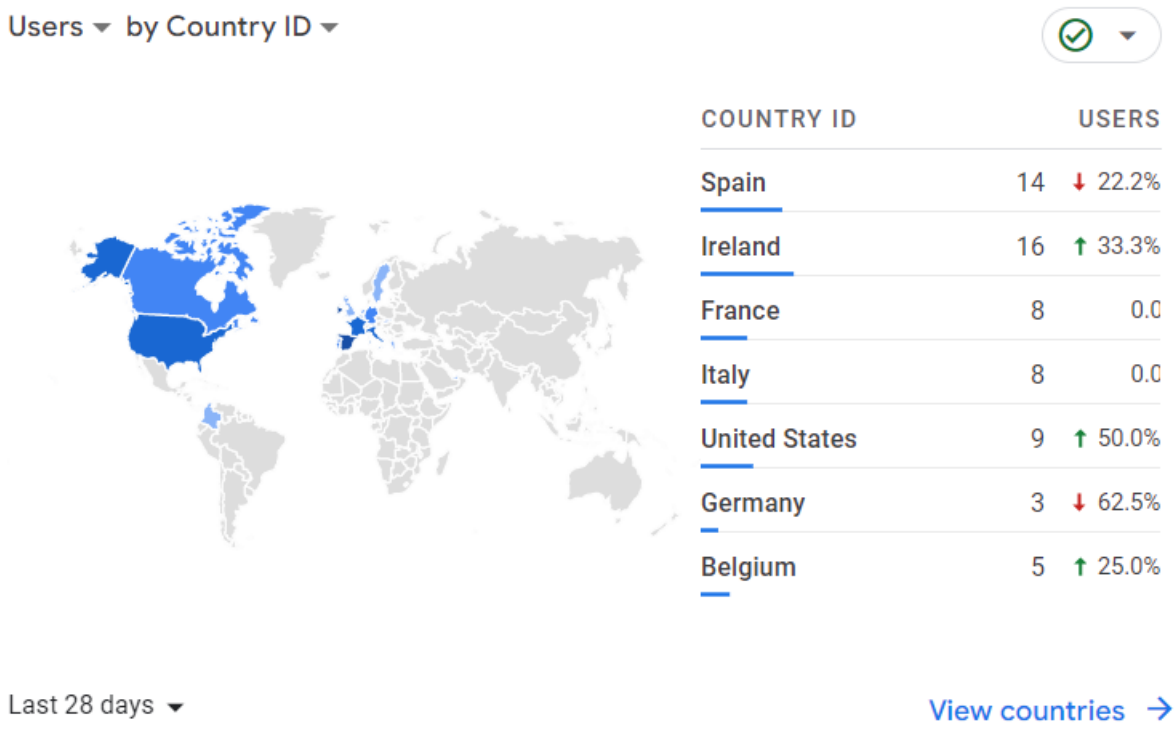

Figure 28. SYNTHEMA.eu geolocation

6 Conclusions

This deliverable outlines SYNTHEMA **stakeholder collaboration framework** and **communication and dissemination** strategies, as well as the project approach towards **exploitation** of results for business, standardization and IPR purposes. All these tasks fall into the scope of WP6 (ie. develop and operate a collaboration framework, design and implement C&D strategies, asses the footprint of the project through KPIs, develop an effective framework for IPR management and contribute to relevant standardization bodies and committees).

With regards to the **stakeholder collaboration framework**, SYNTHEMA impact has been identified and evaluated across a wide spectrum of entities, encompassing policy makers, society as a whole, digital service providers, healthcare professionals and advocate initiatives. The aim is to understand the ecosystem of actors which might be interested in the project findings, to develop a specific value proposition for each category to disseminate them.

The stakeholder engagement efforts will be developed through **an agile communication methodology**. This methodology, organised in six-month sprints along three phases (scout, interact, learn), is designed to continuously develop and strengthen communication streams with key stakeholder groups. The outputs of these sprints will be a **stakeholder map** that will evolve through the duration of the project, **publications**, **social media campaigns**, **surveys** and more.

This deliverable presents that SYNTHEMA seeks to establish robust synergies with leading expert networks in fields such as **AI, HPC, eHealth, precision medicine,** and **hematological diseases**, including **initiatives and networks**, **EU projects**, **open access platforms**, **DIHs** and **European clusters**. Additionally, SYNTHEMA members will leverage connections with these stakeholders including **medical research centres, healthcare service providers, hospitals, data repository providers, clinics and care centres; computing centres from academia and SME; and information security, data aggregation and data analytics, cyber security, technological research and disruptive tech organisations and/or companies.** A specialised member will lead on the creation of **legal and ethical frameworks** to guarantee privacy by-design in the collection and processing of health-related personal data and attain an ethics-wise algorithm co-creation. This collaboration between **healthcare professionals, digital services providers and health data experts** will result in the federated learning infrastructure, equipped with SMPC and DP protocols.

The **Communication and dissemination (C&D) section** presents how C&D activities are planned and will be implemented for the full duration of the project (four years). The **communication plan objectives** include: enhancing general awareness and interest, clearly

conveying technical and scientific results, delivering high-level messages and promoting awareness. The **dissemination plan** goals are interlinked with those already set for communication activities and also with the overall project objectives: they are all geared towards creating an impact beyond the boundaries of the project. Dissemination will be directed to raising awareness of project results and aiming for action among key stakeholders, mostly through publication of results and research and business events, while facilitating uptake of outcomes and research insights through open science practices, building the bases for a successful exploitation of results.

The **communication activities** will occur in three iterative but distinct phases: **plan & revisit; early bird communication; and targeted communication**. These phases are closely intertwined with dissemination efforts as well. The primary aim of these communication activities is not only to generate excitement and interest around the project but also to actively engage a community of end-users who can interact with and offer valuable feedback to support the project's ongoing activities. Similarly, dissemination activity will be implemented in three different phases during the length of the project: **identify & study**; **outreach & influence**; **embrace & accept**.

The C&D plan adopts a streamlined approach to ensure targeted yet extensive communication and dissemination. For this purpose, a series of **communication and dissemination tools** will be made available to allow the project to reach the right audiences in a friendly and coherent way. This communication toolkit will have specific functions and will be tailored to specific communication and dissemination needs for all phases of the SYNTHEMA C&D plan. Examples of these tools are: the **website**, **social media**, **newsletters**, **press releases**, **slide decks**, **printed material**, **email campaigns**, **surveys**, **multimedia**, **events** and **conferences**.

For example, the public **website** serves as a vital tool to maximize the project visibility and acts as the primary entry point for showcasing its core ideas, approach, news, findings, and results; **social media** aims to support the increase of newsletter subscribers, website visitors, Zenodo metrics (views and downloads), and our online community of social media followers; **newsletters** serve as an effective engagement tool, offering insights into a project key activities and accomplishments; **press releases** showcase and emphasize the project significant milestones; and expertly crafted **slide decks** or **one-pagers** serve as potent engagement tools, effectively conveying SYNTHEMA vision and scope to specialized audiences in a visually appealing and concise manner. Additionally, **brochures, catalogues, posters**, and other paper-based resources are also valuable for promotional purposes. Most of these materials will be available in digital format, allowing for easy printing when needed, such as during events, workshops, or fairs.

Other aspects of the C&D plan presented in this report, are SYNTHEMA commitment to present its work and findings on open access platforms and journals like for example **Zenodo**, **CORDIS** and the project official **website**; the planned contribution to peer-reviewed publications in top **scientific journals**; the planned stakeholder **consultation**; the planned effective **internal communication strategy** that ensures that interest are aligned within the consortium and everybody is duly informed of the latest developments; and the planned **collaborative communication cluster** with other relevant initiatives (eg. Genomed 4All). Lastly, SYNTHEMA aims to develop **training** itineraries for healthcare professionals and patients (WP6, T6.4).

The **exploitation strategy** presented in this document is based upon three main areas of action: **open science**, **standardization** and **IPR**, and this plan has been set out at the proposal stage, aiming to maximise the project impact on different layers of EU society. The main objective of the foreseen plan is to **act as an enabler** that will lead to **AI solutions for anonymisation and synthetic data generation** to tackle the scarcity and fragmentation of data and widen the basis for ethical, GDPR-compliant research in RHD. The potential exploitation routes proposed in the plan are **financial exploitation, research & development, education, community building, knowledge transfer, contributions to open-source projects and standardisation, and contribution to the promotion of an ethical use of AI in the healthcare field.**

The exploitation efforts will be coordinated and support by the **exploitation manager**, who will take care of advising individual partners, where needed, on the best strategies to achieve effective exploitation while ensuring that no conflicts arise with regard to individual IP rights, and will coordinate consortium partners in the effort of exploiting joint results, including the pursue of a collective exploitation and sustainability strategy for the project platform.

In synergy with platform sustainability planning, the exploitation activity is envisioned to be carried out starting on **phase two** - Development of pipelines and resources (**M13 - M36**) until **phase three** - Proof-of-concept validation, refinement and innovation transfer (**M36-M48**) of the project implementation.

For what concerns **research data (i.e., anonymised and synthetic data to be produced during the project)**, SYNTHEMA will consider participation in European open science initiatives with registration within data catalogues addressing **findability**, **interoperability** and **reusability**. With regard to **other research outputs**, algorithms and pipelines for data anonymisation and SDG, those will be made open source and available to the community through GitHub, GitLab or another provider for software development, source code management and distributed version control. SYNTHEMA will also set up an effective system to protect and exploit ***Intellectual Property*** **(IP)** generated throughout the length of the project. The three pillars of the IP strategy are: **protection of IP**, the **technology transfer framework** and the **fair law enforcement system**.

Continuous monitoring and **customization** of the C&D&E Plan are fundamental elements of SYNTHEMA success and this is why we already established tools to monitor communication, dissemination and exploitation efforts. These tools include: a **C&D database,** a **C&D&E tracker**, and **editorial calendar** and **KPI analysis**.

This document shows the work done in the first six months of the project and also serves as a preliminary roadmap for SYNTHEMA communication, dissemination and exploitation activities. Due to its release in the early stages of the project, the concretization of certain aspects of these strategies might be subject to changes throughout the length of the project. Therefore, this can be considered as a living document and any and all changes will be adequately reflected in successive iterations of upcoming deliverables **D6.2** and **D6.3** (Final dissemination and communication report and Exploitation and sustainability plan).