Deliverable 7.1
Stakeholder Engagement Plan

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NextGen

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List of terms and abbreviations

ABBREVIATION	DESCRIPTION
D&C	Dissemination and Communication
GA	Grant Agreement
KPI	Key Performance Indicator
WP	Work Package

Table of contents

1 Introduction

This document is Deliverable 7.1, the Stakeholder Engagement Plan, for NextGen. This plan outlines the goals and strategies for effectively engaging with (key) stakeholders in NextGen.

The overall objective of NextGen is "to build novel and synergistic tools to enable portable multimodal, multiomic and clinically oriented research in high-impact areas or cardiovascular medicine". The results of the project will thus be tools (research portability tools, open-source tools, a data analytics platform) and a mini European Health Data Space. The sustainability of the analytics platform will be guaranteed beyond the project duration. NextGen tools will significantly benefit end-users, i.e. researchers, innovators and healthcare professionals, contributing to an increased quality and quantity of research and improved clinical efficacy and efficiency in the cardiovascular genomics domain, through better data integration.

NextGen project outputs align with wider impacts under destination 5 and include contributing to EU-wide research and innovation, translational benefits to citizen healthcare, international visibility and leadership, reduction in disease burden through personalized medicine, improved quality and outcome of healthcare and enhanced trust in innovative technologies.

NextGen's objective, and its accompanying path towards impact, requires an interdisciplinary approach. Indeed, partners in NextGen consist of many different backgrounds (internal stakeholders) and the scale and significance of impacts reaches from individual patients to health data spaces and healthcare systems as a whole. Engaging all these different stakeholders is crucial for NextGen's success, as it ensures the inclusion of these diverse perspectives, fosters collaboration, and promotes transparency. Yet, their diverse perspectives also require a versatile approach, which is the point we start from in this plan.

The Stakeholder Engagement Plan establishes clear objectives which ensure that stakeholders are effectively informed, consulted, involved, collaborated with, and empowered throughout the project lifecycle. By actively involving internal and external stakeholders, NextGen seeks to build a robust, supportive network that will drive the project forward and maximise its impact on cardiovascular healthcare.

1.1 Structure of the Deliverable

In the next chapter, we describe the identification of the different stakeholders in the project. Chapter 3 deals with the approach used to design methods and tools to engage these specific stakeholders. Chapter 4 then sketches a timeline for the stakeholder engagement activities in the project. Chapter 5 describes feedback mechanisms for monitoring and evaluation of stakeholder engagement. The conclusion summarises the plan.

This Deliverable is iterative, as the plan is subject to change based on novel identified stakeholder groups, engagement opportunities that may arise during the project or content such as (un)successful outcomes or lessons learned to be shared deviate from the original plan. Our iterative approach to stakeholder management accounts for these changes.

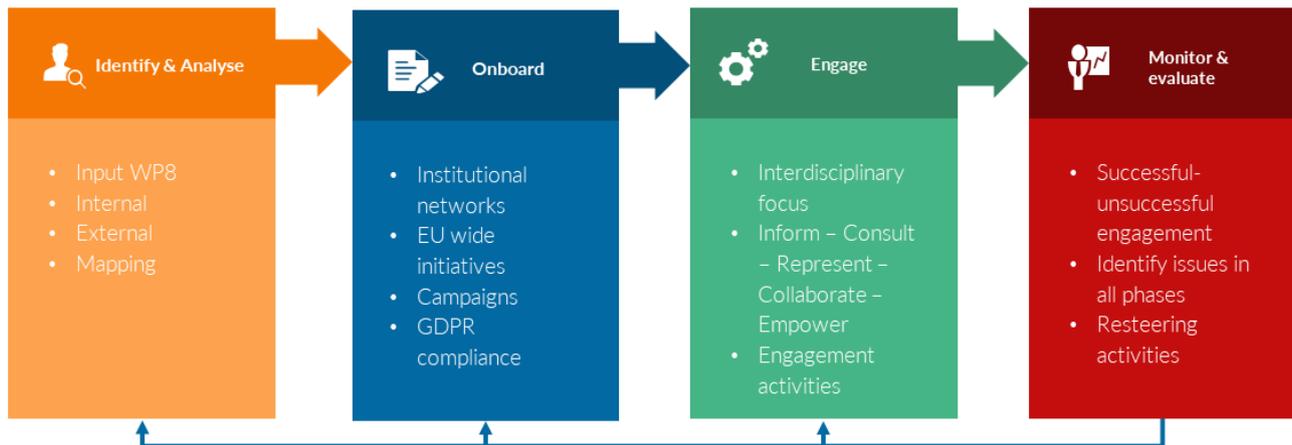## 1.2 Place of the Deliverable in the project

The Stakeholder Engagement Plan is the basis for the Broader Engagement & Exploitation work package in NextGen (WP7). The aim of WP7 is to co-develop project Deliverables, with a particular focus on our governance and tooling being utilisable on other major platforms and within other key initiatives, in an additive and synergistic manner to existing Horizon Europe, Digital Europe and other funded projects. This will be done via establishment of collaborative relationships with different stakeholders, including EU-wide initiatives and projects, using co-development frameworks for social and economic engagement with communities and through a sustainable patient engagement strategy.

This Deliverable builds upon initial work on stakeholder identification and mapping in NextGen, as part of the Grant Agreement and Deliverable 8.1 "Dissemination and Communication Plan". Thus, it is important to highlight that the Stakeholder Engagement Plan is intricately connected to the Dissemination and Communication (D&C) Plan (D8.1). Each D&C activity planned within NextGen has been designed to enhance and support stakeholder engagement. As outlined in Deliverable 8.1, NextGen's dissemination and exploitation efforts (WP8) will be targeted to clinicians, developers, regulatory authorities, healthcare policy makers, patients, and other relevant stakeholders. For this, a first set of Personas was being made. Moreover, consortium members will carry out D&C activities within their own wide network of national

and international stakeholders, specifically healthcare organisations, higher education institutes, and patient groups. For example, in WP6 "Regulation, Ethics and Governance", outreach to regulatory and policy makers and patients is expected.

The Stakeholder Engagement Plan further extends and harmonises these efforts by refining the different stakeholder groups and the specific strategies to engage them. Furthermore, the Stakeholder Engagement Plan is a first step in the exploitation strategy of NextGen that will identify drivers and barriers and using a Cost-Benefit Analysis (D7.3) leading to a sustainability plan (D7.2, update in D7.4). Finally, in Deliverable 7.5 we will report on the stakeholder engagement progress.

The diagram below describes the different steps in the engagement process, which is explained in more detail in the next sections.

Identify & Analyse	Onboard	Engage	Monitor & evaluate
• Input WP8 • Internal • External • Mapping	• Institutional networks • EU wide initiatives • Campaigns • GDPR compliance	• Interdisciplinary focus • Inform – Consult – Represent – Collaborate – Empower • Engagement activities	• Successful-unsuccessful engagement • Identify issues in all phases • Resteering activities

2   Stakeholder identification and stakeholder analysis

Identifying and understanding the roles of various stakeholders at local, European, and international levels is crucial for the successful development and implementation of NextGen's tools. Stakeholders are categorised according to different categories, (such as internal and external) based on their relationship to the project, and according to expertise groups.

By systematically identifying and engaging these stakeholders, NextGen will tailor its engagement strategies to address the specific needs, interests, and contributions of each group. The subsequent comprehensive stakeholder analysis will be essential for understanding the influence, interests, and expectations of these stakeholder groups. This analysis will help prioritise engagement efforts and ensure that all relevant perspectives are considered in the development of the tools.

For this chapter of the Deliverable, we will build upon the initial stakeholder identification and target audience identification performed as part of Deliverable 8.1.

2.1   Internal Stakeholders

NextGen harbours partners that fall into each of the next four categories of stakeholders (table 1 adapted from Grant Agreement):

- Domain expertise partners in cardiovascular genomics expressing a need for tools that they will "use": clinical/academic partners UMCU, QMUL, ERLH, GUF, KI, HUS, UVA, TUM, WSPA
  - Of whom partners taking part in the Pathfinder project on biobanks: UMCU, KI, HUS, UVA, TUM
- Partners that will address the need by "contributing to" the development of tools:
  - Data partners: HCF for data management, HL7 and MYDATA for standards
  - IT partners: HIRO for hardware and EURE and SUPSI for software
- Partners indirectly facilitate building tools ("support"): DIA for regulatory, DPOA for legal, LiKe for health economics, NEBS for exploitation and ESC and DPOW for communication/dissemination.

- Partners extending towards the people that ultimately "benefit" from the usage of NextGen tools, namely patients and society as a whole: ESC

Table 1:Overview of consortium partners

	Stakeholder description	UMCU	QMUL	HCF	HIRO	SUPSI	EURE	ERLH	GUF	KI	HUS	UVA	TUM	HL7	MYDTA	DPOW	DIA	DPOA	ESC	WSPAN	LIKE	NEBS
Use	Domain expertise in cardiovascular genomics (WP4+5)	x	x					x	x	x	x	x	x							x		
Contribute to	Data (WP1)			x										x	x							
	IT (WP2+3)				x	x	x															
Support	Facilitating (WP6-7-9)	x														x	x	x			x	x
Benefit	WP8																		x			

The project partners are all stakeholders in their own ecosystems and will act as ambassadors of the project at local, European, and international levels when encountering colleagues in their respective fields.

Within the partner organisations, different people may engage in project activities. These groups of people may include

- **Project Team Members**: Researchers, data scientists, and project managers directly involved in developing and managing the tools. Are responsible for the day-to-day management, research, and development of the tools.
- **Institutional Leaders**: Executives and senior management within the hosting institution who provide strategic direction and support. They provide strategic oversight, resource allocation, and high-level decision-making support.
- **Researchers and Scientists**: Colleagues in data, IT, bioinformatics/genomics, and cardiovascular medicine contribute their knowledge and expertise to the project.

2.2   External stakeholders

External stakeholders too can be categorised according to use, contribution, support and benefit, including cross-fertilisation with other projects

Use

- **Healthcare Providers**: Cardiologists, general practitioners, and other medical professionals (in hospitals or private practice) who will use the personalised medicine tools developed by the project. They offer clinical insights and practical feedback on the usability and relevance of the personalized medicine tools. Contact via local, national, and international ecosystem of clinical partners and ESC at the European level.
- **Academic and Research Institutions, Scientific community in general**: Universities and research centres collaborating on scientific research and contributing to the knowledge base and contributing to the scientific and academic rigor of the project. Contacts through clinical/academic partners.
- **Partners from other (European) projects** include University of Barcelona, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Fakulti Nemocnice U Sv Anny V Brne, Fundacio Hospital Universitari Vall D'Hebron, Spitalul Clinic de Urgenta Bucuresti, Academisch Medisch Centrum bij de Universiteit van Amsterdam, University College London, Muhimbili University of Health and Allied Sciences, Centro de Investigaciones Tecnologicas Biomedicas Y Medioambientales, The Chancellor, Masters and Scholars of the University of Oxford.

Contributes to

- **Bioinformatics and Genomics Experts**: Professionals providing technical expertise in managing and analysing large-scale genomic data, owning and potentially making available specialised knowledge in data analysis and interpretation, and contributing to the project's scientific foundation. Contacts are through clinical partners, EURE, and SUPSI.

- **Technology and Data Management Companies**: Firms providing the technological infrastructure and tools necessary for data storage, analysis, and integration, as well as support for data storage, analysis, and security. Contacts through IT and data partners, one-on-one contacts via other partners
- **Partners from other (European) projects** include Barcelona Supercomputing Center, SRDC Yazilim Arastirma Ve Gelistirme Ve Danismanlik Ticaret Anonim Sirketi, Athina-Erevnitiko Kentro Kainotomias Stis Technologies Tis Pliroforias, Ton Epikoininion Kai Tis Gnosis, Translated Srl, Siemens, Ethniko Kentro Erevnas Kai Technologikis Anaptyxis

Support

- **Regulatory Bodies**: Agencies such as the FDA and EMA that ensure compliance with legal and ethical standards in genomics and personalised medicine. They ensure the project complies with all legal, ethical, and regulatory requirements. Contact through DIA's ecosystem, one-on-one contacts via clinical partners, and strategic partnerships through the consortium as a whole via WP7.
- **Data Privacy and Security Experts**: Specialists who ensure that patient data is handled securely and ethically, protect privacy and confidentiality, develop and implement protocols to protect patient data, and ensure compliance with data protection laws. Contacts through DPOA, privacy and security experts at partner sites.
- **Funding Bodies and Sponsors**: Organisations and individuals providing financial support for the project, including government agencies, private foundations, and industry partners, with which they support with funding, also pursuing policy and strategic interest. Contacts through all consortium partners. Strategic partnerships on a consortium level through WP7.
- **Partners from other (European) projects** include Panetta & Associati Studio Legale, Lynkeus, Regenold GMBH,

Benefit

- **Patients and Patient Advocacy Groups**: Individuals affected by cardiovascular disease and organisations representing their interests, providing valuable insights into patient needs and priorities. They can be involved in sharing experiences and perspectives to ensure that patient needs and preferences are addressed. Contact via local and national ecosystem of clinical partners and ESC at the European level.
- **General public and civil society**: Individuals in the EU and beyond provide insights into the wishes and demands of citizens regarding modern-day technology such as NextGen tools. Their involvement increases the adoption potential of the developed tools in the NextGen toolbox. Contacts are through all partners and ESC at the European level.
- **Partners from other (European) projects** include Stichting Netherlands Heart Institute, SHINE 2Europe LDA, European Heart Network AISBL

2.3 Stakeholder Mapping

To effectively map stakeholders in our ecosystem, we will use an influence-interest matrix that categorises stakeholders based on their level of influence on the project and their interest in its outcomes.

- **High Influence, High Interest**: These stakeholders are critical to the project's success and will be actively engaged in decision-making processes. Examples include project team members, institutional leaders, and key healthcare providers.
- **High Influence, Low Interest**: These stakeholders have significant power but may not be directly interested in the project outcomes. Examples include regulatory bodies and funding bodies. Their engagement will focus on compliance and financial support.
- **Low Influence, High Interest**: These stakeholders are highly interested in the project's success but have limited power to influence outcomes. Examples include patients, patient advocacy groups, and some researchers. Their insights will be actively sought to ensure the project meets patient needs.
- **Low Influence, Low Interest**: These stakeholders have minimal impact on the project and limited interest in its outcomes. Examples might include general community members and peripheral industry partners. They will receive updates to keep them informed.

3 Onboarding

Identifying individual stakeholders for the NextGen project involves a structured process utilising various channels and strategies to ensure comprehensive and effective engagement while ensuring compliance with the General Data

Protection Regulation (GDPR). We will start the onboarding from the partners and their respective ecosystems, networks and communities. For this, we will ask all partners to join us in identifying stakeholders in their respective ecosystems, and we will map them according to the matrix above.

WP7 will prepare an initial stakeholder classification grid, and we will ask all partners to validate it and integrate it into their stakeholder ecosystem. We will work with WP8 to establish the best way to communicate with our different stakeholders for onboarding. Direct outreach to NextGen stakeholders is based on targeted communications to key individuals and organisations via various channels, with relevant, targeted, personalised content and procedures compliant with data protection rules. This may include personal invitations, cold outreach if appropriate in selected cases, and using a referral system, asking connected stakeholders to refer additional experts and interested parties from their own networks. Public Announcements and Calls for Participation using various communication channels (emphasising social media) will be drafted together with WP8. We will use Professional and Academic platforms for distribution. Onboarding will need to be easy, and we will keep the usability of the onboarding process in mind and thoroughly test within WP7 organisations before reaching out to others. Below, we will discuss our general approach to onboarding, starting from institutional networks.

3.1   Leveraging institutional Networks

Every institute is part of an ecosystem consisting of organisations and individuals, including government agencies, academic institutions, non-profits, individual scientists, experts, and practitioners. In the case of university hospitals, hospital referral networks, patients and their loved ones, regulatory bodies, and healthcare insurance companies are specific additional stakeholders. Institutional networks facilitate the exchange of information, resources, and expertise, enhancing collective problem-solving and innovation. Their impact is seen in improved efficiency, scalability, and the ability to address complex societal challenges.

We will leverage existing relationships by utilising the project team's existing professional networks within academic institutions, healthcare organisations, and industry to identify potential stakeholders. Furthermore, we will engage with partners from ongoing and past research collaborations to identify experts and interested parties in genomics and cardiovascular medicine. We will contact members of relevant professional associations, such as the European Society of Cardiology or the American Heart Association.

We will construct mailing lists of email addresses to distribute relevant information to stakeholders. Access involves subscription, verification, and adherence to data protection regulations (e.g., GDPR), ensuring secure storage, authorised usage, and easy deregistration. We will use internal mailing lists from the hosting institution to disseminate information about the project and invite interested parties to participate. In addition, we will access mailing lists from collaborative research networks, consortia, and funded project partnerships to reach a wider audience. Through industry partners, we will utilise to identify stakeholders in the private sector.

3.2   Engaging EU-wide Initiatives

WP7 activities specifically entail broader engagement. A specific group of stakeholders is formed by other Horizon Europe projects (adapted from Grant Agreement). The table below reflects identified other EU wide initiatives as part of NextGen's broader engagement task. We will pursue addition of a (clinical/academic) partner via the EU Hop-On facility to broaden our horizon to other parts of Europe. Furthermore, will perform a gap analysis among stakeholders from other key initiatives and NextGen.

Table 2: Overview of synergies to be found with other Horizon Europe projects.

Horizon Europe Call Title	Examples of synergies	NextGen additions
Innovative tools for the use and re-use of health data (in particular of electronic health records and/or patient registries)	**AIDAVA**: guided data curation tools; **DataTools4Heart**: standardisation tools; **AI4FH**: standardisation clinical tools; **IDEA4RC**: interoperability data space (cancer).	AI data curation in genomics; multimodal data integration; federated genomic techniques; cardiovascular medicine.
New methods for the effective use of real-world data and/or synthetic data	**ONCOVALUE**: structured reports (cancer); **REALM**: standardisation tools/models	Multimodal data integration; metadata cataloguing; decentralised semantics

Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation	Federated computation: **SYNTHEMA** (haematology); **SECURED** (cancer).	As mentioned above, noting cardiovascular focus.
Technologies and solutions for data trading… and interoperability	Non-healthcare-specific projects demonstrating federated dataspaces and interoperability frameworks.	Data authenticity validation; healthcare-driven governance tools and frameworks.

Another EU-wide initiative that we are engaging with is the European Health Data Space initiative, specifically through our internal stakeholder MyData. We have reached out to the Genomic Data Infrastructure (GDI); two senior members from ELIXIR and the European infrastructure for bioinformatics and life-science data (EBI-EMBL) will take part in our SSSHB (see below under 4.2) to co-develop synergistic goals. NextGen actively engages with the European Open Science Cloud.

3.3 GDPR compliance

NextGen will ensure that all stakeholder data collection, storage, and usage practices comply with the General Data Protection Regulation (GDPR) throughout the stakeholder identification process. The project will obtain explicit consent from stakeholders before collecting personal data and provide clear information on how their data will be used and protected.

4 Engagement Methods and Approaches

NextGen is a truly multidisciplinary project, bringing together topics and stakeholders such as medical practitioners (cardiovascular and genomics), medical operators, medical scientists, data scientists, ethics experts, and socio-economic experts. To build upon this strength, we aim to engage our stakeholders in a cross or multidisciplinary manner, across domains and potentially silos, to optimise the value NextGen can bring to these stakeholders.

A wide variety of engaging professional content is available to stakeholders. The key to keeping the NextGen ecosystem alive and interactive is engagement based on interesting subject-matter *content* that feeds into the scientific and technological interests of the stakeholders. We start with topics that interest *us*. Therefore, NextGen engagement methods and approaches address internal and external stakeholders in an interdisciplinary way. Together with WP8, we will co-develop a toolkit with guidelines and templates with project partners and key stakeholders to ensure that engagement efforts are well-targeted, efficient, and effective, ultimately contributing to the successful development and implementation of NextGen's tools for cardiovascular disease.

4.1 Interdisciplinarity as starting point

Deliverable 8.1 identified Personas in the NextGen ecosystem as a target audience. Some of these personas may also be internal stakeholders. Two of these personas are displayed below as an example.

Dr. Henri Dubois
Clinical partner with domain expertise in cardiovascular disease management (e.g. cardiologist from QMUL)

Jamal Richardson
Researcher with expertise in development of pipelines for genomics (e.g. software engineer from SUPSI)

One may think Henri's persona will only fall into the stakeholder group of cardiologists, whereas Jamal may only interact with fellow researchers in the genomics field. However, NextGen is an interdisciplinary project. Rather than only looking at specific personas and their own ecosystems, we are interested in areas of work within the project where categories and people's expertise overlap or cross paths, as we think this is where the magic happens. For this, we aim to actively look for ways Henri and Jamal will not only work together but also engage in activities of the other stakeholder ecosystem.

An example of a stakeholder form that shows the interdisciplinarity of the consortium's ecosystem is the website as a platform for stakeholder engagement (D8.2). The website acts as a platform to put together different stakeholder groups around NextGen's efforts actively. Using, for example, blogs as an engagement strategy, where each post shows an example of NextGen's interdisciplinary approach towards the development of its tools, encouraging interaction through comments and social media sharing, the project aims to gather feedback and stir up professional dialogue, leading to new perspectives that can influence future research directions.

We will update the personas from D8.1 to reflect our updated interdisciplinary stakeholder ecosystem and the engagement strategies below.

4.2   Engagement methods

Different stakeholders will use, contribute to, and support the development or benefit from NextGen tools. We want all stakeholders to feel connected to the Project. NextGen will engage with each stakeholder group to inform, consult, represent, collaborate and empower. These approaches are tailored to meet different stakeholder groups' diverse needs and preferences, ensuring comprehensive and meaningful engagement throughout the project lifecycle. There are both passive and active approaches that we will deploy a mix in NextGen.

4.2.1   Inform

To provide accurate and timely information about NextGen to all stakeholders (see also D8.1), by

- **Emails**: Regular email updates will be sent to stakeholders to provide project news, progress reports, and important announcements. Personalised emails will be used for targeted communication with key stakeholders.
- **Newsletters**: A monthly or quarterly newsletter will be published to share detailed updates, highlight milestones, showcase success stories, and announce upcoming events.
- **Website**: A dedicated project website will serve as a central hub for all information related to NextGen. It will feature news updates, project background, key documents, and resources for stakeholders.
- **Social media**: Platforms like Twitter/X, LinkedIn, and Facebook will engage with a broader audience, share real-time updates, and create an interactive space for discussion and feedback.
- **Webinars and workshops**: We will organise internal and external webinars and workshops on NextGen-specific topics, sharing information and lessons learned, with an emphasis on interdisciplinary/cross-over areas of research and expertise. We will engage stakeholders through the respective partners. We will collaborate with EU partner projects where possible to synergise, inspire and share best practices.

4.2.2   Consult

To seek input and feedback from stakeholders to inform project decisions and ensure that the project meets the needs and expectations of its diverse stakeholders by:

- **Surveys**: Online surveys and questionnaires will gather feedback on specific aspects of the project, such as user needs, expectations, and satisfaction.
- **Focus Groups**: Small, facilitated group discussions will be organised to gain in-depth insights from stakeholders about their experiences, concerns, and suggestions.
- **Public Meetings**: Open meetings will be held to inform the public about the project and provide a forum for questions, comments, and feedback. A dedicated feedback channel will be set up for stakeholders to share their thoughts and suggestions.

4.2.3   Represent

To actively engage stakeholders in the project process to build a sense of ownership and ensure that their perspectives are considered in project planning and implementation, by:

- **Stakeholder Committees**: Committees comprising representatives from key stakeholder groups will be established to provide ongoing input and guidance on project activities and decisions.
- **Working Groups and workshops**: Thematic working groups will be formed to address specific areas of the project, such as data privacy, clinical applications, and technological infrastructure. These groups will involve stakeholders in detailed discussions and planning.
- **Equality, Diversity and Inclusion working group:** activities will be led from the REG board (see below) to provide training on EDI issues and co-create and test/evaluate guidelines for addressing EDI in AI modelling and testing.

4.2.4 Collaborate

To work together with stakeholders in partnership to achieve project goals and leverage their expertise and resources, by:

- **Online Collaboration Tools**: Tools such as Microsoft Teams, Google Docs and Slack will be used to facilitate communication, document sharing, and project management among stakeholders. These platforms will support real-time collaboration and streamline workflows.
- **Partnerships**: Formal partnerships will be actively sought and established with academic and research institutions (via Hop On facility), other EU projects (see table above), healthcare providers, technology companies, and other relevant organisations to co-develop and implement project components if opportunities arise. These can lead to joint research initiatives leveraging expertise and resources of academic and research institutions to advance the scientific goals of NextGen.
- **REG:** Regulation, Ethics and Governance Board ("REGB") led from WP6 will ensure that all ethical and governance obligations, together with any related regulatory and legal requirements, are met and maintained within the project, to the extent possible, and when within the scope and influence of NextGen (see also REG reports). Includes the EDI working group activities (see above), as well as health informatics and ethics-parallel research.
- **SSSHB**: The Scientific, Social Sciences and Humanities Board ("SSSHB") led from in WP7 will ensure both the scientific integrity of the project and that the societal impact of the research is adequately addressed. Membership will include consortium partners with the appropriate competencies and external scientific and scientific, social science and humanities experts. Members participate in clinical decision-making bodies, allowing first-hand insight into ways to translate project outputs into clinical impact.

4.2.5 Empower

To Enable stakeholders to make decisions and take ownership of certain aspects of the project, particularly those that directly affect them, by:

- **Training Sessions**: Workshops and training sessions will be organised to build the capacity of stakeholders, particularly in areas such as genomics, data analysis, and personalised medicine.
- **Co-creation Workshops**: Interactive workshops will be held to engage stakeholders in developing personalised medicine tools, allowing them to contribute ideas and collaborate on design and implementation.

Engagement methods should be considered alongside the D&C approach in D8.1 as these activities have been designed to promote both general and specialised stakeholder engagement within NextGen.

By setting these engagement objectives and approaches, NextGen aims to create a collaborative and inclusive environment where stakeholders feel valued and are motivated to contribute to the project's success. This approach ensures that the development of genomic tools for cardiovascular disease is well-informed, widely supported, and effectively implemented.

5 Engagement Activities and Timeline

NextGen will implement a series of engagement activities over its 48-month duration to ensure continuous and meaningful stakeholder involvement according to the strategy outlined above. These activities will be structured in phases and scheduled to align with key project milestones. In brief, at the start, the emphasis is on getting people to know NextGen and its goals, whereas at the end, more knowledge about the tools and experiences while building the tools, including best practices and lessons learned, are shared. A general timeline of engagement activities is proposed below. Several activities for internal stakeholder engagement have already taken place and are outlined in Table 3.

Table 3: Overview of Engagement Activities up until M6.

Activity	Content	Audience
Workshops	Information governance webinar (10/12 June) Understanding genomic data webinar (26 June)	Whole consortium
Research presentations	Regular short presentations (monthly) in work package 4 (Personalised Medicine) on research topics and related content.	Research members
REG board meetings	Establishment of the REG board, Terms of Reference, planning	REG board members
Executive Board meetings	Updates from efforts in work packages	WP leads and other interested internal stakeholders
Networking event	Participation in HaDEA organized networking event (26 June)	Horizon Europe projects
1-on-1 interviews	Interviews with key stakeholders in the project	WP8 for communication

5.1 Initial Engagement Phase (Months 1-12)

1. **Inception/Onboarding**
   - o **Objective**: Introduce the project, outline its goals and objectives, and initiate stakeholder engagement.
   - o **Activities**: Establish social media presence and partnerships with other projects to reshare posts. Presentation by project leaders, Q&A session, distribution of project documentation.
   - o **Participants**: All identified stakeholders.
   - o **Timeline**: Month 7.
2. **Establishing internal community**
   - o **Objective:** Getting to know each other in the consortium, establishing a basic level of understanding of each others work
   - o **Activities:** Research presentations, pitches, WP meetings, EB meetings, workshops, 1-on-1 interviews
   - o **Participants:** Internal stakeholders
   - o **Timeline:** Months 1-12
3. **Completion of the Stakeholder Mapping and Analysis**
   - o **Objective**: Identify and categorise stakeholders, assess their influence and interest, and prioritise engagement.
   - o **Activities**: Conduct stakeholder analysis, develop stakeholder matrix and grid, create detailed profiles.
   - o **Participants**: Project team, stakeholder engagement specialists.
   - o **Timeline**: Months 7-12.

5.2 Ongoing Engagement (Throughout project)

1. **Regular Progress Updates**
   - o **Objective**: Keep stakeholders informed about project progress, milestones, and any changes.
   - o **Activities**: Send monthly newsletters, update project website, post on social media.
   - o **Participants**: All stakeholders.
   - o **Timeline**: Monthly.
2. **Quarterly Stakeholder Meetings**
   - o **Objective**: Provide updates, discuss progress, gather feedback, and address concerns.
   - o **Activities**: Presentations, interactive discussions, feedback sessions.
   - o **Participants**: Key stakeholders, project team.
   - o **Timeline**: Every 3 months.
3. **Bi-annual Webinars/Workshops**
   - o **Objective**: Engage stakeholders in collaborative activities, brainstorm solutions, and co-develop project components, e.g. on Data Privacy and Personalised Medicine

- o **Activities**: Thematic workshops focusing on specific aspects of the project (e.g., data privacy, clinical applications, genetics).
- o **Participants**: Selected stakeholders, subject matter experts.
- o **Timeline**: Every 6 months.

5.3 Final Engagement Phase (Months 36-48)

1. **Project Results Dissemination**
   - o **Objective**: Share final results, highlight project achievements, and discuss future directions.
   - o **Activities**: Final presentation, distribution of project reports, media briefings.
   - o **Participants**: All stakeholders, broader community, media.
   - o **Timeline**: Month 45.
2. **Stakeholder Satisfaction Survey**
   - o **Objective**: Assess stakeholder satisfaction with engagement efforts and project outcomes.
   - o **Activities**: Conduct online surveys, analyse responses, report findings.
   - o **Participants**: All stakeholders.
   - o **Timeline**: Month 42.
3. **Lessons Learned and Future Planning Workshop**
   - o **Objective**: Reflect on the project's successes and challenges, plan for future initiatives.
   - o **Activities**: Interactive workshop, group discussions, future planning sessions.
   - o **Participants**: Key stakeholders, project team.
   - o **Timeline**: Month 46.

By implementing these engagement activities according to the outlined timeline, NextGen will ensure that stakeholders are continuously involved, informed, and able to contribute meaningfully throughout the project. This structured approach will facilitate effective collaboration and enhance the overall success of the project.

6 Feedback Mechanisms for Monitoring and Evaluation

Effective feedback mechanisms for effective monitoring and evaluation of stakeholder engagement are crucial for ensuring that NextGen maintains productive relationships and continuously receives and analyses stakeholder input to act upon throughout its lifecycle. These mechanisms will help identify potential issues early, improve project outcomes, and foster a collaborative and responsive environment. We will send out specific questionnaires to obtain detailed feedback on topics like data privacy, clinical applications, and user experience with the developed tools. We will organise structured feedback sessions (focus groups) when applicable. Online feedback channels will be developed, and an online portal will be established where stakeholders can submit feedback, suggestions, and concerns at any time. This portal will ensure continuous and easy access to feedback mechanisms. A dedicated email address will be set up for stakeholders to provide feedback. This channel will be monitored regularly to ensure timely responses and action.

WP7 will collect, analyse, and synthesise feedback from various stakeholders. In collaboration with WP9, WP7 will ensure that feedback is systematically reviewed and integrated into project planning and implementation. Deliverable 7.5 will report on stakeholder feedback, key findings, and actions taken will be produced and shared with stakeholders to demonstrate how feedback has influenced project decisions and improvements.

Together with WP8 we will monitor and evaluate the stakeholder engagement according to KPIs that will culminate into D7.5 Stakeholder Engagement Progress Report. KPIs for Communication and Dissemination can be found in D8.1. Additional KPIs for stakeholder engagement will include for example number of stakeholders engaged, attendance and participation rates in meetings, webinars/workshops and events and response rates to surveys and feedback requests.

7 Conclusion

The successful development and implementation of NextGen hinge on robust and effective stakeholder engagement. Through the comprehensive Stakeholder Engagement Plan outlined herein, the project aims to ensure that all relevant

stakeholders are actively informed, consulted, represented, collaborated with, and empowered to foster a collaborative environment, ensure transparency, and leverage the expertise and insights of diverse stakeholder groups.

The comprehensive and interdisciplinary approach to stakeholder engagement outlined in this plan is designed to ensure NextGen not only meets its objectives but to serve as a best practice for future initiatives in the field of personalized medicine.

NextGen's Stakeholder Engagement Plan is a strategic and essential component of the overall success of the project. It enables the project to effectively harness the collective expertise and insights of its stakeholders, ultimately leading to innovative solutions and improved health outcomes for patients with cardiovascular disease.