NextGen

Genome-Centric Multimodal

Deliverable 7.2

Sustainability Plan 1

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List of terms and abbreviations

D&C	Dissemination and Communication
GA	Grant Agreement
IPR	Intellectual Property Rights
KER	Key Exploitable Result
KPI	Key Performance Indicator
TRL	Technology Readiness Level
WP	Work Package

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1 Executive Summary

NextGen is an ambitious and complex project that aims to accelerate breakthroughs at the technology, clinical, and platform levels by building novel and synergistic tools to enable portable multimodal, multi-omic, and clinically oriented research in high-impact areas of cardiovascular medicine.

NextGen tools aim to benefit researchers, innovators, and healthcare professionals by identifying and overcoming health data linkage barriers in exemplar use cases that are complex or intractable from existing technology. Consequently, it will benefit patients, providing faster diagnosis and better treatments (including personal medicine.

To materialise those benefits, NextGen has an equally ambitious plan for the exploitation and sustainability of its results. It aims to overcome many of the traditional pitfalls and barriers to optimising exploitation in collaborative projects. By carefully developing a comprehensive methodology and approach in the early stages, NextGen aims to maximise the impact of the tools and other results in the cardiovascular domain and other domains and markets where relevant.

By breaking down the results into different categories (technology, clinical and platforms) and within these categories, develop tailored approaches, defining results as assets from which value can be created, starting from a high level of granularity and making clear choices and prioritisations, engaging users, customers and a wider stakeholder community throughout the process to better understand needs and expectations (and perceptions) and building solid business cases for the high potential results,.

This document outlines the approach and methodology and provides a clear timeline for the activities in the last 3 years of the project.

2 Introduction

This document is Deliverable 7.2.1, the Sustainability Plan for NextGen. It outlines the goals and strategies for effectively identifying and assessing the exploitation potential of the various assets developed by NextGen.

The overall objective of NextGen is "to build novel and synergistic tools to enable portable multimodal, multi-omic and clinically oriented research in high-impact areas or cardiovascular medicine". The project results will thus be tools (research portability tools, open-source tools, a data analytics platform), the eight clinical use cases and a NextGen 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 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 personalised 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.

2.1 Structure of the Deliverable

In the next chapter, we describe the identification of the overall approach to sustainability and exploitation. Chapter 4 deals with the approach used to design methods and tools to develop the sustainability plan. Chapter 5 then sketches a timeline, and Chapter 6 summarises the main conclusions.

This Deliverable is iterative, as the plan is subject to change based on technology and market developments and opportunities that may arise during the project or results such as (un)successful outcomes or lessons learned to be shared deviate from the original plan—our iterative approach to sustainability planning accounts for these changes.

2.2 Place of the Deliverable in the project

The deliverable is part of WP7 Broader Engagement & Exploitation, specifically task 7.3, Open Science and Sustainability-Driven Exploitation.
The work brings together results and data from most of the NextGen WPs.
It is strongly related to the other tasks of WP7, such as stakeholder engagement (7.1 and 7.2) and Cost-Benefit Analysis (7.4), and feeds into task 7.5, Towards a sustainable NextGen.
The Work builds upon the work done by the clinical pilot partners (WP4, including the assessment of the software as a medical device), the technological development (partners) WP1 (Data Management tools), 2 (Infrastructure and platform) and 3 (integration and analytical tools). It considers the sustainability of results from WP 5 (The Pathfinder) and uses the results of WP 6 (ethics and Regulation) for potential barriers.

The first version of this deliverable D7.2.1 outlines the approach and methodology.

3 Overall approach and starting point

3.1 Overall approach and considerations

Successful exploitation and sustainability of results often prove difficult in Framework Programme collaborative projects such as NextGen. Although the last years and programmes have seen some improvement (partially due to the higher emphasis on exploitation to generate the expected impacts, not in the least through the Impact Pathways and the Key Exploitable Results, as well as initiatives such as the Innovation Radar) there are still significant limitations.

The reasons are manifold, and experiences, several studies and analyses over the past decades have pointed to key factors that hamper the real exploitation of project results, such as:

Issue	Description	NextGen approach
Motivation	If a project does not have the explicit motivation to exploit at the start, the chances of exploitation are negligible; as many projects are research-driven, this explicit motivation is often absent.	NextGen has been aware of the need to focus on the exploitation and sustainability of results, for which a dedicated WP has been established
Timing	Many projects start working on the exploitation potential towards the end, which is often too late to make the results exploitable.	The preparatory work has already started in the first year and will be gradually building up towards the end of the project.
Scope	Most technologies are developed and tested for project purposes, and the application in the project context only often limits their validation and broader validity;	The primary goal is to develop and test the results in the NextGen context. However, by starting to analyse other exploitation potentials (especially of the technical assets) and engaging potential users and customers at an early stage, NextGen aims to extend its scope to other potential domains and markets.
TRL	Many of the technological results reach relatively low TRLs (especially in RIA's) at the end of the project, and further investment is needed to bring them closer to commercial or operational application. The projects often do not provide a convincing business case for such investment;	The relatively low TRL cannot be overcome in the project. Through its approach and quantification of costs and benefits, NextGen aims to develop convincing business cases for further development and investment, both public and private,
Markets	Market analyses are often done superficially (if at all), thereby insufficiently exploring the exploitation potential. Moreover, the results' value proposition, benefits and positioning are often poorly elaborated	By breaking down the assets into individual technologies, a more comprehensive and accurate market analysis can be done, By carefully assessing and

		prioritising NextGen will focus on the highest potential assets.
IPR	Ownership of background and foreground results (IPR) can stand in the way of direct exploitation, and especially foreground exploitation of jointly developed results causes significant complexity;	The consortium agreement and clarity of ownership will create transparent ownership of individual assets. For the project-wide results part of the work in WP7 will be to develop an equitable and feasible exploitation approach.
Business case	The Open Source nature of developments (while understandable from a policy point of view) can make the development of a solid business case difficult;	While all immediate results of NextGen are Open Source, part of the analyses will be on the feasibility of developing business versions.
Granularity of results	The exploitation of the main (combined) results of a project is often difficult, both from an organisational point of view (who will drive it, what are the roles and benefits of the other partners, is a new organisation required, etc), from a technological point of view (for instance not all technologies are sufficiently mature, competing technologies have developed etc), a legal point of view (as mentioned the ownership rights) and a business point of view (how can this be done sustainably, guaranteeing sufficient revenue);	NextGen breaks down the results and assets in different types and within those in different specific products or services. This way it is more feasible to develop clear exploitation or sustainability paths at a granular level.

The above list contains examples and is not exhaustive, but it does indicate some flaws that can and will be (at least partially) addressed by NextGen to maximise the exploitation potential.

3.2 Exploitation and Sustainability: creating value

NextGen's overall approach requires some further explanation. When discussing exploitation, we mean using and applying results beyond the project duration. Exploitation is thus not limited to commercial exploitation but includes any form of use and further development. We, therefore, use the term 'value creation' to indicate that exploitation can have many different forms and that the key driver for exploitability is the viability of the result and the value it brings or can bring.

Many of the results produced (delivered within the project) are not directly suitable for exploitation. NextGen will, therefore, identify which of the results or part of the results can be considered assets (stand-alone developments) and where and how they can create value. We use a simple definition:

"An asset is an item of value to stakeholders. An asset may be tangible (e.g., a physical item such as hardware, firmware, computing platform, network device, or other technology component) or intangible (e.g., humans, data, information, software, capability, function, service, trademark, copyright, patent, intellectual property, image, or reputation)." [1]

3.3 Key Exploitable Results (KERs), types of exploitable results and granularity

In the NextGen proposal, we have identified several KERs and sketched an initial path towards exploitation. These KERs will serve as the starting point and drive the exploitation planning.

Key exploitable results (KERs)	Exploitation options (EO) & potential users (PU)
Personalised medicine algorithms for predicting, preventing, diagnosing, monitoring, and treating cardiovascular disease using multi-omic, multimodal data.	**Main partners to exploit**: Relevant clinical partner PU: Researchers, healthcare providers EO: Software as a medical device IPR Strategy: Restricted
Multimodal integration tooling	Main partners to exploit: HCF **PU**: Researchers and innovators **EO**: Open-source & Software as a service **IPR Strategy**: Open Standards and Restricted.
Open-source vendor-agnostic software for hardware-accelerated secondary and tertiary genomic data analysis.	**Main partners to exploit**: EURE **PU**: Researchers and innovators **EO**: Open-source software **IPR Strategy**: Open access
Dataspace services and tools	Main partners to exploit: HIRO **PU**: International Data Space Association, EHDS **EO:** Open Source with implementation support services **IPR Strategy**: Contributors License Agreement (CLA)

To simplify and structure our approach, the results can be broken down into the following categories of types of results that will be analysed in different ways:

1) (Individual) technological developments (data-oriented architecture and tools, AI/ML technologies, hardware accelerator)
2) Clinical developments (based on the eight NextGen clinical use cases)
3) Project-wide combined results (NextGen dataspace, pathfinder, platform etc).

In addition (particularly for the technological results), we will start from a high level of granularity, assessing the technologies at the individual level and in combined packages. Section 4 elaborates on this further.

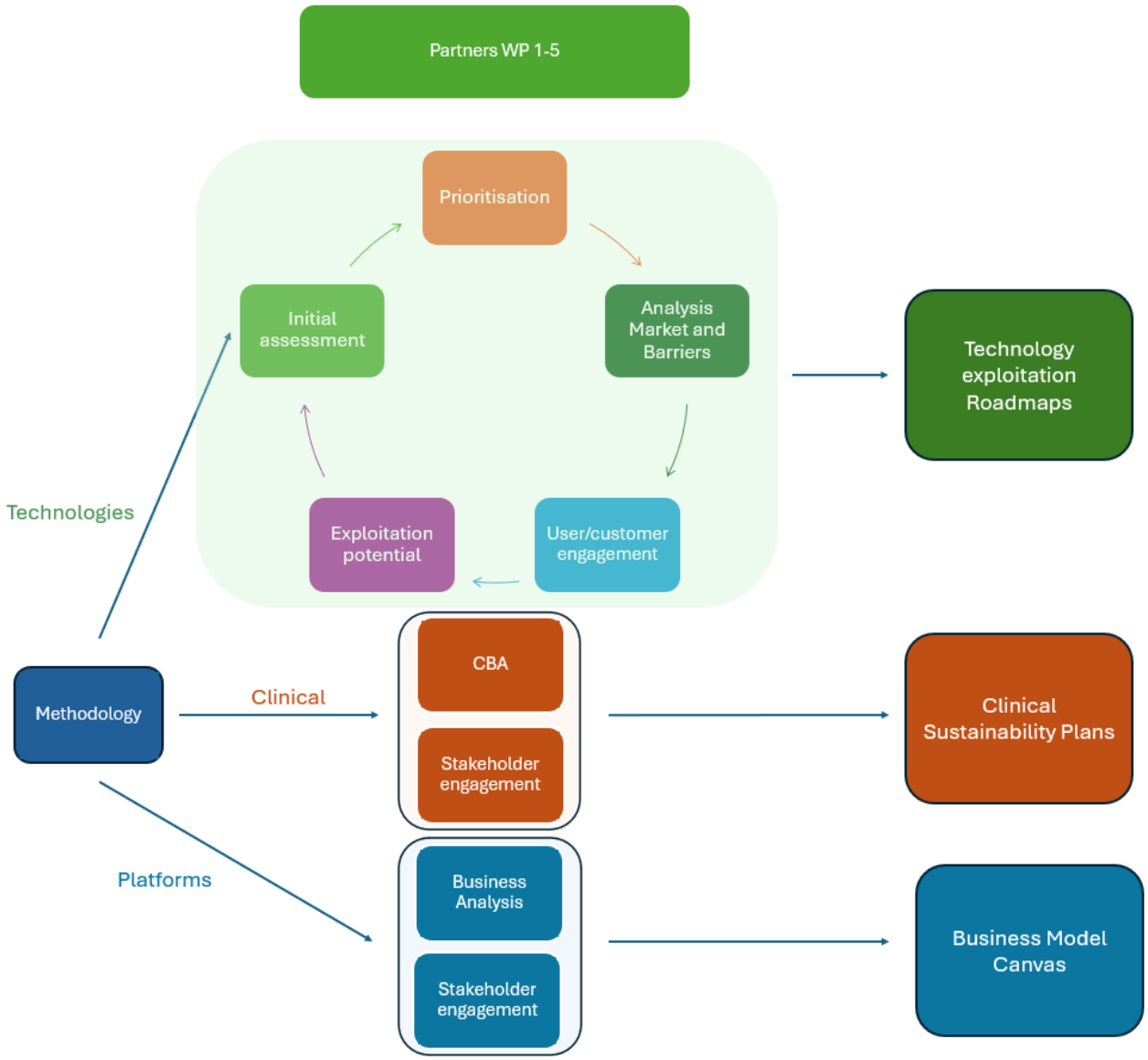
3.4 Iterative and progressive approach

NextGen technology exploitation will go through annual cycles, each time assessing the validity of earlier findings, to finally provide the inputs to the technology exploitation plans of selected technologies (task 7.5).

Clinical sustainability will be progressive as insights and information increase. It will include a CBA and wide stakeholder engagement and result in a sustainability plan, while the project-wide results (platforms etc) will be analysed on different aspects, and result in a Business Model Canvas.

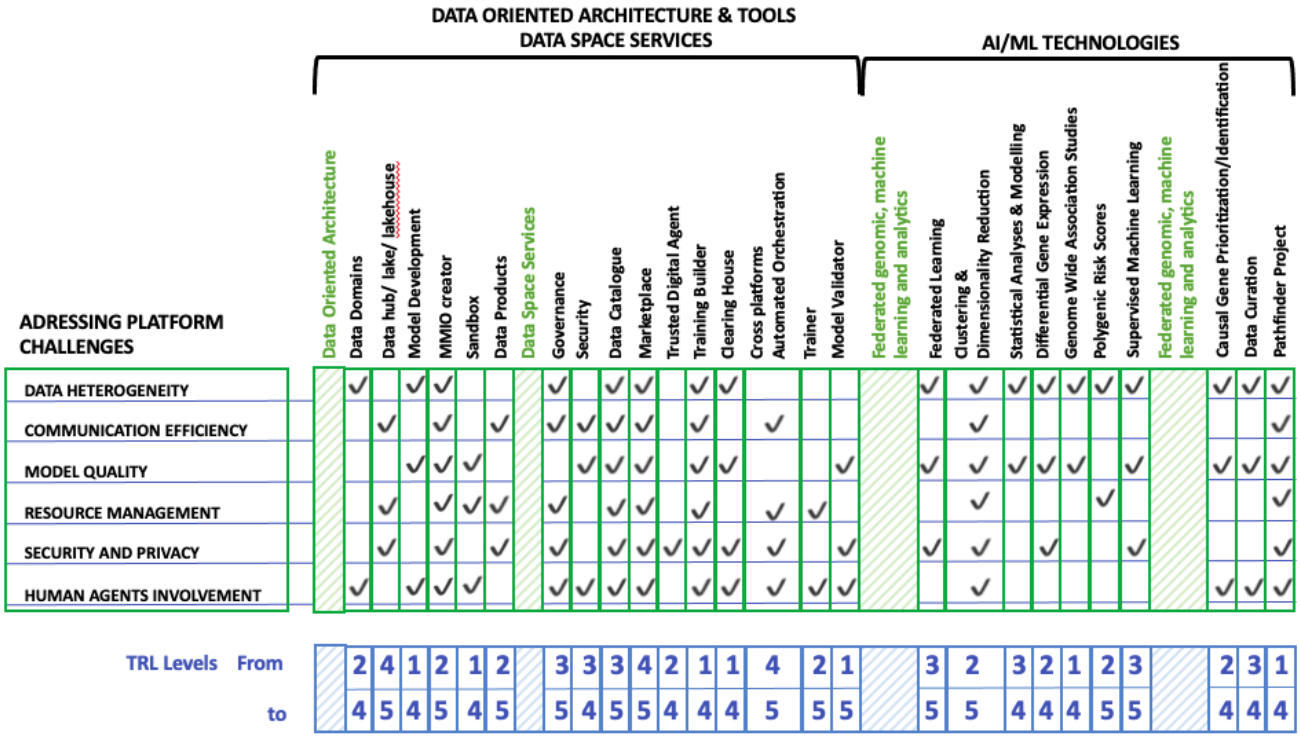
[1] NIST SP 800-160 Vol. 2 Rev. 1

The process is displayed in the image below, and further elaborated in the next Chapter.



4 Methodology of the exploitation/sustainability planning and strategy

4.1 Identifying and assessing potential technological assets



4.1.1 First stage screening

This stage (which will be repeated annually) will identify the results that can be considered exploitable assets. The key elements are laid out in the table below.

Technology:		
End Maturity:	Nature (Open source/proprietary)	Owner
Short description		
Market potential within and beyond the project domain (including potential applications and customers, estimates for market volume, competing technologies/products/services)		
Estimation of volume of work and investment required to reach market maturity		
Asset Potential (The result of the quick screening classifies results into three categories: high, medium and low potential)		

All results will undergo screening three times. The classification may change over the years as markets develop; setbacks or unexpected developments (technology, performance, etc.) will impact the potential of the assets.

4.1.2 Prioritisation

The assets classified as high potential will be analysed in depth (see next section); the medium potential assets will be further discussed if there are reasons for in-depth analysis. Reasons can include high market volume, low additional investment, strategic relevance for the owner etc. Low potentials will not be considered for further analysis.

4.1.3 In-depth analysis

Technology:		
End Maturity:	Nature (Open source/proprietary)	Owner
Short description		
Primary use/application in NextGen		
Potential use in other domains		
Markets related to the identified domains (short description of the markets, needs, barriers and challenges, and potential customers)		
Market analyses (detailed description of the markets including market size, market typology and dynamics, competing products/services, competitors, and pricing)		
Market/Technology Requirements/development and investment needs (what TRL and further development is required to enter the markets? This includes potential combination/embedding with other technologies.		
Market value proposition		

Asset potential (assessment based on the above including strategic relevance and investment capacity, time to market, prioritisation of target markets and segments, identification of key and representative potential customers and interviews with some of these to better understand needs and expectations and how far the asset meets those)

4.1.4 Exploitation Roadmap

In the final year of NextGen, a roadmap will be developed for each asset considered to have high exploitation potential.

The roadmap will describe the following elements:

- **Goal:** describing the final envisaged exploitation result
- **Actions:** describing the needed and planned actions to be executed up to 12 months after the end of the project (technical, business planning, intellectual property, agreements, licenses etc)
- **Roles:** if relevant, roles of the other partners within and outside the project consortium, who will do what
- **Milestones and KPIs**
- **Financial costs and needs**: costs/investments needed to bridge the end of the project to the next steps planned and increase TRL or go to market (you may invest in a patent, in the realisation of a prototype, etc.).
- **Direct Revenues:** expected revenues from, for instance, licensing or service provision or sale of devices. Revenues generate the cash flow that will make the use of the result sustainable over time (provide an estimation concerning the first year and what is expected after 3 years, if possible). Estimate the revenues according to early adopters and potential customers.
- **Other Revenue Sources:** Financial resources needed to cover costs incurred before collecting the first revenues (during the "time to market"—see costs) and their sources. Sources can be partners` budgets, other project grants, national/regional incentives, risk capital, loans, etc. Make sure to obtain them at the right time.
- **Longer term impact:** measurable changes in terms of growth/benefits for the organisation and society at large (if relevant), 3-5 year horizon.

4.2 Assessing the sustainability of clinical results

The clinical results come from the eight use cases. These will be analysed on various aspects, such as the usability and purposefulness of the application and approach, the quality of the clinical results, the investment costs (both in financial terms and in terms of adoption costs, such as training, embedding in existing practices and systems, operational costs etc) as well as the benefits such as patient aspects (life expectancy, quality of life etc), clinical benefits (such as higher accuracy and effectiveness of diagnoses and treatment, increased capacity, patient trust, etc) and economic benefits (such as reduced overall costs, better and more efficient use of resources, etc).

The following approach will be followed:

1) A zero measurement (baseline): capturing the key aspects without using the NextGen tools and approaches.
2) Data specification and collection from the use case owners;

3) A tailored cost-benefit analysis (CBA) will be carried out in task 7.3.
4) A comparative analysis between the zero measurement and the CBA
5) Interviews with clinical specialists and patients (where possible) to capture qualitative dimensions and put the quantitative findings in a qualitative perspective.
6) A gap analysis between the final and required results is needed to understand which steps and developments are needed for adopting NextGen tools and approaches in daily practice. This will be followed by a viability assessment of each use case solution and a selection of the most viable cases.
7) A pathway towards adopting the most viable cases (similar to the roadmap above).
8) A wider use and uptake plan.

Key elements (and potential barriers) in our clinical sustainability planning are of a non-technical or clinical nature, such as specific regulatory requirements (in particular, the medical device regulation)[2], ethical aspects, data and process integrity and security, GDPR etc. These are partially analysed in WP6 and partially in WP7.

4.3 Identifying and assessing Project-wide results

NextGen will produce three project-wide results that can be exploited (for profit) or sustained (not for profit):

1) **NextGen Dataspace:** an interoperable, cross-organization framework for secure and trusted data usage: in short, a dataspace as laid out by the EHDS proposal
2) **Pathfinder:** pilot demonstrating joint data governance, decentralised authentication and semantics (etc), project tools over a network of sites and representing a functional implementation of core EHDS specifications.
3) **NextGen data analytics platform:** advanced federated search and catalogue functionality and allowing deployment of artificial intelligence and genomic algorithms.

These will be analysed along the following lines to understand their potential:

- Market description and potential (profit or non-profit), competitors
- User and customer segments
- Requirements/investment for deployment
- Revenue model for exploitation or sustainability
- Organisational structure

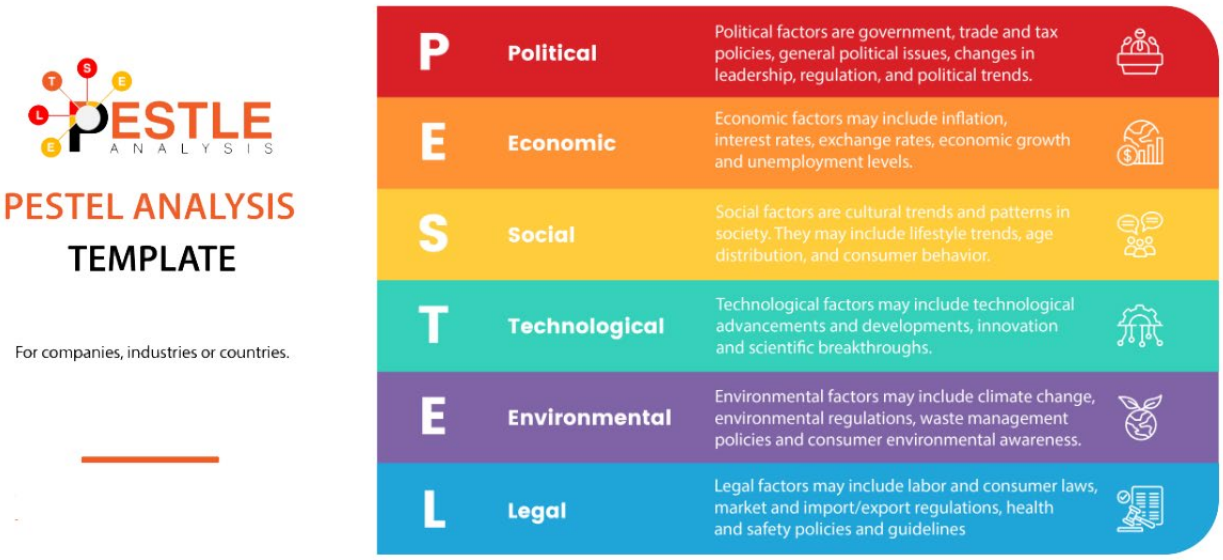
The analysis will result in a fully developed Business Model Canvas (see below) for each prioritised project-wide result.

4.4 Opportunities, Barriers and Challenges

We will conduct a PESTLE analysis to identify how different external factors can or will influence the exploitation potential. This will be particularly relevant for assessing clinical results but can also be applied, where appropriate, to the technological and project-wide assets.

A PESTLE analysis identifies and evaluates how Political, Economic, Social, Technological, Legal, and Environmental factors impact business operations. The strategic planning framework will help the NextGen consortium make its exploitation decisions.

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32017R0745



4.5 Tools

4.5.1 Cost Benefit Analysis (CBA) and data collection

The analysis will be a tailored combination of elements of a CBA and elements of a Cost-effectiveness Analysis (CEA) carried out in task 7.4. It will be based on a broad literature review of CBA and CEA for clinical pilots.

The CBA will include non-health benefits and costs:

- cost savings (financial benefits)
- productivity gains (indirect benefits)
- wellbeing and convenience (intangible benefits)

The CEA will include the health benefits of the methods in the pilots:

- clinical measures – cardiovascular events
- disease-specific quality of life (QoL) measures, HeartQoL
- more generic measures of health – symptom-free days

The data will be defined in task 7.4 and collected by the clinical pilot partners.
In addition to the health analysis, wider concepts and methods for analysing CBA/CEA AI tools will be applied where relevant and feasible.

4.5.2 Business Model Canvas

Where appropriate, we base our business model on Alex Osterwalder's Business Model Canvas. We will use the BMC, particularly to exploit project-wide results, but we will develop additional BMCs where the need is expressed.

This Model Canvas provides an organised way to design the assumptions about the key partners, key resources and key activities of the value chain, as well as the value proposition, customer relationships, channels, customer segments, cost structures, and revenue streams.

The canvas is divided into nine building blocks, each representing a key plan aspect.

Key Partners	Key activities	Unique Value	Customer	Customer

		Proposition	relations	segment
	Key resources		Channels	
Cost structure		Revenue streams		

The Business Model Canvas focuses on three things: the left side concentrates on the business (internal focus), the right side concentrates on customers (external focus), and the middle is the exchange of value between the two other parts (business and customer), which is the value proposition.

Below are all the descriptions of the Business Model Canvas sections:

- Customer segments: These help identify the different groups of customers that the business serves; they represent the main target.
- Value proposition: Describes the set of elements and characteristics in service of a product with a distinctive value that the business offers to its customers.
- Channels: Identifies the different avenues through which the business interacts with its customers and becomes part of the sales cycle.
- Customer relationships: This section describes the business's different relationships with its customers. It highlights the points of engagement between the company and the customer.
- Revenue streams: Identifies the business's different sources of financial gain.
- Key resources: Identifies the key resources (e.g. physical, intellectual property, human, financial) the business needs to operate.
- Key activities: Identifies the key actions that the business undertakes to deliver its value proposition to the client.
- Key partners: Identifies the key partners (external companies) with whom the business may collaborate to deliver its value proposition to the client.
- Cost structure: Identifies the key costs of operating a business.

This business model approach is a preliminary version that will be integrated with the outcomes from the detailed analyses, including a market analysis as described above.

4.5.3 Qualitative analysis: Interviews and focus groups

A key element is acquiring relevant information is more qualitative. Engagement of users (including medical), customers and patients will enable the team to gain deeper insights into the perception of elements of the work (for instance, the trust from patients and doctors, (perceived) effectiveness and efficiency etc) but also give direction of the needs and requirements of potential customers (especially related to the developed technologies in different markets).

The following broad categories of target stakeholders have been identified:

Target Group	Results
Healthcare professionals	Clinical results, platforms
Healthcare authorities, agencies, insurers	Clinical results, platforms
Patients	Clinical results
Clinical researchers	Clinical results, platforms, technologies
Technology and data researchers	Technologies, platforms
Technology and data customers	Technologies, platforms
Technology integrators, developers	Technologies

Small but representative samples in each target group will be interviewed semi-structured. These will be identified together with the relevant project partners. For each target group, an interview protocol will be developed with the key questions to be answered. Interviews are scheduled to take less than 30 minutes. In the final year of NextGen, an online focus group will be organised for each of the target groups to validate the results.

4.5.4 Wider stakeholder engagement

Wider stakeholder engagement will be established in close collaboration with WP 8. Presentations, news items, and workshops are foreseen to create awareness of exploitation and sustainability planning and attract interest while generating feedback and input.

5 Sustainability Planning and timing