

**INTELCOMP PROJECT
A COMPETITIVE INTELLIGENCE
CLOUD/HPC PLATFORM FOR AI-BASED
STI POLICY MAKING**

Report on the needs of Science, Technology and Innovation policy in the three pilot domains: Artificial Intelligence, Climate Change/Blue Economy and Health/Cancer

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ACRONYMS

AI – Artificial Intelligence

DG RTD – European Commission Directorate-General Research & Innovation

DG Sante – European Commission Directorate-General for Health and Food Safety

EBCP – Europe’s Beating Cancer Plan

EC – European Commission

ECIS – European Cancer Information System

EDIH – European Digital Innovation Hub

EIC – European Innovation Council

EIT – European Institute of Innovation and Technology

EOSC – European Open Science Cloud

ERA – European Research Area

EU – European Union

HE – Horizon Europe

ICT – Information and communications technology

(I)ML – (Interactive) Machine Learning

JRC – Joint Research Centre

MSCA – Marie Skłodowska-Curie Actions

OECD – Organisation for Economic Co-operation and Development

PATSTAT – Worldwide Patent Statistical Database

R & D – Research & Development

SDG – Sustainable Development Goal

SME – Small and Medium-sized Enterprises

STI – Science, Technology and Innovation

TEF – Testing and Experimentation facilities

TRL – Technology Readiness Level

UN – United Nations

UNCAN – European Initiative to Understand Cancer

EXECUTIVE SUMMARY

The IntelComp project is a Horizon 2020 Innovation Action to build a platform that will be able to analyze large volumes of textual data using Artificial Intelligence (AI) services. The IntelComp platform is designed to assist Public Administrations along the whole Science, Technology and Innovation (STI) policy-cycle. It will also assist all relevant stakeholders of STI policy (academia, industry and citizens) to co-create policies in the three specific domains where the platform will be tested: AI, climate change and health.

This document provides a framework of STI policy for the IntelComp project, based on an analysis of the policy needs in each of the project domains.

A brief review of the theory of innovation is used to help identify the notions modern policy making needs to address. The main lessons from the innovation system literature suggest that information infrastructures need to be conceived to capture the elements of diversity of the system. We need to reflect the role of the different actors in an innovation system, and the taxonomies of innovation.

To make the conceptual framework sufficiently practical to frame questions relevant for policy makers, we select a structure that is both user-friendly and responds to actual needs. The structure combines two dimensions:

- The function within an innovation system that policy makers wish to address

- The stage of the policy cycle when they formulate the question, following the simplistic five stage approach.

By applying this logic we have designed 160 questions which are domain agnostic. We include in these questions all the components and taxonomies of an innovation system. To validate the relevance of the questions and get a sense of the STI priorities for which the current information is perceived to be insufficient, a limited number of interviews were conducted. It is worthwhile noting that the majority of policy questions are perceived to be relevant by STI policy makers.

Finally, to attain a more focused and domain-specific list of policy questions reflecting the needs of the respective actors, we enrich the generic STI policy framework by:

- Identifying domain-specific needs and barriers via three consultation workshops, with a focus on agenda setting and evaluation, which represent the two policy stages most closely linked to the IntelComp platform.
- Providing a summary of the domain-specific policy and regulatory contexts, through desk research, covering the following components per domain: 1) Vision, policies / strategies and their operational objectives; 2) Targets; 3) Main pieces of regulation; 4) Roadmaps and corresponding monitoring frameworks (accounting for the operational objectives, policy outcomes and measurement of outputs) and 5) Enabling conditions (including indicators and the measurement type when available).

1. INTRODUCTION

The **IntelComp project** is a Horizon 2020 Innovation Action to build a platform that will be able to analyze large volumes of textual data, varying from government open data to open access scholarly works (e.g. OpenAIRE Research Graph) using Artificial Intelligence (AI) services. The IntelComp platform is designed to assist Public Administrations and policymakers along the whole Science, Technology and Innovation (STI) policy-cycle: agenda setting, policy formulation, policy adoption, implementation, monitoring and evaluation. It will also assist all relevant stakeholders of STI policy (academia, industry and citizens) to co-create policies in the three specific domains where the platform will be tested: AI, climate change and health.

This document provides a framework of STI policy for the IntelComp project, based on an analysis of the policy needs in each of the project domains. Our analysis is based on a Public Administration and stakeholder consultation, and on a summary of the policy and regulatory contexts in each domain.

More specifically, we develop and use a generic (domain-agnostic) STI policy framework. To attain a more focused and domain-specific list of policy questions reflecting the needs of the respective actors, we enrich it by:

- Identifying domain-specific needs and barriers via three consultation workshops.
- Providing a summary of the domain-specific policy and regulatory contexts, through desk research.

This framework of STI policy is just the first step in the process of involving users to develop the IntelComp platform. The cultural dimension, acceptance and fluency of policy makers and stakeholders are also important dimensions to take into account in that process. Training and support to policy makers and stakeholders are then crucial to give them the opportunity to explore and think out of the box and away from traditional reflection paths in STI policy.

Ultimately, this document shall serve the purpose to assist Public Administrations -the main target group of the project- and stakeholders, by offering a framework of STI policy for strengthening their data analysis competences.

The structure of this document is the following: the next section provides a review of the theoretical strands associated to the IntelComp framework: the functions of the innovation system' approach and the policy cycle model. Section 3 provides a widely encompassing list of domain-agnostic policy questions that IntelComp could aim to address. Finally, a preliminary overview of STI policy needs in the three domains (AI, climate change and health) is presented in Section 4.

2. INTELCOMP CONCEPTUAL UNDERPINNINGS

Evidence-based STI policy needs solid conceptual underpinnings. A brief review of the theory of innovation is used to help identify the notions modern policy making needs to address (section 2.1). This led to the selected conceptual underpinnings of the IntelComp project itself (section 2.2).

2.1 Conceptual underpinnings from the literature

2.1.1 Basic theoretical models: from exogenous to linear to systemic

The decision on what is relevant evidence and what is not starts with the theoretical model that explicitly or implicitly dominates the minds of policy makers. We can distinguish three periods of modelling:

- A. An initial idea that technological progress was exogenous and changes occurred rapidly, reality being dominated by serendipity. In this case STI policy making is practically irrelevant and economic development worries only about factors of productions and (general or partial) equilibria. This model is outdated and abandoned at least in all developed countries.
- B. A seminal contribution by Arrow (1962) revolutionised economic development policy illustrating the endogeneity of research, productivity growth and social progress. His model was a linear model starting with basic research and ending up with new products and

services leading to growth and development. The value of this model was twofold:

- It shifted the attention of policy makers from exogenous (we rely on good fortune and don't do anything ourselves) to endogenous: we need to intervene.
- It was simple enough to prescribe policy interventions expected to work out effectively without any sophistication or complications for policy makers.

The linear model drew attention to the value of indicators distinguishing between basic research, applied research and development, between inputs and outputs. While every theoretical and policy paper nowadays starts with condemning the linear model, which for many years was the prevailing perspective. It is its simplicity that helped it remain deeply embedded not only in the mindsets of policy makers but also in the academic community, since the policy implication is that the externalities justify the intervention at the early stage of the line. **Although theoretically outdated, the implicit persistence of the linear model in some policy mindsets calls for basic indicators to be systematically monitored.**

- C. Science policy research suggested that although there are important merits in this model, its approach oversimplifies reality. After Arrow, scholars (Rip, 1997; Nelson & Winter, 1982; Bijker et al., 1987; Hughes, 1987; Ziman, 2000) emphasised that technological innovation is the result of social and economic processes, and thus not a deterministic

process. The Kline–Rosenberg model (or chain-link model) de-demonised the automatic process following the pivotal value of basic research: based on corporate innovation they showed that new knowledge is not ipso facto the driver for innovation. Instead, the process begins with the identification of an unfilled market need. This drives research and design, then redesign and production, and finally marketing, with complex feedback loops between all the stages. There are also important feedback loops with the organization's and the world's stored base of knowledge, with new basic research conducted or commissioned as necessary, to fill in gaps. **The complexity at corporate level is also a black box that needs to be opened with indicators explaining the process and potential multiplication effects of business innovation investments.**

After that series, research and innovation studies, focused on trying to understand externalities and complex interactions (Freeman, 1988; Porter, 1990; Lundvall, 1992; Edquist & Johnson, 1997), point out the numerous and frequent interactions and feedback processes between users and producers in innovation processes. This led to the rise of a systemic perspective, which starts with two related basic assumptions. **First, innovation is a multi-actor process that depends on the interaction between different actors (Morgan, 1997; De Bresson, 1996). Second, innovation has a systemic character, and is a result of complex interaction between various actors and institutions (Legendijk & Charles, 1999).**

In the past decades several system approaches for studying innovation have evolved. These vary in both physical and geographical limitations; some are technology specific (Carlsson & Stankiewicz, 1991), others focus on regions or nations (Freeman, 1988), and some on industries and technologies (Hughes, 1987). Also the framing of the approaches varies; some are more focused on knowledge diffusion and learning (Lundvall, 1992), whereas others centre on the development of industries and economic benefits (Porter, 1990). These led to the conceptualisation of a wide variety of systemic approaches. The main distinctions are based on the definition of the system:

- **Geographic or spatially delimited systems.** The innovation system literature starts with the national innovation system. It captures the importance of the geo-political and policy aspects of processes of innovation. The interest in geographically delimited systemic analyses is primarily based on political considerations such as international or interregional competitiveness but also in economies of agglomeration derived from the geographical proximity. In addition to the national innovation system, there are also regional innovation systems - which revived with the EU Research and Innovation Smart Specialisation Strategies, or RIS3 strategies. At the end of the 20th century National Innovation Systems were studied extensively (Nelson, 1993; Lundvall, 1992; Edquist, 1997) demonstrating the value of studying actors and interactions rather than research inputs and outputs alone.
- **National research and innovation systems are also facing challenges.** On the one hand the internet has changed the proximity

argumentation from geographical proximity to technological proximity, while at the same time the empirical observation of the emergence of hubs revived the geographical dimension in the notion of innovation and entrepreneurial ecosystems. Innovation ecosystems may be treated both as business networks and as entire communities meant for innovation. They may assume different scale and design, functioning as regional innovation hubs, nation-wide innovation communities, inter-firm networks, very small network-based ad-hoc groups of individuals, or global wide networks (Smorodinskaya et al., 2017). There has also been significant overlap and even an interchange between scholars studying technological advances through both the Innovation Systems and Innovation Ecosystems approaches. Both fields of study are concerned with research, technology development and innovation; the former more at the macro level of institutional structures needed to take advantage of innovations for economic growth, and the latter at the industry or technological innovation level to sustain business growth (Amitrano et al., 2018).

- **Sectorally or technologically delimited systems.** These are delimited to specific technology fields (generic technologies) or product areas (e.g. Malerba & Orsenigo 1996). The technological specific innovation system approach belongs to this category (Edquist & Johnson, 1997). The rationale of this approach is that the system of institutions supporting technical innovation in one field may have very little overlap with the system of institutions supporting another field, even if the same

geographical region is considered (Nelson, 1993). A Technological Innovation System may be defined as: 'a network of agents interacting in the economic/industrial area under a particular institutional infrastructure (...) and involved in the generation, diffusion, and utilization of technology.' (Carlsson & Stankiewicz, 1991)

Independently of the approach selected, the innovation system literature has exhibited the complexity of STI and the analysis of specific systems pointed at the information that can help explain on a case-by-case basis how learning and new knowledge lead (or not) to innovation and productivity growth in a context-specific way.

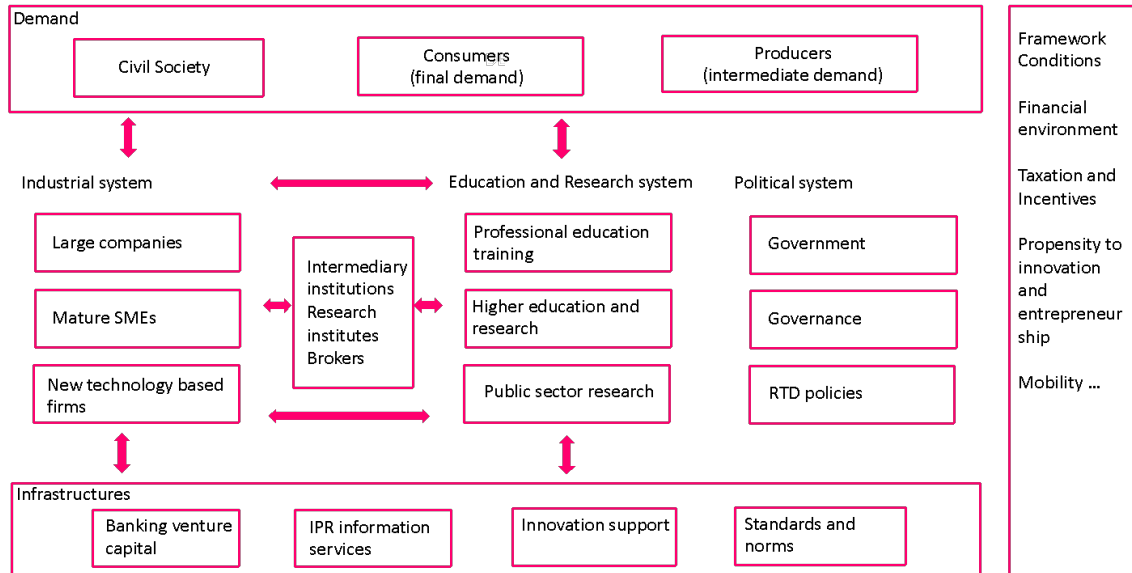
2.1.2 The components and taxonomies of an innovation system

The main lessons from the innovation system literature suggest that information infrastructures need to be conceived to capture the elements of diversity of the system. We need to reflect the existence and role of the following components and taxonomies of an innovation system:

Actors and factors in an innovation system: Arnold & Kuhlmann (Arnold & Kuhlmann, 2001) developed a heuristic tool to analyse and map the actors and/or stakeholders that play a role in innovation processes. This heuristic tool or typology of players gives important insights in the actors (including industrial actors, educational actors, consuming actors, intermediary actors, political and policy/regulatory actors and infrastructural actors) and factors that may shape innovation processes – Figure 1 shows the heuristic map of all actors and factors in

an innovation system. This typology has evolved over the years to include NGOs and most recently civil society as an actor offering legitimacy to STI decisions.

Figure 1. Actors and factors in an innovation system



Source: (Arnold & Kuhlmann, 2001)

Taxonomies of innovation

- *Innovation types by object:* The OECD Oslo Manual (section 3.3.1. Innovation types by object) distinguishes between product and business process innovations (OECD, 2018)

- *Types of innovation according to novelty:* Initial taxonomies started with the distinction between incremental and radical innovations. The former include the adoption of new methodologies such as design thinking, co-creation, rapid prototyping or high-throughput screening. An innovation of this type may just seek to introduce incremental modifications that do not qualify as innovations – e.g. to be able to cater to different customers’ needs – or may seek to bring about product or business process innovations. Conversely radical innovations are considered to transform the status quo, while a disruptive innovation takes root in simple applications in a niche market and then diffuses throughout the market, eventually displacing established competitors (OECD, 2018).

Incremental innovation is the most frequent and less risky. Non-incremental innovation terminology has always been disorganised. The problem is that researchers use several terms to describe a single concept (non-incremental innovation), including: disruptive innovation, radical innovation, nonlinear innovation, discontinuous innovation, breakthrough innovation, paradigm-shifting innovation, revolutionary innovation, really new product, major innovation, boundary expanding innovation, strategic innovation and game changing innovation (Ahmadi, 2018). Disruptive innovations, which are relatively rare, have three main characteristics: they initially provide inferior performance, they are adopted by a market which is currently underserved and they have a steep improvement trajectory (Christensen, 1997).

- *Geographical dimension.* The element of novelty may refer to a company, the regional market, the national market or the global market. The larger the market the higher the impact of an innovation and any public intervention that has supported it.

2.2 The conceptual framework of IntelComp

To make the conceptual framework sufficiently practical to frame questions relevant for policy makers, we select a structure that is both user-friendly and responds to actual needs. The structure combines two dimensions:

- The function within an innovation system that policy makers wish to address
- The stage of the policy cycle when they formulate the question.

These two dimensions are used as a guidance to embed the components and taxonomies of an innovation system analysed above, because our empirical knowledge about them (e.g. global innovations and disruptive innovations being higher risk but, if successful, leading to higher impacts) helps respond to policy questions.

2.2.1 Crucial functions of the innovation system

Academics have tried to make a comprehensive list of functions to be applied when mapping the key activities in innovation systems, and to describe and explain shifts in technology specific innovation systems. We chose to use the functions suggested by the Utrecht and Chalmers universities (Hekkert et al.,

2007) because of the clarity of the functions and their encompassing nature that can help understand the needs of policy makers in detail independent of the domains applied. These functions are:

- **Entrepreneurial activities:** Innovation theory recognizes the presence of active entrepreneurs as a first and prime indication of the performance of an innovation system. A well-functioning system leads to a climate in which entrepreneurial activities blossom and policy makers wish/are expected to create this climate conducive to innovation profiting entrepreneurs, who together will invest and set an ecosystem in motion. Policy questions relate to how to foster an entrepreneurial climate and typical indicators to help capture the relevance, effectiveness and efficiency of policy include e.g. support to industry-financed R&D and human resources.
- **Knowledge development:** New knowledge is the result of the recombination of existing knowledge, hence learning is at the core of knowledge development, which following the Chain-Link model needs to occur throughout the research and innovation process. Three typical indicators to map this function over time are: 1) R&D projects, 2) patents, and 3) investments in R&D, whereas the policy question is how do we perform compared to peers?
- **Knowledge diffusion through networks:** Productivity gains occur through the diffusion of knowledge benefitting society. The trade-off of private and social returns of investment, including in particular appropriability regimes versus facilitating the flow of knowledge is at the core of this function. Policy

makers can offer direct incentives for networking locally, nationally or internationally in an effort to gain synergies from collaboration. However, focus on favouring diffusion that can benefit the territory of the policy making agency versus global diffusion is an issue that divides pure research policy from innovation policy at the service of territorial development. The effectiveness of network building is the core policy question with indicators related to the cost and scope of local and global networks.

- **Guidance of the search:** When various technological options exist, specific foci are chosen for further investments. It represents a selection among a variety of alternatives and this can take the form of selections between or within sectors and/or technologies. The relevant questions here are “who guides”? Incumbent businesses, emerging technological areas or societal needs? And who selects? Are long-term goals more important than expected immediate gains? How risky does policy wish to be? While policy makers may be reluctant to guide out of fear of adverse selection, no guidance (neutrality in support tools) is probably translated into favouring incumbent businesses and technologies.
- **Market formation:** Guidance is particularly difficult at early stages of innovation and TLRs 1-5. Like with infant industry arguments in the 19th and early 20th centuries here it is important to create protected spaces for new technologies. Favourable tax regimes and mandatory standards are policies often used to protect emerging technologies. Public procurement can also be used to help proof of concept, create lead markets and share initial risks.

- **Resources mobilisation:** Financial and human resources are the ingredients of basic input to all activities within the innovation system. For a specific technology, the allocation of sufficient resources is necessary to make knowledge production possible. In this sense, this function can be regarded as an important input to knowledge creation and knowledge diffusion for the creation of absorptive capacity. Policy makers need to know the gaps they can successfully fill in.
- **Creation of legitimacy/counteract resistance to change:** It is increasingly recognised that STI policy is not a matter for researchers (whether in business or academia) only and society has a role to play, not only in the form of Citizen Science but also in the role of interest groups and their lobby actions. These can be benign in the form of society guiding research agendas towards what is perceived as important for its values or less so blocking progress to safeguard vested interests.

2.2.2 Stages of the policy cycle

The intelligence about the functions of the innovation system differs depending on the stage of the policy cycle, and this is why the conceptual framework distinguishes between the information needed in the different stages. The five stages model applied for IntelComp is shown in Figure 2 and further explained below.

Figure 2. Five stages policy cycle model

- **Agenda setting: Definition of the problem(s) to address**

Understand the array of sectoral/technological/institutional potential for a specific future period, determined by internal and external factors

- **Policy formulation: Explore different courses of action**

How can these dimensions be addressed; good practices, positive and negative experiences; rationale

- **Policy adoption: Make a choice**

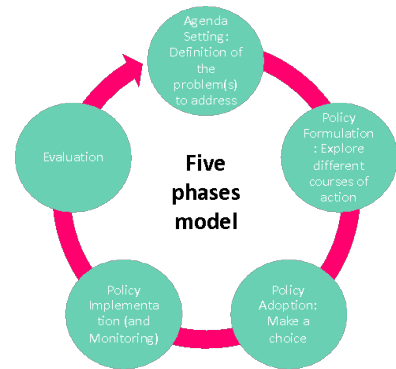
Build an intervention logic to select based on national characteristics and the actions identified in the previous stage

- **Policy Implementation and Monitoring**

Implement efficiently and simultaneously collect all data necessary for corrective action and evaluation

- **Evaluation**

Check coherence, efficiency, effectiveness, value added and impact to help adapt the design of the next cycle



Agenda Setting

At the start of policy making the problem(s) to be addressed need to be defined. Policy makers need information to understand the array of sectoral/technological/institutional potential for a specific future period, determined by internal and external factors. While policy makers may have solid knowledge of the past performance in their area of competence, emerging changes constitute important information to guide them to the next (usually 5-7 years) policy cycle. Policy needs refer to the decision on priorities and budget

allocations. Indicative questions to be answered include: Which are the research/innovation areas for which the country/region has already accumulated knowledge? Which areas are the ones where most disruptive technologies will occur in the next decade? Which are the areas where the highest growth of demand in the global market is expected? Which are the societal challenges the country can contribute to solving? And as a result of the combination of the responses to these questions: Which strategic priorities to adopt?

The information needed is on the current and emerging global societal challenges, the way these challenges are translated into their own context, the way their peers adopt their agendas and the potential of civil society to co-create the agendas but also on opportunities to improve the country's economic benefits in the years to come by identifying sectors or products and technologies with increasing global demand. The outcome can lead to strategic priorities forming R&I Smart Specialisation Strategies as well as lower priority areas to be supported.

Data to respond to this question are partly available open access: strategic documents at the national level or by international organisations, patents and publications/citations in specific technological areas (in absolute figures, growth rates or shares), production and international trade statistics, local or access to research infrastructure. Other sets of data are more costly or difficult to obtain from commercial databases (e.g. Bloomberg, Amadeus) to map the business sector activities in the various areas under consideration.

Policy Formulation

Knowledge is insufficient because policy makers have limited resources and need to explore different courses of action. The policy formulation is based on the agenda but investigates alternative paths. A selection, based on specific criteria will need to be made and then translated into specific policy interventions. Sometimes the policy formulation and subsequent policy adoption are integrated into one stage because of their close connection.

Policy adoption

Once the strategic priorities are adopted agencies need data to decide on an appropriate policy mix. The crucial questions here are: What are the most appropriate ways to intervene in order to meet the societal targets set by the agenda? Which tools have been more efficient / effective or generate the highest impact in the past? Which tools have been more efficient/effective or generating the highest impact in other countries/regions? How and at what cost can national competences be improved to cope with the challenges of the agenda? How can the policy mix be best suited to the principles of Responsible Research and Innovation (RRI)?

Data to respond to these questions will be generated by extracting information on types of potential interventions from policy documents. Classic intervention tools (grants, tax incentives) but also more complex policies like Financial Instruments and Innovative Public Procurement will be addressed to help escape from path-dependencies. Important evidence will be gathered from evaluation studies which

will demonstrate the most efficient interventions in general or in peer countries/regions. These evaluations will help adopt a good intervention logic based on theories validated in these evaluations. The interventions will be scrutinised to see how they can best respond to RRI targets such as gender equality, science literacy, public engagement, open access, ethics. Other specific policies such as environmental priorities can be addressed by using technologies for re-use and recycling etc.

Policy Implementation and real-time monitoring

Policy implementation is a real time activity and is more a stage of tailor-made data generation than reliance on existing data. Procurement processes, project selection, contract signature and project monitoring will generate the data necessary to ex post evaluate projects and programmes. However, while implementing policies a real time monitoring will be necessary for continuous adjustments if necessary. Important questions are: Are there any disruptive technologies appearing in the areas where programmes are launched or about to be launched? Are there any emerging new challenges?

Data for monitoring such real-time changes can be extracted from new patent concentrations and venture-capital investments. Information and administrative data gathered during the implementation process may also be useful.

Evaluation

Based on the data and information generated during implementation systematic evaluations of efficiency, effectiveness and impact of the policy mix implemented are conducted to help update strategies in the next policy cycle. Policy questions become more complex: Were targets met? How can I increase efficiency? How did we perform compared to peers? Which results are attributed to which interventions? Evaluations require significant data to check the intervention logic and run counterfactual evaluations. Data for this can be extracted from company registries and Amadeus-type databases. Combining inputs to respond to these questions have always been a challenge because of lack of data and attribution problems.

3. OUR APPROACH - FROM INNOVATION THEORY TO A PRACTICAL TOOL FOR STI ACTORS

The challenge for a project like IntelComp is to shape the questions that may interest policy makers in any function of the innovation system and in any stage of the policy cycle. Then, we further develop the conceptual framework of IntelComp with an extensive domain-agnostic list of questions that STI policy makers may need answers to. Key questions cannot receive simple answers hence they were subdivided into more concrete partial questions. Finally, we include in these questions all the components and taxonomies of an innovation system described above.

In the end, policy makers need to interpret and understand the information provided by the project. Here, it is important to draw the line (if any) between the data scientist type of profile and the policy maker type of profile inside Public Administrations, and the open question on how to assure deep expertise in both data and policy.

This section starts with an analysis of the dimensions accounted for in the definition of STI policy questions (section 3.1). We have designed 160 questions which are domain, technology and sector agnostic. Section 3.2 details these questions and explains their rationale and resulting concepts. Finally, as this set of questions is just the first step towards identifying the STI policy needs that will be addressed with the IntelComp platform, section 3.3 introduces the criteria to take into account when defining the platform.

3.1 Dimensions accounted for in the definition of STI policy questions

The conceptual basis of IntelComp as explained in section 2 is grounded on the functional delimitation of the innovation system and on the concept of the policy cycle, the simplistic five stage approach. The combination of the two dimensions results in a grid which can be used as the basis for the formulation of STI policy questions. By applying this logic we have designed 160 questions which are domain, technology and sector agnostic (see Figure 3).

The high number of questions does reflect the fact that today's STI policy questions are of obvious complexity. Taking complexity on board will slow down the policy process even more; ignoring it will contribute to missing the targets. Hence, the potential of a platform like IntelComp to be an accelerator or catalyst of information processing, and a contributor in the end to the timely response to those questions.

Figure 3. IntelComp Grid - Domain agnostic STI policy questions

	Phase 1. Agenda setting	Phase 2. Policy formulation	Phase 3. Policy adoption	Phase 4. Policy implementation and monitoring	Phase 5. Evaluation
Function 1. Entrepreneurial activity					
Function 2. Knowledge creation					
Function 3. Knowledge diffusion through networks					
Function 4. Guidance (creating legitimacy for stakeholders, visibility and clarity)					
Function 5. Market formation (create markets through regulation of incentives)					
Function 6. Human and financial Resources mobilisation					
Function 7. Creation of legitimacy for society/counteract resistance to change					

160 questions

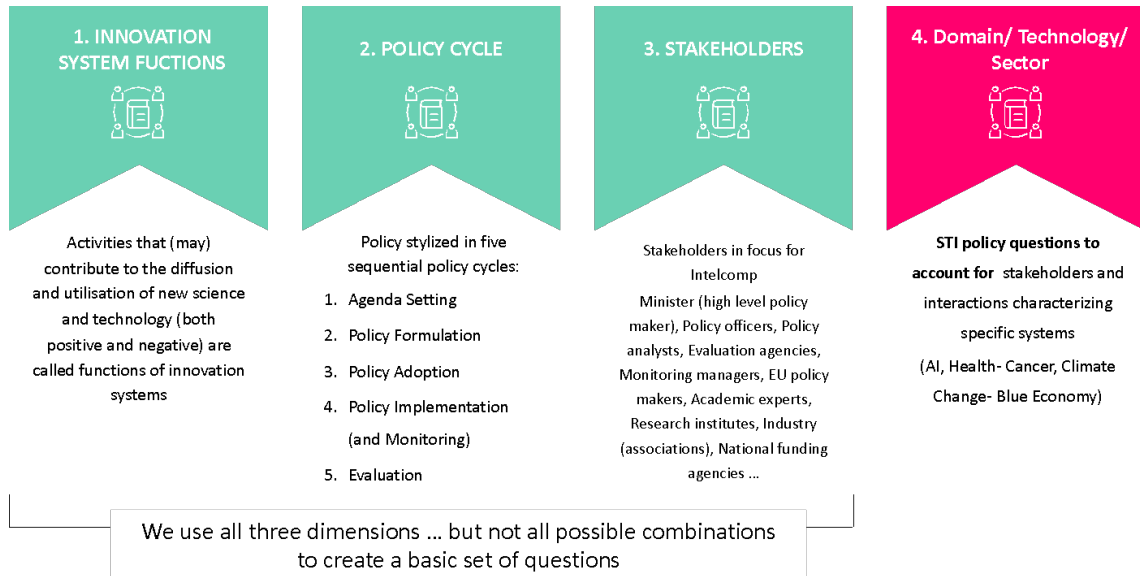
Besides the innovation system functions and the policy cycle stages, we define the questions taking into account the different types of users of the IntelComp platform: the main target group (policy makers), and member of academia, industry and citizen associations.

Moreover, different domains such as climate change, health, circular economy, etc., or technologies such as AI, nanotechnologies, biotechnologies etc., or economic sectors, have different systemic idiosyncrasies and require tailored STI policy questions, data sources and information.

For these reasons the design of policy questions in IntelComp includes both a foundation of domain/technology/sector agnostic STI policy questions and aspires to identify relevant questions in the three domains in focus, AI, Health-Cancer and Climate Change-Blue Economy (see Figure 4).

Finally, a fourth dimension when defining the questions is geography and the differences in relevance and formulation of policy questions between different levels (global, EU, national, macroregional, regional, local).

Figure 4. Dimensions accounted for in the definition of STI policy questions



3.2 Key policy questions, their rationale and resulting concepts

The identification of the basic set of 160 policy questions is the first step towards identifying the STI policy needs that will be addressed with IntelComp. These questions were designed without a specific domain, technology or sector in mind. In the subsequent subsections we formulate policy questions per stage of the policy cycle and function of the innovation system when pertinent (and hence not for all possible combinations).

To validate the relevance of the questions and get a sense of the STI priorities for which the current data is perceived to be insufficient, a limited number of interviews were conducted - in total four interviews were conducted with STI policy makers from four Member States (Cyprus, Finland, Greece and Sweden). While the results only provide signals and are by no means representative of the STI priorities in the EU 27 it is worthwhile noting that the majority of policy questions are perceived to be relevant by STI policy makers.

The policy questions are further complemented with provisional indications of the overarching concepts derived from the policy questions and sources of data.

3.2.1 Agenda setting

The stage of Agenda Setting is about the definition of the problem(s). It implies the understanding of the sectoral/ technological/ institutional potential for a specific future period, determined by internal and external factors. Policy questions in agenda setting cover all seven functions of the innovation system.

Table 1. Agenda Setting – Entrepreneurial activity

Relevant	Very relevant	Highly relevant
Agenda Setting: Intelligence gathering, problem identification		
Function 1 Entrepreneurial activity		
<p><i>Key question: Where should resources be invested (individual companies, sectors, value chains) to support the national innovation system to successfully undertake RDI and compete internationally?</i></p> <p><i>Rationale A: Understand which companies are active in emerging fields (emerging field defined under Knowledge Creation) and likely to excel in the future, this is where you want to invest</i></p> <p><i>Rationale B: Understand where local companies have an RDI specialisation (the answer to these questions will be prepared during the monitoring and evaluation part of the cycle)</i></p>		
Policy questions		Concepts, Sources [provisional]
Are companies adapting to technological transformation trends in their respective sectors? How do they compare with major (international) competitors?		<p>Concepts</p> <ul style="list-style-type: none"> Company RDI activity Company technology uptake Company RDI investment Company RDI funding received
Which companies emerge with specific disruptive technologies in the country/ macroregion/ region/city?		
Are companies emerging with specific disruptive technologies scaling up?		<p>Sources</p> <ul style="list-style-type: none"> Company websites Crunchbase¹/ Dealroom²/ Eutopia³/ Cleantech⁴/ Pitchbook⁵ EU Industrial R&D Investment Scoreboard Community Innovation Survey data
Are scale ups leaving the country/ macroregion/ region/ city?		
Does the country/ macroregion/ region/ city attract entrepreneurial talent?		

1 See: <https://www.crunchbase.com>

2 See: <https://dealroom.co>

3 See: <https://www.eutopiagreen.com>

4 See: <https://www.cleantech.com>

5 See

Who are the persistent innovators in the country/ macroregion/ region/ city?	Incubator, Accelerator, Investment angels websites Companies issuing Initial Public Offering (IPOs) Mergers & Acquisitions (Zephyr, Crunchbase, etc.)
In which R&D fields do the persistent innovators invest?	
In which R&D fields is the highest share of all company R&D investments?	
In which R&D fields is the country improving its revealed comparative advantage?	

Table 2. Agenda Setting – Knowledge creation

Relevant	Very relevant	Highly relevant
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Agenda Setting: Intelligence gathering, problem identification	
Function 2 Knowledge creation	
<p><i>Key question: In which fields is new knowledge coming up?</i></p> <p><i>Rationale: Does it make sense to support national research in the new fields of knowledge likely to make breakthroughs?</i></p>	
Policy questions	Concepts, Sources [provisional]
Which scientific fields demonstrate the highest growth in terms of publications/citations globally? Distinction to be made between basic and applied research (distinction between interdisciplinary publications, basic research and applied research)	<p>Concepts</p> <ul style="list-style-type: none"> Scientific outputs Scientific institutions Scientific teams
Which are the emerging interdisciplinary fields globally?	<p>Sources</p> <ul style="list-style-type: none"> Elsevier, Web of Science OpenAire FP1 – FP7, Horizon 2020, Horizon Europe
Which are the research teams in the country undertaking research in these fields?	
Which are the research teams in the country that might be successful if guided towards these research areas?	

Table 3. Agenda Setting – Knowledge diffusion through networks

Relevant	Very relevant	Highly relevant
Agenda Setting: Intelligence gathering, problem identification		
Function 3. Knowledge diffusion through networks		
<i>Key question: Does the diffusion function work well in the country?</i>		
<i>Rationale: Understand the mechanisms of knowledge diffusion</i>		
Policy questions		Concepts, Sources [provisional]
Which knowledge diffusion channels work best in good practices per discipline at national level?		<p>Concepts Diffusion channels: Foreign Direct Investment (flows and investments inwards and outwards), Trade, Human capital, Patent rights etc. Collaboration: research, technology</p> <p>Sources UN Comtrade Patstat, Elsevier, Web of Science, OpenAire, FP1 – FP7, Horizon 2020, Horizon Europe OECD International direct investment database and World Bank (International Monetary Fund, Balance of Payments database) Orbis Bureau van Dijk National data</p>
Which diffusion channels work best per discipline internationally?		
Which networks e.g., clusters, hubs, intermediaries operate nationally per discipline?		
What are themes in common between the actors of the ecosystem? What are observed concentration patterns?		
Are actors of the ecosystem collaborating? What are forms of collaboration?		
What are the cross sectoral or cross technological collaborations occurring and among which actors?		

Table 4. Agenda Setting – Guidance

Relevant	Very relevant	Highly relevant
Agenda Setting: Intelligence gathering, problem identification		
Function 4. Guidance		
<i>Key question: Which are the current societal priorities expecting research to provide results?</i>		
<i>Rationale: Understand global and own priorities, capture momentum in terms of EU financing priorities</i>		
Policy questions		Concepts, Sources [provisional]
To which global, EU societal challenges are research groups contributing to?	Concepts Scientific/ Technology outputs per SDG or domain specific societal challenge	
Are there specific national/macroregional societal challenges?	Sources Elsevier, Web of Science, OpenAire, FPI – FP7, Horizon 2020, Horizon Europe Patstat	

Table 5. Agenda Setting – Market formation

Relevant	Very relevant	Highly relevant
Agenda Setting: Intelligence gathering, problem identification		
Function 5. Market formation		
<i>Key question: What are the appropriate tools to form new markets?</i>		
<i>Rationale: Find the most appropriate tools to help form lead markets</i>		

Policy questions	Concepts, Sources [provisional]
What is the content of policy papers for new markets for emerging technologies?	<p>Concepts Supply and demand Technology markets (identification/ formation)</p> <p>Sources Policy documents Public procurement websites Incubators/Accelerators/Investment Angels</p>
Which are the markets for emerging technologies?	
What is the regulation globally for these technologies?	
What is the role of public procurement for these technologies (theoretically/ practically)?	

Table 6. Agenda Setting – Resources mobilization

Relevant	Very relevant	Highly relevant
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Agenda Setting: Intelligence gathering, problem identification	
Function 6. Resources mobilisation	
<p><i>Key question: What are the resources needed and how can they be obtained?</i> <i>Rationale: Find out what is needed and how national resources can be mobilised</i></p>	
Policy questions	Concepts, Sources [provisional]
What are the national/regional financial resources available in the country? Are they used to leverage EU funding through synergies?	<p>Concepts National STI funding, EU STI funding, EIB funding, Private Funding, Skills Supply, Skills demand</p> <p>Sources National grants, EU grants, loans, venture capital, tax incentives etc.</p>
Which financial resources were most effectively used in the previous cycle (evidence from the evaluation part of the cycle)?	
What is the size of resources needed to become competitive in each emerging technology?	
What type of resources can be mobilised outside the national public funding (EU, foundations)?	

For which technologies are companies successfully attracting private funding?	Online job adverts Online trainings (e.g., MOOC, coursera) University websites (curricula) LinkedIn
Is there sufficient tech talent supply?	
Is there sufficient tech talent demand?	
Is there a gap between supply and demand?	

Table 7. Agenda Setting – Creation of legitimacy/counteract resistance to change

Relevant	Very relevant	Highly relevant
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Agenda Setting: Intelligence gathering, problem identification	
Function 7. Creation of legitimacy/counteract resistance to change	
<i>Key question: What is the opinion of stakeholders on new technologies?</i> <i>Rationale: Find out potential problems and corresponding perceptions</i>	
Policy questions	Concepts, Sources [provisional]
Are there any foresight studies conducted and what are the outcomes?	Concepts Public opinion
What is the public opinion on specific topics (old and new ones)?	
What is the role of the press?	Sources Social media (e.g., twitter, facebook, Instagram), online news, blogs
Is resistance expected? Where? Why? How?	
What are the reasons justifying the political choices made?	

3.2.2 Policy formulation

During the stage of Policy Formulation different courses of action are explored. It namely focuses on the dimensions to be addressed and how; the good practices, positive and negative experiences; and the rationale. Policy questions in policy formulation cover all seven functions of the innovation system.

Table 8. Policy formulation – Entrepreneurial activity

Relevant	Very relevant	Highly relevant
Policy formulation		
Function 1. Entrepreneurial activity		
<i>Key question: What is the role of entrepreneurs in the new policy?</i>		
<i>Rationale: Organise the role of the business sector</i>		
Policy questions		Concepts, Sources [provisional]
What is a reasonable amount of R&I investments to be expected from the business sector?		Concepts Business R&D and innovation expenditures by STI private actors
What is the role of large companies? SMEs? New Technology Based Firms? Inward investments?		Sources Company websites Crunchbase ⁶ / Dealroom ⁷ / Eutopia ⁸ / Cleantech ⁹ / Pitchbook ¹⁰

6 See: <https://www.crunchbase.com>

7 See: <https://dealroom.co>

8 See: <https://www.eutopiagreen.com>

	<p>EU Industrial R&D Investment Scoreboard</p> <p>Community Innovation Survey data</p> <p>Incubators, Accelerators, Investment angels websites</p> <p>Companies issuing Initial Public Offering (IPOs)</p>
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Table 9. Policy formulation – Knowledge creation

Relevant	Very relevant	Highly relevant
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Policy formulation	
Function 2. Knowledge creation	
<p><i>Key question: How much, what type of new knowledge can be produced in the country?</i></p> <p><i>Rationale: Find out capabilities and constraints</i></p>	
Policy questions	Concepts, Sources [provisional]
<p>In terms of R&D support what is the best balance of continuing current specialisation with shifts towards higher ambitions?</p>	<p>Concepts R&D support</p> <p>Sources National sources of R&D funding EU R&D funding Private R&D</p>

9 See: <https://www.cleantech.com>

10 See

Table 10. Policy formulation – Knowledge diffusion through networks

Relevant	Very relevant	Highly relevant
Policy formulation		
Function 3. Knowledge diffusion through networks		
<i>Key question: How can knowledge diffusion be reinforced?</i> <i>Rationale: Select potential support mechanisms</i>		
Policy questions		Concepts, Sources [provisional]
Which current diffusion channels to continue supporting?		Concepts Diffusion channels supported Technology uptake Research collaboration Sources National data Company websites Elsevier, Web of Science, OpenAire, FP1 – FP7, Horizon 2020, Horizon Europe Patstat
What type/how many new channels are needed?		

Table 11. Policy formulation – Guidance

Relevant	Very relevant	Highly relevant
Policy formulation		
Function 4. Guidance		
<i>Key question: What are the societal challenges to address in priority?</i> <i>Rationale: Select what is important and feasible</i>		

Policy questions	Concepts, Sources [provisional]
What is a list of appropriate challenges to address?	Concepts SDGs, Challenges (Domain specific) Sources Policy documents
What are the priority criteria?	
Which are the countries to work with on the priority challenges?	

Table 12. Policy formulation – Market formation

Relevant	Very relevant	Highly relevant
Policy formulation		
Function 5. Market formation		
<i>Key question: Who can be involved to use which tools?</i>		
<i>Rationale: Find out the appropriate tools and the public entities to get involved</i>		
Policy questions		Concepts, Sources [provisional]
Which public entities can be involved in regulating each topic?		Concepts Stakeholder engagement Public procurement
How can public procurement be mobilised? What resources? Which procedures?		
		Sources Public procurement websites Policy documents

Table 13. Policy formulation – Resources mobilization

Relevant	Very relevant	Highly relevant
Policy formulation		
Function 6. Resources mobilisation		
<i>Key question: How should the financial and human resources be divided into different types of tools?</i>		
<i>Rationale: Find out available and potential resources</i>		
Policy questions		Concepts, Sources [provisional]

What are the appropriate algorithms/functions to divide resources?	<p>Concepts Resources optimization Domain specific considerations to be accounted for</p>
Where can current investments have multiplication effects for financial and human resources (education of researchers)?	<p>Sources National data Domain specific sources to be considered</p>

Table 14. Policy formulation – Creation of legitimacy

Relevant	Very relevant	Highly relevant
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Policy formulation	
Function 7. Creation of legitimacy/counteract resistance to change	
<p><i>Key question: How can potential resistance be mitigated?</i> <i>Rationale: Find out what is likely to come and how it was addressed by frontrunners</i></p>	
Policy questions	Concepts, Sources [provisional]
How did other countries create legitimacy or counteracted resistance?	<p>Concepts Public opinion</p> <p>Sources Social media (twitter, facebook, Instagram), online news, blogs</p>

3.2.3 Policy adoption

The Policy Adoption stage is about making a choice. It includes building an intervention logic based on national characteristics and the actions identified in

the previous stage. At the level of domain, technology and sector agnostic questions the STI policy questions during the policy adoption phase are limited to the function of Guidance. The potential for AI data models would predominantly derive from the possibility to identify relevant public entities from policy documents and working papers of public authorities.

Table 15. Policy adoption – Guidance

Relevant	Very relevant	Highly relevant
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Policy adoption	
Function 4. Guidance	Concepts, Sources [provisional]
<i>Key question: Which public entities will be involved in which policies?</i>	<p>Concepts Stakeholder engagement</p> <p>Sources Policy documents</p>

Table 16. Policy adoption – Resources mobilization

Relevant	Very relevant	Highly relevant
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Policy adoption	
Function 6. Resources mobilisation	Concepts, Sources [provisional]
<i>Key question: What is the final decision on the budget allocation?</i>	<p>Concepts Public funding</p>

	Sources National data
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3.2.4 Implementation and monitoring

The stage of Implementation and monitoring is about implementing STI policies efficiently and simultaneously collecting all data necessary for corrective action and evaluation. At the level of domain, technology and sector agnostic questions the STI policy questions during the implementation and monitoring phase include all functions of the innovation system.

Table 17. Policy Implementation – Entrepreneurial activity

Relevant	Very relevant	Highly relevant
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Implementation	
Function 1. Entrepreneurial activity	
<i>Key question: What is the policy mix to support R&I in enterprises?</i> <i>Rationale: Compare own and other interventions</i>	
Policy questions	Concepts, Sources [provisional]
Are financial incentives effective?	Concepts Types of funding Types of support mechanisms Types of beneficiaries
Which financial incentives are effective?	
Under which circumstance have financial incentives been successful?	
Are individual grants effective? What type? Under which circumstances?	Sources National sources
What is the most appropriate policy for high tech startups?	
What is the most appropriate policy for triggering/increasing R&D in	

traditional SMEs?	
How to differentiate between persistent innovators and others?	

Table 18. Implementation – Knowledge creation

Relevant	Very relevant	Highly relevant
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Implementation	
Function 2. Knowledge creation	
<i>Key question: What is the policy mix to support locally produced new knowledge?</i>	
<i>Rationale: Compare own and other interventions</i>	
What is the appropriate mix between institutional funding and competitive funding?	Concepts Types of funding Types of support mechanisms Types of beneficiaries Sources National sources
Are individual grants effective? What type? Under which circumstances?	
How can high performers be prioritised?	
Who are appropriate evaluators of proposals with a strong technological component?	
Are proposals representing the state of the art in a technology? Are they involving highly prolific organisations/experts?	

Table 19. Implementation – Knowledge diffusion through networks

Relevant	Very relevant	Highly relevant
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Implementation
Function 3. Knowledge diffusion through networks

<i>Key question: How is diffusion best supported?</i>	
<i>Rationale: Compare collective with individual support</i>	
Policy questions	Concepts, Sources [provisional]
Are networking measures (between academia and business, or in clusters) effective? What type of support measures are used (only additional cost or research as well)?	Concepts Diffusion channels support mechanisms and funding
Under which circumstance are networking measures effective?	Sources National sources (beneficiaries, outputs, etc.)
What are policy mechanisms that support/motivate the creation of networks (e.g., cluster policy, innovation hubs, etc.)?	
Are cluster measures effective? What type? Under which circumstances?	
How do individual grants compare to collaborative grants?	

Table 20. Implementation – Guidance

Relevant	Very relevant	Highly relevant
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Implementation	
Function 4. Guidance	
<i>Key question: Who runs the selected area of societal challenges?</i>	
Which policy entity is in charge of selecting societal challenges? Which entity is implementing them? How?	Concepts Stakeholder engagement Sources Policy documents

Table 21. Implementation – Market formation

Relevant	Very relevant	Highly relevant
Implementation		
Function 5. Market formation		
<i>Key question: What are the main global features for market formation?</i>		
<i>Rationale: Coordinate for regulatory framework and public procurement</i>		
Policy questions		Concepts, Sources [provisional]
Are there niche markets in which the country has a competitive advantage?	<p>Concepts Supply and demand Technology markets (identification/ formation)</p> <p>Sources Policy documents Public procurement websites Incubators/ Accelerators/Investment Angels</p>	
What is the global/European regulatory framework at the moment?	<p>Concepts Regulation types</p>	
What type of regulation is expected in the near future?	<p>Sources Regulation texts Foresight documents</p>	

Table 22. Implementation – Resources mobilization

Relevant	Very relevant	Highly relevant
Implementation		

Function 6. Resources mobilisation	
<i>Key question: Is leverage possible during implementation?</i>	

Table 23. Implementation – Creation of legitimacy

Relevant	Very relevant	Highly relevant
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Implementation	
Function 7. Creation of legitimacy/counteract resistance to change	
<i>Key question: How is the opinion of stakeholders evolving over time? Unit of analysis technology</i>	<p>Concepts Public opinion</p> <p>Sources Social media (twitter, facebook, Instagram), online news, blogs</p>

Table 24. Monitoring – Innovation system functions 1- 4

Relevant	Very relevant	Highly relevant
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Monitoring	
Functions 1, 2, 3 and 4. Entrepreneurial activity, Knowledge creation and Knowledge diffusion through networks, Guidance	
<i>Key question: How smooth is each programme progressing? Rationale: Find out how policies evolve and drawbacks to correct</i>	
Policy questions	Concepts, Sources [provisional]
How long does it take to launch calls?	Concepts

How fast is the system?	Implementation per stage (days, functions, outputs) Sources National sources
How bureaucratic is the system?	
How long does it take to sign a contract? To pay in each stage?	
What is the process? Possibility for information? For feedback?	
Are projects delivering on time? What they promised?	

Table 25. Monitoring – Market formation

Relevant	Very relevant	Highly relevant
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Monitoring	
Function 5. Market formation	
<i>Key question: Are regulatory interventions supporting financial incentives?</i> <i>Rationale: Find out what is happening during the cycle</i>	
Policy questions	Concepts, Sources [provisional]
Is new regulation adopted in the country? Outside the country? Does it reflect new findings?	Concepts Regulation types Sources Regulation texts
Is there any procurement of R&D and innovative products?	Concepts Innovative public procurement
What is the share of public procurement of innovation compared to off the shelf procurement?	Sources Public procurement websites National sources

Table 26. Monitoring – Resources mobilization

Relevant	Very relevant	Highly relevant
Monitoring		
Function 6. Resources mobilisation		
<i>Key question: Is absorption of resources according to targets?</i>	<p>Concepts Funding absorption</p> <p>Sources National sources</p>	

Table 27. Monitoring – Creation of legitimacy/counteract resistance to change

Relevant	Very relevant	Highly relevant
Monitoring		
Function 7. Creation of legitimacy/counteract resistance to change		
<i>Key question: Are there any shifts in the stakeholders' opinions?</i>	<p>Concepts Public opinion</p> <p>Sources Social media (twitter, facebook, Instagram), online news, blogs</p>	

3.2.5 Evaluation

The evaluation stage is about checking coherence, efficiency, effectiveness, value added and impact to help adapt the design of the next cycle. Policy questions are considered at two levels, the project and programme level.

Table 28. Evaluation project level - Innovation system Functions 1-4

Relevant	Very relevant	Highly relevant
Evaluation		
Function 1. Entrepreneurial activity, Function 2. Knowledge creation, Function 3. Knowledge diffusion through networks, Function 4. Guidance		
<i>Key question: What are the results, outcomes and impact of projects and programmes?</i>		
<i>Rationale: Find out potential problems and corresponding perceptions</i>		
Unit of analysis: projects		
Policy questions		Concepts, Sources [provisional]
How many scientific publications were published? In top 1% or top 10% of scientific journals? (distinction between interdisciplinary publications, basic research and applied research) (using journal classification?/calls for proposals)		Concepts Scientific outputs Sources National sources combined with Elsevier, Web of Science, OpenAire
How were citations in publications associated to projects compared to scientific discipline average?		
How many presentations in top scientific conferences? (distinction between interdisciplinary, basic and applied research)		
How many people were trained as researchers? As technicians?		Concepts Skills supply, job creation
How many new jobs were created for researchers during the project?		
How many new jobs were created after the project (research and beyond) within the country?		Sources National sources
How many patents were produced (applications/grants) in the European Patent Office and in the US PTO? How many were used inhouse? How many were licenced? What royalties did they produce?		Concepts Technological innovations
What new products have been developed? How many were launched in the		Sources

market? What was their contribution to turnover, profits, exports, taxes?	National sources Patents (patstat) Crunchbase ¹¹ / Dealroom ¹² / Eutopia ¹³ / Cleantech ¹⁴ / Pitchbook ¹⁵
How many new production processes have been developed? How many were launched in the shopfloor? What was their impact on productivity?	
How many new algorithms, software...were developed? Used?	
What has been the leverage of national support measures for EU competitive funding?	<p>Concepts EU competitive funding leverage</p> <p>Sources National sources Elsevier, Web of Science, OpenAire, FP1 – FP7, Horizon 2020, Horizon Europe</p>

Table 29. Evaluation programme level - Innovation system Functions 1-4

Relevant	Very relevant	Highly relevant
Evaluation		
Function 1. Entrepreneurial activity, Function 2. Knowledge creation, Function 3. Knowledge diffusion through networks, Function 4. Guidance		
<i>Key question: What are the results, outcomes and impact of projects and programmes?</i>		
<i>Rationale: Find out potential problems and corresponding perceptions</i>		
Unit of analysis: programme		

11 See: <https://www.crunchbase.com>

12 See: <https://dealroom.co>

13 See: <https://www.eutopiagreen.com>

14 See: <https://www.cleantech.com>

15 See

Policy questions	Concepts, Sources[provisional]
Are currently available strategies/policies coherent?	<p>Concepts Coherence</p> <p>Sources National sources</p>
What was the cost per publication? At scientific discipline level?	<p>Concepts Efficiency</p> <p>Sources National sources</p>
What was the cost per patent? At scientific discipline level?	
What is the cost benefit analysis of each programme?	
What were the private returns on investment?	
What were the social returns on investments? Taxes generated?	<p>Concepts Effectiveness</p> <p>Sources Elsevier, Web of Science, OpenAire FP/Horizon 2020/ Horizon Europe Patstat National sources Business Demography and Main Economic Indicators</p>
What was the research employment created?	
What was total employment created?	
What are the multiplication effects of each programme?	
Has the sectoral specialisation of the research system changed towards higher value added activities?	<p>Concepts Relevance</p> <p>Sources National sources</p>
Has the sectoral specialisation of the productive system changed towards higher value added activities?	
Which societal challenges have been addressed?	<p>Concepts Relevance</p> <p>Sources National sources</p>

Table 30. Evaluation programme level – Market formation

Evaluation
Function 5. Market formation

Key question: Have the regulation and public procurement been adequate?

Rationale: Find out regulatory and procurement outcomes

Policy questions	Concepts, Sources [provisional]
Has the regulation adopted facilitated the creation/access to new markets?	
Has public procurement of innovation produced effective results? Has it created lead markets?	

3.3 From STI policy questions to IntelComp solutions: criteria accounted for

The list of 160 questions includes important questions for all functions of the innovation system and stages of the policy cycle. The current list is not exhaustive and many other questions could be added or current questions can be reformulated to account for the divergent needs of STI policy makers across different Member States and domains, technologies or sectors. The challenge we face is not to create an exhaustive list of STI policy questions but understand the possible policy issues to address in IntelComp. Criteria to account for in this process include:

- **The complexity of the analysis of STI policy needs:** The needs of STI policy makers considering all functions of the innovation system are wide ranging and synthetic in nature, which makes the analysis complex and multifaceted, going beyond the calculation of a couple of indicators and requiring contextual information which is most of the time of a qualitative nature. To therefore address the needs of STI policy makers, IntelComp should not be bound by a small number of narrowly defined policy questions. Instead, IntelComp will build upon the identified policy questions to expand in the domains the wealth and variability of their formulation.
- **The needs as expressed by the domain representatives:** The less highly relevant policy questions could easily be transformed to highly relevant questions when considering different domains, technologies

and sectors or when put in a specific context (e.g. consider policy questions on legitimacy or market formation which may be of high relevance for AI but less so for Cancer). The identification of the domain needs have kick started with the consultation workshops on STI needs (see section 4 for the details on the workshops results).

- **The technical feasibility:** an assessment of the technical feasibility using AI techniques and the availability of suitable (open) data sources, has started internally within the consortium namely by ideating on promising sources that could be used across all three domains and the technical solutions. Overall, the intention is to use AI based tools to provide answers to STI policy questions that are not necessarily possible to answer using traditional indicators.
- **The involvement of users in platform development:** Most of the time, users can more or less express their needs, which are more or less correctly translated by the development of any system, protocol, platform or environment. However, too often the result is a “dashboard type” of interface that shows outputs but does not really allow for understanding. Then, the consortium should assure that users in also create those interfaces in order to ensure its adoption. In that sense, IntelComp will not (exclusively) address specific policy questions, as it wants to be truly agnostic, but will put together the necessary and widest possible incubator of new questions and information. This disruptive approach tries to mitigate the risk of ending up with a semi-rigid dashboard prone to obsolescence.

4. PRELIMINARY OVERVIEW OF DOMAIN SPECIFIC STI POLICY NEEDS

In sections 2 and 3 we have developed a generic (domain-agnostic) STI policy framework. To attain a more focused and domain-specific list of policy questions reflecting the needs of the respective actors, we have enriched it by:

- Identifying domain-specific policy needs and barriers via three domain-specific consultation workshops.
- Providing a summary of the domain-specific policy and regulatory contexts, through desk research.

This section provides a preliminary overview of STI policy needs in the three domains, AI, Climate Change and Health. It is based on the insights from the three domain specific consultation workshops with a focus on Agenda Setting and Evaluation, which represent the two policy stages most closely linked to IntelComp platform.

The inputs from the workshops are further complemented with views from desk research covering the following components per domain: 1) Vision, policies / strategies and their operational objectives; 2) Targets; 3) Main pieces of regulation; 4) Roadmaps and corresponding monitoring frameworks (accounting for the operational objectives, policy outcomes and measurement of outputs) and 5) Enabling conditions (including indicators and the measurement type when available).

As IntelComp adopts the Public-Private-People Partnerships living labs approach, engagement with domain specific public policy makers, industry, academia and civil society is foreseen to co-create STI policies. The conclusion of the consultations on scope have been relevant for the domains of Climate Change and Health in which cases it has been decided to focus on the intersection between Climate Change and the Blue Economy, and Cancer, respectively. In the case of AI no further demarcation has been proposed.

In the subsequent sub-sections we look at each domain separately and provide a synthesis of the consultation workshops and desk research. Each section starts with a summary including main highlights. The information provided in these sections should be read as work in progress as it will progressively account for the outcomes of the living labs, which will further refine and possibly re-define their STI needs leading to the selection of solutions for the IntelComp platform.

4.1 Towards the identification of STI policy needs in the domain of Artificial Intelligence

This section synthesizes insights on STI policy needs in the domain of AI collected during the first six months of IntelComp. The STI policy needs derive from IntelComp's conceptual framework applied to the domain of AI via the consultation of relevant actors in the domain, and has been complemented by desk research.

4.1.1 Scope

The scope within AI is delineated by the EU vision to create EU global leadership in human-centric AI. The Commission has agreed with Member States on a Coordinated Plan on AI that identifies “areas where the partnership between the EU and Member States is particularly effective in making Europe a hub for the development and use of cutting-edge, human-centric AI”.

4.1.2 Summary on domain specific needs from consultations

The participants in the AI consultation workshop belong to Public Administrations, Industry, Academia and Citizen Organizations. When asked about STI priorities in the domain of AI, they do not only mention priorities in research, technology development and innovation. They do also point at other priorities for AI development and uptake in the EU.

In Box 1 we have grouped these priorities in the areas of action of the Coordinated Plan on AI of the European Union and Members States (see section 4.1.4 below). Besides enabling conditions (data and computing capacity), participants highlighted several priorities related to STI: to build and mobilize research capacities, and also to provide an environment for developers to test and experiment (Testing and Experimentation Facilities) and for SMEs and Public Administrations to take up AI (European Digital Innovation Hubs – EDIHs—related to AI technologies). In addition to this, several points were made to ensure that AI works for people and is a force for good in society.

Box 1. STI priorities in the domain of AI

- **Data.** Availability of national data to train AI systems. Data sharing, data services and data aggregation
- **Computing capacity.** Infrastructures
- **Research capacities.** AI Research (including capabilities)
- **Testing and Experimentation Facilities and European Digital Innovation Hubs.** Research and technology transfer in AI (including enterprise needs such as SME support/ via DIH etc.). Testing in AI (to match priorities with opportunities)
- **Supply of skills.** AI Skills (research and technical skills), education and respective training
- **Trust in AI systems.** Comparison of innovation systems (including national contexts for setting up laws/ guidelines). AI Relation to Citizens
- **AI in the public sector.** Platform (technical) training for Public Administration (for procurement needs)
- **Other.** AI relation to decision-making. Natural resources. Multi-lingual aspects (e.g. search engine tools)

As expected, participants also remarked these priorities when selecting needs in the agenda setting stage of the policy cycle, which covers the analysis of the context of the policy interventions and the definition of the problem to be addressed by the STI policies. Regarding the monitoring and evaluation of these policies, participants pointed at patents related to funded projects (Box 2).

Box 2. STI agenda setting & evaluation needs in the domain of AI

- Data collection that would help them also be informed about AI: quantitative inventory of the situation about AI advancement and uptake (real-time check-up of the domain).
- Knowledge transfer, technology uptake and business development
- Dealing with data spaces. Data spaces promotion in order to foster industry as well as developing green algorithms especially devoted to energy. Data sharing
- Apps and requests handling
- Interoperability and national legislation. Legal obligation to share the data in an interoperable way at national level as a requisite to sharing at supranational level.
- Laws or guidelines set up in order to use AI in the STI context
- Services that administrations offer to citizens, specifically in thematic analysis, taking information from open data
- Links between projects and patents (mapping)

The participants also gave a general perspective of what happens in their countries. Some examples are listed in the box below (Box 3).

Box 3. Country specific perspectives on AI

- In Spain a national strategy for AI has been published which involves several aspects such as policy development tools and the needs of building a new excellent network of both Universities and R&D centers working on AI. In the region of Aragon, working more in industry and tourism sector. The Basque

Country region has developed its own strategy regarding AI and the new Basque AI Centre was presented at the end of July as a public-private collaboration example.

- In Italy AI is crosscutting across strategies in different domains
- In Greece the strategy on AI has been drafted and will be under public consultation soon
- In Portugal they are working on digital transformation and transition strategy for 2030 which includes AI, machine learning, data spaces, data sharing. Main objective is to provide the information and the intelligence to the enterprises, the government, the decision makers so they can in real time provide information to develop politics, solutions etc.

As explained in sections 2 and 3, the starting point for the identification of policy needs has been via a list of domain agnostic policy questions. During the workshop and in the break-out group on agenda setting, the participants indicated additional questions or proposed a reformulation of the policy questions to better fit the needs of the AI domain. In addition to this, participants signaled top priority questions (Table 31).

Table 31. Additional/Reformulated Agenda Setting questions in the domain of AI

Entrepreneurial activity: Where should resources be invested (individual companies, sectors, value chains) to support the national innovation system to successfully undertake R&D and

<i>compete internationally?</i>	
Highest priority “must be known” sub-questions selected by the participants	<ul style="list-style-type: none"> • Which companies emerge with specific disruptive technologies and functional applications, and agents developing and using those AI technologies? • Are scale ups leaving the country/region/city? • Does the country/region/city attract entrepreneurial talent?
Missing needs / reformulation of the question	<ul style="list-style-type: none"> • How to account for the convergence between AI and other technologies? • How will IntelComp define AI technologies? • What is the regulation at the sectoral level for R&D activities in AI technologies?
<i>Knowledge creation: In which fields is new knowledge coming up?</i>	
Highest priority	<ul style="list-style-type: none"> • Which are the emerging interdisciplinary fields globally?
Missing needs / reformulation of the question	<ul style="list-style-type: none"> • How to differentiate between basic and applied research in AI technologies? • How will IntelComp take account of the patenting limitations in software in order to measure knowledge creation in AI technologies?
<i>Knowledge diffusion: through networks: Does the diffusion function work well in the country?</i>	
Highest priority	<ul style="list-style-type: none"> • Which networks e.g., clusters, hubs, intermediaries operate nationally? • Are actors of the ecosystem collaborating? What are forms of collaboration?
Missing needs / reformulation of the question	<ul style="list-style-type: none"> • Which diffusion channels operate for scientific publication, for patents or for software? • How can AI technologies be categorized, assessed and mapped into Technology Readiness Levels (TRL) (e.g., maturity and availability

	<p>levels) (useful for Funding Authorities)?</p> <ul style="list-style-type: none"> • What are the multidisciplinary teams created for applying for public funding in order to reach TRL 7? • At what TRLs are research centers collaborating with companies?
<p><i>Market formation: What are the appropriate tools to form new markets?</i></p>	
<p>Missing needs / reformulation of the question</p>	<ul style="list-style-type: none"> • What information is needed to identify a market? • Who will pay for emerging technologies in a new market?
<p><i>Resources mobilisation: What are the resources needed and how can they be obtained?</i></p>	
<p>Highest priority</p>	<ul style="list-style-type: none"> • What are the national/regional financial resources available in the country? • Is there sufficient tech talent supply? • Is there a gap between supply and demand?
<p>Missing needs / reformulation of the question</p>	<ul style="list-style-type: none"> • Are there sufficient engineers at research centers and universities working at TRLs 5 and 6? • Do Public Administrations have the necessary technical skills, time and computer capacities to train AI systems? • What are the public financial resources available for the different TRLs in AI technologies? • What are the public financial resources by type of research (basic or applied)? • Do interdisciplinary teams have an appropriate mix of researchers and engineers? • Do SMES have enough resources to train AI systems?

In the break-out group on evaluation the participants also indicated additional questions or proposed a reformulation of the policy questions to better fit the needs of the AI domain. In addition to this, participants signaled top priority questions (Table 32).

Table 32. Additional/Reformulated Evaluation questions in the domain of AI

<i>Entrepreneurial activity, Knowledge creation, Knowledge diffusion through networks, and Guidance: What are the results, outcomes and impact of projects and programmes?</i>	
Highest priority “must be known” sub-questions selected by the participants. Unit of analysis: projects	<ul style="list-style-type: none"> • How were citations in publications associated to projects compared to scientific discipline average? • What new products have been developed? How many were launched in the market? What was their contribution to turnover, profits, exports, taxes? • How many new production processes have been developed? How many were launched in the shopfloor? What was their impact on productivity?
Highest priority. Unit of analysis: programmes	<ul style="list-style-type: none"> • What were the social returns on investments? Taxes generated? • Has the sectoral specialization of the research system changed towards higher value added activities? • Has the sectoral specialization of the productive system changed towards higher value added activities?
Missing needs / reformulation	<ul style="list-style-type: none"> • Important for funding agencies: What are the socio-economic effects of all projects? • Missing AI researchers professional trajectories

<p>of the question</p>	<ul style="list-style-type: none"> ● Go beyond bibliometric analysis e.g. webscrapping for impact assessment ● Can the use of Open Access reach /attract more young professionals? ● What are the themes and relations between projects (+ Detect topological changes in connections among projects, e.g. emerging hybridization of fields, etc ..?) ● Missing considerations related to qualitative and multi-lingual dimension (e.g. there are social dimensions linked to sources, national practices; social and cultural / ethical dimensions linked to multilingual semantics) ● Linking to the above, it is crucial to mix sources (taxonomies, semantics, etc.) to avoid creating silos of knowledge ● Look at knowledge transfer from bi-directional perspective and understand what data propels AI algorithms as data is one key factor in AI development and adoption ● Missing information on (how many) databases used for AI systems ● Links between (AI) regulation and communication (with researchers, different fields of science e.g. differences in theory and practice) ● Identify links / establish Communication and information flow – e.g. for multi-level governance (EU/ Federal/ regional / etc.)
<p><i>Market formation? Have the regulation and public procurement been adequate?</i></p>	
<p>Highest priority</p>	<ul style="list-style-type: none"> ● Has the regulation adopted facilitated the creation/access to new markets? ● Has public procurement of innovation produced effective results? Has it created lead markets?
<p>Missing needs / reformulation of the question</p>	<ul style="list-style-type: none"> ● Go beyond public procurement of innovation (is not necessarily the only way to commission AI-based systems)

4.1.3 Summary on domain specific needs from desk research

Table 33 below summarises in a simplistic manner the EU intervention logic on AI starting with the vision and corresponding operational objectives. The main target relates to accelerate private and public investments in AI technologies, leveraging EU funding available, for example, through Digital Europe, Horizon Europe and the Recovery and Resilience Facility. The roadmap corresponds to the joint actions of the Coordinated Plan on AI with its related long term outcomes for the STI related actions. The monitoring system is not yet defined, neither are immediate outputs.

Table 33. EU intervention logic in AI [provisional simplistic view]

Vision	The global leadership of Europe in adopting the latest technologies, seizing the benefits and promoting the development of human-centric, sustainable, secure, inclusive and trustworthy AI		
Operational objectives	Boost the EU's technological and industrial capacity and AI uptake across the economy, both by the private and public sectors. This includes investments in research and innovation and better access to data	Prepare for socio-economic changes brought about by AI by encouraging the modernisation of education and training systems, nurturing talent, anticipating changes in the labour market, supporting labour market transitions and adaptation of social protection	Ensure an appropriate ethical and legal framework, based on the Union's values and in line with the Charter of Fundamental Rights of the EU

		systems.	
Targets	The EU as a whole (public and private sectors combined) should aim for more than EUR 20 billion per year over the following decade of investments in AI technologies		
Policies / Programmes	Horizon Europe Digital Europe Programme Recovery and Resilience Facility	and	EU regulation Horizon Europe Digital Europe Programme Recovery and Resilience Facility
Roadmap/ Actions	Coordinated Plan on AI in Europe		
STI actions/ Initiatives	European partnerships Networks of AI excellence centers. AI lighthouse for Europe AI related calls under Horizon Europe TEFs and EDIHs. AI-on-demand platform Actions to fund and support access to finance for AI start-ups and scale-ups		
STI Outcomes	Research and innovation excellence Improve European competitiveness The broad uptake and deployment of AI technologies		
STI Outputs			

Vision, Ambition Statements and Targets

The **EU Vision** is the so-called European approach to AI, i.e. “the global leadership of Europe in adopting the latest technologies, seizing the benefits and promoting the development of human-centric, sustainable, secure, inclusive and trustworthy AI”.

EU **ambition statements** on AI, including the values on the basis of which the EU aims to advance the development and uptake of AI, are set out in the EC’s *Communication on Artificial Intelligence for Europe* (COM(2018) 237 final)¹⁶:

- *“Boost the EU’s technological and industrial capacity and AI uptake across the economy, both by the private and public sectors. This includes investments in research and innovation and better access to data.”*
- *“Prepare for socio-economic changes brought about by AI by encouraging the modernisation of education and training systems, nurturing talent, anticipating changes in the labour market, supporting labour market transitions and adaptation of social protection systems.”*
- *“Ensure an appropriate ethical and legal framework, based on the Union’s values and in line with the Charter of Fundamental Rights of the EU. This includes forthcoming guidance on existing product liability rules, a detailed analysis of emerging challenges, and cooperation with*

¹⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A237%3AFIN>

stakeholders, through a European AI Alliance, for the development of AI ethics guidelines.”

These ambitions have one associated quantifiable **target**:

- *“The EU as a whole (public and private sectors combined) should aim for more than EUR 20 billion per year over the following decade.”*

Building on the approach set out in the Communication, in 2018 the Commission agreed with Member States on a Coordinated Plan on AI (EC’s *Communication Coordinated Plan on Artificial Intelligence* (COM(2018) 795 final)¹⁷. This plan laid the ground for cooperation, defined areas for investments and encouraged members States to develop national strategies on AI.

Its latest version of April 2021 is the policy framework for AI policies in Europe (EC’s *Communication Fostering a European Approach to Artificial Intelligence* (COM(2021) 205 final)¹⁸.

In particular, it establishes the following four **key policy objectives**:

1. Set enabling conditions for AI development and uptake in the EU.
2. Make the EU the place where excellence thrives from the lab to the market.
3. Ensure that AI works for people and is a force for good in society

¹⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:795:FIN>

¹⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:205:FIN&qid=1619355277817>

4. Build strategic leadership in high impact sectors.

To achieve those objectives, it proposes to focus on **17 areas (3 as enabling conditions, 10 horizontal and 7 sectoral action areas) and 40 key actions** (included in Appendix 1 of the Communication) for the EC and the EC together with its Member States.

The role of STI policy

The Coordinated Plan on AI puts forward 4 areas to make the EU the place where excellence thrives from the lab to the market:

- Collaboration of the Commission and Member States with stakeholders in European partnerships relevant to AI technologies.
- Build and mobilise research capacities.
- Provide tools through and AI-on-demand platform and an environment for developers to test and experiment (Testing and Experimentation Facilities-TEF), and for SMEs and public administrations to take up AI (European Digital Innovation Hubs-EDIH).
- Fund and scale innovative ideas and solutions for AI.

In the first area the Commission supports **European partnerships** through Horizon Europe and fosters their strategies via strategic research agendas. These partnerships bring together the Commission, Member States and private and/or public actors to overcome fragmentation of research effort. They provide a legal structure to pool funding, talent and infrastructures, gain critical mass and

enhance efficiency. According to Appendix 1 of the 2021 Review of the Coordinated Plan, the key action is to establish a co-programmed European partnership on AI, Data and Robotics.

In the second area the Coordinated Plan puts forward several **actions to boost research and innovation excellence**:

- Create a research community of closely networked AI excellent research centers in basic and applied research to increase cooperation between teams. These networks are funded by Horizon Europe and by national and regional funds.
- Create an AI lighthouse for Europe, i.e. a centre of research, innovation and expertise that would be a world reference of excellence in AI and that can attract investments and the best talents in the field (This is a key action according to Appendix 1).
- Advance the state of the art in various areas of research, defined and funded by AI related calls under Horizon Europe (This is a key action according to Appendix 1).

The third area includes **actions to ensure deployment and uptake of AI technologies**, especially by SMEs. The Commission together with Member States is co-funding TEFs to provide developers with an infrastructure for testing AI technologies in a given sector, in real or close-to-real conditions, before bringing it to the market. These infrastructures are large-scale reference sites to optimize investments and avoid duplication or competing efforts. Launching calls for TEFs under the Digital Europe Programme is a key action according to Appendix 1.

The Commission together with Member States is also supporting networks of EDIHs in AI-relevant areas to provide technical and financial advice to SMEs.

These EDIHs will make use of the tools made available by the AI platform that offers a toolbox of AI resources for SMEs and the public sector. Setting up the network of EDIHs and establishing the AI-on-Demand platform as the central European AI toolbox are key actions according to Appendix 1.

Finally, the fourth area on STI policy of the Coordinated Plan includes **actions to fund and support access to finance for AI start-ups and scale-ups**, through different instruments like the AI/Blockchain Investment Scheme and its Support Programme, the European Innovation Council (EIC), among others.

Overview of monitoring framework in place supporting the measurement of outputs

The Coordinated Plan does not include a monitoring system or framework. However, it states that the Commission will, in collaboration with Member States, monitor the implementation of the joint actions. This monitoring mechanism should be well-designed, and Member States are invited to collaborate by providing the necessary information of actions taken and progress achieved.

Appendix 1 of the 2021 Review of the Coordinated Plan also defines a timeline for the implementation of 40 key actions. We assume that the monitoring mechanism will follow-up the actual period of execution of those actions.

This monitoring information on the implementation of the Coordinated Plan will feed into its new review. In consultation with Member States the Commission will propose in 2022 a timeline and a methodology for this review.

Enabling conditions

Three factors create broad enabling conditions for AI technologies to succeed in the EU: an appropriate governance and coordination framework, data and computational infrastructure. The 2021 Review of the Coordinated Plan proposes accordingly the following **areas of action under enabling conditions: acquire pool and share policy insights; tap into the potential of data; and foster critical computing capacity.**

The first area includes **actions to gather knowledge or intelligence on the evolution of STI in AI technologies.** These actions are then of particular relevance to IntelComp, and cover:

- *AI Watch* (run by the Commission's Joint Research Center - JRC). It monitors, for instance, industrial, technological and research capacity; AI skills; AI uptakes and their impact on the economy, society and public service. Among others, AI Watch has published studies on monitoring the evolution of AI technologies and on the operational definition of AI¹⁹. These studies will serve as a reference when defining the indicators provided by the IntelComp platform for the agenda setting stage of the policy cycle.
- *Eurostat*. It has included an AI related question in the survey on the use of ICT in firms²⁰. This survey will also serve as a reference when defining the indicators provided by the IntelComp platform for the agenda setting stage of the policy cycle.

¹⁹ https://knowledge4policy.ec.europa.eu/ai-watch_en#search-our-knowledgebase Reference

²⁰ <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20210413-1>

Besides, to gather the necessary knowledge to feed into EU policymaking on AI, the Commission launched an open public consultation to collect stakeholders' opinion on the EU's AI policies. It included view in actions to build an ecosystem of excellence.²¹

4.2 Towards the identification of STI policy needs in the domain of Climate Change in the Blue Economy

This section synthesizes insights on STI policy needs in the domain of Climate Change and especially on Blue Economy collected during the first six months of IntelComp. They stem from IntelComp's conceptual framework applied to the domain of Climate Change - Blue Economy via the consultation workshop, and has been completed by desk research.

4.2.1 Scope

In the domain of Climate Change, IntelComp will focus on Blue Economy. A sustainable Blue Economy plays a key role on achieving the objectives of the European Green Deal and the long-term vision of the EC to achieve climate neutrality by 2050. The intersection between Climate Change and Blue Economy is defined following the EC's approach on the sustainable Blue Economy, which focuses on:

- Climate neutrality and zero pollution

²¹ <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12270-White-Paper-on-Artificial-Intelligence-a-European-Approach/public-consultation>

- Circular economy and preventing waste
- Biodiversity and investing in nature
- Coastal resilience
- Responsible food systems.

4.2.2 Summary on domain specific needs from consultations

During the IntelComp workshop that took place on the domain of Climate Change in the Blue Economy, the participants were asked on their STI priorities and placed their perceptions (Box 4). Some of the STI priorities obtained from this interaction were in general data availability and accessibility, the engagement of EU in measuring adaptation and mitigation, as well as the link between academia, industry and public actors to work on closing gaps, building synergies and identifying commonalities.

Box 4. STI priorities in the domain of Climate Change – Blue Economy

- Climate Change impact on social needs
- Thematics in focus: Energy (production of clean energy from the ocean which includes floating wind, thermal, wave and tidal energy); Aquaculture (low emissions from aquaculture, high nutritious foods); Biodiversity (fishery stocks); Plastics
- Engagement of EU in measuring of adaptation and mitigation
- Link between STI and education (all levels) in the pilot domain
- Link between academic, industry and public stakeholders to work on closing gaps, building synergies and identifying commonalities

- General data availability/ accessibility
- Dialogue between stakeholder groups (and citizens) to build bridges between these groups
- Perception and public awareness

Participants also reported their needs in the agenda setting stage of the policy cycle, which covers the analysis of the context of the policy interventions and the definition of the problem to be addressed by the STI policies (Box 5).

Box 5. STI agenda setting needs in the domain of Climate Change – Blue Economy

- How to use Innovation to deal with the effects of climate change
- Identify the most prominent technologies tackling climate change
- Data Interconnectivity (Climate Change/ Blue Economy)
- Highlight technologies/procedures/solutions that have worked on a smaller scale
- Highlight priorities that have not been perceived, what has potential and needs more support because it can provide solutions or in what direction stakeholders believe support should move to achieve mitigation
- Newly created sectors (offshore energy and mainly aquaculture): how the enterprises work, what they do and how

As explained in sections 2 and 3, the starting point for the identification of policy needs has been via a list of domain agnostic policy questions. During the workshop and in the break-out group on agenda setting, the participants

indicated additional questions or proposed a reformulation of the policy questions to better fit the needs of the Climate Change/Blue Economy domain. In addition to this, participants signaled top priority questions (Table 34).

Table 34. Additional/Reformulated Agenda Setting questions in the domain of Blue Economy

<p><i>Innovation system function: Entrepreneurial activity</i></p> <ul style="list-style-type: none"> • Public to private sector technology transfer
<p><i>Innovation system function: Knowledge creation</i></p> <ul style="list-style-type: none"> • Which are the most important Climate Change problems in the Mediterranean sea? • What type of research is needed on climate change (global analysis)? • What are the specific technological challenges related to Climate Change adaptation/mitigation? <p>Interdisciplinarity between engineering, economics, etc.</p>
<p><i>Innovation system function: Knowledge diffusion through networks</i></p> <ul style="list-style-type: none"> • Which knowledge diffusion channels related to Climate Change work best in good practices/ per discipline at national / international level? • What are common themes between the actors of the blue growth ecosystem in your country? What concentration patterns can be observed? • What are the digital technologies with the highest potential to tackle Climate Change? • What are public/ private innovations (incl. cutting edge innovation) developed by companies? <p>Cross-sectoral collaborations – looking at specific examples/cases (identifying, showcasing good practices)</p>

Innovation system function: Guidance

- Legal accountability for violation (of a considered human / social right)
- Link between climate change and e.g., migration and other social phenomena

Innovation system function: Market formation

- What is the role of public procurement for climate change adaptation/ mitigation (theoretically/ practically)?

Innovation system function: Resources mobilization

- What are the national/regional financial resources linked to climate change projects available in the country? Are they used to leverage EU funding through synergies?

Innovation system function: Creation of legitimacy/counteract resistance to change

- Reformulation/addition: If Climate Change adaptation / mitigation measures are implemented, is resistance expected? Where? Why? How?
- Missing: What are the political priorities? Who will benefit?

Participants also reported their needs in the (monitoring) and evaluation stage of the policy cycle (Box 6).

Box 6. STI Evaluation needs in the domain of Climate Change – Blue Economy

- Continuous monitoring and evaluation of employee skills in the sector (upskilling and reskilling)
- Monitoring data to get a systemic overview to inform decision-making

Finally, the participants indicated additional questions or proposed a reformulation of the policy questions in monitoring and evaluation to better fit the needs of the Climate Change/Blue Economy domain. In addition to this, participants signaled top priority questions (Box 7).

Box 7. Additional/Reformulated Evaluation questions in the domain of Climate Change – Blue Economy

Unit of analysis: Projects

- What are the national priorities? Needs to be included as an indicator to understand the outputs (is there a reason why stakeholders are doing different things)
- What are the effects of projects on individual communities?
- Timing: Added value of projects will only be appreciated after long term achievements. How will you draw conclusions and when? When is the evaluation launched (some results might not be visible directly afterwards)? Will you take into consideration the relaunch of an evaluation at a later time?
- Connection between education and employment (including upskilling and reskilling)
- What are the training and education interests of academics? This could give a good idea of trends in the area
- Have policies incentivized technology advancements (market uptake of products)?

Unit of analysis: programmes

- What are the multipliers of green transition/ growth?
- How do we capture externalities?
- What is the effect of migration as an effect of climate change?
- Social Cohesion and link to climate change adaptation programmes
- How can we/ what elements positively influence/change human behaviour? How do we bridge climate and social behaviour? Can social behaviour become a driver for adjustments of technological adaptation?
- What revenues (beyond monetary revenues) are there to sustain the activities and in what ways can their value be measured?
- What “demonstrators” or solutions exist and should be scaled-up / replicated?
- Who are the existent actors and / or solutions (e.g. climate change mission board)? Did the initiatives/ solutions work well and how can we put what we already have to better use (e.g. scale-up, new products, etc.)?
- What is the geographical scope and level of analysis? Important to assess whether there are collective movements (and at what level)?

4.2.3 Summary on domain specific needs from desk research²²

Table 35 below summarises in a simplistic manner the EU intervention logic on Climate Change – Blue Economy starting with the vision, corresponding operational objectives and initiatives. The monitoring system is not yet defined, neither are immediate outputs. As listed below, programmes such as Horizon Europe and Life are funding instruments for helping EU countries to tackle climate change and achieve a sustainable blue economy.

²² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0240&from=EN>

Table 35. EU intervention logic in Climate Change and Blue Economy [provisional simplistic version]

Vision	Climate-neutral Europe by 2050 and sustainable blue economy				
Operational objectives	<p>Achieve the objectives of climate neutrality and zero pollution</p>	<p>Circular economy and preventing waste</p>	<p>Biodiversity and investing in nature</p>	<p>Support climate adaptation and coastal resilience</p>	<p>Responsible food systems</p>
Targets [impacts]	<p>expanding offshore renewable energy, which could generate a quarter of the EU's electricity in 2050, multiply five-fold the capacity for offshore renewable energy by 2030 and 30-fold by 2050</p> <p>a 90% reduction of greenhouse gas emissions from maritime transport, decarbonise maritime transport</p>	<p>turning blue economy sectors more circular.</p>	<p>minimising the environmental impacts of fishing on marine habitats with measures such as specifications for fishing gear and mesh sizes, closed areas and seasons</p>	<p>developing nature-based solutions to adapt to sea level rise, depollute areas or fight eutrophication.</p>	<p>contributing to the transition towards a sustainable, low-carbon food system</p>
Policies	<p>Horizon Europe</p> <p>InvestEU</p> <p>Blue Careers ocean literacy programme</p> <p>Life programme</p>	<p>Life programme</p>	<p>Life programme</p> <p>Horizon Europe</p>	<p>Life programme</p>	<p>EU programmes Copernicus</p> <p>European Marine Observation and Data Network</p>

<p>Initiatives (including STI initiatives)</p>	<p>FuelEU initiative</p> <p>Power up' flagship initiative</p> <p>Vision And Strategies Around the Baltic Sea' initiative (VASAB)</p> <p>Clean Energy for EU Islands Initiative</p> <p>WestMed initiative</p> <p>Cooperation initiatives (CESEC High Level Group; North Seas Energy Cooperation)</p> <p>Support fishing fleets in adopting cleaner engines and techniques</p> <p>Promote the use of EU funds to green maritime transport</p> <p>Create a Blue Forum for users of the sea</p> <p>Pursue the objective of zero-emission ports</p> <p>Support Member State to prepare for and respond to marine pollution accidents</p>	<p>Implementation of the Directive on Single Use Plastic Products and fishing gear to address the problem of marine plastic pollution while safeguarding the single market</p> <p>Further developing and harmonising methods for measuring unintentionally released microplastics,</p> <p>Delivering harmonised data on microplastics concentrations in seawater</p> <p>Standards for the circular design of fishing gear that facilitate re-use and recyclability</p> <p>European Maritime, Fisheries and Aquaculture Fund</p> <p>Action to halve plastic litter at sea, nutrient loss into the sea and the use and risk from chemical pesticides by 2030</p>	<p>Table a proposal for legally binding EU targets to restore degraded ecosystems</p> <p>New action plan for conserving fisheries resources and protecting marine ecosystems by the end of 2021</p> <p>Identify and designate additional marine protected areas and define strict protection by the end of 2021</p> <p>Promote and support local participatory initiatives combining the regeneration of marine resources with the preservation of local livelihoods</p>	<p>Close the knowledge gaps and stimulate innovation for increased climate resilience for coastal areas</p> <p>Boost the capacity for Copernicus and EMODNet observation for better anticipation of the effects of extreme weather events</p> <p>Stimulate cooperation between coastal regions and islands sharing common needs in</p>	<p>Table by 2023 a legislative proposal for a framework that will include fisheries and aquaculture products</p> <p>Put forward in 2022 a legislative proposal for modern, sustainable marketing standards for seafood</p> <p>Adopt a dedicated initiative on algae in 2022</p> <p>Support the digital transition of fisheries control and promote the enforcement of fisheries rules</p> <p>Assess the potential and research and investment needs regarding cell-based seafood</p>
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		<p>Action to restrict intentionally added micro-plastics and develop labelling, standardisation, certification and regulatory measures on the unintentional release of micro-plastics</p> <p>Ensure that litter caught in fishing operations is reported at port</p> <p>Ensure that plastic fishing gear is collected and recycled after its use</p> <p>Revision of the ship recycling Regulation and the EU requirements</p>		<p>the same sea basin</p> <p>Assist Member States in long-term planning to phase in investments</p>	<p>Implementing the common fisheries policy</p> <p>Strengthen fisheries management in the Mediterranean and the Black sea</p> <p>Working on implementing the Western Mediterranean multiannual fisheries management plan</p>
STI Outputs	-	-	-	-	-

Vision, Ambition Statements and Targets

While many societal and political steps towards tackling climate change have been taken internationally, first by the United Nations Framework Convention on Climate Change, then by Kyoto and culminating in the historic Paris agreement, the EU has in a very complementary way designed climate strategies. The latest and by far the most comprehensive, complete and multifactorial: the European Green Deal. Through this broad plan, the ultimate goals are to turn climate and environmental challenges into opportunities, and to make the transition fair and inclusive for all.

The EC has set the vision of a climate-neutral Europe by 2050 with no net emissions of greenhouse gases and reducing greenhouse-gas emissions by at least 55% of 1990 levels by 2030. For achieving this transformation, a sustainable blue economy is essential. Blue Economy will help achieve both the European Green Deal and the Recovery Plan for Europe. The European Green Deal will transform the EU into “a modern, resource-efficient and competitive economy, ensuring no net emissions of greenhouse gases by 2050 and economic growth decoupled from resource use” while the Recovery Plan for Europe aims to “boost the green and digital transitions and make Europe’s economy fairer, more resilient and more sustainable for future generations”.

The intersection between Climate Change and Blue Economy is defined following the EC’s approach on a sustainable blue economy which focuses on:

- Climate neutrality and zero pollution
- Circular economy and preventing waste

- Biodiversity and investing in nature
- Coastal resilience
- Responsible food systems.

For implementing this vision, EC has announced several strategies and action plans. The main strategies/action plans of the above mentioned pillars are:

- EU offshore renewable energy strategy
- Circular Economy Action Plan
- EU biodiversity strategy
- EU strategy on adaptation
- Farm to Fork Strategy

Each strategy/action plan has set its own objectives as follows:

The **EU offshore renewable energy strategy** aims at developing offshore renewable energy, reducing maritime transport greenhouse gas emissions and make ports' infrastructures greener and use them as energy hubs.

The **Circular Economy Action Plan** aims at reducing by 50% plastic litter at sea and by 30% microplastics released into the environment, collecting and recycling the plastic fishing gear and revising the regulation for ship recycling and offshore platforms decommissioning.

The **EU biodiversity strategy** for 2030 aims at protecting at least a 30% of the EU's sea area, maintaining and restoring coastal vegetation.

The **EU strategy on adaptation** aims at increasing climate resilience for coastal areas, better anticipating the effects of extreme weather events and regional sea-

level rise and stimulating cooperation between coastal regions and islands sharing common needs in the same sea basin.

The **Farm to Fork Strategy** aims at a sustainable, low-carbon food system which reaches at least 25% of the EU's agricultural land under organic farming and a significant increase in organic aquaculture by 2030.

The role of STI policy

The EC's five main strategies/action plans referring to a sustainable blue economy all analyse the role of research and innovation for tackling climate change and having a sustainable blue economy:

1. As Commission mentioned "Offshore renewable energy is among the renewable technologies with the greatest potential to scale up". The EU is a global leader in such energy and industries on developing ocean energy technologies, mainly wave and tidal. At this moment, no specific ocean technology prevails but such technologies could help EU energy system and decarbonize EU islands. Energy industries are also strong in the emerging technology of floating offshore wind. There are lots of floating designs and under constructions, none of which is operated at this stage. By 2024, 150 MW of floating offshore wind turbines will be operated. Other early stage and promising technologies are algal biofuels, ocean thermal energy conversion (OTEC) and floating photovoltaic installations. R&I priorities in offshore wind focus on wind turbine design, infrastructure development, circular advanced materials and digitalization while other innovations expected to rise in the upcoming years are superconducting generators, advanced tower materials and the added value of offshore wind energy as well as optimisation of

existing manufacturing processes in sectors such as large-scale blade production which should be a future R&I focus.

2. The promotion of digital technologies and climate services can support decision-making. Databases, services development on extreme events and new instruments such as Destination Earth and Digital Twins can help our understanding of climate impacts. In addition, climate knowledge platforms are important in decision-making. Among them, Climate-ADAPT is a tool which gives information on climate impact and adaptation. The Commission will “promote and support the use of its Risk Data Hub to harmonise the recording and collection of comprehensive and granular climate-related risk and losses data, and promote national level public private partnerships to collect and share such data; explore with European Insurance and Occupational Pensions Authority (EIOPA) and industry the best ways to improve the collection of uniform and comprehensive insured loss data, and will empower EIOPA as needed; extend the scope of public access to environmental information in the INSPIRE Directive to include climate-related risk and losses data.”
3. As far as the transition to a sustainable food system is concerned the Commission is going to spend EUR 10 billion under Horizon Europe on R&I on food, bioeconomy, natural resources, agriculture, fisheries, aquaculture, the environment and the use of digital technologies and nature-based solutions for agri-food. Fishers and aquaculture producers have to follow new production means by using nature-based, technological, digital, and space-based solutions for enhancing climate results.
4. As for the biodiversity conservation the investment in research, innovation and knowledge exchange are important for data collection and nature-based

solutions development as well as testing and developing the way of prioritising 'green' over 'grey' solutions. Moreover, as Communication (COM(2020) 380 final) refers "the future Horizon Europe programme will include a long-term strategic research agenda for biodiversity, including a science policy mechanism for research-based options for ratcheting up the implementation of biodiversity commitments, with increased funding". The Commission will boost and facilitate partnerships to link science, policy and practice and implement nature-based solutions as well as will increase its support to the Intergovernmental science-policy Platform on Biodiversity and Ecosystem Services.

5. In the EU Strategy for offshore renewable energy priorities are in design, infrastructure development, circular advanced materials and digitalization. In the upcoming years superconducting generators, advanced tower materials and the added value of offshore wind energy are the innovations expected to be increased. Moreover, a future R&I focus should be the optimisation of the large-scale blade production. Horizon Europe and the Innovation Fund will support "the development and testing of new and innovative offshore renewable energy technologies, components and solutions" as well as "the demonstration of innovative clean technologies at commercial scale, such as ocean energy, new floating offshore wind technologies or projects to couple offshore wind parks with battery storage or hydrogen production".

Domain-specific regulatory context

The main regulations related to Climate Change and in particular the intersection of Climate Change and Blue Economy are summarized below in Table 36.

Analysing the impact of regulation on innovation forms part of evaluations and impact assessment at the national and EU levels but is often captured only qualitatively due to the lack of data. As Climate Change is an R&D intensive domain and regulation is a key instrument towards achieving 2030 targets the STI data needs should be further investigated in consultation with the domain experts.

Table 36. Regulations related to Climate Change – Blue Economy (non exhaustive)

Issue Date			Version	Comments
Regulation 994/2008	(EC)	No	EU emissions trading system (EU ETS)	2
Regulation 920/2010	(EC)	No	EU emissions trading system (EU ETS)	2
Regulation 2018/842			Effort Sharing - binding annual greenhouse gas emission reductions by Member States from 2021 to 2030	2
Regulation 1005/2009	(EC)	No	EU Ozone Regulation	2
Regulation (EU) No 2019/631			Transport - light vehicles EU setting CO2 emission performance standards for new passenger cars and for new light commercial vehicles	2
Regulation (EU) 2019/1242			Transport - heavy-vehicles EU setting CO2	2

			emission performance standards for new heavy-duty vehicles	
Regulation 2015/757			Transport - Shipping	2
Delegated Regulation (EU) 2016/2071			Transport - Shipping	2
Implementing Regulation 2016/1927			Transport - Shipping	2
Implementing Regulation 2016/1928			Transport - Shipping	2
Inception Assessment (Roadmap)		Impact	Transport - Aviation	2
Regulation (EU) 517/2014			Fluorinated greenhouse gas	2
Regulation (EU) 525/2013			Climate Monitoring Mechanism	2
Regulation 1380/2013	(EU)	No	Common Fisheries Policy	
Regulation 1315/2013	(EU)	No	Development of the trans-European transport network and repealing Decision No 661/2010/EU Text with EEA relevance	
Directive 2014/94/EU			Deployment of alternative fuels infrastructure with EEA relevance	

Directive (EU) 2019/883	Port reception facilities for the delivery of waste from ships	
Directive (EU) 2019/904	Reduction of the impact of certain plastic products on the environment	

Notes:

Type 1: Regulations targeting the promotion of innovation. This includes for example intellectual property regulation, which impacts companies and their innovation behaviour directly.

Type 2: General regulation without the dedicated goal to promote innovation. This is the dominant type. Regulation in this category targets health and safety, or environmental regulations, but also market regulations are integrated in this type. General regulations have a direct impact on companies. As a consequence of the regulation, they need to modify existing products (incremental innovation effect) or introduce radical product or process innovations. This has potential effects on the environmental pressures but also consumers and society.

Type 3: The third group concerns regulations affecting companies' strategies and activities but not necessarily affecting (positively) their innovation activities. Here, reporting requirements and the often labelled 'administrative burden' -type of regulation is meant.

Overview of monitoring framework in place supporting the measurement of outputs

Monitoring, reporting and evaluation are crucial for every strategy. At this moment there is no specific monitoring framework for the European Green Deal or the strategies/action plans. The creation of indicators for monitoring the process of the actions is expected in the upcoming years. According to the EC

study (2021)²³ referring to the Blue Economy Sustainability Framework a number of sustainability criteria and indicators are presented for each Blue Economy subsector. Table 37 below gives an overview of such indicators on subsectors.

Table 37. Overview of indicators for each Blue Economy subsector

Subsector	Criteria	Indicator	Unit
Extraction of minerals (including the deep-sea extraction - seabed mining-)	Impact on environment	Technologies applied to reduce the impact of dredging plume, noise, vibration and heat	No. and type of technologies No./year
	Impact on environment	Number of times that turbidity is not in compliance with regulations	No./year
Extraction of oil and gas	Emissions to water	Produced water subject to treatment	% produced water subject to treatment
	Oil spills response	Frequency of oil spill response exercises and trainings	No. of exercises and trainings/ year
	Waste management	Existence of drilling waste management plan	Yes/no
	Impact on environment	Technologies applied to	No. and type of

²³ <https://cinea.ec.europa.eu/system/files/2021-05/Sustainability%20criteria%20for%20the%20blue%20economy%20.pdf>

		reduce the impact of noise, vibration and heat	technologies
	Impact on ecosystems	Refuge effect for species	Yes/no, if yes: specify
Extraction of water	Impact on ecosystems	Salinity increase	ppm above ambient salinity
	Impact on ecosystems	Temperature increase	°C above ambient temperature
	Infrastructure capacity	Amount of discharged brine	Million tons/year
	Chemical use	Discharge of chemicals	Tons/chemical/year
Fish and shellfish harvesting	Status of stock	Exploitation of stock at Maximum Sustainable Yield	% stock exploited at Maximum Sustainable Yield (per species)
	Fishery management	Use of selective fishing techniques/gears	Yes/no. If no, specify
	Fishery management	Use of non-destructive fishing techniques/gears	Yes/no. If no, specify
Fish and shellfish processing	Waste management	Treatment of waste water	Yes/no
	Waste management	Use of recycled packaging materials	Yes/no
	Waste water management	Re-use of fish waste	Yes/no
Marine plant and algae harvesting	Status of stock	Exploitation of stock at Maximum Sustainable Yield	% stock exploited at Maximum Sustainable Yield

			(per species)
	Harvesting management	Use of selective harvesting techniques/gears	Yes/no. If no, specify
	Harvesting management	Use of non-destructive harvesting techniques/gears	Yes/no. If no, specify
Aquaculture	Chemical use	On-farm documentation available with detailed information on chemicals use, compliant with regulations (including anti-biotics)	Yes/no. If yes: specify
	Supply chain	Existence and effective implementation of a company policy to ensure inputs/raw materials are obtained from sustainable sources	Score 1. Policy does not exist 2. Policy exists but not implemented 3. Policy exists and implemented
	Farm management	Mortalities reduction program exists and implemented	Yes/no. If yes: specify
	Farm management	Number of escape events	No. of escapes / year
	Farm management	Number of escaped fish	No. of escaped fish / year
	Water quality	Measures taken to reduce nutrient eutrophication	No. and type of measures taken
	Water quality	Phosphorous (P) and	mg/L

		nitrogen (N) concentrations	
	Impact on ecosystems	Refuge effect for species	Yes/no, if yes: specify
Renewable energy	Impact on ecosystems	Species fatalities due to collisions	No. and type of fatalities/year
	Impact on ecosystems	Refuge effect for species	Yes/no, if yes: specify
Transport infrastructure	Introduction of invasive species	Onboard ballast water treatment system available and functioning	Yes/no
	Oil spills response	Frequency of Oil Spill Response exercises and trainings	No. of exercises or trainings / year
	Water quality	Measures taken to reduce nutrient emissions	Yes/no. If yes: specify
	Use of shore power	Availability of shore power infrastructure in port	Yes/no
Transport shipping	Emissions to air	Measures taken to reduce emissions to air through exhaust cleaning	Yes/no. If yes: specify if measure involves disposal of sludge produced by Exhaust Gas Cleaning System
	Emissions to air	Average fuel Sulphur content per bunkering	% avg, fuel Sulphur content per kind of fuel

	Introduction of invasive species	Onboard ballast water treatment system available and functioning	Yes/no
	Waste management	Waste management systems (sludge handling) available and functioning	Yes/no
	Level of fuel consumption	Fuel consumption	Tons/kind of fuel/year
	Impact on ecosystems	Sewage discharge in Particular Sensitive Sea Areas	Yes/no
	Chemical use	Use of chemicals for antifouling, stern tube oils, external hydraulic fluids, gear oils for thrusters and controllable pitch propellers, boiler/cooling water treatment, cleaning agents, refrigerants.	Yes/no for each application. If yes: specify.
	Use of shore power	Onboard infrastructure to connect to shore power	Yes/no
Tourism	Level of energy consumption	Specific energy use	kWh/m2yr
	Level of water consumption	Water consumption per guest night	Litres/guest night
Coastal defense and	Flood safety	Open vs. closed coastal	Open or closed

flood protection		defence or flood protection system	system. If closed, specify impact on fish migration
	Flood safety	Existence of natural barriers	No. and type of natural barrier (e.g. (wetlands, mangroves, reefs)
	Impact on ecosystems	Refuge effect for species	Yes/no, if yes: specify

On **Adaptation Strategy**: The Regulation on the Governance of the Energy Union and Climate Action specifies the reports on adaptation for the Member States but the comparison between them is challenging due to the specificity of each country. The Commission will develop more indicators and a framework for monitoring better the climate adaptation.

On **CE Action Plan**: The Commission will strengthen the monitoring on national plans and measures for a quick transition to circular economy and will update the Monitoring Framework for the Circular Economy. The Commission will also proceed to create new indicators on the action plan focus areas and interlinkages between circularity, climate neutrality and the zero pollution ambition, as well as to develop existing indicators on resource use to assess material consumption and environmental impacts associated with production and consumption patterns. Moreover, the measurement of circularity will be enhanced under Horizon Europe projects and Copernicus data.

On **Farm to Fork Strategy**: The Commission will monitor the transition to a sustainable food system as well as the progress of each target and the reduction of the environmental and climate footprint of the EU food system. Data will be

collected for a thorough assessment of the impact of all actions in this strategy on competitiveness, the environment and health. For achieving the objectives, the strategy will be reviewed by mid-2023 in case that further actions should be added.

Enabling conditions

A sustainable blue economy can achieve the European Green Deal objectives through the solutions provided although there are factors affecting the sustainability as referring below:

- The offshore renewable energy for being sustainable have to affect in a positive way the environment and have economic, social and territorial cohesion. As it is growing over the years all players of the supply chain have to keep pace to this rate. The sea spaces for developing offshore renewable energy have to be designed carefully for not affecting the marine ecosystems. Moreover, public authorities have to assess the environmental, social and economic sustainability of the offshore renewable energy and make sure that there is no negative impact on fisheries and aquaculture, shipping, tourism, defence or infrastructure deployment by conducting a development plan that people embrace.
- The transition to sustainable food systems cannot succeed if people are not ready to change their diets. The economic crisis makes this transition even difficult as people cannot afford frequently a quality meal. Food waste and consumption patterns have to change for eliminating the environmental footprint. Not only EU but the whole world has to make efforts for achieving a sustainable transition.

- As marine ecosystem has not unlimited resources illegal practices are not helping in its sustainability and good environmental status restoration.
- The cooperation of all stakeholders in EU is crucial for the transition to the circular economy.

4.3 Towards the identification of STI policy needs in the Cancer domain

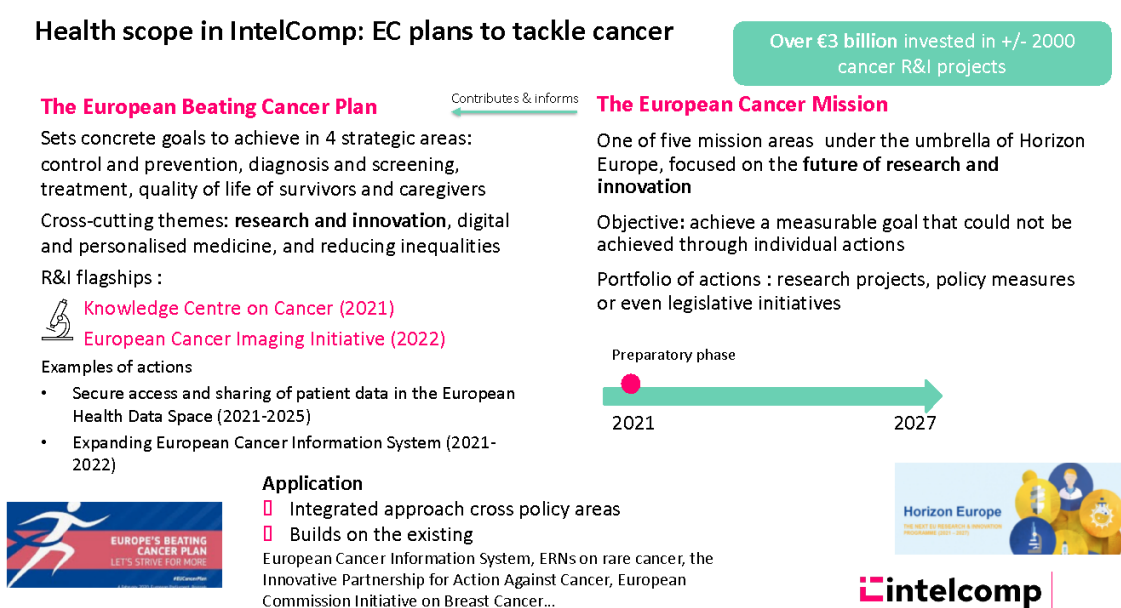
This section synthesizes insights on STI needs in the domain of Cancer collected during the first six months of IntelComp. The STI needs derive from IntelComp's conceptual framework applied to the domain of Cancer via the consultation of actors during the workshop, and has been complemented by desk research.

In summary, it can be said that the actors consulted emphasize the need for improvements and enhancement of current means of assessment of STI measures. They highlight the role of having a good variety of data sources available (including qualitative and mixed-language data sources). Moreover, they point towards the need for better inter-connectivity of both data and stakeholders (e.g. practitioners in basic and applied research, with policymakers and links with industry) for better and more efficient policy planning. There also appears to be a great need for a better assessment of impact (beyond current traditional means such as publications, etc.). Not underestimating the need of an analysis of new and emerging trends (e.g digitalization, personalized medicine...), some actors also pointed out to be interested in the role that gender/age may have in research teams and/ or research approaches.

4.3.1 Scope

In the domain of Health, IntelComp will focus on Cancer (see Figure 5). The scope within cancer is delineated by the EU approach in its “European Beating Cancer Plan” and thus covers the following strategic areas: 1) control and prevention, 2) diagnosis and screening, 3) treatment and 4) quality of life of survivors and caregivers. With this plan Europe presents how it will “support, coordinate or supplement” efforts of Member States, given that health is primarily a responsibility of Member States.

Figure 5. IntelComp scope in the Health domain: Cancer



4.3.2 Summary on domain specific needs from consultations

The actors who participated to the IntelComp workshop/interviews on Cancer when asked on their STI priorities placed particular emphasis on data (Box 8). Different perspectives were included, such as enhancing analytics of clinical trials, doing so not just after the trial but also in the medium to longer term, as well as issues on data sharing, inter-operability and replicability of outcomes. Related to the need for medium to longer term monitoring, several actors emphasized on the patient and the need to measure and compare qualitative impacts such as Quality of Life (QoL). Moreover, several points were made on the survival of companies with the potential to bring innovative solutions to the market and the role of the public sector.

Box 8. STI priorities in the domain of Cancer

- **Knowledge:** Clinical trials as a driver of research. Importance of monitoring effects, producing statistics, attribution to policy measures
- **Knowledge diffusion:** Improving (inter-)connectivity between stakeholders and information sharing. Includes considerations on the needs of both public and private entities
- **Guidance:** The needs of patients at the center. Includes early diagnosis, quality of life, clinical pathways, the patients' journey, measuring/comparing qualitative impacts (such as QoL, life expectancy gains)
- **Better data:** Includes information sharing, data inter-operability, data protection elements and speeding up data transfer

- **Human capital:** Upskilling (digital and soft skills)
- **Entrepreneurship:** The development of health technologies. Includes the role of scale-ups and their sustainability. It is necessary to consider why good hybrid devices/software solutions are not included/considered in the procurement process (they often miss out on these opportunities and then do not survive on the market)
- **Other:** Understanding the intersection of data between the different policy stages (from foresight, agenda-setting to evaluation)

With respect to evaluations, the actors voiced the following needs they struggle to fulfill during the evaluation phase with a strong domain focus (summarised in Box 9). Among the take-aways we observe a greater need for the ability to continue monitor patients in the medium to longer term as well as enhance the analytical and explanatory power of the data collected by linking data or stimulating more exchange on results or the ability to reproduce outcomes.

Box 9. STI evaluation needs in the domain of Cancer

- Quantifying health impact
- Comparing / measuring qualitative impact and patient experience (quality of life, life expectancy gains, etc.)
- Assessment of relevant qualitative data sources, for e.g., during a gap analysis for efficient policy programme planning
- Longer term monitoring of Patient-reported outcome measures and Patient-reported experience measures

- Connecting science practitioners with data analysis to ensure reproducibility of research and technology transfer
- Assessing/ Evaluating medium/long-term indicators to select the right projects to receive funding
- Toolbox for the analysis of various data sources and respective relations
- Exchange platform to discuss results and ask questions
- Improving the evaluation process as a whole (including efficiency)

As explained in sections 2 and 3 the starting point for the identification of policy needs has been via a list of domain agnostic policy questions. During the workshop and in the context of evaluation the participants indicated additional questions or proposed a reformulation of the policy questions to better fit the needs of the cancer domain. A listing is provided in Box 10 for both levels, at the project and programme level.

Box 10. Additional Evaluation questions in the domain of Cancer

Unit of analysis: project

- Identification of new collaborations arising (including Public-Private Partnerships)
- Adoption and replicability of innovations to different healthcare systems in the EU.
Whether possible/ happening?
- Advancements in Technology Readiness Level (TRL) or Interactive Machine Learning (IML) for the different areas of projects?
- Identification of TRL tranches were projects need more support?
- Project replicability

- Post-marketing data collection (after clinical trials)
- Creation of other ancillary jobs e.g., start-up ecosystem regulators
- Training and skills – evolution/new directions of trained personnel? Adoption of different career profiles?
- Do gender/ age aspects play a role (e.g. research teams' approaches, etc.)?

Unit of analysis: programme

- Means to track long term employment
- Retaining skilled / trained talent (also non-EU) (is linked to the creation of employment)
- Mapping of complementary/synergetic/substitute sources of funding
- For subsequent programming period the time window to receive results is important (Cancer is a “race against time”)
- Definition of whether the programme is realistic (e.g., time, budget, resources)
- Situational analysis for prioritization (e.g., what field of cancer linked to what return on investment? Quality of life of patients?) – it may be a secondary need, but it can help leverage funds
- Measuring research outcomes with a focus on different age groups, namely pediatrics and gender distinctions
- The impact on citizens (Do socio-demographic variables play a role (long-term assessment/monitoring/ evaluation))?

Finally, among the domain agnostic policy questions, signals towards those of top priority are included in Table 38 below. These results should be seen as preliminary as several iterations with actors as foreseen within the living labs are required, before conclusions informing choices for IntelComp can be drawn.

Table 38. STI priorities for Health expressed during the consultation workshop

Framework	List of selected sub-questions selected by the participants	
Entrepreneurial activity, Knowledge creation, Knowledge diffusion through networks, guidance	Unit of analysis: projects	<p>Top priority of selected sub-questions</p> <ul style="list-style-type: none"> ● What new products have been developed? How many were launched in the market? What was their contribution to turnover, profits, exports, taxes? ● How many new algorithms, software....were developed? Used? <p>Others selected:</p> <ul style="list-style-type: none"> ● How many presentations in top scientific conferences? (distinction between specialization, basic and applied research) ● How many people were trained as researchers? As technicians? ● How many new jobs were created for researchers during the project? ● How many new jobs were created after the project (research and beyond) within the country?
	Unit of analysis:	<p>Top priority of selected sub-questions</p> <ul style="list-style-type: none"> ● Are currently available strategies/policies coherent?

	<p>programmes</p>	<ul style="list-style-type: none"> ● What were the social returns on investments? Taxes generated? ● Which societal challenges have been addressed? ● Has the sectoral specialization of the productive system changed towards higher value added activities? <p>Others selected:</p> <ul style="list-style-type: none"> ● What has been the leverage of national support measures for EU competitive funding? ● What was the research employment created? ● What is the cost benefit analysis of each programme? ● What are the multiplication effects of each programme? ● Has the sectoral specialization of the research system changed towards higher value added activities?
<p>Market formation</p>		<p>Top priority of selected sub-questions</p> <ul style="list-style-type: none"> ● Has the regulation adopted facilitated the creation/access to new markets? ● Has public procurement of innovation produced effective results? Has it created lead markets?

4.3.3 Summary on domain specific needs from desk research

Table 39 below summarises in a simplistic manner the EU intervention logic on Cancer starting with the vision and corresponding operational objectives. Targets include quantifiable targets and showcase the impacts expected including direct targets on cancer but also related targets which are considered a prerequisite to achieving objectives and represent key enabling conditions. Main policies/programmes follow which also provide an indication of the available

funding. The roadmap corresponds to 42 actions including 10 Flagship actions. From those we distinguish the STI actions and initiatives which represent the focus of IntelComp. Upon this basis outcomes and outputs can be conceptualized which would anticipate monitoring STI needs for especially the policy cycle phase of evaluation but also for monitoring and implementation.

Table 39. EU intervention logic on Cancer (provisional simplistic version)

Vision	To leave no stone unturned to take action against cancer contributing to a stronger European Health Union
Operational objectives	<ul style="list-style-type: none"> ● “New technologies, research and innovation and the service of patient-centred cancer prevention and care” ● “Saving lives through sustainable cancer prevention” ● “Improving early detection of cancer” ● “Ensuring high standards in cancer care” ● “Improving the quality of life for cancer patients, survivors and carers” ● “Reducing cancer inequalities across the EU” ● “Putting childhood cancer under the spotlight”
Targets	<ul style="list-style-type: none"> ● “By 2030, more than 3 million lives saved, living longer and better”. This is consistent with UN Sustainable Development Goal (SDG) 3: Ensure healthy lives and promote well-being for all at all ages. ● “By 2030, reduce by one third of premature mortality from cancer through prevention and treatment and promote mental health and well-being”. UN Sustainable Development Goal (SDG) 3. ● “Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all” Targets from areas representing enabling conditions ● “A tobacco-free generation: ensuring that less than 5% of the population

	<p>uses tobacco by 2040” and a 30% relative reduction in prevalence of current tobacco use in persons aged 15+ years</p> <ul style="list-style-type: none"> • “Reduce harmful alcohol consumption in line with the targets of the UN Sustainable Development Goals (relative reduction of at least 10% in the harmful use of alcohol by 2025) and reduce young people’s exposure to alcohol marketing” • “A 10% relative reduction in prevalence of insufficient physical activity” • “A 30% relative reduction in prevalence in mean population intake of salt/sodium” • Halt the rise in diabetes and obesity • “In Line with EU’s Action Plan: Towards Zero Pollution for Air, Water and SoilHalve the aim is to halve premature deaths caused by air pollution by 2030 and align the EU’s air quality standards with the World Health Organization’s guidelines and reduce exposure to carcinogenic substances and radiation” 			
Policies / Programmes	EU4Health programme	Horizon Europe (especially Cancer Mission)	Digital Europe programme	Legislative proposals
Roadmap/ Actions	<p>EBCP 10 flagship initiatives EBCP 42 actions</p>			
STI actions/ initiatives	<p>KNOWLEDGE-DIFFUSION</p> <p>EU Knowledge Centre on Cancer</p> <p>EU Network of national comprehensive Cancer Centres</p> <p>Helping Children with Cancer</p>		<p>KNOWLEDGE CREATION</p> <p>European Cancer Imaging Initiative</p> <p>EIT and MSCA</p>	<p>DATA (Platforms)</p> <p>European Cancer Information System</p> <p>Cancer Inequalities Registry</p>

	<p>Initiative</p> <p>European Reference Networks</p> <p>Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)</p> <p>2 dedicated HE partnerships on healthcare (including cancer)</p> <p>1. Innovative Health initiative 2. Transforming Health and Care systems</p> <p>Innovative Partnership for Action Against Cancer (IPAAC)</p>	<p>projects (Horizon Europe) Projects</p> <p>EU Cancer Treatment Capacity and Capability Mapping' project</p> <p>European Initiative to Understand Cancer (UNCAN)</p>	<p>Genomic for Public Health project (alongside the 1+ Million Genomes Initiative)</p> <p>Repository of digital twins in healthcare</p> <p>European Open Science Cloud</p>
<p>STI Outcomes</p>	<ul style="list-style-type: none"> • "Reducing cancer inequalities across the EU" • "Putting childhood cancer under the spotlight" • "Ensuring high standards in cancer care" 	<ul style="list-style-type: none"> • "New technologies, research and innovation" • "Saving lives through sustainable cancer prevention" • "Improving early 	<ul style="list-style-type: none"> • "New technologies, research and innovation and the service of patient-centred cancer prevention and care" • "Improving early detection of cancer"

		detection of cancer” <ul style="list-style-type: none"> • “Putting childhood cancer under the spotlight” 	
STI Outputs			

Vision, Ambition Statements and Targets

The EU **Vision** is a political commitment *“to leave no stone unturned to take action against cancer”*.

EU **operational objectives** on cancer are summarised in the Europe's Beating Cancer plan published in early 2021.²⁴ The plan is a key EU public health initiative and an essential part of the European Health Union process launched in November 2020. It includes the following ambition statements:

- *“New technologies, research and innovation and the service of patient-centred cancer prevention and care”*
- *“Saving lives through sustainable cancer prevention”*
- *“Improving early detection of cancer”*

²⁴ See: https://ec.europa.eu/commission/presscorner/detail/en/ip_21_342

- *“Ensuring high standards in cancer care”*
- *“Improving the quality of life for cancer patients, survivors and carers”*
- *“Reducing cancer inequalities across the EU”*
- *“Putting childhood cancer under the spotlight”*

The **targets** of the EU’s Beating Cancer plan are in alignment with the UN’s SDGs targets in ‘Good Health and Well-Being’ and include the following associated quantifiable targets:

- *“By 2030, reduce by one third of premature mortality from cancer through prevention and treatment and promote mental health and well-being”*
- *“Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”*

The targets from areas representing enabling conditions are:

- *“A tobacco-free generation: ensuring that less than 5% of the population uses tobacco by 2040” and a 30% relative reduction in prevalence of current tobacco use in persons aged 15+ years*
- *“Reduce harmful alcohol consumption in line with the targets of the UN Sustainable Development Goals (relative reduction of at least 10% in the harmful use of alcohol by 2025) and reduce young people’s exposure to alcohol marketing”*
- *“A 10% relative reduction in prevalence of insufficient physical activity”*
- *“A 30% relative reduction in prevalence in mean population intake of salt/sodium”*
- *Halt the rise in diabetes and obesity*

- *“In Line with EU’s Action Plan: Towards Zero Pollution for Air, Water and Soil Halve the aim is to halve premature deaths caused by air pollution by 2030 and align the EU’s air quality standards with the World Health Organization’s guidelines and reduce exposure to carcinogenic substances and radiation”*

The **scope** of the plan covers every stage of the disease: from prevention, early detection, diagnosis and treatment to an improved quality of life for cancer patients and survivors. Cross-cutting themes include research and innovation, digital and personalised medicine, financial instruments and action to reduce cancer inequalities across the EU.

Operationally, the plan consists of **10 flagship initiatives and 42 supporting actions**, to be rolled out over the coming years (from 2020 to 2030). The plan will establish actions across policy areas, from social policy to agriculture.

The plan will make use of all available **programmes** and corresponding funding instruments amounting to a total of €4 billion budget to support Member States, including the new ambitious EU4Health programme, Horizon Europe, and the Digital Europe programme:

- *EU4Health programme*: The EU4Health programme was established in light of the Covid-19 crisis. This new programme will go beyond crisis response and address healthcare systems’ resilience. It will pursue 4 main goals: to improve and foster health in the Union, to tackle cross-border health threats, to improve medicinal products, medical devices and crisis-relevant products, to strengthen health systems, their resilience and resource efficiency. Actions will fall under four strands: disease prevention, crisis preparedness, health systems, and digital, with

a cross-cutting focus on cancer. As such it will invest in the Europe's Beating Cancer Plan.

- *Horizon Europe's Cancer Mission:* One key element of the foreseen EU investment in cancer research and innovation is the Horizon Europe's Mission on Cancer which debuted in November 2020. The mission will combine actions – such as research projects, policy measures or even legislative initiatives – to achieve a measurable goal that could not be achieved through individual actions. Headed by a Mission Board for Cancer, the initiative is still in its preparatory phase. The Mission on Cancer will help better understand cancer and therefore inform the R&I elements of the Beating Cancer Plan. On the governance, the Mission is governed by DG RTD while the Beating Cancer Plan is overseen by DG SANTE. These two initiatives are among the main actions under the European Health Union plan and are supported by the JRC resources and expertise.
- *Digital Europe programme:* According to the Europe beating cancer plan, the Digital Europe programme is foreseen to provide financial support of up to €250 million for cancer-related projects, and support wider digital investments, such as relating to electronic data, cybersecurity and digital skills from which the health sector will benefit. This will help in ensuring an enhancement of digitalization, the use of AI and supercomputing for better diagnosis and treatment. There are also the envisioned launch of the European Health Data Space that can help data sharing to help in the fight to beat cancer.

Since health is primarily a responsibility of Member States we looked indicatively into two country cases, France and Spain, to better understand whether the

analysis at country level would significantly expand thematically or re-prioritise action wise the current overview at the EU level. This understanding may be hampered by a strong disparity of considerations in different national health systems, and a problem to infer considerations at EU level.

France

For instance, in the beginning of 2021 France announced its new strategy against cancer with the aim to reduce preventable deaths by 60.000 a year (leading to 40% overall reduction by 2040). Moreover, it strongly envisions a tobacco-free younger generation in the future targeting 20 year-old in 2032. Improvement is also needed in reducing alcohol consumption, as France can be seen as one the largest consumers in a comparison amongst developed economies. It also wants to increase cancer tests by 1 million per year, targeting 10 million tests per year by 2025.

The national long-term objectives are aligned with the EU's goals, namely focusing on:

- Cancer prevention
- Treatment (effects) after diagnosis
- Better treatment results for children
- Better treatment results for severe cancer forms

In order to achieve these goals, France has increased its investments to fund cancer research by 20% with a total budget of €1.7 billion between 2021-2025.

Spain

Another example is Spain that recently announced an update of their Cancer Strategy in line with the newly launched European Beating Cancer Plan. Similar to the EU, the national strategy considers cancer prevention as a central priority and integrates precision medicine as a new approach to cancer diagnosis and treatment. The national strategy is yet to place greater emphasis on reducing tobacco and alcohol consumption. It defines as its strategic priorities for action specifically related to STI:

- Enrich information gathering on both national/international level/regional
- Include socio-demographic variables
- Assess the possibilities that have opened up by the availability of computerised clinical data through the shared clinical history to assess clinical outcomes and complement the information in population-based registers
- Maintenance existing population-based cancer registries (and consolidate new population registers)
- Achieve full coverage in the child cancer registry

The role of STI Policy

Cancer research, innovation and new technologies play a central role in the fight against cancer. In the EU, STI in cancer is framed by a number of initiatives:

- The Commission presented in February 2021 the **SAMIRA Action Plan – the Strategic Agenda for Medical Ionising Radiation Applications**. “The Plan will improve EU coordination, ensure that radiological and nuclear technologies continue to benefit the health of EU citizens, and contribute to the fight against cancer and other diseases. This Action Plan is the first follow-up to Europe’s Beating Cancer Plan”. The Plan ensures that EU citizens have access to high-quality radiological and nuclear technologies in medicine with the highest safety standards and include actions such as implementation of a Research Roadmap for medical applications of nuclear and radiation technology.
- On cancer specifically, **a new Knowledge Centre on Cancer** was launched in June 2021 **within the JRC** to help coordinate scientific and technical cancer-related initiatives at EU level. It will contribute to the European Health Data Space as well as to the research under the Cancer Mission. The knowledge centre will operate under the governance of DG SANTE and DG RTD. This Knowledge Centre will: 1) Expand the European Cancer Information System (ECIS) 1) Develop and provide European Guidelines and Quality Assurance schemes for cancer prevention, screening, diagnosis, treatment and care; 3) Evidence-clearing house (via the Knowledge Gateway and Best Practices) for Cancer prevention policies and 4) Be an independent data broker, foster interoperability while expanding the EC IT cancer systems, gateways, platforms and databases
- By 2025, the EC will establish, **an EU Network linking recognised National Comprehensive Cancer Centres** in every Member State. It will facilitate the uptake of quality-assured diagnosis and treatment,

including training, research and clinical trials across the EU. The European Reference Networks will support the network by connecting experts and sharing expertise across the EU.

- Under Horizon Europe, Europe also supports research on cancer through its research initiatives (such as the European Institute of Innovation and Technology, the Marie Skłodowska-Curie Actions) while creating **two partnerships dedicated to healthcare, including cancer**. The first is the **Innovative Health Initiative** which will promote cooperation between the health industry, academia and other stakeholders to translate scientific knowledge into innovations. The second is the **Partnership on Transforming Health and Care Systems**, offering insights to care authorities, regions and healthcare providers on how to better take up research and innovation opportunities.
- Focusing on the policy area, the 2018- 2021 Innovative Partnership for Action Against Cancer (iPAAC) joint action, building on the work of its predecessors the EPAAC and CANcon joint actions, brings together authorities from 24 European countries and aims to develop innovative approaches to advances in cancer control.
- In terms of the **digitalisation of cancer research and treatment**, new digital technologies, particularly AI and HPC are seen as major opportunities to exploit health data. Outside the EU, computational tools are used to improve knowledge sharing about cancer (e.g. the cancer genome atlas program). The main development in this area is the upcoming **European Health Data Space** which will enable cancer patients to securely access and share their health data in an integrated

format in the electronic health records between healthcare providers and across borders in the EU. From 2022, Europe will implement Testing and Experimentation Facilities, supported by Digital Innovation Hubs, to link cancer imaging data to tools such as HPC and AI to improve diagnostic for example. The cancer imaging data will be collected through the European Cancer Imaging Initiative making anonymised data available to researchers and innovators.

- To support Member States in making the most of the rapid evolution of genomics in cancer prevention, diagnosis and treatment, in 2021 the Commission will launch, the 'Genomic for Public Health' project which is expected to give secure access to large amounts of genomic data for research, prevention and personalised medicine purposes.
- To assist researchers working on personalised cancer treatments through tailored support and new digital platforms – New platforms, hosted on the European Open Science Cloud (EOSC), will support interdisciplinary cancer research and enable the delivery of advanced personalised treatments. This collaboration will allow researchers to access, analyse and process research data across disciplines and national borders, including through the European Reference Networks and the EU Network of Comprehensive Cancer Centres while fully complying with data protection laws.

The initiatives above stress the importance of knowledge sharing which has been key and in the past decades research has allowed to understand the factors driving cancer. Also, personalised medicine has particularly garnered attention to address the disease specifically for each patient, powered by digitisation and computer-based analytical tools. The use of this data is particularly relevant when

pooled at the European level in order to develop the personalised solutions that cancer patients need.

Initiatives on STI equally aim to support the link between academic research, innovation and industrial production. Industry and academia play a central role in the area of R&I in the Cancer domain contributing significantly to scientific knowledge creation to better understand, and ultimately beat Cancer, as well as finding new and innovative technologies for diagnosis and patient treatment. The EU emphasizes links with academia and industry under the new ERA, to boost the EU's knowledge base and reestablish its industrial leadership. Likewise, the European stakeholders expect to be transparently included in and informed on this pivotal transformation ensuring EU competitiveness and sustainability, as stated in the Horizon Europe's Strategic Plan for 2021-24. The need for these critical links and synergies in R&I is also reflected in the new European Partnerships.

Domain-specific regulatory context

The main EU pieces of regulation on Cancer within the health domain are summarized in Table 40 below. From an STI perspective, as Cancer is an R&D intensive domain, there are several regulations targeting the promotion of innovation. We classify those as type I regulations following Blind's (2012) innovation typology which include "Regulations targeting the promotion of innovation".

Table 40. EU Regulatory framework (non-exhaustive) for Cancer

Regulation	Description	Innovation typology
Regulation (EC) No1901/2006	Medicinal products for children	(1)
Regulation (EC) No 141/2000	Medicinal products for rare diseases ('Orphan medicines')	(1)
Regulation 2017/745	medical devices	(1)
Regulation (EC) No 1394/2007	Advanced therapy medicinal products	(1)
Regulation (EC) No 726/2004	Laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	(1)
Regulation 536/2014 on	Clinical trials on medicinal products for human use (so called Clinical Trials Regulation – CTR)	(1)
European Health Data Space	A legislative proposal for the European health data space is envisaged for the fourth	(1)

	quarter of 2021	
Proposed Health Technology Assessment Regulation [SWD(2018) 41 final - SWD(2018) 42 final]	The proposed regulation on HTA aims to strengthen EU-level cooperation among Member States for assessing health technologies	(1)
Directive 2014/40/EU	Tobacco Products Directive	(2)
Directive 2011/64/EU	Tobacco Taxations Directive	(2)
Directive 2010/13/EU	Audiovisual Media Service Directive (related to commercial communications on unhealthy food and drink)	(2)
Directive 2004/37/EC	Carcinogens and Mutagens Directive	(2)
Council Directive 2013/59/EURATOM	Directive on protection from ionising radiation, particularly from Radon	(2)
Directive (EU) 2019/1158	Directive on work-life balance for parents and carers	(2)

Notes:

Type 1: Regulations targeting the promotion of innovation. This includes for example intellectual property regulation, which impacts companies and their innovation behaviour directly.

Type 2: General regulation without the dedicated goal to promote innovation. This is the dominant type. Regulation in this category targets health and safety, or environmental regulations, but also market regulations are integrated in this type. General regulations have a direct impact on companies. As a consequence of the regulation, they need to modify existing products (incremental innovation effect) or introduce radical product or process innovations. This has potential effects on the environmental pressures but also consumers and society.

Type 3: The third group concerns regulations affecting companies' strategies and activities but not necessarily affecting (positively) their innovation activities. Here, reporting requirements and the often labelled 'administrative burden' -type of regulation is meant.

The consequence for STI policy makers is that STI needs arise as a result of the need to understand the regulatory impact on R&D and Innovation. Hence, the need to attribute R&D innovation activities to a piece or bundle of regulations and also the impact of that R&D and Innovation on health, society, the environment and the economy. Table 41 below provides two examples of regulations and list the STI data needs as reflected in existing Evaluation and Impact Assessment studies.

Table 41. Examples of regulations in Cancer and STI data needs

Regulation	Description	STI data needs	
		Impact of regulation on R&D and innovation	Health, Economic and Environmental impacts
Medicinal products for children Regulation (EC) No 1901/2006	Encourages the development of suitable medicine for children, promotes high quality research,	Research & Development (R&D) costs of Paediatric Investigation Plans (PIP) or waiver	<ul style="list-style-type: none"> ● Avoided mortalities ● Avoided hospitalization ● Avoided Adverse

	<p>improves the information available on the use of medicines in children, and prioritises the therapeutic needs in this group. This is to be achieved via a set of obligations, rewards and incentives for both new/on-patent products, and off-patent products, with an additional set of tools for transparency, information and research stimulation.</p>	<p>applications, over a period, including costs incurred in relation to preclinical studies, the development of a paediatric formulation, phase II and phase III clinical studies.</p>	<p>drug events</p> <ul style="list-style-type: none"> • Avoided ambulatory services/outpatient treatment • Avoided Informal care services <p>Better treatment per paediatric episode</p>
<p>Medicinal products for rare diseases ('Orphan medicines')</p> <p>Regulation (EC) No 141/2000</p>	<p>Offers a set of incentives aimed at (potential) developers of orphan medicines to encourage them to invest in the development of these products to a greater extent than they would do under</p>	<ul style="list-style-type: none"> • Research & Development (R&D) costs, over a period, on products that have a potential application for the treatment of rare diseases • Clinical Trials by International Classification of 	<ul style="list-style-type: none"> • Clinical effect to patients • Clinical efficacy and effectiveness • Wider benefits accruing to patients' family members or carers • Medical expertise

	<p>normal market conditions.</p>	<p>Diseases category</p> <ul style="list-style-type: none"> ● Number of patients recruited for clinical trials for orphan medicines ● Number of companies with active compounds in development for orphan ● Conditions by nationality of corporate headquarters ● Number of specialist centres for orphan diseases ● Clinical trials begun for orphan diseases ● Research projects for orphan diseases ● EU funded projects for rare diseases, count and value ● Number of companies with active compounds in development for orphan conditions by nationality of corporate 	<p>on rare diseases</p> <ul style="list-style-type: none"> ● Research networks and infrastructures facilitating knowledge exchange ● Improving diagnostic tools and time to diagnosis ● Stimulating the creation of patient organisations
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Overview of roadmaps and monitoring frameworks in place supporting the measurement of inputs, outputs, outcomes and impacts

The implementation of Europe's Beating Cancer plan will be monitored by means of a roadmap and progress indicators, and the Commission will establish an EU cancer plan implementation group. The objective will be to “develop an EU-wide framework to monitor trends and report on key cancer prevention and care indicators at national and EU level and inform on progress of Europe’s Beating Cancer Plan as part of the Cancer Inequalities Registry program with emphasis on disparities and inequalities”. Potential elements to include are: Cancer (inequalities) registry (closely linked to ECIS, possibly also including a dashboard), Country Profiles (regularly updated), Overall Report on State of Cancer Prevention and Care in the EU (regularly updated).

Existing monitoring frameworks on cancer include the following:

- *European Cancer Information System (ECIS)*: ECIS provides the latest information on indicators that quantify cancer burden across Europe. It supports research as well as public-health decision-making in the field of cancer and to serve as a point of reference and information for European citizens. From 2021, it will include new indicators detailed also by cancer staging, and a new section on childhood cancers. New features will also include more detailed data at sub-national level, thus facilitating linkages with environmental and socioeconomic data. It will

help monitor progress and future needs in addressing cancer at EU and national level.

- *European Network of Cancer Registries (ENCR)*: The ENCR promotes collaboration between cancer registries, defines data collection standards, provides training for cancer registry personnel and regularly disseminates information on incidence and mortality from cancer in the EU and Europe.

More information on the roadmap of Europe's Beating Cancer plan is expected to better define the monitoring needs at EU level. The expectation is that a monitoring framework for the EU roadmap will contain at least some of the components included in Table 42. Further consultations within the cancer living lab will allow us to understand better the current monitoring practice but more importantly the needed STI monitoring components which IntelComp could provide.

Table 42. Example of a monitoring framework (Spanish Cancer Strategy)

Pillar	Explanation	Example - Spain
Inputs	Finance, organisational and legal inputs	<ul style="list-style-type: none"> • Annual funding granted in the field of strategic health action on cancer • Average funding of research projects in the area of cancer financed in ISCIII calls for proposals. • Coordinated and multicentre cancer research projects financed by CIBER research groups and Health Research Institutes in the area of cancer out of the total number of cancer projects in

		ISCIII calls for proposals.
Activities	Activities planned	<ul style="list-style-type: none"> ● Percentage of research projects in the area of cancer funded in ISCIII calls for proposals. ● Accredited health research institutes with cancer as a priority area ● Clinical trials in the area of non-commercial cancer ● Autonomous plan for postgraduate training in cancer research.
Outputs	Results directly produced	<ul style="list-style-type: none"> ● Number of Spanish publications on cancer in journals with impact factor signed by research groups of the CIBER and Health Research Institutes in the area of cancer over the total number of Spanish publications on cancer in journals with impact factor ● Coherence in the Cancer Strategy and regional cancer plans.
Outcomes	Consequential effects on beneficiaries	<ul style="list-style-type: none"> ● Potential years of life lost at 75 years of age ● Potential years of life lost to life expectancy at the time of diagnosis ● Incidence of cancer (incidence of cancer in youth)
Impacts	Longer term effects on society, environment and economy	<ul style="list-style-type: none"> ● Cancer mortality rate ● Premature mortality from cancer ● survival (5 years after) ● percentage of conservative surgery in breast

		cancer
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Source: Based on the Spanish Cancer Strategy (approved update January 2021)

Enabling conditions

To ensure the defeat of a major disease, such as cancer, it is important to look at the conditions surrounding it and having an impact on the pathway of a policy's success or failure. In this regard, there is a clear relation between lifestyle aspects and cancer. A study suggests that around one third of common cancers can be traced back to unhealthy lifestyles and are, thus, avertible (McKenzie F, et al, 2016). For example, researchers have found that the higher the alcohol consumption of a person, the greater the chance of developing cancer is (Chiara Scoccianti, et al., 2016). For this reason, it is important to not only tackle cancer alone but to ensure that the associated conditions are dealt with accordingly. As such, lifestyle is adaptable and can significantly contribute to lower cancer diagnosis and better life quality of patients trying to beat cancer (Jeroen W.G. Derksen, et al., 2018).

The EBCP also clearly acknowledges these linkages and, amongst its 42 actions, lists several initiatives associated to conditions having an impact and increasing the risk of developing cancer. This includes actions "achieving a Tobacco-free Europe" and ensuring a reduction in the consumption of alcohol. It also envisions actions to promote healthy diets and sports. Moreover, as environmental causes are important risk factors for cancer, the EC also includes programs to ensure less

contact with hazardous substances (e.g. from pollution) and radiation. Cancers caused by infections can also be reduced via vaccination programmes.

The following list provides an overview of associated enabling factors that can be attributed to the development of cancer (Jemal A, Torre L, Soerjomataram I, Bray F (Eds), the Cancer Atlas, 2019):

- Risk factors for the development of cancer
- Alcohol consumption
- Smoking (Male/Female differences)
- Infections (Hepatitis, HPV, etc.)
- Obesity (Male/ Female differences)
- Radiation
- Pollution

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