# DRAFT STRATEGIC RESEARCH AND INNOVATION AGENDA (SRIA) ON PANDEMIC PREPAREDNESS

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# I. EXECUTIVE SUMMARY

Despite previous infectious disease outbreaks like influenza, SARS-CoV-1 and MERS, the world proved itself unprepared for such a crisis as the COVID-19 pandemic. The lack of readiness was evident in the inadequately developed portfolio of medical countermeasures, the lack of awareness in politics and society, the poor level of international solidarity and the difficulties in dealing with the social challenges associated with the pandemic. European and global healthcare systems face numerous challenges in detecting, preventing, responding to, and managing infectious diseases outbreaks in a coordinated and efficient manner.
The COVID-19 pandemic highlighted how quickly launched but uncoordinated research efforts led to a fragmented research landscape, wasting resources rather than producing urgently needed diagnostic, preventive and therapeutic options. This fragmentation, accompanied by additional legal and regulatory obstacles on the national level, particularly affected the implementation of multicentred cross-border clinical trials, especially those not commercially driven.

At the same time, the record-breaking availability of diagnostic tests and vaccines against SARS-CoV-2, owing to the relentless efforts of the scientific and medical communities, the pharmaceutical industry and a high level of governmental investments impressively demonstrates the importance of well-resourced collaboration in R&I for a rapid response to emerging health threats. While there is uncertainty as to whether vaccination technologies will be as advanced to combat other newly emerging pathogens as they were for the development of a vaccine for SARS-CoV-2, there can be no doubt that this is a vital area of research and development.

The COVID-19 pandemic has been a wake-up call and various health research initiatives, networks and institutions targeting relevant pandemic issues have been launched by the European Union, its Member States and worldwide. Still, the research landscape remains a patchwork with overlapping efforts on the one hand, and totally or partially uncovered areas on the other. Europe needs a One Health, pan-European, cross-sectoral, coordinated health research approach based on an ambitious vision and dedicated leadership to be better prepared for future pandemics of equal or even greater impact than COVID-19. To this end, it will be essential to improve resources, structures and working methods of medical research rapidly, in a coordinated manner, and in the best possible way, thus contributing to the benefit of the European citizens' health and wellbeing.

Tackling the challenges and gaps mentioned above is an essential prerequisite for Europe to be prepared for future emerging health crises. The future **European Partnership for Pandemic Preparedness (BE READY NOW)** will address these challenges from a comprehensive research perspective, with the **vision** to *establish a European research and innovation ecosystem that is optimally prepared for future health crises caused by infectious diseases, that can respond to them swiftly and efficiently, and that is fully integrated in the wider European institutional health framework.*
The Partnership will build upon existing and emerging European and national initiatives, networks and organisations and act as a harmonising, integrating, and coordinating entity. The Partnership has the primary objective of "*Enhancing Research and Innovation to be better prepared for and to respond to emerging health threats*". It will operate in and interact with the wider European institutional Health framework and the different actors[1] therein and their respective instruments[2], as detailed in Appendix n°5. Complementarity of the actions and close collaboration between all actors will be assured by appropriate governance mechanisms.

[1] The European Commission (EC), the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and institutions of Member States
[2] E.g. Horizon Europe, EU4 Health

To realise this vision, the **Strategic Research and Innovation Agenda (SRIA)** defines the thematic priorities and strategic objectives of the Partnership, which can be assigned to three overarching principles:

- Understand and prepare (in interpandemic periods)
- Prevent and anticipate (in interpandemic periods)
- Respond and control (during a pandemic event)

As such and beyond the immediate strategic basis for the Partnership, the SRIA is a guiding document for the European research ecosystem. It will be updated regularly and is intended to engage a wide array of stakeholders, including research funding organisations, research communities across relevant disciplines, national and international policymakers, as well as representatives from business, society, politics, and the broader public interest.

Further, the SRIA will provide clear guidance on crisis preparedness and response, co-designed and supported by European Member States. This includes establishing and reinforcing complementary research and innovation strategies, based on evidence-based planning, with further (also evidence-based) review of their effectiveness and feasibility in the health and social sectors, and subsequent feedback to further develop these agendas. A central task in this regard is to harmonise and, if necessary, redesign research infrastructures, cohorts and platforms and the investments in these at European and national level.

**Expected Impact of the SRIA on Pandemic Preparedness**

By analysing existing gaps in research programs and structural deficits, describing approaches to address them, and carefully describing priorities for action and stakeholders to be involved, the SRIA will contribute to a Europe that is better prepared for pandemics.

With its focus on coherent research and innovation, the SRIA will contribute to strengthening and improving the relevant European research ecosystem, thus enabling Health care systems to faster detect and prevent threats, and rapidly develop countermeasures in a coordinated manner. Similarly, the SRIA will facilitate the optimal integration of the European research system into the broader European health architecture.

The SRIA will also improve communication between research, politics, and society, thereby increasing awareness, understanding, transparency and ultimately social acceptance.

Taken together, the SRIA provides guidance towards an ever-warm, well-coordinated European research ecosystem, ready to respond to outbreaks in an inclusive manner that also substantially contributes to global cooperation and coordination. This approach aims to reduce the timespan from outbreak detection to the roll-out of efficient countermeasures.

## II. INTRODUCTION

**Background**

In the last century, the world has witnessed several epidemics/pandemics. Since the early 1900s, there have been at least eleven serious viral outbreaks, caused by emerging pathogens which span five virus families[3][4], and against which there are/were no or only insufficient countermeasures available (at least not in the region of the outbreak). Examples are influenza, Mpox virus, Ebola and finally the recent COVID-19 pandemic. Severe pandemic events are often characterised by human-to-human transmission, particularly when airborne transmission is possible. However, epidemics that are difficult to contain can also be vector-borne (e.g. Zika or Chikungunya) or pathogens transmitted directly or indirectly between animals and humans (zoonosis and reverse zoonosis).. Additionally, the ongoing HIV and antimicrobial resistance (AMR) pandemics have shown that pandemics can also emerge through slower transmission routes, such as sexual and parenteral ones.

The spread of pathogens is fuelled not only by natural factors but also by man-made global issues such as population growth (especially in resource-poor settings), climate changes, environmental degradation leading to increased migration and habitat loss, and high global mobility.

COVID-19, as the best-documented pandemic in history, has demonstrated the multitude of existing challenges that societies worldwide (including Europe) and their health care systems are faced with. While it is natural for healthcare systems to be "unprepared" in the face of an emerging pathogen in terms of immediately appropriate medical and non-medical countermeasures, it must be acknowledged that the COVID-19 crisis has revealed serious shortcomings in terms of the overall ability of healthcare systems to respond to a new pathogen.

Preparatory approaches for the rapid development of new diagnostics, therapies and vaccines were nowhere near as advanced as they could have been. This also applies to the knowledge base regarding physiopathology understanding and social and public health measures. COVID-19 revealed a widespread lack of coordinated, cross-border defence strategies to prevent, detect, combat, and manage health crises on a global scale. This has had a particularly severe impact on the Global South, but the EU, with health systems majorly in the responsibility of the Member States, also suffered immensely from a lack of coordination.

In the area of research and innovation, this resulted globally in many hastily implemented, uncoordinated, and sometimes competing activities. This led to a fragmented research landscape, yielding many non-significant or inconclusive results (e.g., numerous underpowered clinical trials). As a consequence, there was a considerable waste of time and resources in the development of urgently needed countermeasures, as well as in providing the public and decision-makers with sound scientific data quickly and transparently.

At the same time, COVID-19 has also revealed promising approaches to fight the pandemic as well as the prerequisites needed to make these approaches successful. Firstly, the development of several COVID-19 vaccines in record time provides evidence of the critical importance of collaborative R&I to respond rapidly to emerging health threats, as well as of the strategic value of public-private collaborations. Secondly, COVID-19 highlighted the benefits of modern information technologies, data collection, processing and sharing, but also the challenges that still exist in terms of fair access to these technologies and information, and their optimal use by politics, society, and research in compliance with applicable ethical and legal principles. Thirdly, strategic, structural, and institutional consequences were drawn during and after the pandemic at both national and European level. Pandemic response strategies were developed and new structures (e.g. HERA) were created.

[3] https://doi.org/10.3389/fmicb.2020.631736

[4] https://doi.org/10.1016/S1473-3099(20)30484-9

Moreover, new research initiatives and networks were established, and old ones strengthened and/or restructured.
As a result, Europe's current state of pandemic preparedness and response is significantly better than before the outbreak of SARS-CoV-2. Mistakes made and those to be avoided in the future are largely known, awareness of existing gaps has been raised and the structural basis has been improved. Nevertheless, significant efforts are still needed to raise pandemic preparedness in Europe to a level that allows for the quickest and most efficient Europe-wide response to future outbreaks. Moreover, the wide array of initiatives and networks newly established resulted in an extremely complex landscape, lacking an overarching coordination. The improvement of the necessary research ecosystem is an indispensable prerequisite for this, in which the new European Partnership for Pandemic Preparedness plays a central role.
The tasks of the Partnership are manifold. It must stimulate research to narrow the existing knowledge gaps on pathogens, diseases and their spread, as well as on the development of countermeasures and the assessment of their impact. Additionally, it must boost health innovations in the biotech, information technology, and public health sectors. And last but not least, it must help ensure that the research systems of the EU and the Member States are kept in a state of constant readiness, enabling them to respond immediately to future pandemics in a coordinated way.
This challenge must be tackled together with a range of stakeholders. These include the relevant EU institutions and authorities, those of its Member States (among themselves often very differently organised), and finally a number of existing initiatives and networks with similar objectives.

The present SRIA is the central guiding document of the Partnership to meet these challenges in a targeted manner. The SRIA is the result of a process in which all partners collaborated to link the vision of the Partnership to a portfolio of R&I actions. It also forms the basis for annual or multiannual work plans, and defines the long-term logic of actions that will allow the Partnership to reach its objectives. The SRIA follows and complements the consortium agreement of BE READY.

**Gap analysis**

While identifying, analysing and narrowing gaps will be a central task of the Partnership over its lifespan, the work of the Partnership will start by relying on two recently performed exercises. Firstly, in 2022 a thorough gap analysis was carried out by the BE READY partners, based on the relevant literature (scientific papers, policy papers, guidelines) and supplemented by expert input. The abstract is in Appendix n°5 and the full report is available on the BE READY website[5]. Secondly, the University of Antwerp performed numerous stakeholder interviews with the aim to understand the extent to which we were able to deliver a timely and efficient clinical research response to the COVID-19 pandemic in Europe, whether the knowledge gaps were addressed adequately, and what were the barriers and enablers for a coordinated EU research response. In addition to the identified gaps, the SRIA builds on lessons learned from previous EU partnerships and initiatives[6] (see chapter VII).

The most prominent requirements resulting from these analyses are:

- To accelerate and increase the gain of knowledge on emerging infectious diseases, including a vast array of pathogen-specific topics (pathophysiology, natural reservoirs, drivers and dynamics of emergence and spread). Whenever possible, this should rely on a One Health approach to conduct coordinated and systematic studies on the local, regional and global origins and reservoirs of zoonotic pathogens as well as on drivers, processes and pathways for their emergence, spread and persistence. In addition, more research is needed into the effect of preventing diseases by ensuring healthy ecosystems.
- To accelerate and improve digitalisation, interconnection and interoperability of data storage systems, and to agree on data standards in the EU and globally. This includes capturing, storing, linking and managing data in a "FAIR" manner. Particularly, IT systems should be improved to enable better modelling (including IA-based), data sharing, forecasting of health and care needs and better coordination of interventions within the healthcare system.
- To strengthen research on vaccine and therapeutic development, and other urgently needed innovations, and to contribute where possible from the research side to better supply chain management and to equitable access globally.
- To enable research to better inform public health management, e.g. by evidence based crisis guidelines that determine when to act and at what scale, how to coordinate, and what research is needed during a pandemic. Likewise, to encourage public engagement in research, policymaking and implementation, by developing a research based communication strategy, that aims also at encouraging European citizens to participate in clinical research and to raise awareness that clinical research is the cornerstone for assuring safety and effectiveness of interventions against infectious diseases both in pandemic free periods as well as in response to outbreaks.
- To improve research coordination and integration between European Member States but also between different sectors, and at multiple levels. This applies particularly to clinical research, where the importance of including a maximum number of patients in a minimal amount of time is essential for the timely generation of evidence that will inform clinical management and public health. This applies as well to surveillance (including genomic surveillance), data sharing, and the planning and implementation of research and innovation agendas, which are adjustable and/or scalable to national, European and global level.
- To enable the European research ecosystem to immediately respond to a pandemic by coherent, comprehensive, multidisciplinary (clinical) research. This means to provide an ever-warm and coordinated research base and mandatorily requires pre-positioned resources, networks and infrastructures as well as the necessity to involve pan-European stakeholders and (most

[5] https://beready4pandemics.eu/news/work-package-3-gap-analysis-synthetic-report
[6] https://doi.org/10.1016/j.cmi.2021.10.011
https://doi.org/10.1016/S1473-3099(21)00705-2

importantly) the Member States to implement concrete, actionable and measurable steps to respond in a coordinated and efficient manner.

**Stakeholder involvement**

To successfully address the gaps listed above and to work towards an integrative European research response to future pandemics, it will be mandatory for the Partnership to build upon and work together with the existing and emerging institutions, initiatives and networks, on the European and Member State level. These have been identified in 2024 by a mapping exercise of the partner countries involved in the preparation of the Partnership (see Chapter VII). Above all, this requires the definition of clear responsibilities and ways of interaction, thus striving towards an overall reduction in the complexity that has arisen. The numerous institutional and personal overlaps between the various initiatives should help building this cooperation. The aim of the SRIA is also to point out ways to avoid duplicating efforts and, where possible, to avoid using resources in areas that are already or will soon be comprehensively covered by existing initiatives or those currently being set up (e.g. the ONE HEALTH-AMR Partnership on antimicrobial resistance). However, the exchange of information with these initiatives must be assured and must be organised by mutual agreement, and where possible by mutual representation in the given government structures.

**Actors involved in the development of the SRIA**

The Strategic Research and Innovation Agenda is a long-term collaborative document written by the Coordination and Support Action BE READY *"Building a European strategic Research and Innovation Area in Direct Synergy with EU and International Initiatives for Pandemic Preparedness",* supported by the Horizon Europe funding program. This consortium is formed by 21 partners affiliated with 15 countries, including 13 European Member States, Norway and the United Kingdom.

The written content of the SRIA is the result of a broad assessment and consultation process relying on:

- First drafts by BE READY members
- Inputs from recognised experts in a wide range of disciplines from European Member States and institutions (comprising the Expert group); involved in the WP3 meetings of BE READY and in charge of drafting the SRIA
- Scientific guidance from the External Advisory Board of the CSA BE READY; consulted in *February-March 2024*
- Inputs from authorities and government agencies of European Member States; consulted in January 2024 and on the consolidated draft SRIA (mid 2024)
- Inputs from stakeholders involved in pandemic preparedness at regional, national, European and international level; consulted in January 2024 and during the public consultation (fall 2024)
- A public consultation of the general public (fall 2024). The results have been taken into account in the production of the SRIA, and a quantitative analysis of the answers received can be found in Appendix 8.

## III. VISION, MISSION AND STRATEGIC OBJECTIVES

### Vision of the Partnership

*To establish a European research and innovation ecosystem that is optimally prepared for future health crises caused by infectious diseases, that can respond to them swiftly and efficiently, and that is fully and sustainably integrated in the wider European institutional Health framework.*

### Mission of the Partnership

*To foster coordination and collaboration between the EU, Member States and their relevant health and research institutions to promote and accelerate* ***preparedness research,*** *by agreeing on common priorities, increasing understanding, boosting innovation, and contributing to improved and sustainable processes and structures within the research ecosystem.*

The Strategic Research and Innovation Agenda is a key tool for the Partnership to implement this vision and fulfil this mission, by defining concrete research priorities and objectives.

### Objectives

The SRIA articulates the proposed priorities and actions around three main areas:

- Understand and prepare: i.e. increasing scientific knowledge on pandemic relevant matters and contributing to a better prepared European research ecosystem and ultimately to better prepared health systems and societies.
- Prevent and anticipate: i.e. improving infrastructures, processes and workflows to establish an ever-warm research system that is ready to respond through coordinated networks covering all aspects of research relevant to pandemic preparedness, better prediction models and monitoring capacities. This includes the mutual acknowledgment of long-term research and innovation priorities related to pandemic preparedness and alignment between funders, policymakers and existing and emerging research networks and structures;
- Respond and control: i.e. providing guidance on scenarios for the best possible utilisation of research resources for the rapid development of countermeasures, and for optimally implemented monitoring and surveillance systems.

The specific objectives of the SRIA aim at addressing all the research domains already identified as crucial for a good response to pandemic/epidemic crises throughout the development pipeline, going from basic and pre-clinical research, over clinical research, to public health and implementation research. They will include detection, diagnosis, prophylaxis, therapeutic, public health, and societal domains. These approaches should be presented as a “One Health approach” as much as possible to help understand, prevent, and prepare to respond to emerging and re-emerging events.

In this frame, the approach on research and innovation to be followed is structured around five priorities:

During inter-epidemic period:

1. Accelerate knowledge on Emerging Infectious Diseases (EID) through basic, clinical and applied research in a coordinated and integrative manner.
2. Boost health innovation and early development of innovation, possibly up to human proof of principle.
3. Train, educate and communicate.
4. Strengthen research ecosystem readiness by (i) preparing for the clinical and public health response to health threats endangering European Citizens, (ii) providing tools for public policies and societies to cope with infectious diseases outbreaks and pandemics, and (iii) reinforcing infrastructures and networks for a better alignment of existing or emerging initiatives.

At the time of a crisis:

5. Conduct research activities to develop, monitor and evaluate interventions aimed at combating pathogens for the well-being of European citizens and globally.

Care was taken to design the actions under these priorities with a minimum of overlap. However, since strengthening and further developing pandemic-relevant research is a multidimensional endeavour some of the proposed tasks will fit in two or more priorities.

Of note, the SRIA activities will focus on the HERA priority pathogens potentially responsible for emerging or re-emerging events, WHO blueprint pathogens and national prioritisation lists, with the exception of antimicrobial-resistant pathogens as long as these are not potentially capable of triggering a fast-moving epidemic/pandemic. While BE READY recognises the threat of the AMR pandemic, the problem of the slow AMR pandemic will be addressed in detail in other networks/organisations such as the One Health-AMR Partnership.

## IV. RESEARCH AND INNOVATION PRIORITIES AND ACTIONS

The SRIA addresses the aforementioned objectives with a series of corresponding priorities to which targeted actions are assigned. The priorities and actions describe adequate research approaches having a high probability to provide firm evidence for the whole of Europe. Each action identifies the general research activities that are to be further broken down into specific support measures in the course of the Partnership.
Possible initial examples of such measures and research focuses are listed in Appendix n°2 of the SRIA.

## PRIORITY 1 ACCELERATE KNOWLEDGE IN A COORDINATED AND INTEGRATIVE MANNER

A prerequisite for improved preparation for epidemics/pandemics is closing knowledge gaps in various aspects. This includes a better understanding of the pathogens, their reservoirs, the causes and dynamics of their transmission to humans. It also means investing in efforts and ways to minimise transmission, as well as in increased research in therapeutic targets and in the identification and/or further development of therapeutic and diagnostic options. In this context, and since the emergence of infectious diseases of zoonotic origin is significantly determined by social, economic, ethical, and political factors, it is important to adopt an integrative approach. This approach should include social and environmental aspects and incorporates environmental and social science research alongside the biomedical disciplines.

### Action 1.1 Increase knowledge on understanding, identifying and addressing therapeutic targets on pathogens

This action targets the understanding, identification, and/or better description of appropriate therapeutic targets, i.e. the molecular mechanisms essential to the life cycle of the pathogen, as well as the identification of antigenic structures appropriate for vaccine development. Beyond that, the action also comprises the screening of chemical libraries to identify “leads”—molecules capable of blocking the target mechanism. Furthermore, it involves developing these leads further through medicinal chemistry to compounds with optimal therapeutic activity. This can be completed with the identification of biomolecules with potential antimicrobial activities as well as of potential syndromic treatments.

### Action 1.2. Increase knowledge on pathophysiology (pathogen behaviour in humans, host response)

This action targets the study of how diseases or disorders alter normal bodily functions, aiming to understand their underlying mechanisms, progression, and effects on health. This includes basic immunological research necessary for the development/improvement of vaccine therapeutics and syndromic treatments, as well as closing knowledge gaps on pathophysiology and studies on host response mechanisms (to the pathogen as well as to vaccines) and their monitoring. Additionally, this action should explore the mechanisms by which pathogens cross species barriers, contributing to a deeper understanding of their potential to adapt to and infect new hosts, which is critical for predicting and mitigating future zoonotic threats.

### Action 1.3 Increase knowledge on environmental and social aspects driving pathogen emergence

The action addresses the relevant environmental and societal factors that are fundamental to efficient surveillance and early warning systems. Appropriate research approaches will be addressed through cross-sectoral collaboration between human, animal and environmental health, which are the main components of the One Health approach. The Partnership will collaborate closely with several relevant initiatives/networks in place (see Chapter VII). Activities falling under this action also include reviewing the effectiveness of existing barrier measures and public health policies to limit direct and indirect human exposure to zoonotic pathogens (paying close attention to animal workers), including vector-borne diseases, and, if proven currently insufficient, exploring novel prevention strategies to further reduce the risk of emergence.

Since many if not most reservoirs of emerging or re-emerging pathogens are located outside Europe, and since these pathogens will most probably disproportionally affect vulnerable non-European

populations, this also means working with stakeholders worldwide and especially in the global South, whenever possible.

### Action 1.4 Increase knowledge on transmission dynamics and epidemiology

This action targets a comprehensive understanding of the dynamics of pathogen transmission within and between populations, essential for effective epidemic control. It encompasses:

1. **Epidemiological studies**: Conducting comprehensive epidemiological studies to analyse drivers and patterns of pathogen transmission, including the identification of key factors influencing transmission dynamics such as the role of asymptomatic and sub-clinical infections as well as human behaviour.
2. **Mathematical modelling**: Developing mathematical models to simulate the spread of pathogens within communities, considering factors such as population density, mobility patterns, and environmental conditions.
3. **Intervention strategies**: Exploring the effectiveness of various intervention strategies (e.g., quarantine measures, vaccination campaigns, testing, public health messaging) in mitigating transmission and controlling outbreaks.
4. **Socio-cultural, political and legal factors**: Collaborating with social scientists, legal experts and policymakers to understand the socio-cultural factors influencing individuals' behaviours and attitudes towards disease prevention measures. This includes examining how political and legal frameworks affect the implementation of non-pharmacological control measures, such as quarantine, restrictions on mobility, and suspension of commercial activities, to better inform the design of targeted interventions.
5. **Environmental impact**: Assessing the impact of environmental factors (e.g., climate change, urbanisation, land use changes) on pathogen transmission dynamics (also at the animal-human interface) and identifying strategies for mitigating environmental drivers of disease emergence. The One Health approach should be applied as an integrated health approach, based on strengthening collaboration amongst the human, animal and environmental health fields.

Through these efforts, this action aims to improve our understanding of pathogen transmission dynamics, in order to enhance our capacity for early detection and control of infectious disease outbreaks and share knowledge as widely as possible.

## PRIORITY 2 BOOST HEALTH INNOVATIONS

This priority encompasses research-targeted actions that contribute to the development of health innovations in all fields relevant to enhancing European pandemic preparedness. The actions will partially build on the main outcomes of research performed in the frame of priority 1 and additionally stimulate research approaches and processes, which are key for a smooth end-to-end development of measures. A close cooperation with the private sector by mutual exchange of knowledge, techniques and instruments will be sought. This includes, for example, biomarkers, signatures, targets and countermeasures identified in an academic context, as well as predictive, preventive, diagnostic or therapeutic tools developed by the private sector.

In addition, close collaboration with existing epidemic bodies (e.g. the Independent Panel for Pandemic Preparedness and Response[7] (IPPR), the WHO Pandemic Hub[8], the SUNRISE Project[9]) and non-profit actors (e.g. FIND[10], CEPI[11]) will be sought. The aim is to maximise synergies to close the gap between basic research/discovery and industrial manufacturing. It also includes developing innovative tools for better collaboration between the different stakeholders (e.g. clinical research, IT), and exploring how innovations in other sectors can be harnessed for health research.

Strengthening the integration between academia and industry finally involves fostering and supporting the development of spin-off/start-up companies in an open innovation vision.

### Action 2.1 Increase biotech development for medical countermeasures

The activities under this action should be undertaken in cooperation with industry partners whenever possible, up to the creation of joint start-ups. They aim both at improving the basis for the rapid innovative development of therapeutic products (e.g. immunomodulating drugs), vaccines and diagnostics, and at accelerating these innovation processes themselves.

One focus will be on establishing and/or further developing advanced metagenomics/sequencing platforms. These platforms are prerequisites for tracking the evolutionary pathways of the emerging pathogens (or newly emerging dangerous variants) and for providing scientific guidance for the development of diagnostic tests, public health measures and vaccines/drugs. High-throughput screening technologies will be essential for identifying and optimising therapeutic candidates rapidly, enhancing the efficiency of drug discovery processes.

Other key areas to be addressed should aim at accelerating and improving the development of vaccines and (immunomodulating) drugs against infectious diseases with pandemic or epidemic potential. This includes supporting (monovalent and combined) vaccine platforms of all eligible technologies (where appropriate including those for use in animals), as well as targeted activities to build, strengthen and evolve drug development platforms, including the exploration of alternative delivery methods/routes and the development of user-friendly storage conditions to enhance accessibility and usability.

Further activities will be dedicated to the development, optimisation, and implementation of generic, affordable easy-to-use (ideally point of care, less invasive and multi-pathogen) diagnostic tests for humans and animals, adaptable to any emerging pathogen with robust quality standards, compatible

[7] https://theindependentpanel.org/
[8] https://pandemichub.who.int/
[9] https://sunrise-europe.eu/
[10] https://www.finddx.org/
[11] https://cepi.net/

with the current medical and veterinary diagnostic routines and thorough consideration of preapproval pathways and regulatory requirements.

Finally, activities directed to the development and evaluation of innovative physical solutions to limit the spread of pathogens (ventilation, filtration, masks, disinfectants, surface coatings, screens) will also fall under this action.

### Action 2.2 Promote digitalisation in pandemic preparedness research

Modern information technology (IT) approaches can provide a multitude of benefits for pandemic preparedness research, as well as to health care and public health services. To accelerate pandemic-relevant research innovation, it will be crucial to develop appropriate state-of-the-art digitalisation methods and tools and to enable research to better use these instruments. Integrating artificial intelligence (AI) is essential to enhance data analysis and predictive modelling capabilities.

The digital tools should cover the whole spectrum of pandemic preparedness research and innovation: improved surveillance, diagnostics, and vaccines and therapeutics development. Examples include (but are not limited to) gamification measures, development of remote sensing devices for patient monitoring in domestic settings, digitalised monitoring of laboratories and clinical trial capacities, and the development and implementation of "*digital twins*" to reliably simulate the corresponding "*biological twins*".

Cooperation between publicly funded research and the private sector should be strongly encouraged to maximise synergism by mutual exchange of knowledge, techniques and instruments.

### Action 2.3 Foster innovation in tools and processes to improve R&D

This action will contribute to shorten the gap between the identification of an emerging pathogen and the achievement of proof of concept for the clinical development of candidate medications (vaccines, drugs, immunotherapies). Such a rapid and smooth transition from basic research to promising products requires seamless and efficient processes with clear role allocations at the interfaces of the stakeholders involved (academia, private and public sector). It requires as well that academic research approaches give early consideration to the needs of the private sector and regulatory procedures (i.e. by early cooperation with regulatory bodies).

To this end, activities under this action – ideally shaped as joint early development programmes between academic research teams and private partners – will aim at developing preclinical research methods, models, technologies and products, which are as close as possible to the requirements of the subsequent steps of the product development chain. Special attention will be given to the development and/or improvement of adequate, statistically sound high-quality biological and preclinical models (*in vitro*, *ex vivo*, *in vivo*) for the assessment of promising vaccines/therapeutics (or combinations thereof). When possible, activities will also address pharmacokinetics and toxicity as well as the evaluation of risks of emerging resistance and of host resilience factor.

Another focus will address the initial lack of adequate preclinical models for testing candidate therapeutics and vaccines, as it constitutes a major obstacle in the development of medical countermeasures against emerging pathogens. In addition to the continued search for and improvement of animal models that are as widely applicable as possible (particularly in high-security facilities), the main emphasis will therefore be on the development of biological models that can reliably mimic the physiological microenvironment of a specific organ/tissue (organoids, in vitro 3D cell

culture, etc.). This approach will be implemented parallelly to the study of digital and biological twins (see Action 2.2). It will minimise the need for animal models, thus accelerating data collection (infection studies, drug screening, etc.) and addressing ethical concerns related to animal experimentation.

## PRIORITY 3 EDUCATE, TRAIN, COMMUNICATE

A sufficient number of well-trained healthcare and health research workers, a high standard of evidence-based information and the transparent and efficient communication of this information are the most important prerequisites for preparing for and responding to a health crisis. A major obstacle on the way to such a workforce is the current education and training in narrow professional and organisational silos. Overcoming this barrier requires activities that are necessarily cross-cutting and always require the involvement of multiple sectors and stakeholders from research in different disciplines, the health and education systems, policy and civil society. Another challenge in maintaining a skilled workforce to respond to pandemics is that such professionals are essential during pandemics but less in demand during the many years in between. As a result, many scientists with relevant expertise are gradually lost after the pandemic and move on to other research topics. Developing mechanisms to minimise these fluctuations caused by the unpredictability of pandemics would be crucial. Given the very different systems in Europe, these hurdles represent a significant challenge that can only be partially addressed in this SRIA. The following measures are therefore limited to approaches that can be significantly advanced by the research stakeholders.

### Action 3.1 Educate – Contribute to the consideration of pandemic aspects in academic curricula

The curricula of healthcare professionals often overlook the importance of research, in particular in epidemic or pandemic context. Young healthcare professionals only encounter research for pandemic preparedness and response after graduation, depending on their chosen speciality and personal interest. This is far too late to attract a sufficient number of motivated people to a career in pandemic-related research fields. The activities under this action thus aim to introduce the topic as early as possible in the academic curricula, to promote specialisation in it, to early introduce research aspects in medical education, and to provide the necessary holistic view.

While the Partnership will not be in the position to directly influence these curricula, it will offer workshop formats (e.g. summer schools) for students of the relevant disciplines, which will be organised by the partner institutions. To this end, cooperation with suitable national and international organisations will be sought (e.g. Students for Global Health).

### Action 3.2 Train – Prepare and engage current and future generations of researchers and healthcare workers in managing and responding to current and upcoming health crisis

Activities under this action will focus on delivering high-quality interdisciplinary education and training to the next generation of researchers and healthcare workers. The goal is to enable them to tackle complex health crises, which have far-reaching social, economic, political and environmental implications beyond their direct impact on human health. To effectively address complex challenges, it is essential to foster collaboration across disciplines by encouraging scientists to learn each other's language and work together. Beyond academia, engagement with societal actors, including policymakers and practitioners, is equally crucial for developing comprehensive solutions.

In the context of pandemic preparedness, continuous investment in healthcare professionals and researchers is vital. Establishing a system for regularly updating these experts ensures they have access to the latest information. This system should go beyond merely disseminating information; it should also focus on enhancing skills and knowledge, empowering professionals to contribute proactively to the early detection of emerging health threats. By continuously strengthening their expertise and resources, the response to future health crises can be both faster and more effective.

European universities will be encouraged to participate in multi-national (pilot) training programmes for healthcare workers and researchers, which may – just as the early education attempts mentioned above (see action 3.1) – result in a much needed, sustainably financed and Europe-wide revision of academic curricula.
Cutting-edge European exchange programs such as the ATHENS Programme[12] should also be supported and broadened in order to strengthen a sense of *Europeanness* in the future generation of researchers. This applies not only to the diverse expertise that is immediately required, but also to preparation for the many personal, professional (see also action 5.2) and organisational challenges that a health crisis entails. Given the emergence of many health threats at the animal-human-environment interface, multi-sectoral, One Health preparedness is essential and should be addressed. Early-career researchers should also be familiarised at an early stage with the needs of network-based clinical research, industrial product development and the associated regulatory requirements. More emphasis should be put on flexibility and resilience within the workforce, ensuring that professionals are adaptable and capable of responding to evolving challenges during health crises.

The Partnership will aim to facilitate the development and sharing of capacities in the individual building blocks of pandemic preparedness, such as surveillance, outbreak investigation and response, logistic preparedness and surge capacities, R&D, and ethical, societal, and legal aspects.

### Action 3.3 Communicate – Develop research to identify risk and public health communication strategies in the era of misinformation and disinformation during health emergencies

During pandemics, informing the public about health risks and providing guidance is crucial. Effective communication practices are needed to maintain public trust and prevent misinformation fuelled by poorly communicated science and information overload. Evidence-based approaches, combining public health and social sciences, are required to improve communication strategies; activities under this action will primarily aim at investigating and validating methods for an improved research communication. This implies taking a critical retrospective view on what has succeeded or failed during previous crises. It also involves developing guidelines from the research angle together with stakeholders in politics and the wider public, thereby understanding and considering the mode of action of modern media and social networks. Reactive communication strategies are critical to ensure individual and community-based compliance of public health measures, especially during long-term crises. More research is needed on the public understanding and perception of a crises to successfully implement these strategies effectively and achieve their desired impact.

[12] http://athensnetwork.eu/index.html

## PRIORITY 4 STRENGTHENING RESEARCH ECOSYSTEM READINESS

Research ecosystem includes complex and interconnected network of institutions, organisations and resources involved in the research process, and various elements that contribute to generating, disseminating and applying knowledge. There are many challenges and tasks for science and research in preparing for and being ready to respond to a pandemic as a well-coordinated, responsive and inclusive ecosystem. They range from the immediate strengthening of research infrastructures, networks and their processes, to the best possible preparatory development of therapeutic, diagnostic, and non-medical options for action, including evidence-based and responsible information for the public and decision-makers. In addition, this ecosystem must be able to act immediately once an outbreak strikes. It must thus be structured and organised as a warm base, meaning also that structural support must be given during interpandemic periods.

### Action 4.1 Implement transversal activities

*i. Fostering data harmonisation and sharing*

The goal of this action is to provide a unified framework for health data exchange across the EU, following the **European Health Data Space**[13] requirements. The recent COVID-19 pandemic boosted the generation of an unprecedented amount of health-related digital data and this trend is bound to grow in the coming years. These data present specific challenges critical for effective monitoring and response to outbreaks: to this end and building on already existing approaches (e.g. ELIXIR, BY-COVID, GISAID) the Partnership will strive to:

- Ensure data privacy and security compliance with the EU General Data Protection Regulation (GDPR) to maintain patient trust and confidentiality
- Promote interoperability with standardised data formats to ensure data exchange and to enable sharing of information
- Facilitate real-time data sharing to quickly identify and respond to outbreaks
- Enhance cross-border collaboration

Data sharing rely on standardised protocols at the European level, generating comparable data with agreed-upon models, assays, data repositories and standards. This work therefore needs to be done in a coordinated manner between Member States, following established roadmaps such as the one implemented by the GloPID-R data sharing working group[14].

*ii. Supporting infrastructures*

Research infrastructures supported by the European Commission[15] have proven themselves extremely useful over the past decades, as they provide valuable resources and services for research communities to conduct research and foster innovation. The future Partnership will make specific efforts to support the development of missing or insufficient capacities, and the maintenance of the existing and newly created infrastructures during inter-epidemic periods. These infrastructures need to encompass all aspects of research relevant for pandemic preparedness: basic, preclinical and clinical research, addressing public health and societal issues, and establishing robust data sharing and management.

[13] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
[14] https://www.glopid-r.org/our-work/data-sharing/
[15] https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/our-digital-future/european-research-infrastructures_en

Ultimately, the action will contribute to a sustainable set of interconnected infrastructures, being able to attract a stable source of private and public funding to secure its long-term continuity of clinical research operations. It will be of utmost importance that these infrastructures are integrated in the ecosystem and used by the Partnership. This action will build on the work done by ISIDORe (Integrated Services for Infectious Disease Outbreak Research[16]), a European initiative designed to enhance preparedness and responsiveness to epidemic-prone pathogens. It offers a comprehensive, One Health-driven portfolio of research services and resources, spanning from basic to applied sciences, including social sciences.

*iii. Forecasting and modelling research*

Developing capacities to be able to detect, predict and monitor is key for an optimal control of a crisis associated to the spread of an infectious microorganism. In the context of an emerging or re-emerging pathogen of zoonotic origin, it is of main importance to be in position to anticipate the potential of crossing-over. This highlights the need to fully integrate a One Health approach.

Activities under this action are in line with Actions 1.3 and 1.4. They will foster the development of interoperable mathematical models for forecasting transmission of epidemics/pandemics and the development/adaptation of protocols for early description of new pathogens (transmissibility, $R_0$, incubation period, secondary attack rates, etc.). Strong models rely on strong, comparable data (see Action 4.1.i). These activities will be done in close collaboration with related EU-funded initiatives such as the ESCAPE project[17].

Additionally, efforts will focus on developing research to enable a more effective surveillance to detect emerging pathogens resistant to antimicrobial agents, or vectors resistant to treatment. Innovative and society-inclusive (e.g. by Citizen Science) surveillance methodologies, including contact tracing, will be explored from local to global scales.

### Action 4.2 Set up development platforms in basic and pre-clinical research

Efficiently combating an outbreak requires the fastest possible availability of appropriate medical countermeasures, especially diagnostics, medicines and vaccines. Since the nature of the pathogen responsible for an outbreak can rarely be predicted, it is a top priority to establish, further develop and then support development platforms, allowing for a more flexible response. Partly building on the results of priorities 1 and 2, the aim of this action is to strengthen development platforms, to keep them ready for use and to interconnect them as far as possible.

A heuristic approach should be considered whenever possible. Examples include:

- Broad-spectrum antivirals, which can help mitigating the progression of an outbreak while waiting for more targeted therapeutics and vaccines
- Novel vaccine technologies allowing rapid development and adaptability, such as mRNA or viral vectors based (e.g. vesicular stomatitis virus (VSV)-based vaccines or measles virus (MV)-based vaccines). A close collaboration will be sought with the future *European Hub for vaccine development* funded by the EU4Health programme[18]

[16] https://isidore-project.eu
[17] https://www.escapepandemics.com/analytics-tools
[18] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/EU4H-2024-PJ-01-

- Tests and assay platforms to quickly evaluate infection and countermeasure responses.

Special attention will also be paid to the organisation of collection and availability of diagnostic reference products (strains, natural and synthetic positive controls, specific antibodies), and biological specimens from human and veterinary clinical research programmes on emerging events. An example of good practice in this regard is the EVAg project[19] for cataloguing of viral samples.

### Action 4.3 Set up ever-warm clinical studies networks ready to pivot in case of outbreak

The ever-warm networks of clinical studies will consist of cohort (observational) studies and clinical trials (interventional studies), as described below. Both these networks of cohorts and clinical trials will work synergistically and dynamically. The possibility of studies transitioning between cohorts and trials is also anticipated.

*i. Cohorts*

In a pandemic scenario, cohorts are the most feasible design to explore the natural history of the disease. They allow for the investigation of transmission routes, clinical stages of infection, genome associations, effects of public health interventions, burden, and long-term sequelae. Cohorts' data (possibly harmonised across different settings) can provide early information to design innovative randomised controlled trials (RCT), including trial simulations, and lay the ground for interventional studies. Cohorts provide the unique opportunity to target subgroups of underserved populations not usually included in RCT: children, elderly, pregnant women, patients transplanted or affected by haemato-oncological diseases. This allows for the assessment of vaccination effectiveness, early therapy or breakthrough infections. Cohorts also contribute to the transferability of results from the RCT to underserved populations. Lastly, it is worth noting that cohorts can represent a useful tool to study epidemics of smaller magnitude (e.g. the seasonal flu, sexually transmitted infections…).

Under this action, collaboration with existing European cohorts will be sought to further develop a network of (European) cohorts that are aligned for maximum efficiency in an emergency response. This will require the harmonisation of the cohort infrastructures and their processes such as data standards and repositories (see Action 4.1.i above) to make better use of these valuable resources for pandemic research. The overarching goal of this action is the implementation of perpetual cohorts in interpandemic times, which are ready to pivot in case of outbreaks. This series of perpetual cohorts needs to be defined strategically (e.g. in terms of priority population groups and geographic spread) to address questions relevant to the SRIA.

*ii. Clinical Trials networks*

Large-scale multinational clinical trials are essential to reach scale fast and timely collect good-quality data to yield robust, significant results to guide policymakers and authorities. The goal of this action is to set up an ever-warm network of clinical trial sites across Europe, able to pivot in case of outbreaks and swiftly implement such large-scale multinational trials.

The network will consist of a number of perpetual multinational clinical trials, that are strategically selected by the future Partnership for optimal pandemic preparedness purposes. Particular reflexion will be given to the type of trials needed, as well as the target population groups to address questions

1?order=DESC&pageNumber=1&pageSize=50&sortBy=startDate&isExactMatch=true&status=31094501,31094502&frameworkProgramme=43332642

[19] https://www.european-virus-archive.com/evag-project

relevant to the SRIA. The common denominator of these selected trials is that their protocol integrates the possibility of rapidly pivoting to respond to an epidemic.

For maximum efficiency, the trial network will build as much as possible on existing initiatives, both on national level (through the engagement with key partners in each Member State) and on European level (e.g. multinational trials implemented by Ecraid or EU-response). Ultimately, the goal is for every Member State to be part of at least one such perpetual multinational trial. Member States with trial sites that are not yet part of such multinational trials, will be supported to integrate the necessary capacity to reach this goal. While ideally the network trial sites are kept warm by the actual implementation of one or more trials (i.e. enrolling patients), different participating modalities might be envisaged.

In case of an emergency, through this warm-based trial network, the Partnership will enable a coordinated clinical trial response in Europe. This response will be based on independent scientific advice (currently provided through the EC-funded CoMeCT project[20]) and in close coordination with the Clinical Trial Coordination Mechanism (set up as a sub-group of the HERA board).

Further details of the implementation and operationalisation of this warm-based trial network will be described in the Partnership Proposal.

### Action 4.4 Establish social and behavioural sciences and Public Health research networks

*i. Social and behavioural sciences research networks and community engagement*

The work described here will be done in close collaboration with activities under the scope of Priority 3.

Social sciences are essential for understanding the intricate interplay between individuals, communities, and public health interventions during health crises. By fostering interdisciplinary collaboration among sociologists, psychologists, anthropologists, political scientists, and other experts, the Partnership will facilitate a holistic approach to pandemic preparedness. This will enable researchers to explore the social, cultural, psychological, and political dimensions of health crises, shedding light on factors that influence public behaviour, community resilience, government and societal robustness in crisis management, and effective intervention strategies. Research in political science will also address crucial areas such as the factors impacting a country's preparedness, inequalities in health, including the burden of disease on disadvantaged populations, and population trust. Social sciences research networks will play a pivotal role in informing evidence-based policies and interventions that promote community well-being and resilience in the face of emerging health threats.

Effective communication channels play a major role in bridging the gap between scientific expertise and public understanding. These channels must (i) simplify the scientific message while ensuring it remains precise, and (ii) explain the limitations and estimates inherent to the data and models. Research supported by the Partnership will be instrumental in establishing such communication channels, ensuring that the scientific community can effectively engage with the broader public.

The challenge here is to build trust, before the crisis, and maintain trust during the crisis. In this frame, the following activities will be included in the Partnership:

- encourage “literacy in emerging diseases and research” during inter-epidemic time in society, to develop an understanding of the challenges, mechanisms, and issues raised by these

[20] https://comectproject.org/

diseases and by research (concept of scientific uncertainty, knowledge building, participation in clinical studies, etc.)

- promote participatory research, involving patient associations, families, consumer associations, and citizens who may make a useful contribution to area such as health care, clinical studies, research ethics, public health policies, and consideration of scientific uncertainty
- learn from past crises, particularly the COVID-19 crisis, by collecting, sharing, and analysing information from historical and comparative recollections of these crises.

*ii. Public Health and Implementation research*

This action will be carried out in close collaboration with the activities implemented under the scope of Action 4.3 and 4.4.i. It aims at developing research on Infection, Prevention and Control (IPC) measures in health services and on Public Health and Social Measures (PHSM). Strengthening the evidence base for the effectiveness and cost effectiveness of PHSM is needed, as stated in action 1.4. To this end, a comprehensive and more detailed mapping of existing research on PHSMs is a precondition. The Partnership will thus support studies to better understand the role of social behavioural and human contact patterns.

In collaboration with Action 4.1.iii, the Partnership will seek to contribute to the development of tools to rapidly assess the effectiveness and efficacy of PHSMs and combinations thereof (such as travel restrictions, social distancing, etc.), and to quantify how each of these contributes to prevent transmission of any emerging infectious disease. Ahead of an outbreak, recurrent epidemic events (e.g. annual influenza) will be used to carry out randomised and quasi-randomised trials between crises to evaluate the effectiveness of some specific PHSM, such as personal protection equipment, improved ventilation, and air purification. Methodological research is also needed to advance implementation and evaluation of PHSMs regarding effectiveness and impact, including analyses of changes in population mobility, social contact and disease patterns (cf. Gap analysis).

Last but not least, the Partnership will seek to contribute to research on the ethical, legal and social implications of the development and implementation of PHSMs, both to gain better insight into social response patterns to PHSMs and to describe indicators that are crucial for adhering to or rejecting them. This will be done in strong coordination with the social science research networks mentioned in Action 4.4.i.

## PRIORITY 5 RESEARCH ACTIVITY AND INTERVENTIONS TO BE CONDUCTED AT THE TIME OF A CRISIS

This priority of the SRIA corresponds to the third defining principle, respond and control. As crises are inherently unpredictable, this priority offers a series of reflexions rather than a defined set of actions. It is important to emphasise that the main difference when research has to be conducted during an epidemic is the timing. The previously described priorities will have to be continued, if not reinforced, but the research questions need to be narrowed to address specific priorities. It will be of paramount importance to have an adaptative and flexible research ecosystem and research infrastructures, able to pivot to pandemic requirements in order to guide Member States in their public health decisions.

### Action 5.1 Reinforce – Boost existing research and research ecosystem

As a document aiming at guiding research in the context of pandemic preparedness, the SRIA will be essential for understanding what has been covered and what has not. One of the main pitfalls of conducting research at the time of a crisis is focusing solely on clinical studies. On the contrary, the whole research spectrum needs to be reinforced, including basic and pre-clinical research and research infrastructures, as well as implementation research – as described throughout the SRIA.

For diseases for which there are no clinical data available, ever-warm cohorts (see Priority 4.3.i) will serve as valuable, first-line tools to gain insight into the pathogen's physiopathology, means of transmission, and mitigation strategies.

### Action 5.2 Reorient – Adapt existing research and narrow down research priorities

In the context of a crisis, it is critical to adapt existing research efforts swiftly to address emerging needs and ensure effective resource allocation. This action focuses on reorienting ongoing research and narrowing down priorities to fill critical gaps and avoid redundancy. The first step will be to evaluate the current scope of the SRIA to identify areas that could have been not sufficiently covered or anticipated. The existing priorities described earlier in the SRIA will be reassessed to determine which areas require immediate focus, establishing a prioritisation framework that considers the severity of the crisis, potential research impact, and feasibility of rapid implementation. At the time of a crisis, special care has to be given to maximising efficiency and avoiding duplication of effort. Therefore, the prioritisation framework will be essential to ensure a coordinated European response through the future Partnership, underpinned by strong collaboration and information sharing among research institutions.

To implement this strategy, established advisory frameworks and instances for prioritising research (such as CoMeCT for clinical studies) will be used to ensure that the most critical studies are conducted promptly. Mechanisms to ensure coordination of existing national scientific advisory mechanisms will be developed to ensure ensure a swift collaboration at the time of a crisis. Additionally, a crisis-specific SRIA can be developed, outlining targeted research priorities and actions tailored to the unique characteristics of the crisis. Real-time data and feedback mechanisms will be integrated to adapt the SRIA dynamically as new information becomes available. By reorienting existing research and narrowing down priorities, this approach will enhance the ability to generate timely and relevant scientific knowledge, ultimately guiding public health decisions and interventions more effectively.

## v. IMPLEMENTATION OF THE SRIA BY THE CANDIDATE EUROPEAN PARTNERSHIP FOR PANDEMIC PREPAREDNESS

The Strategic Research and Innovation Agenda (SRIA) is designed to establish common research priorities and objectives, ensuring that pandemic preparedness research across Europe is aligned, coordinated, and impactful. The priorities and actions of the SRIA and the operability of the plan will be subject to regular review and revision. The implementation of the SRIA by the Partnership will be carried out through two primary mechanisms: **Joint Transnational Calls** (JTCs) and **integrative activities** aimed at strengthening the readiness of the research ecosystem. These mechanisms will enable the Partnership to effectively address research gaps, foster collaboration, and ensure that Europe is better prepared for future pandemics. While the practical implementation of these mechanisms will be further defined and refined in the proposal of the Partnership, the general notions are as follows:

### 1. Joint Transnational Calls: translating the research priorities of the SRIA into research projects

The thematic priorities of the SRIA will be transformed into practical steps through the development of Annual Work Plans (AWPs). These AWPs will be key instruments in the operationalisation of the SRIA, providing a yearly roadmap for research and innovation (R&I) activities and defining specific R&I priorities for each year, ensuring that these priorities complement other relevant initiatives under Horizon Europe and beyond. The process of selecting yearly R&I topics will involve a participatory approach, engaging EU and national policy decision-makers, stakeholders, and the scientific community. This inclusive process will ensure that the selected topics are relevant, timely, and avoid unnecessary duplication of efforts.

Once the AWPs are adopted, they will serve as the basis for launching Joint Transnational Calls (JTCs), covering the entire continuum of research. These calls will be central to the Partnership's strategy, aligning national and regional funding programs with the SRIA's long-term objectives and ensuring solid evidence generation in the EU. Special attention will be paid to the following principles:

- Facilitate sharing, use and reuse of data by requiring Open Science and by applying FAIR data principles
- Encourage/ensure multi-country collaboration/networking by requiring multiple countries to partner in a proposal, with a focus on countries with a higher risk of emergence of new pathogens
- Encourage/ensure multidisciplinary collaboration by requiring multiple disciplines to partner in a proposal, e.g., One Health collaborations, collaborations between social and (bio-)medical sciences, collaborations between diagnostic and medication developers
- Encourage/ensure communication and implementation of research results by incorporating requirements on communication and dissemination in all stages of the call for proposals: in the call itself, in proposal requirements, and in reporting. This communication shall seek to reach not only the research ecosystem but also a wider, public audience
- Encourage translation of research into policies
- Encourage participation of patient organisations and public stakeholders

During epidemics/pandemics, the Partnership may organise *ad hoc* (emergency) calls, aligned with other network organisations (e.g. GloPID-R) and partnerships (e.g. OH AMR Partnership). A more detailed list of these initiatives is given below in Appendix 7.

## 2. Integrative activities: strengthening the readiness of the research ecosystem

In parallel with the Joint Transnational Calls, the Partnership will fund a series of strategic integrative activities in line with the SRIA's objective of improving Europe's research ecosystem readiness.

These activities will lead to establishing and supporting EU-wide infrastructures that are crucial for a rapid and coordinated response to emerging health threats. Through dedicated funding, the Partnership will promote life science research infrastructures, EU-wide vaccine and therapeutics trial networks, and pan-European public health research networks. This approach will ensure that clinical research sites remain "ever-warm" and functional, providing a robust foundation for high-impact research and swift mobilisation within a cohesive pan-European network during times of crisis. Building this ecosystem will ensure the lasting, positive impact of the Partnership in the longer term.

To complement these infrastructures, the Partnership will perform a range of transversal activities in line with the objectives of the SRIA, aimed at strengthening the overall research environment. These include: capacity building and knowledge-sharing initiatives designed to improve research capabilities across Europe (especially in EU countries that are underrepresented in the pre-clinical and clinical research landscape for pandemic research, e.g. EU13), effective communication, ethical and regulatory dimensions of research, data management and translation of research into innovation and policy. The Partnership will foresee specific activities aimed at engaging with relevant stakeholders and initiatives in the area of pandemic preparedness at EU and international level to maximise the alignment and to capture opportunities for joint international actions.

# VI. CREATING SYNERGIES WITH SISTER INITIATIVES AT MEMBER STATES', EU AND INTERNATIONAL LEVEL

Creating synergies with other related initiatives is essential 1) to avoid the overlap and duplication of national and EU research funding and 2) to complement each other to cover all the needs in pandemic preparedness and response.

The Partnership will foster synergies with other EU and Horizon Europe initiatives, starting from the calls of the Cluster Health and then Partnerships and Missions and either in terms of its design, implementation, and funding.

It will further build on collaborations and results of these and other initiatives in the field of clinical trials, such as capacity building or acceleration of clinical development for various diseases in developing countries; speeding-up of the research response to outbreaks through coordinated investments; AMR coordination, cooperation and coherence.

The potential areas for collaboration have been identified according to the nature and aim of each specific initiative:

- **EU funding programmes**: based on EU policies that will help define a relevant approach within each specific area and research priorities.
- **EU funded projects under Cluster Health and Partnerships**: close collaboration will be promoted with these initiatives in terms of peer-learning and research priorities selection. For each annual work plan elaborated by the Partnership, a deep analysis and exchange of information will be carried out to avoid duplicate funding. Besides that, an analysis of complementarities among funded projects will be carried out to foster connections among the consortia funded.
- **Other EU funding instruments**: information on complementarities with research priorities will be exchanged to avoid duplications.
- **EU co-funding instruments**: promotion of regional/national complementarities with EU co-funding instruments to leverage EU funding.
- **European Research Infrastructures**: the existing EU Health research infrastructures are a key element as they offer facilities that provide resources and services for the research communities to conduct research and foster innovation in their fields.
- **International initiatives**: the Partnership will articulate with existing international structures to align research priorities in a global perspective.

To avoid duplicate funding, an assessment of potential similarities with the research agendas of the EU initiatives listed in Appendix n°7, as well as potential new initiatives, will be performed when developing each Annual Work Plan of the Partnership. The synergies and potential joint activities below have been identified with the information available at the time of developing this SRIA and may be revised e.g., to incorporate the actions included on the future Horizon Europe work programmes and of new initiatives or instruments.

A list of relevant initiatives and networks identified as of October 2024 can be found in Appendix n°7.

## VII. ACKNOWLEDGEMENTS

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# VIII. APPENDICES

## Appendix n°1 – Abbreviations

| Abbreviations | |
|---|---|
| **AC** | Associated Countries |
| **ACT Accelerator** | Access to Covid-19 Tools |
| **AI** | Artificial Intelligence |
| **CEPI** | Coalition for Epidemic Preparedness Innovation |
| **CSA** | Coordinated and Support Action |
| **EC** | European Commission |
| **ECDC** | European Centre for Disease Prevention and Control |
| **EID** | Emerging Infectious Diseases |
| **EMA** | European Medicines Agency |
| **ERA** | European Research Area |
| **EU** | European Union |
| **EID** | Emerging Infectious Diseases |
| **HERA** | Health Emergency Preparedness and Response Authority |
| **IT** | Information Technology |
| **KETs** | Key Enabling Technologies |
| **KPIs** | Key Performance Indicators |
| **KSO's** | Key Strategic Orientations |
| **MCM** | Medical CounterMeasures |
| **M&E** | Monitoring and Evaluation |
| **MS** | Member States |
| **NSC** | Network Steering Committee |
| **OG** | Operating Group |
| **PHSMs** | Public Health and Social Measure |
| **PPE** | Personal Protective Equipment |
| **PSIP** | Partnership Specific Impact Pathway |
| **R & I** | Research and Innovation |
| **RTD (DG)** | DG Research and Innovation |
| **SDGs** | Sustainable Development Goals |
| **SRIA** | Strategic Research and Innovation Agenda |
| **WHO** | World Health Organisation |

## Appendix n°2 – List of potential research initiatives in line with strategic priorities

*N.B. This appendix is currently under construction. Input is expected from readers to further develop this section.*

### PRIORITY 1 ACCELERATE KNOWLEDGE IN A COORDINATED AND INTEGRATIVE MANNER

#### Action 1.1 Increase knowledge on understanding, identifying and addressing therapeutic targets on pathogens

- Cataloguing the diversity of potential emerging pathogens on selected natural reservoirs
- Deciphering main transmission routes of vector- or animal- borne pathogens in their natural and intermediate hosts along with host-range restriction determinants behind host susceptibility or resistance to infection
- Identifying in-depth evolutionary mechanisms accountable for the unpredictability of emerging events to guide epidemiological investigations and to help anticipate future outbreaks. These include mutational hotspots which can broaden the host tropism of microbiological agents and provide them ability to cross species barriers; zoonotic spillovers and spillbacks between natural reservoirs and other susceptible animal species including humans
- Developing standard procedures based on NGS for the search of unknown emerging agents (the so-called X-agent)
- Research in phylodynamics, phylogeography, and the use of genomic data for monitoring pathogens in time and space at the molecular level (monitoring of variants)
- For known emerging diseases, research for identification of predictive biomarkers of the clinical course in the acute phase, and in the medium and long term.

#### Action 1.2 Increase knowledge on pathophysiology (pathogen behaviour in humans, host response)

- Unravelling the pathophysiological features of zoonotic diseases and host predisposing factors (genetics, co-morbidities, *etc*.) which could increase the risk of developing life-threatening complications and poor prognosis

#### Action 1.3 Increase knowledge on environmental and social aspects driving pathogen emergence

- Identifying the environmental, cultural and socio-demographical drivers promoting the spread of vector- or animal-borne pathogens to humans, such as behaviours promoting exposure, adaptation and transmission
- Characterising interacting networks between natural reservoirs and susceptible hosts of transmissible pathogens, such as their carriers or vectors and their intermediate or incidental hosts in endemic areas as well as in regions presently at risk of emergence due to environmental and climate changes, natural disasters, humanitarian crises, armed conflicts and illegal commerce of wildlife
- Studying the impacts of modern breeding and farming practices within both traditional and intensive agriculture scopes, changes in agricultural paradigms in the context of the agro-ecological transition, biosecurity procedures, intensive urban growth and loss of natural habitat and resources

#### Action 1.4 Increase knowledge on transmission dynamics and epidemiology

- Developing innovative epidemiological surveillance methodologies, including social and environmental indicators, such as contact tracing, together with laboratory markers and pathogen and host genomic

data in integrated systems able to decipher the drivers for pathogen transmission in an integrated and holistic way
- Developing research on the regulatory and legal aspects interfering the provision of non-pharmacological measures to prevent pathogen transmission

## PRIORITY 2 BOOST HEALTH INNOVATIONS

### Action 2.1 Increase biotech development for medical countermeasures

- Developing innovative technical platforms for rapid diagnosis suitable for *in-situ* utilisation and easily adaptable to new emerging agents
- Developing therapeutic agents and vaccines against identified potentially emerging pathogens
- Developing high-throughput sequencing platforms to rapidly and efficiently track the evolutionary pathways of emerging pathogens
- Research in phylodynamics and the use of genomic data for monitoring pathogens in time and space at the molecular level (monitoring of variants)
- For known emerging diseases, identifying predictive biomarkers of the clinical course in the acute phase, and in the medium and long term

### Action 2.2 Promote digitalisation in pandemic preparedness research

- Collecting large homogeneous and high-quality health-related data sets as a step towards the digitisation of patient care
- Developing and implementing novel digital approaches to speed up the access and the transmission of information, such as large-scale data management and sharing centres, computing clouds, *etc*.
- Relying on storage platforms and technologies with the lowest carbon footprint to reduce digital pollution
- Expanding the use of remote sensing and medical devices to provide patient healthcare in domestic settings
- Implementing mathematical models, machine-learning and artificial intelligence algorithms to generate specific digital profiles of a chosen biological model, which can be used to provide a prognostic data repository
- Incorporating “digital twins” that reliably simulate the corresponding “biological twins” into high-resolution models of individual patients with the aim of finding optimal treatment using computational methods

### Action 2.3 Foster innovation in tools and processes to improve R&D

- Coupling approaches to experimental models which could reliably mimic the physiological microenvironment and biological complexity of a specific organ or tissue (organoids, microfluidic organ-on-chips, *in vitro* 3D cell culture *etc*.), thus restricting drastically the need for animal models and facilitating data generation (infection studies, drug screening, *etc*.)

## PRIORITY 3 EDUCATE, TRAIN AND COMMUNICATE

### Action 3.1 Educate – Contribute to the consideration of pandemic aspects in academic curricula

- Supporting European universities in establishing novel training modules that address modern health issues, such as emerging infectious diseases, zoonosis, pandemic preparedness, One Health, *etc*.
- Encouraging public authorities and national education systems to set up promotional campaigns to increase visibility of healthcare professions and R&I sectors among youth

- Promoting the creation of initiatives investing in youth-led research programs, crucial to bring a creative and modern vision on unresolved health issues
- Promoting the establishment of Young Researcher Consortiums or Partnerships on Pandemic Preparedness and Response among European countries (as in the United Nations Youth Delegate Program on Global Health)
- Supporting research studies aiming to identify the drivers behind healthcare workers shortage, and at providing solutions to public authorities on how to address the growing issue of medical and hospital deserts

### Action 3.2 Train – Prepare and engage the future generation of researchers and healthcare workers in managing and responding to current and upcoming health crisis

- Encouraging training programs aimed at educating the scientific community with communication and popularisation skills for all types of audience to improve health information reception and processing by the general public, including regarding the methodology and purposes of the research being conducted during health crises

### Action 3.3 Communicate – Develop research to identify risk and public health communication strategies in the era of misinformation and disinformation during health emergencies

- Boosting research on promotional campaigns to raise public awareness on health risks and on adequate behaviours to remain safe and protect others, especially vulnerable individuals, during a health crisis
- Supporting European health authorities in generating and adapting general guidelines with input from a scientific advisory board and third-party experts
- Supporting human and social science programs dedicated to decipher individual and external factors among the population that can influence their attitude towards medical countermeasures, vaccines and public health measures relying on COVID-19 as a case study (such as personal beliefs, political beliefs, institutional image or social media exposure, populism and “anti-vax” movement, *etc*.)
- Improving the framework for vaccination strategies to help anticipating potential vaccine hesitancy in the context of the emergence of an infectious pathogen
- Exploring the impact of misinformation and fake news on acceptance and compliance of public health measures by the general public and on strengthening resilience of individuals and communities to infodemics will be highly encouraged
- Promoting the development and implementation of automated digital ecosystems to improve infodemic detection and management, using machine learning and artificial intelligence

## PRIORITY 4 STRENGTHENING RESEARCH ECOSYSTEM READINESS

### Action 4.1 Implement transversal activities

- Mobilising research facilities with valuable knowledge and expertise under the shape of hubs or “task forces” and pivot their research efforts to respond to the health crisis (virologists, immunologists, computational and modelling experts, chemists, drug developers, engineers, clinical investigators, etc.)
- Initiating dialogue with the regulatory and ethical authorities to define the procedures for conducting research prior to a health crisis of social and economic impact (notably from a logistical and administrative perspective)

### Action 4.2 Set up development platforms in basic and pre-clinical research

- Reinforcing diagnostic instruments and capacities for clinical and veterinary purposes, which are currently lacking, for all emerging and re-emerging pathogens at risk, as well as for unknown agents, with robust quality standards

- Integrating phylogenomics and phylodynamics, both in the human and animal populations, to reconstruct the evolutionary histories of micro-organisms and track evolutionary changes, such as resistance to vaccines, therapeutic drugs or immune escape (monitoring of variants)
- Enhancing tools to identify predictive biomarkers of the clinical course in the acute phase of emerging disease and its aftermath (long-term sequelae, *etc.*)
- Developing generic and broad diagnostic platforms, protocols and treatment facilities that can be rapidly deployed to epidemic sites or areas with high-risk of pathogen emergence to limit the spread and the burden of emerging infectious diseases on human and animal health

### Action 4.3 Set up ever-warm clinical studies networks ready to pivot in case of outbreak

- Establishing general population-based cohorts and specific cohorts among European countries (healthcare workers, immunocompromised individuals, *etc*.)

### Action 4.4 Boost social and behavioral sciences and Public Health research

## PRIORITY 5 RESEARCH ACTIVITY AND INTERVENTIONS TO BE CONDUCTED AT THE TIME OF A CRISIS

### Action 5.1 Reinforce – Boost existing research and research ecosystem

- Setting up emergency funds to maintain research activities in the event of economic exhaustion
- Advising on how to leverage current assets and personnel in clinical research centers to be rapidly deployed within hours or days after a public health emergency is declared
- Maintaining (if feasible) ongoing therapeutic clinical trials so long-term research projects are not drastically affected or interrupted
- Developping evidence based indicators to evaluate interventions (*performance assessment*)

### Action 5.2 Reorient – Adapt existing research and narrow down research priorities

- Implementing emergency operation plans within research institutions: Non-critical research-related activities and dry laboratory must be performed remotely wherever possible, while projects related to the crisis involving wet laboratory are given priority on site
- Conceiving a well-defined roadmap for essential personnel, such as animal carers in lab facilities or biological waste treatment and disposal managers (setting restricted hours in the vivarium, split schedules, staggered shifts, *etc*.)
- Ensuring (near) real-time insight in vulnerable groups

## Appendix n°3 – Process for regular update of the SRIA

To ensure the relevance of the SRIA, the Partnership will update it at the end of its first phase (expected: winter 2028). A workshop will be held by the Partnership Scientific Advisory Board to identify discrepancies between the current version of the SRIA and the research ecosystem. An Editorial Board will then be established which will be in charge of the writing of an updated version of the SRIA. This second SRIA will include 1) an evaluation of the outcomes of the first SIRA in terms of concrete actions undertaken to close research gaps in pandemic preparedness and policy implementation driven by the SRIA and 2) an updated analysis of research gaps, along with an action plan to address these gaps.

In case of public health threats, a crisis-specific SRIA can be developed (see Action 5.2 above).

## Appendix n°4 – Summary of the gap analysis

*Title: Synthetic report containing an overview of needs, obstacles and weaknesses in the development of an appropriate response to pandemics.*

There is a strong need for improved coordination and integration between different sectors and at multiple levels, e.g. an integrated, collaborative multidisciplinary approach to surveillance and data sharing (within the human domain as well as in an One Health setting), as well as planning and implementation of research and innovation agendas adjusted on national, European and global level.

Further efforts are needed in building research capacity, especially in low and middle income countries.

Among the research topics, highlights are put on the acceleration of knowledge acquisition on Emerging Infectious Diseases, including a vast array of virus-specific topics, and special focus on an integrated One Health approach. In particular, guidance needs to be developed to conduct coordinated and systematic data collection on the drivers, processes, and pathways for zoonotic disease emergence and their subsequent spread and persistence.

In addition, research is needed into the role of 'resilient healthy ecosystems' and their effect on disease prevention ('Global Health').

Better interoperability, integration and multidisciplinary approach is essential for improved pandemic response: capacities for key diagnostic and surveillance activities need to be set up and maintained on a structural basis.

Clear crisis guidance, e.g. when to act and at what scale, and assessment methodology need to developed, maintained and regularly exercised.

National and international laboratory networks need to be strengthened. Further strengthening in multiple sectors is needed: production and supply chains management, vaccine development and mass production etc., while ensuring equitable access to vaccines and drugs worldwide.

Another line of key themes is concerned with the digitalisation, timeliness, linkage, integration, and inter-operability of the IT systems in all the sectors involved, including, among others, health and care services, public health and surveillance systems, laboratory and diagnostic services. Safely collecting, storing, linking and managing data from multiple sources, e.g. laboratory, clinical and epidemiological data, is essential. The aim is to assure operational readiness of information systems, while achieving FAIR data and data management. Furthermore, improvement of IT systems will allow for better modelling, predicting health and care needs, and improved coordination of response within the health system.

Finally, clear public policies and dialogue with the health workforce and the society are needed to achieve public engagement in policy making and implementation. A better understanding and learning how to communicate uncertainties is essential, enhancing transparency. Effectiveness of Public Health and Social Measures (PHSM) needs to be better determined and monitored to improve strategy and decision making and compliance.

## Appendix n°5 – Background at national, EU and global level

One of the main issue identified in the gaps analysis is the fragmentation of the research landscape between different stakeholders at national, regional and European level and a lack of coordination.

The Pandemic Preparedness Partnership aims at fostering a unified understanding of long-term research and innovation priorities for pandemic preparedness, ensuring coordination among funders, policy-makers and research networks. The Strategic Research and Innovation Agenda addresses is the dedicated tool to guide common objectives and address gaps in pandemic preparedness research.

In this context, the mapping of existing policies, strategies and existing programmes at national and EU level is a key step in the preparation of the SRIA, to build on what is already in place, to avoid overlaps and create synergies and added value among them and the future Partnership. The SRIA is based on the existing analysis and strategies adopted by Member states and EU actors, the functions of the different actors at EU level in order to propose a coherent strategy that would add a collective added value for the national and European actors involved in pandemic preparedness.

This Appendix presents the existing national and European strategies and initiatives in pandemic preparedness and the relevant regulations and programmes at EU level.

**Existing efforts at national level**: *National Research agendas on pandemic preparedness; initiatives and programs to support research on infectious diseases and emerging infectious diseases in Europe*

The preparation of the Strategic Research and Innovation Agenda (SRIA) on pandemic preparedness has relied on a mapping of EU Member states and Associated countries Research agendas and initiatives to support research on emerging infectious diseases and Public Health and Social Measures.

Members of the BE READY consortium, Research and Health Ministries, National Institutes of Public Health, Research funding organisations have shared the documentation identified and available at national level directly and through online surveys and interviews.

EU Member States and Associated countries which were not participating in the CSA have been reached through the presentation of the preparation of the SRIA on Pandemic preparedness to the Members of the Health Programme Committee of Horizon Europe and to the HERA Advisory Board.

To develop a coordination mechanism for publicly funded clinical studies and trials for infectious disease, we need to understand the processes and barriers of public funding in Europe, including funders' experience during the COVID-19 pandemic. Therefore, the funding pathways for clinical research of infectious diseases were mapped, before and during the pandemic. First, a database of public and charity funding resources of clinical research and trials for Infectious Diseases in Europe was created. Then, a survey was sent to 238 national funders in 39 countries, and finally, those national funders who responded were interviewed. To discuss a collaboration mechanism of funding of clinical research of during infectious diseases health threats, a meeting will be organised with these interviewed national funders in May 2024. .

The answers received at this stage show on the one hand a commitment of EU Member States and Associated Countries to collaborate on research, and on the other hand a diversity of national research initiatives, which led to a fragmented research response. That's why the Strategic Research & Innovation Area's objective is to propose joint research priorities, based on the priorities identified at Member States level, and in articulation with the existing initiatives.

- On the existence of national health strategies and research agendas:
    - France, Germany, Italy, the Netherlands, Norway, Slovakia, Sweden, have adopted national strategies related to pandemic preparedness, specifically or embedded in national health strategies, and linked with Global Health Strategy
    - Finland, Ireland are in the process of preparing their national strategy
- The research initiatives and strategies developed by EU Member States show common objectives (incomplete list, based on a survey among BE READY partners):
    - **strengthen coordination at EU and international level**
    - **enhance basic knowledge**
    - **foster the translation of research results to innovations**
        - SA-MIE (France)
        - Health Research Federal Strategy (Germany)
        - DSB-CNR strategy for pandemic preparedness (Italy)
        - Pandemic preparedness Agenda (Netherlands)
        - Strategic framework for healthcare 2013-2030 (Slovakia)
        - 10 year national research programme in viruses and pandemics (Sweden)
    - **support the infrastructures necessary for research:**
        - Kiras Security Research (Austria)
        - SA-MIE (France)
        - National Health Security Laboratory (Hungary)
        - Health Research Federal Strategy (Germany)
        - Biobank Norway
        - Pandemic Laboratory Preparedness (Sweden)
    - **Public Health and Social Measures**
        - SA-MIE (France)
        - DSB-CNR strategy for pandemic preparedness (Italy)
        - Pandemic preparedness Agenda (Netherlands)
        - Norwegian science Programme on Covid-19
        - Long term Covid-19 strategy to normalise every day life

**Background at EU level:**

"**Protecting the health of Europeans and collectively responding to cross-border health crises**" is one of the main pillars of the political priority of the Commission "**Promoting our European way of life**". In this context, the Partnership will be firmly anchored within the framework of the **European Health Union**[21] that aims to improve the EU's capacity in the vital areas of prevention, preparedness, surveillance, risk assessment, early warning, and response under this political priority.

The SRIA is an important tool to foster cooperation between Member States and European institutions and stakeholders to strengthen the readiness of the research and innovation ecosystem to be

[21] https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

optimally prepared for future health crises caused by infectious diseases and to respond to them swiftly and efficiently.

This section presents the different European regulations, institutions, policies, strategies and programmes that may have an impact on the design or implementation of the SRIA.

The *EU Regulation 2022/2371 on serious cross-border threats to health* provides the general framework for crisis prevention, preparedness and response and is the first and key reference for the institutional framework. In particular, it lays down rules on "prevention, preparedness and response planning", "emergency research and innovation", that will be taken into account in the design of the SRIA.

This priority of the European Commission builds on existing actors and programmes:

- **The Directorate General Research and Innovation (RTD);**
  The **DG Research and Innovation RTD** defines and implements European research and innovation policy with the goal of reinforcing the scientific and technological base, promoting innovation and turning societal challenges into innovation opportunities. DG RTD is closely involved in the programming of the Horizon Europe Programme and the European Partnerships. Horizon Europe 2021-2027[22] is the framework programme for Research and Innovation.
  DG RTD also supports the European Strategy Forum on Research infrastructures which gathers research infrastructures needed in pandemic preparedness and response.

- **The European Health Emergency Preparedness and Response Authority (HERA) created in** September 2021 develops produces, and procures, medical countermeasures before and during a health crisis. HERA aims to:
  - improve EU health security coordination before and during crises;
  - bring together the EU Member States, industry and relevant stakeholders;
  - develop, produce, procure, stockpile and equitably distribute medical countermeasures;
  - reinforce the global health emergency response architecture.

  The SRIA will take into account the pathogens with high pandemic potential identified as one of the three main priority threats.

**DG for Health and Food Security (DG SANTE);**

- The **DG SANTE** is responsible for EU policy on food safety and health and for monitoring the implementation of related laws including Regulation 2022/2371. The DG aims at building a strong European Health Union to protect and improve public health and is responsible for **EU4 Health 2021 - 2027**, the Programme for the Union's action in the field of health

**The scope of the SRIA on Research and innovation is complementary to the functions of the different building blocks of the European health security framework set-up since 2022, in particular:**

- **Regulation on the extended mandate of the European Medicines Agency** (EMA), 1st March 2022;
- **Council Regulation** (EU) 2022/2372 of 24 October 2022 on a **framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level;**

[22] Regulation (EU) 2021/695 establishing Horizon Europe —

- **The State of Health Preparedness Report**[23]**,**
- **Communication from the Commission on EU Global Health Strategy**, better health for all in a changing world in November 2022[24];
- The Pharmaceutical strategy;
- The European Health Data Space.

The entry into force of these new rules completes the preparedness and response capacities of the European Health Union, creating a legal framework to improve the EU's capacity in the areas of prevention, preparedness, surveillance, risk assessment, early warning, and response. The future European Partnership on Pandemic preparedness needs to articulate with these actors and their workplans.

- The **Serious cross-border threats to health Regulation** gives the EU:
  - a **preparedness planning and integrated surveillance system;**
  - a capacity for accurate risk assessment and targeted response;
  - mechanisms for joint procurement of medical countermeasures;
  - the possibility to adopt common measures at EU level to address future cross-border health threats.

- With its extended mandate, the ECDC can issue **recommendations to Member States regarding health threats preparedness**, host a new excellence network of EU reference laboratories and establish an EU Health Task Force for rapid health interventions in the event of a major outbreak.

- With its extended mandate, **The European Medicines Agency** (EMA)[25] is able to closely monitor and mitigate shortages of medicines and medical devices during major events and public health emergencies and facilitate faster approval of medicines which could treat or prevent a disease causing a public health crisis.

- The **Emergency Framework Regulation allows the establishment of a Health Crisis Board**. The Regulation also enables the activation of the EU fab facilities, emergency research and innovation plans and access to emergency funding.

- **The pharmaceutical strategy**[26] aims to modernise the regulatory framework and support research and technologies that reach patients. It rests aims atensuring access to affordable medicines for patients, and addressing unmet medical needs (in the areas of antimicrobial resistance and rare diseases, for example);
- supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines;enhancing crisis preparedness and response mechanisms, diversified and secure supply chains, address medicines shortages;

- **The European Health Data Space will, in particular,** offer a consistent, secure, trustworthy and efficient framework for the use of health data. Under strict conditions, researchers, innovators, public institutions or industry will have access to large amounts of high-quality health data, crucial to developing life-saving treatments, vaccines or medical devices

[23] https://health.ec.europa.eu/publications/state-health-preparedness-report_en
[24] https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en
[25] https://www.ema.europa.eu/en
[26] https://ec.europa.eu/health/human-use/strategy_en

- **EU Global Health Strategy:** positions global health as an essential pillar of the EU's external policy. It promotes sustainable, meaningful partnerships of equals drawing on the Global Gateway. As the external dimension of the European Health Union, the strategy is designed to guide EU action for ensuring better preparedness and response to health threats.

- **State of Health Preparedness**

Since 2022, the European Commission publishes a *State of Health Preparedness Report* every year. The report presents a mapping of the EU actions that have been put in place to address serious cross-border health threats, with a focus on those actions implementing Regulation (EU) 2022/2371. It highlights the progress made in the fields of preparedness and response. It identifies the challenges facing public health authorities and outlined concrete actions that the Commission will take to address them. State of Health Preparedness Report.

The SRIA will take into account the information reported in the *State of Health Preparedness* in particular the gaps and needs identified.

## Appendix n°6 – Examples of national strategies and programmes in research for pandemic preparedness

| Country | Name of initiative | Abstract | Reference |
|---|---|---|---|
| AUSTRIA | National pandemic preparedness plan for respiratory diseases | The pandemic plan outlines preparations by the Federal Ministry of Social Affairs, Health, Care, and Consumer Protection (BMSGPK) for respiratory pathogen pandemics like SARS-CoV-2. It details measures for effective management, with flexibility for diverse situations. Regular evaluations ensure alignment with evolving conditions, scientific insights, and legal requirements, guiding BMSGPK actions and interagency coordination. | https://www.sozialministerium.at/dam/jcr:4e2ae8df-e938-4f31-be7a-dd5c6cbfe0bf/Pandemieplan%20f%C3%BCr%20respiratorische%20Krankheiten.pdf |
| | Austrian Climate Research Programme (ACRP) | Climate change, One Health - The ACRP focuses on research on climate change and climate actions, adaptation, mitigation and their mutual interrelation. The intent is to provide scientific background for the implementation of the Austrian strategy for adaptation to climate change, the National Energy and Climate Plan (NEKP) and the Paris Agreement in Austria | https://www.klimafonds.gv.at/call/acrp-2022/ ; https://www.ffg.at/ACRP_15.Call_informationday |
| | KIRAS Security Research | Pandemic preparedness, data management in health crises as well as waste water surveillance - KIRAS supports national research projects whose results contribute to the security of all members of society. The Austrian security research programme KIRAS implements three mutually complementary instruments. They range from probing actions to cooperative research and innovation projects and R&D support actions. | https://www.kiras.at/en/home#themes:pathGroup=.bedarfstr%C3%A4ger~.wirtschaft~.gsk~.forschung\|category-filter:path=default |
| FINLAND | No specific R&D&I strategy for pandemic preparedness, but national pandemic preparedness plan in preparation | Participates in : Transformation of Health and Care systems, Phiri, BY-COVID, Pandem-2 and Joint Action on Strengthened International Health Regulations and Preparedness in the EU (SHARP JA) | |
| FRANCE | Acceleration Strategy - Emerging Infectious Diseases SA-MIE | *Objectives :* -Understand, prevent and control the emergence of new pathogens -Contribute to French preparedness to emerging infectious diseases<br>*Challenges* : -Reinforce research and innovation potential in the public and private sectors, and industrial transfer<br>-Increase production capacities for countermeasures to secure access (Health products, PPE)<br>-Build French and European preparedness and resilience to sanitary crisis<br>*Budget* : 750 M€ for 5 years<br><br>*Five axes in continuum -Articulation with EU and international actions, including HERA*<br>*1. Interdisciplinary research*: mechanisms of emergence, understanding EID, propose and evaluate innovative countermeasures for prevention and medical care…<br>*2. Innovation*: maturation and transfer, support for public-private partnerships and start-up creation, fostering the development of countermeasures<br>*3. Development of production capacities for countermeasures* : securing industrial sectors involved in countermeasures production at French or EU level<br>*4. Preparedness and crisis management*: organisational & regulatory aspects<br>*5. Multidisciplinary training*: development of transversal competences necessary for research and innovation in EID | https://www.gouvernement.fr/upload/media/default/0001/01/2022_03_dossier_de_presse_-_france_2030_-_investir_pour_mieux_repondre_aux_maladies_emergentes_infectieuses-_07.03.2022.pdf |
| | Priority research programs and equipment (PEPR) | PEPR MIE (Emerging Infectious Diseases) operated by ANRS \| Emerging Infectious Diseases - aims to effectively prevent and control | https://anr.fr/en/france-2030/programmes-et- |

| | | | |
|---|---|---|---|
| | **EIM - Emerging infectious diseases** | emerging and re-emerging infectious diseases at individual and collective level, and to improve preparedness for the risk of epidemics and/or health crises. | equipements-prioritaires-de-recherche-pepr/maladies-infectieuses-emergentes-pepr-mie/ |
| | **Priority research programs and equipment (PEPR) PREZODE** | PEPR PREZODE, which focuses on the prevention of zoonotic emergences (viruses, bacteria or parasites transmitted to humans by animals or insects). It is managed by IRD, CIRAD and INRAE, and operated by ANR. | https://anr.fr/en/france-2030/programmes-et-equipements-prioritaires-de-recherche-pepr/maladies-infectieuses-emergentes-pepr-mie/ |
| **GERMANY** | **Health Research federal strategy** | German strategy for medical and health research. Highlights<br>I. Collaboration across borders in developing solutions to pressing health problems<br>II. Creating synergies<br>III. Linking up current infrastructures at a European or global level<br>IV. Coordinating the joint establishment of new infrastructures | https://www.gesundheitsforschung-bmbf.de/files/Addendum_Rahmenprogramm_Gesundheitsforschung_barrierefrei.pdf |
| | **Global Health Strategy of the German Federal Government** | Presents the German government's political commitment to global health and strategic priorities:<br>V. promote health and disease prevention<br>VI. mitigate the health impacts of climate change<br>VII. strengthen health systems and facilitate the provision of universal health coverage (UHC) without discrimination<br>VIII. safeguard public health protection, including measures to protect against epidemics and pandemics and through continued medical assistance in humanitarian contexts<br>IX. foster global health research and innovation | https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Broschueren/Global_Health_Strategy.pdf |
| **HUNGARY** | **National Laboratory for Health Security** | The National Laboratory for Health Security has created a collaborative network of research groups previously operating in isolation in Hungary to carry out scientific research to improve health security.<br>During the ongoing COVID-19 pandemic, the need for in-depth scientific analysis based on reliable data and evidence became clear. The vision of the project is to create a scientific basis for data and analysis-based decision-making in both health and disease control in our country. By bringing together these disciplines, new synergies will be made through innovative surveillance systems, big data methods and mathematical modelling.<br>The National Laboratory for Health Security will bring together and coordinate research groups that have been working in isolation in the country, facilitating networking and creating a collaborative research community both on the national and international levels. | https://www.eglab.hu/en/ |
| **ITALY** | **DSB-CNR strategy for pandemic preparedness** | The DSB-CNR strategy to face the Covid-19 pandemic and prepare for future ones is divided into three fundamental pillars, further declined in specific project activities:<br>X. Interaction between pathogen and host<br>XI. Strategies for monitoring and managing the epidemics<br>XII. Prevention strategies | https://dsb.cnr.it/pandemics/home-en.html |
| **LUXEMBOURG** | **Research Luxembourg and Covid-19 Task Force** | The COVID-19 Task Force has been set up in order to offer the health system the combined expertise available within the Luxembourg public research sector | https://www.researchluxembourg.org/en/covid-19-task-force/ |
| | **Pandemic Preparedness Agenda** | Letter from the minister of Health to the parliament 14 April 2022 | https://www.rijksoverheid.nl/documenten/kamerstukken/2022/04/14/kamerbrief-over-beleidsagenda-pandemische-paraatheid |
| | | Letter from the minister of Health to the parliament 4 November 2022. | https://www.rijksoverheid.nl/actueel/nieuws/2022/11/04/versterking-pandemische-paraatheid-op-koers |

| | | | |
|---|---|---|---|
| NETHERLANDS | | News message about investment from the Netherlands in CEPI and FIF-PPR: | https://www.rijksoverheid.nl/actueel/nieuws/2022/10/27/nederland-investeert-in-internationale-pandemische-paraatheid |
| | National action plan strengthening zoonosis policy | Report of expert group zoonosis with recommendations to reduce risks on future zoonotic outbreaks: Zoönosen in het vizier \| Rapport \| Rijksoverheid.nl (includes research recommendations) | https://www.rijksoverheid.nl/documenten/rapporten/2022/07/06/nationaal-actieplan-versterken-zoonosenbeleid<br>https://www.rijksoverheid.nl/documenten/rapporten/2021/06/01/rapport-expertgroep-zoonosen |
| | Societal Impact Team work programme: pdf | The Social Impact Team (MIT) advises the cabinet on the social consequences of pandemics and how to deal with them, such as the corona pandemic and corona measures. The MIT provides the government with solicited and unsolicited advice | https://www.rijksoverheid.nl/ministeries/ministerie-van-sociale-zaken-en-werkgelegenheid/organisatie/commissies/mit ; https://www.rijksoverheid.nl/documenten/rapporten/2022/07/06/nationaal-actieplan-versterken-zoonosenbeleid |
| | Dutch Global Health Strategy 2023-2030 | The Dutch Global Health Strategy 2023-2030: "Working together for health worldwide" aims to contribute in a coordinated and targeted way to improving public health around the world, and thus also in the Netherlands | https://www.government.nl/ministries/ministry-of-health-welfare-and-sport/documents/publications/2022/10/21/dutch-global-health-strategy-2023-2030 |
| | ZonMw, the Netherlands Health Research Organisation | ZonMw runs funding programmes on pandemic preparedness, infectious diseases and COVID-19. | https://publicaties.zonmw.nl/pandemische-paraatheid-themapagina/ ; https://www.zonmw.nl/nl/onderzoek-resultaten/gezondheidsbescherming/programmas/programma-detail/kennisprogramma-pandemische-paraatheid/ |
| | RIVM, , the Netherlands Institute for Public Health and the Environment | Setting up of a National Functionality for Infectious Disease Control (LFI) as part of the RIVM to strengthen the national management of infectious disease control at the time of a pandemic | https://www.rivm.nl/en/news/new-crisis-response-organisation-at-rivm-to-control-future-pandemics ; https://www.rivm.nl/en/who-collaborating-centre-for-infectious-disease-preparedness-and-ihr-monitoring-and-evaluation/fields-of-expertise/research-on-infectious-disease-preparedness-and-ihr-m-e; https://www.rivm.nl/coronavirus-covid-19/omt |
| | Pandemic and Disaster preparedness Center | PDPC aims to prepare society for future pandemics and disasters, reduce vulnerabilities and risks, build resilience through disaster prevention, preparedness and recovery measures. Convergence of the technical, medical and social sciences is essential for developing the next generation of approaches to disasters and pandemics. | https://convergence.nl/pandemic-disaster-preparedness/#:~:text=PDPC%20aims%20to%20prepare%20society%20for%20future%20pandemics,next%20generation%20of%20approaches%20to%20disasters%20and%20pandemics |
| | PDCP pandemic Research agenda | | https://convergence.nl/pdpc-publishes-pandemic-research-agenda/ |
| | Research and investment framework of Wageningen University | In the ERRAZE@WUR research and investment framework, researchers from various disciplines work together to help build the scientific foundation needed to prevent future pandemics and to limit their impact. | https://www.wur.nl/en/Research-Results/Research-programmes/Cross-WUR-programmes/ERRAZE-at-WUR.htm |
| NORWAY | Norwegian Government's Management of the Coronavirus Pandemic | Two-year-long enquiry into the Norwegian authorities' management of the COVID-19 pandemic. | https://www.regjeringen.no/en/dokumenter/nou-2022-5/id2910055/;%20%20 |
| | Long-term COVID-19 strategy to normalise everyday life | Norwegian Government's strategy and emergency preparedness plan for the continued handling of the pandemic. | https:/www.regjeringen.no/en/aktuelt/long-term-covid-19-strategy-to-normalise-everyday-life/id2907426/%20;%20 |

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| | Joint Committee of the Nordic Medical Research Councils | The Joint Committee of the Nordic Medical Research Councils (NOS-M) is a collaborating body for the Nordic research councils that finance medical research. NOS-M aims to coordinate and promote medical research in the Nordic countries, to monitor its progress, and to facilitate information exchange among the countries. The Committee also aims to promote concrete, collaborative Nordic projects in medical research. NOS-M conducts two annual meetings, which rotate between the member countries. Observers from NordForsk, the Nordic Council of Ministers, Science Europe Medical Sciences Committee, Estonia, Latvia and Lithuania are invited to take part in NOS-M meetings and activities. The NOS-M secretariat is hosted by NordForsk. | https:/nos-m.org/publications/;%20 |
| | Norwegian Science Programme on Covid-19 | The Norwegian Science Programme on COVID-19 seeks to address critical knowledge gaps for the response to the COVID-19 pandemic. It focuses on:<br>- The virus and the epidemic: How does the virus behave, mutate and spread? How will the epidemic develop?<br>- Measures and consequences: What are the effects of infection control measures on transmission? What are the consequences of the epidemic and the response on health in the population? What are the consequences of the epidemic and the response for society as a whole and the economy?<br>- The health and care services: How can the services best care for patients with covid-19? How can the services avoid negative consequences for other patient groups during the epidemic? | https:/www.fhi.no/en/more/norwegian-science-programme-on-covid19/ |
| | NorCRIN | National overview of clinical trials | https://www.norcrin.no/en/national-overview-of-covid-19-trials/ |
| | Biobank Norway | Biobank Norway represents one of the world´s largest existing resources within biobanking covering both consented population-based and disease-specific clinical biobanks. Biobanks in Norway also have access to the unparalleled longitudinal health data making it a unique asset for global research and innovation projects within life sciences, disease prevention and treatment. | https://www.forskningsradet.no/en/ |
| PORTUGAL | Call Research 4 Covid-19 (FCT) | Stimulate national collaborative R&D networks, as well as the reorientation of activity in the R&D units supported by the FCT towards R&D initiatives that meet the needs of the National Health Service (SNS) | https://www.dgs.pt/ |
| SLOVAKIA | Draft Research and Innovation Strategy for Smart Specialisation of the Slovak Republic 2021-2027 | Pandemic preparedness/resilience is briefly addressed under Domain 1 - Innovative industry for the 21st century and Domain 5 – Healthy food and environment. | https://www.mirri.gov.sk/wp-content/uploads/2018/10/Research-and-innovation-strategy-for-smart-specialisation-of-the-Slovak-Republic-2021-2027.pdf |
| | Strategic framework for health care 2013-2030 | Strategický rámec starostlivosti o zdravie pre roky 2013 – 2030 (Strategic framework for health care 2013-2030): Increasing the level of pandemic and bio-risk preparedness is mentioned as a priority in the area of public health (part 4.3) without further specification. | https://www.health.gov.sk/?strategia-v-zdravotnictve |
| | Act on economic mobilisation | A general act guiding the state's reaction and measures in response to crisis situations, such as the pandemic, as well as preparedness measures to be taken in the state of safety. | |
| SPAIN | National Early Warning and Rapid Response System (SIAPR). Coordination Centre for Health Alerts and Emergencies (CCAES). | The Centre for the Coordination of Health Alerts and Emergencies (CCAES) is a centre that depends on the General Directorate of Public Health of the Ministry of Health. Its function is to coordinate the management of information and support in the response to situations of national or international health alerts or emergencies that threaten to the health of the population. To this end, the National Early Warning and Rapid Response System (SIAPR) has been created. | https://www.sanidad.gob.es/areas/alertasEmergenciasSanitarias/siapr/home.htm |

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| | | The SIAPR is made up of a network of regional liaison centres, coordinated by a National Liaison Centre, which enables permanent and rapid communication of situations of risk to the health of the population, with the aim of improving prevention and preparedness for situations of risk to health and the coordination of response measures when there is national or international involvement.<br><br>The CCAES acts as the National Focal Point of the system and also has the responsibility for coordination at the international level.<br><br>Establishes coordination mechanisms between all networks of interest with a multi-sectoral approach: NETWORK OF NETWORKS.<br><br>Defines common criteria for detecting and reporting NSPIN/ESPIII (Standardised Reporting Criteria).<br><br>Performs the first public health risk assessment at local level to propose response measures appropriate to the level of risk.<br><br>Coordinates the response between the health sector and other systems (Civil Protection and the Department of Homeland Security) | |
| | **State Plan for Scientific and Technical Research, and Innovation plan 2024-2027 (PEICTI). Ministry of Science and Innovation.** | The Ministry of Science and Innovation is the department of the General State Administration in charge of executing the Government's policy on scientific and technical research, technological development and innovation in all sectors.<br><br>The PEICTI incorporates all the activities undertaken by the General State Administration (AGE) in the field of science, technological development and innovation.<br><br>The mission of the PEICTI is to strategically plan and promote quality scientific and technical research and innovation in Spain, in line with the new regulatory framework for science, innovation and entrepreneurship. The plan fosters collaboration between public and private institutions, ensuring the efficient use of resources and the generation of knowledge that contributes to the country's economic and social progress.<br><br>Health Sector<br><br>Strategic lines: **Infectious diseases**<br><br>Areas of intervention<br><br>▪ Antimicrobial resistance<br>▪ Emerging diseases<br>▪ Pandemic prevention and new early warning/epidemiological surveillance systems<br>▪ Neglected and neglected and vector-borne vector-borne infectious diseases<br>▪ Sexually transmitted diseases | https://www.ciencia.gob.es/InfoGeneralPortal/documento/6e566243-bcb5-45d8-ab77-5cfe533060f2 |
| | **The Strategic Action in Health (AES). Carlos III Institute of Health (ISCIII)** | The Strategic Action in Health (AES) is the main instrument for funding biomedical and health research in Spain and is managed by the Carlos III Institute of Health (ISCIII), as a body under the Ministry | https://www.isciii.es/Noticias/Noticias/Paginas/Noticias/Acci%c3%b3n-Estrat%c3%a9gica-en-Salud-ISCIII-2024.aspx |

| | | | |
|---|---|---|---|
| | | of Science, Innovation and Universities. Through public funds and competitive calls for applications, the AES awards annual financial support to contracts and research projects that promote biomedical and health R&D&I in Spain, and the professional careers of its research community.<br><br>As for the lines of research, it consolidates and expands those oriented towards health protection, infectious diseases and health threats, and the social impact of health policies. | |
| SWEDEN | Pandemic Laboratory Preparedness | Build laboratory capacity to assist the local and national authorities in future pandemics through research (focused on diagnostics, analysis of infection, immunity, and resistance development related to viruses, bacteria and other disease-causing organisms), competence and technology development (focused on sequencing, genetic analysis, immunological methods and management of big data) | https://www.scilifelab.se/capabilities/pandemic-laboratory-preparedness/ |
| | 10-year national research programme in viruses and pandemics launched in 2021 | The research programme is part of the Government's long-term strategy and action plan to counteract and reduce virus outbreaks and pandemics.<br><br>Its objectives are to contribute new knowledge about viral diseases and the infectious properties and methods of different viruses, how viruses are transferred from animals to humans, the development of new medicines, vaccines and therapies, and how knowledge about equal and gender-equal health can be safeguarded during a pandemic. To build up preparedness ahead of future pandemics, the programme also supports research for knowledge about the economic and social effects of large and long-term societal spread. | https://www.vr.se/english/mandates/funding-and-promoting-research/viruses-and-pandemics.html |

## Appendix n°7 – List of key initiatives and networks identified

*N.B. The list of initiatives presented here constitutes a snapshot of the pandemic preparedness landscape as of October 2024. It will be regularly updated throughout the course of the life of the SRIA to ensure relevance.*

| | |
|---|---|
| **RESEARCH** | |
| ERINHA | European Research Infrastructure on Highly Pathogenic Agents |
| ISIDORE | Integrated Services for Infectious Diseases Outbreak Research (ISIDORE): is setting up and offering access to a comprehensive catalogue of integrated and customised research infrastructures' services for epidemics response. |
| PHIRI | Population Health Information Research Infrastructure (PHIRI): to enable MS and AC public health bodies to rapidly make available health and care data for COVID-19 research queries and to exchange best practices. |
| DURABLE | The DURABLE project will support the HERA laboratory network by providing high-quality scientific information in record time in order to prepare and respond to cross-border health threats. |
| EU-HIP | EU-HIP supports countries towards interoperability with HERA's upcoming IT platform, coordinated by SSI |
| ECDC Lab network | EVD-LabNet is a multi-disciplinary network of expert laboratories. Its aim is to strengthen Europe's laboratory capacity and capability to respond to emerging, re-emerging and vector-borne viral disease threats |
| ECRIN | European Clinical Research Infrastructure Network, facilitates multinational clinical research, through the provision of advice and services for the set-up and management of investigator or SME led clinical studies in Europe |
| **DATA SHARING** | |
| Pathogens Portal | Joint effort by the European Commission, EMBL-EBI, the ELIXIR research infrastructure, EU Member States and other partners. The Platform holds over 8,5 million records of diverse data types, including over 4 million viral genomes deposited from 110 countries and it hosts the Cohort Browser with shareable metadata and cross links to clinical-epidemiological or OMICs data |
| BeYond-COVID - BY COVID | 53 organisations (including hospitals) from 19 countries join forces to provide comprehensive open data on SARS-CoV-2 and other infectious diseases across scientific, public health, socio-economic and policy domains |
| European Nucleotide Archive (ENA) | The European Nucleotide Archive (ENA) is an open, supported platform for the management, sharing, integration, archiving and dissemination of sequence data |
| EU Health Data space | The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities |
| European Open Science Cloud (EOSC) | Pan-European project designed to create a virtual environment for sharing and accessing research data across borders and scientific disciplines |
| GISAID | The GISAID Data Science Initiative promotes the rapid sharing of data from priority pathogens, organises a variety of training workshops to aid in the capacity building of collaborative networks, and promotes the development of novel research tools for analysis |

| CLINICAL STUDIES | |
|---|---|
| CoMeCT | Coordination Mechanism for Clinical Trials and Cohorts. CSA which objective is to enhance Europe's clinical research preparedness and response capacity to infectious disease outbreaks with epidemic potential. |
| CONTAGIO | CSA COhorts Network To be Activated Globally In Outbreaks. consortium of investigators from Europe, North America, Latin America, Asia, and Africa, that aims to create coordination mechanisms to rapidly react to infectious disease (re-)emergence in LMICs |
| EU RESPONSE | Pan-European platform for pandemic research and preparedness providing a modular trial network enabling European hospitals to participate at the level of commitment that aligns with their capacity. |
| ECRAID Fundation | Build a "warm-base" European clinical research network for infectious diseases, that has the capacity and capability to function as a platform in hospital care and primary care for a rapid research response in the face of serious infectious disease outbreaks. |
| VACCELERATE | Clinical trials network focusing on vaccine trials; core infrastructure for applied vaccine research with site network (39 countries, 491 sites) and volunteer registry (25 countries, 22 languages, >100,000 volunteers). |
| EU-CARE | With the support of immuno-virological and artificial intelligence components, the project will take advantage of hospital patients, vaccinated healthcare workers, and schools' cohorts from 11 strategic countries across Europe, Russia, Africa, Asia and Central America to science and society |
| ORCHESTRA | Three-year international research project aimed at tackling the coronavirus pandemic, led by the University of Verona and involving 26 partners (extending to a wider network of 37 partners) from 15 countries |
| VERDI | Generate improved evidence on the epidemiology, outcomes, prevention and treatment of variants of SARS-CoV-2 amongst children and pregnant women. It will also improve understanding of the epidemiology and impact of Mpox in children, pregnant women and high-risk group |
| **EU PARTNERSHIPS & Joint undertakings** | |
| Innovative Health Initiative | Improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. Collaboration between universities, research centres, the pharmaceutical and other industries, SME), patient organisations, and medicines regulators |
| European Partnership on Transforming Health and Care systems (THCS) | A partnership with health and care systems owners/organisers and research funders to boost research in policy, uptake and scale-up of innovations to accelerate transformation of national/regional health and care systems. |
| European Candidate Partnership One Health Antimicrobial Resistance (OH AMR) | Fight antimicrobial resistance (AMR)' forming a strong and structured ecosystem with shared evidence, tools and methodologies cutting across sectors |
| European Institute of Innovation and Technology (EIT) | Nurturing entrepreneurial talent and supporting new ideas. European initiative that empowers innovators and entrepreneurs to develop world-class solutions to societal challenges and creates growth and skilled jobs |

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| ERA4Health | Increase European transnational collaborative research funding by creating a funding body for joint programming in priority areas addressing European public health needs. 32 entities and 27 funding organisations from 21 countries |
| European Partnership on Animal Health and Welfare (PAHW) | Structure and support a network of living labs and research infrastructures accelerating the transition towards agroecology throughout Europe. Provide ready-to adopt practices that support farmers in understanding and implementing agroecological practices at the scale needed for positive economic, environmental and social impacts |
| European Partnership on Artificial Intelligence, Data and Robotics | The AI, Data and Robotics (ADR) partnership brings together industry, academia and the European Commission to pursue innovative solutions on a large scale, pooling efforts, resources and investments to generate long-term positive impact |
| Global Health EDCTP3 Joint Undertaking | The European and Developing Countries Clinical Trials Partnership (EDCTP) aims is to accelerate the clinical development of new or improved health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases, including (re-)emerging diseases. |
| **EU-FUNDED PROJECTS** | |
| CORESMA | COVID-19-Outbreak Response combining E-health, Serolomics, Modelling, Artificial Intelligence and Implementation Research. CORESMA aims to immediately generate the most needed clinical and epidemiological data needed for defining targeted public health measures |
| ESCAPE | Stakeholders active in infectious disease modelling, public health risk management and science to policy interactions. Improving data accessibility, Scaling up modelling efforts and facilitating science to policy interaction |
| IDAlert | Infectious Disease decision-support tools and Alert systems to build climate Resilience to emerging health Threats. The project will co-create novel policy-relevant Europe-wide indicators that track past, present, and future climate-induced disease risk across hazard, exposure, and vulnerability domains at the animal, human and environment interface |
| I-MOVE-COVID | Multidisciplinary European network for research, prevention and control of the COVID-19 Pandemic |
| EU-WISH (Joint Action) | EU-WISH will improve national public health wastewater surveillance capacities to facilitate the integration and complementarity with other surveillance systems with a public health perspective to strengthen preparedness and response to cross border health threats. |
| UNITED4Surveillance (Joint Action) | UNITED4Surveillance will contribute to implementation of the new Health Security framework under the EU regulation on serious cross-border threats to health by Integrating existing and new data sources for more comprehensive EU infectious disease surveillance, prevention and control. |
| JA GHI (Joint Action) | European Joint Action to maximise the impact of the EU global health strategy. In the context of the implementation of the new EU Global Health Strategy, better coordination to strengthen this leadership and its visibility is essential to maximise the collective impact of such EU contributions to global health and to shape a new global health order based on our fundamental values. |
| LEAPS | Integrating Multi-Disciplinary Expertise in a Learning and Adaptive European Pandemic Preparedness System. Demonstrate the feasibility of combining genomic One Health surveillance, with genomic epidemiologic modelling for detailed pathogen understanding and precise public health intervention design. LEAPS will develop protocols and models for accelerated medical countermeasure development, availability and accessibility. Co-created epidemic response scenarios against pathogen X |

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| OH4Surveillance | The general objective of OH4Surveillance ('Setting up a coordinated surveillance under the One Health approach') is to support the participating countries to set up and scale up One Health surveillance to priority pathogens in an efficient, coordinated and collaborative manner. The project includes capacity building and surveillance activities. |
| OneBAT | One Health approach to understand, predict and prevent viral emergencies from bats |
| ONE HEALTH EJP | Promoting One Health in Europe through joint actions on foodborne zoonosis, antimicrobial resistance and emerging threats |
| PANDASIA | Pandemic literacy and viral zoonotic spillover risk at the frontline of disease emergence in Southeast Asia to improve pandemic preparedness |
| PANDEM-2 | PANDEM-2 aims to develop new solutions for efficient, EU-wide pandemic management to prepare Europe for future pandemics through innovations in training, building capacity between EU member states responding to pandemics on a cross-border basis. |
| PCR4ALL | Impact and viability of a novel mass PCR testing method as a pandemic-fighting strategy |
| RESPOND | Preparedness of health systems to reduce mental health and psychosocial concerns resulting from the COVID-19 pandemic |
| SHARP JA (Joint Action) | Joint Action Strengthened International HeAlth Regulations and Preparedness in the EU |
| UNDINE | The human genetic and immunological determinants of the clinical manifestations of SARS-CoV-2 infection: Towards personalised medicine |
| VEO | A Versatile Emerging infectious disease Observatory (VEO) will be created for the generation and distribution of high-quality actionable information for evidence-based early warning, risk assessment and monitoring of emerging infectious diseases (EIDs) and antimicrobial resistance (AMR). |
| VIROFIGHT | General-purpose virus-neutralizing engulfing shells with modular target-specificity |
| FIMI | FIMI stands for Foreign Information Manipulation and Interference Toolbox. EU responses to the threat of foreign information manipulation |
| **NETWORKS** | |
| CEPI | Coalition of Epidemic Preparedness Innovations |
| GAVI | The Vaccine alliance (cf. 300 million Euros from the EU) |
| European Patient's Forum | Patient advocacy in Europe providing a cross-disease perspective from a wide patient community to the policy-making process on issues which have a direct impact on patients' lives |
| European Federation of Pharmaceutical Industries and Associations (EFPIA) | Represents the biopharmaceutical industry operating in Europe. Through its direct membership of 37 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs) |
| European Global Health Research Institutes Network | Network of leading research institutions in Europe promoting and advocating for Global Health research and innovation |

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| Sonar Global | Drawing on our global network of researchers and practitioners, Sonar Global bolsters the contribution of the social sciences in the prevention of and response to infectious diseases and antimicrobial resistance (AMR). |
| GLOPID-R | Global Coalition of Research Funders in Infectious Diseases with pandemic potential |
| ISARIC | International Severe Acute Respiratory and emerging Infection Consortium. Global federation of clinical research networks, providing a proficient, coordinated, and agile research response to outbreak-prone infectious diseases. |
| SSHAP | The Social Science in Humanitarian Action Platform (SSHAP) is a programme of work focusing on the social dimensions of emergency responses. |
| ESCMID | The European Society of Clinical Microbiology and Infectious Diseases (ESCMID) is a non-profit organisation. The mission is to improve the diagnosis, treatment and prevention of infection-related diseases. This is achieved by promoting and supporting research, education, training, and good medical practice. |
| **INTERNATIONAL ORGANISATIONS** | |
| FIF (Pandemic fund) - World Bank | Financial Intermediary Fund for Pandemic, Prevention, Preparedness and Response ("Pandemic Fund") - 427 M euros from the EC |
| ZODIAC (AIEA) | Zoonotic Disease Integrated Action (ZODIAC) |
| PREZODE | An innovative international initiative (gathering 180 partners from 15 countries) with the ambition to understand the risks of emergence of zoonotic infectious diseases, to develop and implement innovative methods to improve prevention, early detection, and resilience in order to ensure rapid response to the risks of emerging infectious diseases of animal origin |
| **World Health Organisation (WHO)** | The WHO Hub for Pandemic and Epidemic Intelligence; global network to detect and prevent infectious disease threat |
| | SAGO Scientific Advisory Group on Origins of Novel Pathogens |
| | ACT Accelerator (Access to COVID-19 Tools accelerator) |
| | International Pathogen Surveillance Network (IPSN) will provide a platform to connect countries, improving systems for collecting and analysing samples, using these data to drive public health decision-making |
| | R&D Blueprint: global strategy and preparedness plan that allows the rapid activation of research and development activities during epidemics |
| | WHO COVID-19 Social Science Working Group |
| | Independent Panel for Pandemic Preparedness and Response |
| G7 | Rapid Response Mechanism |

## Appendix n°8 – Online consultation on the SRIA

*a) Methodology*

An online consultation on the present draft of the SRIA was conducted on the EUSurvey platform (https://ec.europa.eu/eusurvey/Public_Consultation_SRIA_PandemicPreparedness) from November 13th until December 15th. The following questions were asked:

**Part 1 - Background questions**

1. Are you responding on behalf of your organisation or in your own capacity?
   - ☐ On behalf of my organisation
   - ☐ As an individual responder

2. If you are responding on behalf of an organisation, please provide its name:

3. If you are responding on behalf of an organisation, under which category does it belong?
   - ☐ Ministry
   - ☐ Public agency or organisation
   - ☐ Funding agency
   - ☐ University/ Research institute
   - ☐ Industry
   - ☐ SME
   - ☐ Hospital/ University hospital
   - ☐ NGO/association/foundation
   - ☐ International or European organisation/ initiative
   - ☐ Other

   If other, please specify:

4. Country of the person/organisation that is submitting feedback:

**Part 2 - Feedback on the SRIA**

Do you agree with the following statements?

1. *The three overarching principles identified (Understand and prepare; Prevent and anticipate; Respond and control) are sound, and in line with the vision of the future Partnership for Pandemic Preparedness* to *establish a European research and innovation ecosystem that is optimally prepared for future health crises caused by infectious diseases, that can respond to them swiftly and efficiently, and that is fully integrated in the wider European institutional Health framework*
   - ☐ Yes
   - ☐ Partially
   - ☐ No
   - ☐ Undecided

   Additional comments/ suggestions (max. 250 characters)

2. *The five priorities proposed (1. Accelerate knowledge in a coordinated and integrative manner; 2. Boost health innovation and early development of innovation; 3. Train, educate and communicate; 4. Strengthen research ecosystem readiness; 5. Conduct research activities at the time of a crisis) provide a comprehensive overview of the R&I that is needed to increase the European pandemic preparedness*
   - ☐ Yes
   - ☐ Partially
   - ☐ No
   - ☐ Undecided

   Additional comments/ suggestions (max. 250 characters)

3. *The actions listed under Priority 1 (Accelerate knowledge in a coordinated and integrative manner) properly address the priority*
   - ☐ Yes
   - ☐ Partially
   - ☐ No
   - ☐ Undecided

   If not, please specify what you think is missing or insufficiently addressed (max. 2000 characters)

4. *The actions listed under Priority 2 (Boost health innovation and early development of innovation) properly address the priority*
   - ☐ Yes
   - ☐ Partially
   - ☐ No
   - ☐ Undecided

   If not, please specify what you think is missing or insufficiently addressed (max. 2000 characters)

5. *The actions listed under Priority 3 (Train, educate and communicate) properly address the priority*
   - ☐ Yes
   - ☐ Partially
   - ☐ No
   - ☐ Undecided

   If not, please specify what you think is missing or insufficiently addressed (max. 2000 characters)

6. *The actions listed under Priority 4 (Strengthen research ecosystem readiness) properly address the priority*
   - ☐ Yes
   - ☐ Partially
   - ☐ No
   - ☐ Undecided

   If not, please specify what you think is missing or insufficiently addressed (max. 2000 characters)

7. *The actions listed under Priority 5 (Conduct research activities at the time of a crisis) properly address the priority*

☐ Yes
☐ Partially
☐ No
☐ Undecided
If not, please specify what you think is missing or insufficiently addressed (max. 2000 characters)

8. *Overall, the SRIA provides sufficient focus on interdisciplinary and cross-sectoral approaches*
   ☐ Yes
   ☐ Partially
   ☐ No
   ☐ Undecided
   If not, please specify how the SRIA could better promote efficient collaboration between different scientific disciplines (max. 2000 characters)

**Part 3 - Mapping work around the SRIA**

Do you agree with the following statements?

1. *The SRIA for pandemic preparedness provides a good overview of the pandemic preparedness landscape (including other European partnerships and international initiatives)*
   ☐ Yes
   ☐ Partially
   ☐ No
   ☐ Undecided
   Additional comments/ suggestions (max. 250 characters)

2. *The SRIA for pandemic preparedness provides a relevant list of potential research initiatives in line with the defined strategic priorities (cf Appendix 2)*
   ☐ Yes
   ☐ Partially
   ☐ No
   ☐ Undecided
   Additional suggestions of research initiatives (max. 5000 characters)

3. *The SRIA for pandemic preparedness provides an adequate synthetic overview of needs, obstacles and weaknesses in pandemic preparedness in Europe (cf Appendix 4)*
   ☐ Yes
   ☐ Partially
   ☐ No
   ☐ Undecided
   Additional comments/ suggestions (max. 250 characters)

*Any other comments on the SRIA for pandemic preparedness (max 5000 characters):*

*Quantitative results*

In total, 107 answers were received from 13 countries (11 European countries, Pakistan and Jamaica).

| | Number |
|---|---|
| Hungary | 66 |
| Belgium | 8 |
| Netherlands | 8 |
| Spain | 6 |
| France | 5 |
| Germany | 4 |
| United Kingdom | 2 |
| Denmark | 1 |
| Finland | 1 |
| Greece | 1 |
| Switzerland | 1 |
| Jamaica | 1 |
| Pakistan | 1 |
| *European organisation* | *2* |
| **Total** | 107 |

*TABLE 1 - GEOGRAPHICAL DISTRIBUTION OF RESPONDENTS*

The geographical distribution of respondents (table 1) showed a clear overrepresentation of Hungary (61% of total answers), reflecting strong outreach and involvement from Hungary in this initiative. While this is a positive sign of engagement from one country, there is room for improvement in ensuring a more balanced geographical representation.

Among the total answers, 25 were provided on behalf of organisations, declined as follows:

| | Number |
|---|---|
| University/ Research institute | 9 |
| Hospital/ University hospital | 3 |
| Industry | 3 |
| NGO/association/foundation | 2 |
| Funding agency | 1 |
| International or European organisation | 1 |
| Public agency or organisation | 1 |
| SME | 1 |
| *Other* | 4 |
| **Total** | **25** |

*TABLE 2 - NATURE OF RESPONDENT ORGANISATIONS*

Next, answers were analysed separating organisations and individual responders. The key findings obtained from the online consultation are presented in Table 3.

| | | Individual responders | Organisations |
|---|---|---|---|
| *The three overarching principles identified are sound, and in line with the vision of the future Partnership* | Yes | **70%** | **68%** |
| | Partially | **23%** | **28%** |
| | No | **5%** | **0%** |
| | Undecided | **2%** | **4%** |
| *The five priorities proposed provide a comprehensive overview of the R&I needed to increase the European pandemic preparedness* | Yes | **72%** | **68%** |
| | Partially | **21%** | **24%** |
| | No | **6%** | **0%** |
| | Undecided | **1%** | **8%** |
| *The actions listed under Priority 1 properly address the priority* | Yes | **62%** | **76%** |
| | Partially | **30%** | **20%** |
| | No | **5%** | **0%** |
| | Undecided | **2%** | **4%** |
| *The actions listed under Priority 2 properly address the priority* | Yes | **61%** | **52%** |
| | Partially | **29%** | **40%** |
| | No | **6%** | **4%** |
| | Undecided | **4%** | **4%** |
| *The actions listed under Priority 3 properly address the priority* | Yes | **71%** | **64%** |
| | Partially | **24%** | **32%** |
| | No | **4%** | **0%** |
| | Undecided | **1%** | **4%** |
| *The actions listed under Priority 4 properly address the priority* | Yes | **61%** | **48%** |
| | Partially | **29%** | **48%** |
| | No | **7%** | **0%** |
| | Undecided | **2%** | **4%** |
| *The actions listed under Priority 5 properly address the priority* | Yes | **61%** | **60%** |
| | Partially | **29%** | **24%** |
| | No | **5%** | **12%** |
| | Undecided | **5%** | **4%** |
| *The SRIA provides sufficient focus on interdisciplinary and cross-sectoral approaches* | Yes | **63%** | **52%** |
| | Partially | **27%** | **28%** |
| | No | **4%** | **12%** |
| | Undecided | **6%** | **8%** |
| *The SRIA provides…* | | | |
| *… a good overview of the pandemic preparedness landscape* | Yes | **57%** | **32%** |
| | Partially | **20%** | **36%** |
| | No | **7%** | **8%** |
| | Undecided | **12%** | **16%** |
| | No answer | **4%** | **8%** |
| *… a relevant list of potential research initiatives in line with the defined strategic priorities (cf Appendix 2)* | Yes | **55%** | **44%** |
| | Partially | **22%** | **24%** |
| | No | **4%** | **4%** |
| | Undecided | **15%** | **16%** |
| | No answer | **5%** | **12%** |
| *… an adequate synthetic overview of needs, obstacles and weaknesses in pandemic preparedness in Europe (cf Appendix 4)* | Yes | **55%** | **52%** |
| | Partially | **24%** | **20%** |
| | No | **6%** | **0%** |
| | Undecided | **7%** | **20%** |
| | No answer | **7%** | **8%** |

*TABLE 3 - SUMMARY OF RESPONDENT FEEDBACK ON KEY SRIA COMPONENTS (PERCENTAGE BREAKDOWN)*

Most importantly, the feedback highlights strong overall agreement with the overarching principles and priorities of the SRIA, with a majority of individual (70%-72%) and organisational (68%) respondents finding them sound and comprehensive in addressing R&I needs for pandemic preparedness. However, around 20%-30% partially agree, indicating room for further refinement.

When assessing the effectiveness of actions under specific priorities, responses show some variability. Actions under Priority 1 and Priority 3 received the strongest support, with up to 76% of organisations and 71% of individuals agreeing they properly address the priorities. In contrast, Priority 2 and Priority 4 show lower levels of agreement, with only 48%-52% of organisations fully satisfied and a significant portion (40%-48%) partially agreeing.

The interdisciplinary and cross-sectoral focus of the SRIA is seen as sufficient by 63% of individuals and 52% of organisations, but 12% of organisations find it lacking, underscoring the need for stronger emphasis on this aspect.

The SRIA's ability to provide a comprehensive overview of the pandemic preparedness landscape was met with mixed responses ; while 57% of individuals agreed, only 32% of organisations were satisfied, with 36% partially agreeing and a notable portion (12%-16%) undecided or providing no response.

Finally, while the SRIA's list of potential research initiatives and assessment of needs, obstacles, and weaknesses is broadly supported (55%-52% agreement), the high proportion of partial agreement (20%-24%) and organisational indecision (20%) highlights areas that could benefit from clearer communication and further consultation.

Overall, these findings can be summarised as follows:

- There is **strong agreement** on the relevance of the overarching principles and priorities, but variability in agreement across specific actions and priorities suggests areas for refinement.
- **Interdisciplinary approaches** and the SRIA's focus on the **pandemic preparedness landscape** need improvement to increase stakeholder confidence, especially among organisations.
- Priority 1 and Priority 3 actions are seen as the strongest, while Priority 2 and Priority 4 require better alignment with stakeholder expectations.
- Many respondents are **undecided** on some aspects, particularly regarding the SRIA's landscape overview and research needs, indicating a need for clearer communication or further consultation.

The present version of the SRIA has taken into account the findings and suggestions from the online consultation and has been amended between January and March 2025.